SENATE—*Wednesday, September 24, 1997*

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—

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

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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 roles 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 Members 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.

Mr. KENNEDY. Mr. President, I join in expressing all of our appreciation for the Senator's involvement. As has been pointed out he brings a very unique perspective to the understanding of these issues based on a long and very distinguished career. We are all very much in his debt for his involvement in the time he has taken with the shaping of the legislation. We have certainly appreciated the opportunity to work with him on a lot of different provisions and will continue to do so and look forward to in the future, as well.

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

Footnotes at end of article.

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, 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 device 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 possibly 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 American 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 maim 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 had 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 valve. 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 5 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 1,230 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?

The PRESIDING OFFICER. The Senator from Massachusetts has 7 minutes.

Mr. KENNEDY. Mr. President, I yield myself 3 minutes.

Just a short while ago, we heard some comments on the floor about how this whole process has taken a long period of time. It has taken a period of time. But I think one can see from any fair review of the history of the legislation that very substantial progress has been made in making this a better bill. As I pointed out earlier in the debate, of the 20 major health safety issues identified by the administration, 19 have been addressed, not only in our committee markup, but also in the negotiations that we had prior to the time of the legislation coming to the floor. There is the one remaining item, which deals with safety and medical devices. It is extremely important. We have given focus to this issue because it deserves the focus that we have given it.

Mr. President, I have in my hand the statement of the administration policy. It indicates that it has two major concerns with the bill. One is the technical provision with regard to the budget agreement and how they are going to allocate to PDUFA, which is a technical issue. But the other issue mentioned by the administration is this particular provision:

First, section 404 of the bill would lower the review standard for marketing approval by precluding the FDA from reviewing medical devices for uses other than those for which the manufacturer says they are intended.

The administration indicates, as they did in the letter in September, as they did in June, that this particular provision is dangerous in terms of the consumers in this country.

We have reviewed, over the course of the debate, the dangerous situations that have been the result of medical device disasters. We are committed to avoiding that kind of disaster in the future. We have a good safety record at the present time, but we are endangering that record with section 404. We noted that virtually every consumer group supports changing section 404. It is enormously important. It goes to the fundamental question of providing FDA with the power and authority to pursue the protections of the American health in the area of medical devices.

Mr. President, I ask unanimous consent that the statement of the administration policy supporting our position regarding 404 be printed in the RECORD.

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

EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT AND BUDGET,
Washington, DC, September 24, 1997.

STATEMENT OF ADMINISTRATION POLICY

(This statement has been coordinated by OMB with the concerned agencies.)

S. 830—FDA MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

(Senator Jeffords (R) VT)

The Administration applauds the Senate for its bipartisan effort to improve S. 830 since it was reported by the Senate Committee on Labor and Human Resources, and appreciates the Senate's responsiveness to concerns that have been raised. Because of the importance of obtaining a five-year extension of the Prescription Drug User Fee Act (PDUFA), the Administration has no objection to passage of the bill by the Senate at this time. However, the Administration finds that the provisions identified below are unacceptable and as the legislative process continues, will work to ensure that our remaining concerns are resolved.

In general, this legislation represents a significant step toward accomplishing our mutual goal of assuring the agency's optimum performance while protecting the health of the American public. The Administration, however, continues to have two major concerns with the bill.

First, section 404 of the bill would lower the review standard for marketing approval by precluding the Food and Drug Administration (FDA) from reviewing new medical devices for uses other than those for which the manufacturer says they are intended. Second, the PDUFA trigger as proposed in S. 830 undercuts the bipartisan budget agreement (BBA) by requiring budget increases for FDA not envisioned by the BBA, and would interfere with HHS' ability to allocate resources appropriately throughout the Department.

In order to be able to support the final bill, the Administration will continue to work with the House of Representatives and in conference to resolve these and other identified issues.

Mr. KENNEDY. We hope that we can be convincing as this legislation goes forward. We have not been convincing here on the floor. We hope provisions can be accepted that will make 404 acceptable in terms of the public health issues. I want to express my sincere appreciation to the chairman of the committee, Senator JEFFORDS, who has been a chairman's chair. He is strong in his belief. He is a fighter for the things that he champions. He has been willing to accommodate differing views. He protects his strong posture and positions on his own views, and I respect that. I thank the other Members of this body for their courtesy during the course of what I know has been a continuing discussion and debate on a very important measure. I thank all of our Members for their courtesy and consideration as we move toward a vote on this legislation. I thank my chairman.

At the time when the Senator from Vermont is prepared to yield back his time, I will be prepared to do so likewise and move to our vote.

UNANIMOUS-CONSENT REQUEST

Mr. JEFFORDS. Mr. President, first, I have a unanimous-consent request, which has been cleared on both sides.

I ask unanimous consent that it be in order to consider amendment No. 1184, as modified, with changes that are at the desk; further, that the amendment be agreed to, and the motion to reconsider be laid upon the table.

I'm sorry, Mr. President, I withdraw that request at this moment.

The PRESIDING OFFICER. It is withdrawn.

Mr. JEFFORDS. Mr. President, first of all, I thank the ranking member for his help on this bill. We agree on 19 out of 20 provisions. His steadfast and articulate objection to the 20th, relative to section 404, has been done sincerely

and very well done on that issue. I believe that we have a good bill, but we remain open to suggestions, as always, as to how the bill can be improved. I am extremely pleased that the Senate has overwhelmingly approved S. 830 yesterday. I believe this is an important step forward for ensuring a stronger and more efficient FDA.

Throughout this process, we have had the benefit of input from all interested parties on how best to modernize the Agency, while ensuring that its stellar standard for public safety remains as strong as ever. I am extremely proud of the strong support of this legislation expressed by the health community. For instance, the National Health Council, a coalition of over 100 health and patient organizations, has urged the Senate to move forward with this legislation. We have also received support from physician groups, including the American Medical Association and the American Academy of Pediatrics.

We must remember that drugs and medical devices delayed at the FDA are often lives lost. When cardiac defibrillators were first developed in the late 1980's, they brought new hope and opportunity to many of the 350,000 Americans who would otherwise suffer sudden cardiac death each year.

But the first version of this technology required opening the chest and separating the ribs to apply this technology to the heart. This procedure carried a 4.2 percent mortality rate.

Improvements to this defibrillator technology were widely available in Europe two years before patients could benefit in this country. The new technology did not require cracking the patient's chest, but only a small incision to allow the technology to be threaded through a vein into the heart.

During this unnecessary 2-year delay, it is estimated that 1,056 Americans died from complications related to the more invasive technique. Delay does cost lives.

And far from allowing dangerous products on the market as Senator KENNEDY has alleged, section 404 of this bill keeps intact FDA's authority to investigate technological issues which raise new safety and effectiveness questions, does not limit FDA's enforcement authority, and does not touch FDA's regulations which require that medical device applications be truthful and not omit any material facts.

Section 404 does quite appropriately keep FDA out of regulating the practice of medicine. That is important and we should fight to protect the intent of this provision.

Patients will also benefit from other provisions of the bill including the registry of clinical trials, fast-track approval for drugs treating life-threatening diseases, expanded access to investigational therapies, and the incentives established to investigate pediatric uses of drugs.

I want to thank the patient, consumer, and physician groups, and all the others we have worked with, for their commitment to working toward real reforms that strengthen the FDA and the contributions they have made in crafting this bipartisan measure.

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

The PRESIDING OFFICER. The Senator from Vermont has 9 minutes remaining.

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

The PRESIDING OFFICER. The Senator from Florida is recognized.

Mr. MACK. Mr. President, I thank Senator JEFFORDS for yielding.

First of all, I want to commend him for a tremendous amount of work. This is an incredibly complicated piece of legislation. It has involved a lot of different interest groups in some issues that have become very charged.

So I again want to thank the Senator from Vermont for his willingness to work with Senator FRIST and I as we worked on the so-called off-label issue.

I also want to express my appreciation to Senator KENNEDY. He had some deep concerns about the legislation, and as a result of extensive discussions we were able to find a compromise. I think it was one of the reasons that this bill was able to move forward.

So I thank Senator JEFFORDS and Senator KENNEDY. And I also want to put in a comment with respect to Mark Smith, my staffer who has worked on this issue for more than some 2½ years.

Again, I thank Senator JEFFORDS for what he has done.

Mr. JEFFORDS. I thank the Senator for his comments, and I want to praise him for his efforts with respect to off-label. This is an incredibly important amendment that Senator MACK and Senator FRIST have worked out with the FDA and the minority. That is going to give a great deal of assistance to people in this country who are in need of help in straightening out a relatively difficult area with such preciseness. The Senator from Florida did a good job.

AMENDMENT NO. 1184, AS MODIFIED

Mr. President, I ask unanimous consent that it be in order to consider amendment No. 1184, as modified, with changes that are at the desk; further, that the amendment be agreed to, and the motion to reconsider be laid upon the table.

The PRESIDING OFFICER. Is there objection? Without objection, it is so ordered.

The amendment (No. 1184), as modified, was agreed to, as follows:

Strike section 809 and insert the following:

SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

"(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

"(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

"(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

"(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

"(I) the individual patient for whom the prescription order will be provided; or

"(II) the physician or other licensed practitioner who will write such prescription order; and

"(B) the licensed pharmacist or licensed physician—

"(i) compounds the drug product using bulk drug substances—

"(I) that—

"(aa) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph; or

"(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

"(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

"(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph and the United States Pharmacopeia chapter on pharmacy compounding;

"(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

"(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

"(v) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

"(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary regarding the regulation of drugs that are compounded in the State and are distributed outside of the State, that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

"(2)(A) The Secretary shall, after consultation with the National Association of Boards

of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

"(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

"(i) the date that is 180 days after the development of the standard memorandum of understanding; or

"(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi),

whichever occurs first.

"(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

"(4) The provisions of paragraph (1) shall not apply—

"(A) to compounded positron emission tomography drugs as defined in section 201(ii); or

"(B) to radiopharmaceuticals.

"(5) In this subsection, the term 'compound' does not include to mix, reconstitute, or perform another similar act, in accordance with directions contained in approved drug labeling provided by a drug manufacturer and other drug manufacturer directions consistent with that labeling.".

Mr. JEFFORDS. Mr. President, I ask unanimous consent that Senator ABRAHAM be added as a cosponsor of S. 830.

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

Mr. JEFFORDS. Mr. President, if the minority is ready and will yield all remaining time, I will yield mine.

It is my understanding the minority will yield this time. I yield the remainder of my time.

The PRESIDING OFFICER. Without objection, the minority time is yielded.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the administration policy that was received as a message be printed in the RECORD.

I thank them for bringing it to our attention at this time.

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

EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT, AND BUDGET,

Washington, DC, September 24, 1997.

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

S. 830—FDA Modernization and Accountability Act of 1997

(Sen. Jeffords (R) VT)

The Administration applauds the Senate for its bipartisan effort to improve S. 830 since it was reported by the Senate Committee on Labor and Human Resources, and appreciates the Senate's responsiveness to concerns that have been raised. Because of the importance of obtaining a five-year extension of the Prescription Drug User Fee Act (PDUFA), the Administration has no objection to passage of the bill by the Senate at this time. However, the Administration finds that the provisions identified below are unacceptable and as the legislative process continues, will work to ensure that our remaining concerns are resolved.

In general, this legislation represents a significant step toward accomplishing our mutual goal of assuring the agency's optimum performance while protecting the health of the American public. The Administration, however, continues to have two major concerns with the bill.

First, section 404 of the bill would lower the review standard for marketing approval by precluding the Food and Drug Administration (FDA) from reviewing new medical devices for uses other than those for which the manufacturer says they are intended. Second, the PDUFA trigger as proposed in S. 830 undercuts the bipartisan budget agreement (BBA) by requiring budget increases for FDA not envisioned by the BBA, and would interfere with HHS' ability to allocate resources appropriately throughout the Department.

In order to be able to support the final bill, the Administration will continue to work with the House of Representatives and in conference to resolve these and other identified issues.

Mr. JEFFORDS. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed for a third reading, and was read the third time.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall it pass? On this question, the yeas and nays have been ordered, and the clerk will call the roll.

The assistant legislative clerk called the roll.

The PRESIDING OFFICER (Mr. SANTORUM). Are there any other Senators in the Chamber who desire to vote?

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

[Rollcall Vote No. 256 Leg.]

YEAS—98

Abraham	Dodd	Kempthorne
Akaka	Domenici	Kerrey
Allard	Dorgan	Kerry
Ashcroft	Durbin	Kohl
Baucus	Enzi	Kyl
Bennett	Faircloth	Landrieu
Biden	Feingold	Lautenberg
Bingaman	Feinstein	Leahy
Bond	Ford	Levin
Boxer	Frist	Lieberman
Breaux	Glenn	Lott
Brownback	Gorton	Lugar
Bryan	Graham	Mack
Bumpers	Gramm	McCain
Burns	Grams	McConnell
Byrd	Grassley	Mikulski
Campbell	Gregg	Moseley-Braun
Chafee	Hagel	Moynihan
Cleland	Harkin	Murkowski
Coats	Hatch	Murray
Cochran	Helms	Nickles
Collins	Hollings	Reid
Conrad	Hutchinson	Robb
Coverdell	Hutchison	Roberts
Craig	Inhofe	Rockefeller
D'Amato	Inouye	Roth
Daschle	Jeffords	Santorum
DeWine	Johnson	Sarbanes
Sessions	Specter	Torricelli
Shelby	Stevens	Warner
Smith (NH)	Thomas	Wellstone
Smith (OR)	Thompson	Wyden
Snowe	Thurmond	

NAYS—2

Kennedy	Reed

The bill (S. 830), as amended, was passed, as follows:

S. 830

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food and Drug Administration Modernization and Accountability Act of 1997".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. References.

TITLE I—IMPROVING PATIENT ACCESS

Sec. 101. Mission of the Food and Drug Administration.
Sec. 102. Expanded access to investigational therapies.
Sec. 103. Expanded humanitarian use of devices.

TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

Sec. 201. Interagency collaboration.
Sec. 202. Sense of the committee regarding mutual recognition agreements and global harmonization efforts.
Sec. 203. Contracts for expert review.
Sec. 204. Accredited-party reviews.
Sec. 205. Device performance standards.

TITLE III—IMPROVING COLLABORATION AND COMMUNICATION

Sec. 301. Collaborative determinations of device data requirements.
Sec. 302. Collaborative review process.

TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES

Sec. 401. Policy statements.
Sec. 402. Product classification.
Sec. 403. Use of data relating to premarket approval.
Sec. 404. Consideration of labeling claims for product review.
Sec. 405. Certainty of review timeframes.
Sec. 406. Limitations on initial classification determinations.
Sec. 407. Clarification with respect to a general use and specific use of a device.
Sec. 408. Clarification of the number of required clinical investigations for approval.
Sec. 409. Prohibited acts.

TITLE V—IMPROVING ACCOUNTABILITY

Sec. 501. Agency plan for statutory compliance and annual report.

TITLE VI—BETTER ALLOCATION OF RESOURCES BY SETTING PRIORITIES

Sec. 601. Minor modifications.
Sec. 602. Environmental impact review.
Sec. 603. Exemption of certain classes of devices from premarket notification requirement.
Sec. 604. Evaluation of automatic class III designation.
Sec. 605. Secretary's discretion to track devices.
Sec. 606. Secretary's discretion to conduct postmarket surveillance.

Sec. 607. Reporting.
Sec. 608. Pilot and small-scale manufacture.
Sec. 609. Requirements for radiopharmaceuticals.
Sec. 610. Modernization of regulation of biological products.
Sec. 611. Approval of supplemental applications for approved products.
Sec. 612. Health care economic information.
Sec. 613. Expediting study and approval of fast track drugs.
Sec. 614. Manufacturing changes for drugs and biologics.
Sec. 615. Data requirements for drugs and biologics.
Sec. 616. Food contact substances.
Sec. 617. Health claims for food products.
Sec. 618. Pediatric studies marketing exclusivity.
Sec. 619. Positron emission tomography.
Sec. 620. Disclosure.
Sec. 621. Referral statements relating to food nutrients.

TITLE VII—FEES RELATING TO DRUGS

Sec. 701. Short title.
Sec. 702. Findings.
Sec. 703. Definitions.
Sec. 704. Authority to assess and use drug fees.
Sec. 705. Annual reports.
Sec. 706. Effective date.
Sec. 707. Termination of effectiveness.

TITLE VIII—MISCELLANEOUS

Sec. 801. Registration of foreign establishments.
Sec. 802. Elimination of certain labeling requirements.
Sec. 803. Clarification of seizure authority.
Sec. 804. Intramural research training award program.
Sec. 805. Device samples.
Sec. 806. Interstate commerce.
Sec. 807. National uniformity for nonprescription drugs and cosmetics.
Sec. 808. Information program on clinical trials for serious or life-threatening diseases.
Sec. 809. Application of Federal law to the practice of pharmacy compounding.
Sec. 810. Reports of postmarketing approval studies.
Sec. 811. Information exchange.
Sec. 812. Reauthorization of clinical pharmacology program.
Sec. 813. Monograph for sunburn products.
Sec. 814. Safety report disclaimers.

SEC. 3. REFERENCES.

Except as otherwise expressly provided, wherever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

TITLE I—IMPROVING PATIENT ACCESS

SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(2) by inserting after subsection (a) the following:

"(b) MISSION.—

"(1) IN GENERAL.—The Secretary, acting through the Commissioner, and in consultation, as determined appropriate by the Secretary, with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products, shall protect the public health by taking actions that help ensure that—

"(A) foods are safe, wholesome, sanitary, and properly labeled;

"(B) human and veterinary drugs, including biologics, are safe and effective;

"(C) there is reasonable assurance of safety and effectiveness of devices intended for human use;

"(D) cosmetics are safe; and

"(E) public health and safety are protected from electronic product radiation.

"(2) SPECIAL RULES.—The Secretary, acting through the Commissioner, shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Secretary, acting through the Commissioner, shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements, and to achieve appropriate reciprocal arrangements with other countries.".

SEC. 102. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter D—Unapproved Therapies and Diagnostics

"SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

"(a) EMERGENCY SITUATIONS.—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs (including investigational biological products), or investigational devices, (as defined in regulations prescribed by the Secretary) for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

"(b) INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may provide to such physician after compliance with the provisions of this subsection, an investigational drug (including an investigational biological product), or investigational device, (as defined in regulations prescribed by the Secretary) for the diagnosis, monitoring, or treatment of a serious disease or condition if—

"(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the risk to the person from the investigational drug or investigational device is not greater than the risk from the disease or condition;

"(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

"(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

"(4) the product sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) or 520(g) and any regulations promulgated under section 505(i) or 520(g) describing the use of investigational drugs or investigational devices in a single patient or a small group of patients.

"(c) TREATMENT INDS/IDES.—Upon submission by a product sponsor or a physician of a protocol intended to provide widespread access to an investigational product for eligible patients, the Secretary shall permit an investigational drug (including an investigational biological product) or investigational device to be made available for expanded access under a treatment investigational new drug application or investigational device exemption (as the terms are described in regulations prescribed by the Secretary) if the Secretary determines that—

"(1) under the treatment investigational new drug application or investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

"(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

"(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an effective investigational new drug application or investigational device exemption; and

"(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

"(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

"(5) the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i) or 520(g);

"(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

"(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the product may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 505(i) or 520(g) and regulations promulgated under section 505(i) or 520(g). The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be of the same type of information that is required by section 402(j)(3).

"(d) TERMINATION.—The Secretary may, at any time, with respect to a person, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug (including an investigational biological product) or investigational device if the requirements under this section are no longer met.".

SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.

Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by adding at the end the following flush sentences:

"The request shall be in the form of an application submitted to the Secretary. Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.";

(2) in paragraph (4)—

(A) in subparagraph (B), by inserting after "(2)(A)" the following: ", unless a physician determines that waiting for such an approval from an institutional review committee will cause harm or death to a patient, and makes a good faith effort to obtain the approval, and does not receive a timely response from an institutional review committee on the request of the physician for approval to use the device for such treatment or diagnosis"; and

(B) by adding at the end the following flush sentences:

"In a case in which a physician described in subparagraph (B) uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use."; and

(3) by striking paragraph (5) and inserting the following:

"(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.".

TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

SEC. 201. INTERAGENCY COLLABORATION.

Section 903(b) (21 U.S.C. 393(b)), as added by section 101(2), is amended by adding at the end the following:

"(3) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.".

SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION EFFORTS.

It is the sense of the Committee on Labor and Human Resources of the Senate that—

(1) the Secretary of Health and Human Services should support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States;

(2) the Secretary of Health and Human Services should regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

(3) the Office of International Relations of the Department of Health and Human Services (as established under section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383)) should have the responsibility of ensuring that the process of harmonizing international regulatory requirements is continuous.

SEC. 203. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 906. CONTRACTS FOR EXPERT REVIEW.

"(a) IN GENERAL.—

"(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with expertise in a relevant discipline, to review, evaluate, and make recommendations to the Secretary on part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

"(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary shall use the authority granted in paragraph (1) whenever the Secretary determines that a contract described in paragraph (1) will improve the timeliness or quality of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. Such improvement may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

"(b) REVIEW OF EXPERT REVIEW.—

"(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter within 60 days after receiving the recommendations.

"(2) LIMITATION.—A final decision under paragraph (1) shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).

"(3) AUTHORITY OF SECRETARY.—Notwithstanding subsection (a), the Secretary shall retain full authority to make determinations with respect to the approval or disapproval of an article under this Act, the approval or disapproval of a biologics license with respect to a biological product under section 351(a) of the Public Health Service Act, or the classification of an article as a device under section 513(f)(1).".

SEC. 204. ACCREDITED-PARTY REVIEWS.

(a) IN GENERAL.—Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 523. ACCREDITED-PARTY PARTICIPATION.

"(a) ACCREDITATION.—Not later than 1 year after the date of enactment of this section, the Secretary shall accredit entities or individuals who are not employees of the Federal Government to review reports made to the Secretary under section 510(k) for devices and make recommendations to the Secretary regarding the initial classification of such devices under section 513(f)(1), except that this paragraph shall not apply to a report made to the Secretary under section 510(k) for a device that is—

"(1) for a use in supporting or sustaining human life;

"(2) for implantation in the human body for more than 1 year; or

"(3) for a use that is of substantial importance in preventing the impairment of human health.

"(b) ACCREDITATION.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest. The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.

"(c) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any entity or individual accredited under this section, after providing notice and an opportunity for an informal hearing, if such entity or individual acts in a manner that is substantially not in compliance with the requirements established by the Secretary under subsection (b), including the failure to avoid conflicts of interest, the failure to protect confidentiality of information, or the failure to competently review premarket submissions for devices.

"(d) SELECTION AND COMPENSATION.—A person who intends to make a report described in subsection (a) to the Secretary shall have the option to select an accredited entity or individual to review such report. Upon the request by a person to have a report reviewed by an accredited entity or individual, the Secretary shall identify for the person no less than 2 accredited entities or individuals from whom the selection may be made. Compensation for an accredited entity or individual shall be determined by agreement between the accredited entity or individual and the person who engages the services of the accredited entity or individual and shall be paid by the person who engages such services.

"(e) REVIEW BY SECRETARY.—

"(1) IN GENERAL.—The Secretary shall require an accredited entity or individual, upon making a recommendation under this section with respect to an initial classification of a device, to notify the Secretary in writing of the reasons for such recommendation.

"(2) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under paragraph (1) by an accredited entity or individual with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

"(3) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended by the accredited entity or individual under this section, and in such case shall notify in writing the person making the report described in subsection (a) of the detailed reasons for the change.

"(f) DURATION.—The authority provided by this section terminates—

"(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k); or

"(2) 4 years after the date on which the Secretary notifies Congress that at least 35 percent of the devices that are subject to review under subsection (a), and that were the subject of final action by the Secretary in the fiscal year preceding the date of such notification, were reviewed by the Secretary under subsection (e),

whichever occurs first.

"(g) REPORT.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall contract with an independent research organization to prepare and submit to the Secretary a written report examining the use of accredited entities and individuals to conduct reviews under this section. The Secretary shall submit the report to Congress not later than 6 months prior to the conclusion of the applicable period described in subsection (f).

"(2) CONTENTS.—The report by the independent research organization described in paragraph (1) shall identify the benefits or detriments to public and patient health of using accredited entities and individuals to conduct such reviews, and shall summarize all relevant data, including data on the review of accredited entities and individuals (including data on the review times, recommendations, and compensation of the entities and individuals), and data on the review of the Secretary (including data on the review times, changes, and reasons for changes of the Secretary).".

(b) RECORDKEEPING.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

"(f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person in accordance with section 523(d), and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

"(2) Within 15 days after the receipt of a written request from the Secretary to a person accredited under section 523 for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.".

SEC. 205. DEVICE PERFORMANCE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

"Recognition of a Standard

"(c)(1)(A) In addition to establishing performance standards under this section, the Secretary may, by publication in the Federal Register, recognize all or part of a performance standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet premarket submission requirements or other requirements under this Act to which such standards are applicable.

"(B) If a person elects to use a performance standard recognized by the Secretary under subparagraph (A) to meet the requirements described in subparagraph (A), the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to fulfill or satisfy any requirement under this Act.

"(2) The Secretary may withdraw such recognition of a performance standard through publication of a notice in the Federal Register that the Secretary will no longer recognize the standard, if the Secretary determines that the standard is no longer appropriate for meeting the requirements under this Act.

"(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

"(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

"(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

"(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

"(C) A person relying on a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of 2 years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.".

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(x) The falsification of a declaration of conformity submitted under subsection (c) of section 514 or the failure or refusal to provide data or information requested by the Secretary under section 514(c)(3).".

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended—

(1) by striking "(e)" and inserting "(e)(1)"; and

(2) by inserting at the end the following:

"(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any performance standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.".

TITLE III—IMPROVING COLLABORATION AND COMMUNICATION

SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

"(C)(i)(I) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person, to support an approval of an application. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

"(II) Any clinical data, including 1 or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary—

"(aa) that such data are necessary to establish device effectiveness; and

"(bb) that no other less burdensome means of evaluating device effectiveness is available that would have a reasonable likelihood of resulting in an approval.

"(ii) The determination of the Secretary with respect to the specification of valid scientific evidence under clause (i) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.".

SEC. 302. COLLABORATIVE REVIEW PROCESS.

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by striking "paragraph (2) of this subsection" each place it appears and inserting "paragraph (4)";

(2) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(3) by inserting after paragraph (1) the following:

"(2)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application from the applicant that has been filed as complete under subsection (c), to discuss the review status of the application.

"(ii) If the application does not appear in a form that would require an approval under this subsection, the Secretary shall in writing, and prior to the meeting, provide to the applicant a description of any deficiencies in the application identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

"(iii) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

"(B) The Secretary shall notify the applicant immediately of any deficiency identified in the application that was not described as a deficiency in the written description provided by the Secretary under subparagraph (A).".

TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES

SEC. 401. POLICY STATEMENTS.

Section 701(a) (21 U.S.C. 371(a)) is amended—

(1) by striking "(a) The" and inserting "(a)(1) The"; and

(2) by adding at the end the following:

"(2) Not later than February 27, 1999, the Secretary, after evaluating the effectiveness of the Good Guidance Practices document published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.".

SEC. 402. PRODUCT CLASSIFICATION.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter D—Classification of Products and Environmental Impact Reviews

"SEC. 741. CLASSIFICATION OF PRODUCTS.

"(a) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar

form of request) under this Act, may submit a request to the Secretary respecting the classification of an article as a drug, biological product, device, or a combination product subject to section 503(g) or respecting the component of the Food and Drug Administration that will regulate the article. In submitting the request, the person shall recommend a classification for the article, or a component to regulate the article, as appropriate.

"(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the article or the component of the Food and Drug Administration that will regulate the article and shall provide to the person a written statement that identifies the classification of the article or the component of the Food and Drug Administration that will regulate the article and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person or for public health reasons.

"(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of the classification of the article or the component of the Food and Drug Administration that will regulate the article and may not be modified by the Secretary except with the written consent of the person or for public health reasons.".

SEC. 403. USE OF DATA RELATING TO PREMARKET APPROVAL.

(a) IN GENERAL.—Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

"(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

"(i) approving another device;

"(ii) determining whether a product development protocol has been completed, under section 515 for another device;

"(iii) establishing a performance standard or special control under this Act; or

"(iv) classifying or reclassifying another device under section 513 and subsection (1)(2).

"(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).".

(b) CONFORMING AMENDMENT.—Section 517(a) (21 U.S.C. 360g(a)) is amended—

(1) in paragraph (8), by adding "or" at the end;

(2) in paragraph (9), by striking ", or" and inserting a comma; and

(3) by striking paragraph (10).

SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR PRODUCT REVIEW.

(a) PREMARKET APPROVAL.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end the following flush sentences:

"In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.".

(b) PREMARKET NOTIFICATION.—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

"(C) Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to make a substantial equivalence determination. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and shall request information accordingly.

"(D) The determination of the Secretary under this subsection and section 513(f)(1) with respect to the intended use of a device shall be based on the intended use included in the proposed labeling of the device submitted in a report under section 510(k).".

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsections (a) and (b) shall be construed to alter any authority of the Secretary of Health and Human Services to regulate any tobacco product, or any additive or ingredient of a tobacco product.

SEC. 405. CERTAINTY OF REVIEW TIMEFRAMES.

(a) CLARIFICATION ON THE 90-DAY TIMEFRAME FOR PREMARKET NOTIFICATION REVIEWS.—Section 510(k) (21 U.S.C. 360) is amended by adding at the end the following flush sentence:

"The Secretary shall review the report required by this subsection and make a determination under section 513(f)(1) not later than 90 days after receiving the report.".

(b) ONE-CYCLE REVIEW.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is amended by inserting after paragraph (2) the following:

"(3) Except as provided in paragraph (1), the period for the review of an application by the Secretary under this subsection shall be not more than 180 days. Such period may not be restarted or extended even if the application is amended. The Secretary is not required to review a major amendment to an application, unless the amendment is made in response to a request by the Secretary for information.".

SEC. 406. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.

Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

"(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act that is unrelated to a substantial equivalence decision, including a failure to comply with the requirements relating to good manufacturing practices under section 520(f).".

SEC. 407. CLARIFICATION WITH RESPECT TO A GENERAL USE AND SPECIFIC USE OF A DEVICE.

Not later than 270 days after the date of enactment of this section, the Secretary of Health and Human Services shall promulgate a final regulation specifying the general principles that the Secretary of Health and Human Services will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

SEC. 408. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.

(a) DEVICE CLASSES.—Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking "clinical investigations" and inserting "1 or more clinical investigations".

(b) NEW DRUGS.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: "Substantial evidence may, as appropriate, consist of data from 1 adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation), if the Secretary determines, based on relevant science, that such data and evidence are sufficient to establish effectiveness.".

SEC. 409. PROHIBITED ACTS.

Section 301(l) (21 U.S.C. 331(l)) is repealed.

TITLE V—IMPROVING ACCOUNTABILITY

SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND ANNUAL REPORT.

Section 903(b) (21 U.S.C. 393(b)), as amended by section 201, is further amended by adding at the end the following:

"(4) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with relevant experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act and other relevant statutes. The Secretary shall biannually review the plan and shall revise the plan as necessary, in consultation with such persons.

"(B) OBJECTIVES OF AGENCY PLAN.—The plan required by subparagraph (A) shall establish objectives, and mechanisms to be used by the Secretary, acting through the Commissioner, including objectives and mechanisms that—

"(i) minimize deaths of, and harm to, persons who use or may use an article regulated under this Act;

"(ii) maximize the clarity of, and the availability of information about, the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act, including information for potential consumers and patients concerning new products;

"(iii) implement all inspection and postmarket monitoring provisions of this Act by July 1, 1999;

"(iv) ensure access to the scientific and technical expertise necessary to ensure compliance by the Secretary with the statutory obligations described in subparagraph (A);

"(v) establish a schedule to bring the Administration into full compliance by July 1, 1999, with the time periods specified in this Act for the review of all applications and submissions described in clause (ii) and submitted after the date of enactment of this paragraph; and

"(vi) reduce backlogs in the review of all applications and submissions described in clause (ii) for any article with the objective of eliminating all backlogs in the review of the applications and submissions by January 1, 2000.

"(5) ANNUAL REPORT.—

"(A) CONTENTS.—The Secretary shall prepare and publish in the Federal Register and solicit public comment on an annual report that—

"(i) provides detailed statistical information on the performance of the Secretary under the plan described in paragraph (4);

"(ii) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary;

"(iii) analyzes any failure of the Secretary to achieve any objective of the plan or to meet any statutory obligation;

"(iv) identifies any regulatory policy that has a significant impact on compliance with any objective of the plan or any statutory obligation; and

"(v) sets forth any proposed revision to any such regulatory policy, or objective of the plan that has not been met.

"(B) STATISTICAL INFORMATION.—The statistical information described in subparagraph (A)(i) shall include a full statistical presentation relating to all applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act and approved or subject to final action by the Secretary during the year covered by the report. In preparing the statistical presentation, the Secretary shall take into account the date of—

"(i) the submission of any investigational application;

"(ii) the application of any clinical hold;

"(iii) the submission of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for approval or clearance;

"(iv) the acceptance for filing of any application or submission described in clause (iii) for approval or clearance;

"(v) the occurrence of any unapprovable action;

"(vi) the occurrence of any approvable action; and

"(vii) the approval or clearance of any application or submission described in clause (iii).

"(C) SPECIAL RULE.—If the Secretary provides information in a report required by section 705 of the Food and Drug Administration Modernization and Accountability Act of 1997 or a report required by the amendments made by the Government Performance and Results Act of 1993 and that information is required by this paragraph, the report shall be deemed to satisfy the requirements of this paragraph relating to that information.".

TITLE VI—BETTER ALLOCATION OF RESOURCES BY SETTING PRIORITIES

SEC. 601. MINOR MODIFICATIONS.

(a) ACTION ON INVESTIGATIONAL DEVICE EXEMPTIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

"(6)(A) The Secretary shall, not later than 120 days after the date of enactment of this paragraph, by regulation modify parts 812 and 813 of title 21, Code of Federal Regulations to update the procedures and conditions under which a device intended for human use may, upon application by the sponsor of the device, be granted an exemption from the requirements of this Act.

"(B) The regulation shall permit developmental changes in a device (including manufacturing changes) in response to information collected during an investigation without requiring an additional approval of an application for an investigational device exemption or the approval of a supplement to such application, if the sponsor of the investigation determines, based on credible information, prior to making any such changes, that the changes—

"(i) do not affect the scientific soundness of an investigational plan submitted under paragraph (3)(A) or the rights, safety, or welfare of the human subjects involved in the investigation; and

"(ii) do not constitute a significant change in design, or a significant change in basic principles of operation, of the device.".

(b) ACTION ON APPLICATION.—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

"(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section 520(g), to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

"(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

"(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.".

(c) ACTION ON SUPPLEMENTS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is further amended by adding at the end the following:

"(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

"(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a premarket approval supplement is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

"(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

"(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

"(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

"(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.".

SEC. 602. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

"SEC. 742. ENVIRONMENTAL IMPACT REVIEW.

"Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).".

SEC. 603. EXEMPTION OF CERTAIN CLASSES OF DEVICES FROM PREMARKET NOTIFICATION REQUIREMENT.

(a) CLASS I AND CLASS II DEVICES.—Section 510(k) (21 U.S.C. 360(k)) is amended by striking "intended for human use" and inserting "intended for human use (except a device that is classified into class I under section 513 or 520 unless the Secretary determines such device is intended for a use that is of substantial importance in preventing impairment of human health or such device presents a potential unreasonable risk of illness or injury, or a device that is classified into class II under section 513 or 520 and is exempt from the requirements of this subsection under subsection (l))".

(b) PUBLICATION OF EXEMPTION.—Section 510 (21 U.S.C. 360) is amended by inserting after subsection (k) the following:

"(l)(1) Not later than 30 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a notification under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the notification shall be exempt from the requirement to provide notification under subsection (k) as of the date of the publication of the list in the Federal Register.

"(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the notification requirement of subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such notification is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice.".

SEC. 604. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking "paragraph (2)" and inserting "paragraph (3)"; and

(B) in the last sentence, by striking "paragraph (2)" and inserting "paragraph (2) or (3)";

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

"(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

"(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A) for classification of a device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), the Secretary shall by written order classify the device. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

"(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

"(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.".

SEC. 605. SECRETARY'S DISCRETION TO TRACK DEVICES.

(a) RELEASE OF INFORMATION.—Section 519(e) (21 U.S.C. 360i(e)) is amended by adding at the end the following flush sentence:

"Any patient receiving a device subject to tracking under this section may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.".

(b) PUBLICATION OF CERTAIN DEVICES.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall develop and publish in the Federal Register a list that identifies each type of device subject to tracking under section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)). Each device not identified by the Secretary of Health and Human Services under this subsection or designated by the Secretary under section 519(e)(2) shall be deemed to be exempt from the mandatory tracking requirement under section 519 of such Act. The Secretary of Health and Human Services shall have authority to modify the list of devices exempted from the mandatory tracking requirements.

SEC. 606. SECRETARY'S DISCRETION TO CONDUCT POSTMARKET SURVEILLANCE.

(a) IN GENERAL.—Section 522 (21 U.S.C. 360l) is amended by striking "SEC. 522." and all that follows through "(2) DISCRETIONARY SURVEILLANCE.—The" and inserting the following:

"SEC. 522. (a) DISCRETIONARY SURVEILLANCE.—The".

(b) SURVEILLANCE APPROVAL.—Section 522(b) (21 U.S.C. 360l(b)) is amended to read as follows:

"(b) SURVEILLANCE APPROVAL.—

"(1) IN GENERAL.—Each manufacturer that receives notice from the Secretary that the manufacturer is required to conduct surveillance of a device under subsection (a) shall, not later than 30 days after receiving the notice, submit for the approval of the Secretary, a plan for the required surveillance.

"(2) DETERMINATION.—Not later than 60 days after the receipt of the plan, the Secretary shall determine if a person proposed in the plan to conduct the surveillance has sufficient qualifications and experience to conduct the surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health and to provide safety and effectiveness information for the device.

"(3) LIMITATION ON PLAN APPROVAL.—The Secretary may not approve the plan until the plan has been reviewed by a qualified scientific and technical review committee established by the Secretary.".

SEC. 607. REPORTING.

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the first sentence by striking "make such reports, and provide such information," and inserting "and each such manufacturer or importer shall make such reports, provide such information, and submit such samples and components of devices (as required by paragraph (10)),";

(B) in paragraph (8), by striking "; and" and inserting a semicolon; and

(C) by striking paragraph (9) and inserting the following:

"(9) shall require distributors to keep records and make such records available to the Secretary upon request; and";

(2) by striking subsection (d); and

(3) in subsection (f), by striking ", importer, or distributor" each place it appears and inserting "or importer".

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3), the following:

"(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or"; and

(3) by adding at the end the following flush sentence:

"In this subsection, the term 'wholesale distributor' means any person who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.".

SEC. 608. PILOT AND SMALL-SCALE MANUFACTURE.

(a) NEW DRUGS.—Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end the following:

"(4) A new drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the new drug and to obtain approval of the new drug prior to scaling up to a larger facility, unless the Secretary determines that a full scale production facility is necessary to ensure the safety or effectiveness of the new drug.".

(b) NEW ANIMAL DRUGS.—Section 512(c) (21 U.S.C. 360b(c)) is amended by adding at the end the following:

"(4) A new animal drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the new drug and to obtain approval of the new drug prior to scaling up to a larger facility, unless the Secretary determines that a full scale production facility is necessary to ensure the safety or effectiveness of the new drug.".

SEC. 609. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include (but not be limited to) consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FINAL REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic or monitoring purposes, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, 1 or more disease states.

(b) DEFINITION.—In this section, the term "radiopharmaceutical" means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

SEC. 610. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

"(a)(1) Except as provided in paragraph (4), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

"(A) a biologics license is in effect for the biological product; and

"(B) each package of the biological product is plainly marked with—

"(i) the proper name of the biological product contained in the package;

"(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

"(iii) the expiration date of the biological product.

"(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

"(B) The Secretary shall approve a biologics license application on the basis of a demonstration that—

"(i) the biological product that is the subject of the application is safe, pure, and potent; and

"(ii) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

"(3) A biologics license application shall be approved only if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(4) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).".

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking "(d)(1)" and all that follows through "of this section.";

(B) in paragraph (2)—

(i) by striking "(2)(A) Upon" and inserting "(d)(1) Upon;" and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking "subparagraph (A)" and inserting "paragraph (1)"; and

(ii) by striking "this subparagraph" each place it appears and inserting "this paragraph".

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

"(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.".

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking "virus, serum," and all that follows and inserting "biological product.".

(d) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.".

(e) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking "section 351(a)" and inserting "section 351(i)"; and

(B) by striking "262(a)" and inserting "262(i)"; and

(2) in subparagraph (B)(iii), by striking "product or establishment license under subsection (a) or (d)" and inserting "biologics license application under subsection (a)".

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved full new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

SEC. 611. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) PERFORMANCE STANDARDS.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall publish in the Federal Register performance standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) RESPONSIBILITIES OF CENTERS.—The Secretary of Health and Human Services shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) COLLABORATION.—The Secretary of Health and Human Services shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 612. HEALTH CARE ECONOMIC INFORMATION.

(a) IN GENERAL.—Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading if the health care economic information directly relates to an indication approved under section 505 or 507 or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a), 507, or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.".

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.

SEC. 613. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is further amended by adding at the end the following:

"Subchapter E—Fast Track Drugs and Reports of Post-Market Approval Studies

"SEC. 561. FAST TRACK DRUGS.

"(a) DESIGNATION OF DRUG AS A FAST TRACK DRUG.—

"(1) IN GENERAL.—The Secretary shall facilitate development, and expedite review and approval of new drugs and biological products that are intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. In this Act, such products shall be known as 'fast track drugs'.

"(2) REQUEST FOR DESIGNATION.—The sponsor of a drug (including a biological product) may request the Secretary to designate the drug as a fast track drug. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(4) of the Public Health Service Act.

"(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track drug and shall take such actions as are appropriate to expedite the development and review of the drug.

"(b) APPROVAL OF APPLICATION FOR A FAST TRACK DRUG.—

"(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track drug under section 505(b) or section 351 of the Public Health Service Act (21 U.S.C. 262) upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.

"(2) LIMITATION.—Approval of a fast track drug under this subsection may be subject to the requirements—

"(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the clinical benefit of the drug; and

"(B) that the sponsor submit copies of all promotional materials related to the fast track drug during the preapproval review period and following approval, at least 30 days prior to dissemination of the materials for such period of time as the Secretary deems appropriate.

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track drug using expedited procedures (as prescribed by the Secretary in regulations) including a procedure that provides an opportunity for an informal hearing, if—

"(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

"(B) a post-approval study of the fast track drug fails to verify clinical benefit of the fast track drug;

"(C) other evidence demonstrates that the fast track drug is not safe or effective under conditions of use of the drug; or

"(D) the sponsor disseminates false or misleading promotional materials with respect to the fast track drug.

"(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK DRUG.—

"(1) IN GENERAL.—If preliminary evaluation by the Secretary of clinical efficacy data for a fast track drug under investigation shows evidence of effectiveness, the Secretary shall evaluate for filing, and may commence review of, portions of an application for the approval of the drug if the applicant provides a schedule for submission of information necessary to make the application complete and any fee that may be required under section 736.

"(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

"(d) AWARENESS EFFORTS.—The Secretary shall—

"(1) develop and widely disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a comprehensive description of the provisions applicable to fast track drugs established under this section; and

"(2) establish an ongoing program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.".

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track drugs that describes the policies and procedures that pertain to section 561 of the Federal Food, Drug, and Cosmetic Act.

SEC. 614. MANUFACTURING CHANGES FOR DRUGS AND BIOLOGICS.

(a) IN GENERAL.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 602, is further amended by adding at the end the following:

"Subchapter E—Manufacturing Changes

"SEC. 751. MANUFACTURING CHANGES.

"(a) IN GENERAL.—A change in the manufacture of a new drug, including a biological product, or a new animal drug may be made in accordance with this section.

"(b) CHANGES.—

"(1) VALIDATION.—Before distributing a drug made after a change in the manufacture of the drug from the manufacturing process established in the approved new drug application under section 505, the approved new animal drug application under section 512, or the license application under section 351 of the Public Health Service Act, the applicant shall validate the effect of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

"(2) REPORTS.—The applicant shall report the change described in paragraph (1) to the Secretary and may distribute a drug made after the change as follows:

"(A) MAJOR MANUFACTURING CHANGES.—

"(i) IN GENERAL.—Major manufacturing changes, which are of a type determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of a drug, shall be submitted to the Secretary in a supplemental application and drugs made after such changes may not be distributed until the Secretary approves the supplemental application.

"(ii) DEFINITION.—In this subparagraph, the term 'major manufacturing changes' means—

"(I) changes in the qualitative or quantitative formulation of a drug or the specifications in the approved marketing application for the drug (unless exempted by the Secretary from the requirements of this subparagraph);

"(II) changes that the Secretary determines by regulation or issuance of guidance require completion of an appropriate human study demonstrating equivalence of the drug to the drug manufactured before such changes; and

"(III) other changes that the Secretary determines by regulation or issuance of guidance have a substantial potential to adversely affect the safety or effectiveness of the drug.

"(B) OTHER MANUFACTURING CHANGES.—

"(i) IN GENERAL.—As determined by the Secretary, manufacturing changes other than major manufacturing changes shall—

"(I) be made at any time and reported annually to the Secretary, with supporting data; or

"(II) be reported to the Secretary in a supplemental application.

"(ii) DISTRIBUTION OF THE DRUG.—In the case of changes reported in accordance with clause (i)(II)—

"(I) the applicant may distribute the drug 30 days after the Secretary receives the supplemental application unless the Secretary notifies the applicant within such 30-day period that prior approval of such supplemental application is required;

"(II) the Secretary shall approve or disapprove each such supplemental application; and

"(III) the Secretary may determine types of manufacturing changes after which distribution of a drug may commence at the time of submission of such supplemental application.".

(b) EXISTING LAW.—The requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) that are in effect on the date of enactment of this Act with respect to manufacturing changes shall remain in effect—

(1) for a period of 24 months after the date of enactment of this Act; or

(2) until the effective date of regulations promulgated by the Secretary of Health and Human Services implementing section 751 of the Federal Food, Drug, and Cosmetic Act,

whichever is sooner.

SEC. 615. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary of the Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 616. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking "subsection (i)" and inserting "subsection (j)"; and

(B) by striking at the end "or";

(2) by striking the period at the end of paragraph (2) and inserting "; or";

(3) by inserting after paragraph (2) the following:

"(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

"(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

"(B) a notification submitted under subsection (h) that is effective."; and

(4) by striking the matter following paragraph (3) (as added by paragraph (2)) and inserting the following flush sentence:

"While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).".

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

"Notification Relating to a Food Contact Substance

"(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination, the fee required under paragraph (5), and all information required to be submitted by regulations promulgated by the Secretary.

"(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

"(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

"(C) In this paragraph, the term 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

"(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

"(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

"(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

"(5)(A) Each person that submits a notification regarding a food contact substance under this section shall be subject to the payment of a reasonable fee. The fee shall be based on the resources required to process the notification including reasonable administrative costs for such processing.

"(B) The Secretary shall conduct a study of the costs of administering the notification program established under this section and, on the basis of the results of such study, shall, within 18 months after the date of enactment of the Food and Drug Administration Modernization and Accountability Act of 1997, promulgate regulations establishing the fee required by subparagraph (A).

"(C) A notification submitted without the appropriate fee is not complete and shall not become effective for the purposes of subsection (a)(3) until the appropriate fee is paid.

"(D) Fees collected pursuant to this subsection—

"(i) shall not be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services;

"(ii) shall be credited to the appropriate account of the Food and Drug Administration; and

"(iii) shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

"(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.";

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: "The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective."; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking "subsections (b) to (h)" and inserting "subsections (b) to (i)".

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

SEC. 617. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end the following:

"(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) that is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made if—

"(i) an authoritative scientific body of the Federal Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or a subdivision of the scientific body or the National Academy of Sciences, has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(ii) a person has submitted to the Secretary at least 120 days before the first introduction of a food into interstate commerce a notice of the claim, including a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied;

"(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii), and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this paragraph, a statement shall be regarded as an authoritative statement of such a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(D) A claim submitted under the requirements of clause (C), may be made until—

"(i) such time as the Secretary issues an interim final regulation—

"(I) under the standard in clause (B)(i), prohibiting or modifying the claim; or

"(II) finding that the requirements of clause (C) have not been met; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.

Where the Secretary issues a regulation under subclause (i), good cause shall be deemed to exist for the purposes of subsections (b)(B) and (d)(3) of section 553 of title 5, United States Code. The Secretary shall solicit comments in response to a regulation promulgated under subclause (i) and shall publish a response to such comments.".

SEC. 618. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

(a) GENERAL AUTHORITY.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

"SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

"(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof are accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharmacopoeia) shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

"(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b) to the holder of an approved application under section 505(b)(1) for the drug, the holder agrees to the request, and the studies are completed within any such timeframe and the reports

thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(d) CONDUCT OF PEDIATRIC STUDIES.—

"(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

"(A) the sponsor of an application for an investigational new drug under section 505(i);

"(B) the sponsor of an application for a drug under section 505(b)(1); or

"(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug.

"(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

"(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

"(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under subsection (b)(2) or (j) of section 505 for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under subsection (b)(2) or (j), respectively, of section 505 until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

"(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.

"(g) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).

"(h) STUDY AND REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—

"(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

"(2) the adequacy of the incentive provided under this section;

"(3) the economic impact of the program; and

"(4) any suggestions for modification that the Secretary deems appropriate.

"(i) TERMINATION OF MARKET EXCLUSIVITY EXTENSION AUTHORITY FOR NEW DRUGS.—Except as provided in section 618(b) of the Food and Drug Administration Modernization and Accountability Act of 1997, no period of market exclusivity shall be extended under subsection (a) for a drug if—

"(1) the extension would be based on studies commenced after January 1, 2004; and

"(2) the application submitted for the drug under section 505(b)(1) was not approved by January 1, 2004.

"(j) DEFINITIONS.—In this section, the term 'pediatric studies' or 'studies' means at least 1 clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age-groups in which a drug is anticipated to be used.".

(b) MARKET EXCLUSIVITY UNDER OTHER AUTHORITY.—

(1) THROUGH CALENDAR YEAR 2003.—

(A) DETERMINATION.—If the Secretary requests or requires pediatric studies, prior to January 1, 2004, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the sponsor of an application, or the holder of an approved application, for a drug under section 505(b) of such Act (21 U.S.C. 355(b)), the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(B) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(2) CALENDAR YEAR 2004 AND SUBSEQUENT YEARS.—

(A) NEW DRUGS.—Effective January 1, 2004, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act, from the sponsor of an application for a drug under section 505(b) of such Act, nothing in such law shall be construed to permit or require the Secretary to ensure that the period of market exclusivity for the drug is extended.

(B) ALREADY MARKETED DRUGS.—

(i) DETERMINATION.—Effective January 1, 2004, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the holder of an approved application for a drug under section 505(b) of such Act, the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(ii) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act).

(3) DEFINITIONS.—In this subsection:

(A) DRUG.—The term "drug" has the meaning given the term in section 201 of such Act.

(B) PEDIATRIC STUDIES.—The term "pediatric studies" has the meaning given the term in section 505A of such Act.

(C) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

SEC. 619. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) DEFINITION.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

"(ii) The term 'compounded positron emission tomography drug'—

"(1) means a drug that—

"(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

"(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

"(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.".

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking "; or (3)" and inserting the following: "; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3)".

(2) SUNSET.—Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date or which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later.

(c) REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of compounded positron emission tomography drugs and the special techniques and processes required to produce these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall establish—

(i) appropriate procedures for the approval of compounded positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use compounded positron emission tomography drugs.

(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date or which the Secretary establishes procedures and requirements under paragraph (1), whichever is later.

(B) EXCEPTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a compounded positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) for such drugs.

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule, to the extent the notices and rule relate to compounded positron emission tomography drugs:

(1) A notice entitled "Regulation of Positron Emission Tomographic Drug Products: Guidance; Public Workshop", published in the Federal Register on February 27, 1995.

(2) A notice entitled "Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products; Availability", published in the Federal Register on April 22, 1997.

(3) A final rule entitled "Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography", published in the Federal Register on April 22, 1997.

(e) DEFINITION.—As used in this section, the term "compounded positron emission tomography drug" has the meaning given the term in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).

SEC. 620. DISCLOSURE.

Chapter IV (21 U.S.C. 341 et seq.) is amended by adding after section 403B the following:

"DISCLOSURE

"SEC. 403C. (a) No provision of section 403(a), 201(n), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

"(b) In this section, the term 'radiation disclosure statement' means a written statement that discloses that a food or a component of the food has been intentionally subject to radiation.".

SEC. 621. REFERRAL STATEMENTS RELATING TO FOOD NUTRIENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

"(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, then the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information panel for ___ content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.".

TITLE VII—FEES RELATING TO DRUGS

SEC. 701. SHORT TITLE.

This title may be cited as the "Prescription Drug User Fee Reauthorization Act of 1997".

SEC. 702. FINDINGS.

Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in appropriate letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate.

SEC. 703. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

(A) by striking "Service Act, and" and inserting "Service Act,"; and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug or biological product that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.";

(2) in the second sentence of paragraph (3)—

(A) by striking "Service Act, and" and inserting "Service Act,"; and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug or biological product that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.";

(3) in paragraph (4), by striking "without" and inserting "without substantial";

(4) by striking paragraph (5) and inserting the following:

"(5) The term 'prescription drug establishment' means a foreign or domestic place of

business which is at 1 general physical location consisting of 1 or more buildings all of which are within 5 miles of each other, at which 1 or more prescription drug products are manufactured in final dosage forms.";

(5) in paragraph (7)(A)—

(A) by striking "employees under contract" and all that follows through "Administration," and inserting "contractors of the Food and Drug Administration,"; and

(B) by striking "and committees," and inserting "and committees and to contracts with such contractors,";

(6) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking "August of" and inserting "April of"; and

(ii) by striking "August 1992" and inserting "April 1997";

(B) by striking subparagraph (B) and inserting the following:

"(B) 1 plus the decimal expression of the total percentage increase for such fiscal year since fiscal year 1997 in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia."; and

(C) by striking the second sentence; and

(7) by adding at the end the following:

"(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) 1 business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has power to control both of the business entities.".

SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) by striking "Beginning in fiscal year 1993" and inserting "Beginning in fiscal year 1998";

(2) in paragraph (1)—

(A) by striking subparagraph (B) and inserting the following:

"(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.";

(B) in subparagraph (D)—

(i) in the subparagraph heading, by striking "NOT ACCEPTED" and inserting "REFUSED";

(ii) by striking "50 percent" and inserting "75 percent";

(iii) by striking "subparagraph (B)(i)" and inserting "subparagraph (B)"; and

(iv) by striking "not accepted" and inserting "refused"; and

(C) by adding at the end the following:

"(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes indications for other than rare diseases or conditions. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), provided that the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

"(F) EXCEPTION FOR SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A supplement to a human drug application for an indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).

"(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement is filed, the Secretary may waive and refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to waive and refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a waiver or refund under this paragraph shall not be reviewable.";

(3) by striking paragraph (2) and inserting the following:

"(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

"(A) IN GENERAL.—Each person that—

"(i) is named as the applicant in a human drug application; and

"(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement;

shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only 1 fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than 1 applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

"(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

"(i) that did not manufacture the product in the previous fiscal year; and

"(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which manufacture of the product began."; and

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking "is listed" and inserting "has been submitted for listing"; and

(ii) by striking "Such fee shall be payable" and all that follows through "section 510." and inserting the following: "Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable."; and

(B) in subparagraph (B), by striking "505(j)." and inserting the following: "505(j), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, or is a product approved under an application filed under section 507 that is abbreviated.".

(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

"(1) APPLICATION AND SUPPLEMENT FEES.—

"(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in each of fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

"(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in each of fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

"(2) FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

"(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.".

(c) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in the subsection heading, by striking "INCREASES AND";

(2) in paragraph (1)—

(A) by striking "(1) REVENUE" and all that follows through "increased by the Secretary" and inserting the following: "(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary";

(B) in subparagraph (A), by striking "increase" and inserting "change";

(C) in subparagraph (B), by striking "increase" and inserting "change"; and

(D) by adding at the end the following flush sentence:

"The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.";

(3) in paragraph (2), by striking "October 1, 1992," and all that follows through "such schedule." and inserting the following: "September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b).."; and

(4) in paragraph (3), by striking "paragraph (2)" and inserting "this subsection".

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively, and indenting appropriately;

(2) by striking "The Secretary shall grant a" and all that follows through "finds that—" and inserting the following:

"(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that—";

(3) in subparagraph (C) (as so redesignated by paragraph (1)), by striking ", or" and inserting a comma;

(4) in subparagraph (D) (as so redesignated by paragraph (1)), by striking the period and inserting ", or";

(5) by inserting after subparagraph (D) (as so redesignated by paragraph (1)) the following:

"(E) the applicant is a small business submitting its first human drug application to the Secretary for review."; and

(6) by striking "In making the finding in paragraph (3)," and all that follows through "standard costs." and inserting the following:

"(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

"(3) RULES RELATING TO SMALL BUSINESSES.—

"(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

"(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

"(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

"(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.".

(e) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(1) by striking "fiscal year 1993" and inserting "fiscal year 1997"; and

(2) by striking "fiscal year 1992" and inserting "fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)".

(f) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(1) in paragraph (1), by adding at the end the following: "Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of section 735(6).";

(2) in paragraph (2)—

(A) in subparagraph (A), by striking "Acts" and inserting "Acts, or otherwise made available for obligation,"; and

(B) in subparagraph (B), by striking "over such costs for fiscal year 1992" and inserting "over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997"; and

(3) by striking paragraph (3) and inserting the following:

"(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fees under this section—

"(A) $106,800,000 for fiscal year 1998;

"(B) $109,200,000 for fiscal year 1999;

"(C) $109,200,000 for fiscal year 2000;

"(D) $114,000,000 for fiscal year 2001; and

"(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

"(4) OFFSET.—Any amount of fees collected for a fiscal year which exceeds the amount of fees specified in appropriation Acts for such fiscal year, shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under appropriation Acts for a subsequent fiscal year.".

(g) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND FEES.—Section 736 (21 U.S.C. 379h) is amended—

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following:

"(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund, of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.".

(h) SPECIAL RULE FOR WAIVER, REFUNDS, AND EXCEPTIONS.—Any requests for waivers, refunds, or exceptions for fees paid prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act.

SEC. 705. ANNUAL REPORTS.

(a) FIRST REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in section 702(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) SECOND REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 706. EFFECTIVE DATE.

The amendments made by this title shall take effect October 1, 1997.

SEC. 707. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 703 and 704 cease to be effective October 1, 2002 and section 705 ceases to be effective 120 days after such date.

TITLE VIII—MISCELLANEOUS

SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

"(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

"(2) The establishment shall also provide the information required by subsection (j).

"(3) The Secretary is authorized to enter into cooperative arrangements with foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).".

SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

"(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.

"(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).".

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

(c) CONFORMING AMENDMENTS.—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively.

(2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is amended by striking "section 502(d) and".

(3) Section 102(9)(A) of the Controlled Substances Act (21 U.S.C. 802(9)(A)) is amended—

(A) in clause (i), by striking "(i)"; and

(B) by striking "(ii)" and all that follows.

SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in the fifth sentence, by striking "paragraphs (1) and (2) of section 801(e)" and inserting "subparagraphs (A) and (B) of section 801(e)(1)"; and

(2) by inserting after the fifth sentence the following: "Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.".

SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 203, is further amended by adding at the end the following:

"SEC. 907. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may, directly or through grants, contracts, or cooperative agreements, conduct and support intramural research training in regulatory scientific programs by

predoctoral and postdoctoral scientists and physicians, including support through the use of fellowships.

"(b) LIMITATION ON PARTICIPATION.—A recipient of a fellowship under subsection (a) may not be an employee of the Federal Government.

"(c) SPECIAL RULE.—The Secretary, acting through the Commissioner of Food and Drugs, may support the provision of assistance for fellowships described in subsection (a) through a Cooperative Research and Development Agreement.".

SEC. 805. DEVICE SAMPLES.

(a) RECALL AUTHORITY.—

(1) IN GENERAL.—Section 518(e)(2) (21 U.S.C. 360h(e)(2)) is amended by adding at the end the following:

"(C) If the Secretary issues an amended order under subparagraph (A), the Secretary may require the person subject to the order to submit such samples of the device and of components of the device as the Secretary may reasonably require. If the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.".

(2) TECHNICAL AMENDMENT.—Section 518(e)(2)(A) (21 U.S.C. 360h(e)(2)(A)) is amended by striking "subparagraphs (B) and (C)" and inserting "subparagraph (B)".

(b) RECORDS AND REPORTS ON DEVICES.—Section 519(a) (21 U.S.C. 360i(a)) is amended by inserting after paragraph (9) the following:

"(10) may reasonably require a manufacturer or importer to submit samples of a device and of components of the device that may have caused or contributed to a death or serious injury, except that if the submission of such samples is impracticable or unduly burdensome, the requirement of this paragraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.".

SEC. 806. INTERSTATE COMMERCE.

Section 709 (21 U.S.C. 379a) is amended by striking "a device" and inserting "a device, food, drug, or cosmetic".

SEC. 807. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.

(a) NONPRESCRIPTION DRUGS.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 614(a), is further amended by adding at the end the following:

"Subchapter F—National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics

"SEC. 761. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS.

"(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—

"(1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and

"(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

"(b) EXEMPTION.—

"(1) IN GENERAL.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

"(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

"(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

"(C) would not unduly burden interstate commerce.

"(2) TIMELY ACTION.—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

"(c) SCOPE.—

"(1) IN GENERAL.—This section shall not apply to—

"(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

"(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

"(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

"(d) EXCEPTIONS.—

"(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or 507 or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

"(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

"(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after the date of enactment of this section.

"(2) STATE INITIATIVES.—This section shall not apply to a State public initiative enacted prior to the date of enactment of this section.

"(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this Act.".

(b) INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking "prescription drugs" each place it appears and inserting "prescription drugs, nonprescription drugs intended for human use,".

(c) MISBRANDING.—Paragraph (1) of section 502(e) (21 U.S.C. 352(e)(1)) is amended to read as follows:

"(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

"(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

"(ii) the established name and quantity or, if deemed appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if deemed appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall not apply to nonprescription drugs not intended for human use; and

"(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if deemed appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, but nothing in this clause shall be deemed to require that any trade secret be divulged: *Provided*, That the requirements of this clause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics: and *Provided further*, That this clause shall not apply to nonprescription drugs not intended for human use.

"(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or (iii) or this clause of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.".

(d) COSMETICS.—Subchapter F of chapter VII, as amended by subsection (a), is further amended by adding at the end the following:

"SEC. 762. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

"(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), a State or political subdivision of a State shall not impose or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

"(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling and packaging that—

"(1) protects an important public interest that would otherwise be unprotected;

"(2) would not cause a cosmetic to be in violation of any applicable requirements or prohibition under Federal law; and

"(3) would not unduly burden interstate commerce.

"(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

"(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.".

SEC. 808. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i), the following:

"(j)(1) The Secretary, acting through the Director of the National Institutes of Health and subject to the availability of appropriations, shall establish, maintain, and operate a program with respect to information on research relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated, and, to the extent practicable, coordinated with other data banks containing similar information.

"(2)(A) After consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention, the Secretary shall, in carrying out paragraph (1), establish a data bank of information on clinical trials for drugs, and biologicals, for serious or life-threatening diseases and conditions.

"(B) In carrying out subparagraph (A), the Secretary shall collect, catalog, store, and disseminate the information described in such subparagraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

"(3) The data bank shall include the following:

"(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to sections 505 and 520 of the Federal Food, Drug, and Cosmetic Act that provides a description of the purpose of each experimental drug or biological protocol, either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall consist of eligibility criteria, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information must be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

"(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

"(i) under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations; or

"(ii) as a Group C cancer drug.

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

"(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that finds that such disclosure would not substantially interfere with such enrollment.

"(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h) shall not be authorized or appropriated for use in carrying out this subsection.".

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report that shall consider, among other things—

(A) the public health need, if any, for inclusion of device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act; and

(B) the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigation is required to be publicly disclosed.

SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

"(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

"(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

"(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

"(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

"(I) the individual patient for whom the prescription order will be provided; or

"(II) the physician or other licensed practitioner who will write such prescription order; and

"(B) the licensed pharmacist or licensed physician—

"(i) compounds the drug product using bulk drug substances—

"(I) that—

"(aa) comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph; or

"(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

"(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

"(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph and the United States Pharmacopeia chapter on pharmacy compounding;

"(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

"(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

"(v) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

"(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary regarding the regulation of drugs that are compounded in the State and are distributed outside of the State, that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

"(2)(A) The Secretary shall, after consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

"(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

"(i) the date that is 180 days after the development of the standard memorandum of understanding; or

"(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi),

whichever occurs first.

"(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

"(4) The provisions of paragraph (1) shall not apply—

"(A) to compounded positron emission tomography drugs as defined in section 201(ii); or

"(B) to radiopharmaceuticals.

"(5) In this subsection, the term 'compound' does not include to mix, reconstitute, or perform another similar act, in accordance with directions contained in approved drug labeling provided by a drug manufacturer and other drug manufacturer directions consistent with that labeling.".

SEC. 810. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 613(a), is further amended by adding at the end the following:

"SEC. 562. REPORTS OF POSTMARKETING STUDIES.

"(a) SUBMISSION.—

"(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as prescribed by the Secretary in regulations issued by the Secretary.

"(2) AGREEMENTS PRIOR TO EFFECTIVE DATE.—An agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of this section, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

"(b) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—Any information pertaining to a report described in paragraph (1) shall be considered to be public information to the extent that the information is necessary—

"(1) to identify the sponsor; and

"(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

"(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides a status of the postmarketing studies—

"(1) that sponsors have entered into agreements to conduct; and

"(2) for which reports have been submitted under subsection (a)(1).".

(b) REPORT TO CONGRESSIONAL COMMITTEES.—Not later than October 1, 2001, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report containing—

(1) a summary of the reports submitted under section 562 of the Federal Food, Drug, and Cosmetic Act; and

(2) an evaluation of—

(A) the performance of the sponsors in fulfilling the agreements with respect to the conduct of postmarketing studies described in such section of such Act;

(B) the timeliness of the Secretary's review of the postmarketing studies; and

(C) any legislative recommendations respecting postmarketing studies.

SEC. 811. INFORMATION EXCHANGE.

(a) IN GENERAL.—Chapter VII (2 U.S.C. 371 et seq.), as amended by section 807, is further amended by adding at the end the following:

"Subchapter G—Dissemination of Treatment Information

"SEC. 771. DISSEMINATION OF TREATMENT INFORMATION ON DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

"(a) DISSEMINATION OF TREATMENT INFORMATION.—

"(1) IN GENERAL.—Notwithstanding sections 301(d), 502(f), 505, and 507 and section 351 of the Public Health Service Act (42 U.S.C. 262), and subject to the requirements of paragraphs (2) through (6) and subsection (b), a manufacturer may disseminate to a health care practitioner, a pharmacy benefit manager, a health maintenance organization or other managed health care organization, or a health care insurer or governmental agency, written information concerning the safety, effectiveness, or benefit (whether or not such information is contained in the official labeling) of a drug, biological product, or device for which—

"(A) an approval of an application filed under section 505(b), 505(j), or 515, a clearance in accordance with section 510(k), an approval in accordance with section 507, or a biologics license issued under section 351 of the Public Health Service Act, is in effect; and

"(B) if the use is not described in the approved labeling of the product, the manufacturer has submitted to the Secretary a certification that a supplemental application for that use will be submitted to the Secretary pursuant to paragraph (3) or the manufacturer has received an exemption under paragraph (3)(C).

"(2) AUTHORIZED INFORMATION.—A manufacturer may disseminate the written information under paragraph (1) only if the information—

"(A) is in the form of an unabridged—

"(i) reprint or copy of a peer-reviewed article from a scientific or medical journal (as defined in subsection (c)(5)) of a clinical investigation, with respect to a drug, biological product or device, that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, biological product, or device that is the subject of such clinical investigation; or

"(ii) reference textbook (as defined in subsection (c)(4)) that includes information about a clinical investigation with respect to a drug, biological product, or device, that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, biological product, or device that is the subject of such clinical investigation; and

"(B) is not false, not misleading, and would not pose a significant risk to the public health.

"(3) COMMITMENT TO FILE A SUPPLEMENTAL APPLICATION; INCENTIVES FOR RESEARCH.—

"(A) IN GENERAL.—A manufacturer may disseminate information about a use not described in the approved labeling of a drug, biological product, or device pursuant to paragraph (1) only if—

"(i) the manufacturer has submitted to the Secretary a certification that the studies needed to file a supplemental application for such use have been completed and such supplement will be filed within 6 months after the date of the initial dissemination of information under paragraph (1); or

"(ii)(I) the manufacturer has submitted to the Secretary a proposed protocol and schedule for conducting the studies needed to submit a supplemental application for such use and has certified that the supplement will be submitted within 36 months after the date of the initial dissemination of information under paragraph (1); and

"(II) the Secretary has determined that the protocol for conducting such studies is adequate and that the schedule for completing such studies is reasonable.

"(B) EXTENSION.—

"(i) LONGER PERIOD OF TIME.—The Secretary may grant a longer period of time for a manufacturer to submit a supplemental application pursuant to subparagraph (A) if the Secretary determines that the studies needed to submit a supplemental application cannot be completed and submitted within 36 months.

"(ii) EXTENSION OF 3-YEAR PERIOD.—The Secretary may extend the time within which a manufacturer must submit a supplemental application pursuant to subparagraph (A) if the manufacturer demonstrates that the manufacturer has acted with due diligence to conduct the studies in a timely manner. Such extension shall not exceed a period of 24 months.

"(C) EXEMPTIONS.—A manufacturer may file a request for an exemption from the requirements set forth in subparagraph (A). Such request shall be submitted in the form and manner prescribed by the Secretary and shall demonstrate that—

"(i) due to the size of the patient population or the 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.

The Secretary shall act on a request for an exemption under this subparagraph within 60 days after the receipt of the request. If the Secretary fails to act within 60 days, the manufacturer may begin to disseminate information pursuant to paragraph (1) without complying with subparagraph (A). If the Secretary subsequently denies the request for an exemption, the manufacturer either shall cease dissemination or shall comply with the requirements of subparagraph (A) within 60 days after such denial. If the manufacturer ceases dissemination pursuant to this subparagraph solely on the basis that the manufacturer does not comply with subparagraph (A), the Secretary may take appropriate corrective action, but may not order the manufacturer to take corrective action.

"(D) REPORT.—A manufacturer who submits a certification to the Secretary under subparagraph (A) shall provide the Secretary periodic reports that describe the status of the studies being conducted to obtain adequate evidence for approval of a supplemental application.

"(4) INFORMATION ON NEW USES.—

"(A) IN GENERAL.—If the information being disseminated under paragraph (1) meets the requirements of this section, a manufacturer

may disseminate information under paragraph (1) concerning the new use of a drug, biological product, or device (described in paragraph (1)) 60 calendar days after the manufacturer has submitted to the Secretary—

"(i) a copy of the information; and

"(ii) any clinical trial information the manufacturer has relating to the safety or efficacy of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information.

If any of the information required to be provided under clause (ii) has already been provided to the Secretary, the manufacturer may meet the requirements of clause (ii) by providing any such information obtained by the manufacturer since the manufacturer's last submission to the Secretary and a summary that identifies the information previously provided.

"(B) ADDITIONAL INFORMATION.—If the Secretary determines that the information submitted by a manufacturer under subparagraph (A)(i) with respect to a new use of a drug, biological product, or device fails to provide data, analyses, or other written matter, that is objective and balanced, the Secretary may require the manufacturer to disseminate along with the information described in subparagraph (A)—

"(i) additional information with respect to the new use of the drug, biological product, or device that—

"(I) is in the form of an article described in paragraph (2)(A); and

"(II) provides data, analyses, or other written matter, that is scientifically sound;

"(ii) additional objective and scientifically sound information that pertains to the safety or efficacy of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary, or where appropriate, a summary of such information, or any other information that the Secretary has authority to make available to the public;

"(iii) an objective statement prescribed by the Secretary based on information described in clause (i) or (ii), provided the manufacturer has access to the data that forms the basis of such statement unless the Secretary is prohibited from making such data available to the manufacturer; and

"(iv) a statement that describes any previous public announcements by the Secretary relevant to the new use.

"(5) NEW INFORMATION.—If a manufacturer that is disseminating information pursuant to paragraph (1) becomes aware of new information relating to the safety or efficacy of a new use of a drug, biological product, or device for which information was disseminated under paragraph (1), the manufacturer shall notify the Secretary with respect to the new information. If the Secretary determines that the new information demonstrates that a drug, biological product, or device may not be effective or may present a significant risk to public health, the Secretary shall, in consultation with the manufacturer, take such appropriate action as the Secretary determines necessary to ensure public health and safety. The Secretary may limit the types of new information that must be submitted under this paragraph.

"(6) CESSATION OF DISSEMINATION; CORRECTIVE ACTION.—The Secretary may order a manufacturer to cease the dissemination of all information being disseminated pursuant to paragraph (1) if—

"(A) the Secretary finds that a supplemental application does not contain adequate information for approval for the use that is the subject of the information;

"(B) the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies necessary to file a supplemental application for the use that is the subject of the information being disseminated; or

"(C) the Secretary determines that the information being disseminated does not comply with the requirements set forth in this section, after providing notice, an opportunity for a meeting, and for minor violations of this section (if there has been substantial compliance with this section), an opportunity to correct such information.

If the Secretary orders cessation of dissemination pursuant to this paragraph, the Secretary may order the manufacturer to take appropriate corrective action.

"(7) SPONSORED RESEARCH.—If a manufacturer has sponsored research that results in information as described in paragraph (2)(A), another manufacturer may not distribute the information under this section, unless such manufacturer is required by the Secretary to distribute the information.

"(b) DISCLOSURE STATEMENT.—In order to afford a full and fair evaluation of the information described in subsection (a), a manufacturer disseminating the information shall include along with the information—

"(1) a prominently displayed statement that discloses—

"(A) that the information concerns a use of a drug, biological product, or device or other attribute of a drug, biological product, or device that has not been approved by the Food and Drug Administration;

"(B) if applicable, that the information is being disseminated at the expense of the manufacturer;

"(C) if applicable, the name of any authors of the information who are employees of, or consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

"(D) the official labeling for the drug, biological product, or device and all updates with respect to the labeling;

"(E) if applicable, a statement that there are products or treatments that have been approved for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

"(F) the identification of any person that has provided funding for the conduct of a study relating to a new use of a drug, biological product, or device for which such information is being disseminated; and

"(2) a bibliography of other articles from a scientific reference textbook or scientific or medical journal that have been previously published about the new use of a drug, biological product, or device covered by the information disseminated (unless the information already includes such bibliography).

"(c) DEFINITIONS.—As used in this section:

"(1) HEALTH CARE PRACTITIONER.—The term 'health care practitioner' means a medical provider that is licensed to prescribe a drug or biological product, or to prescribe or use a device, for the treatment of a disease or other medical condition.

"(2) MANUFACTURER.—The term 'manufacturer' includes a person who manufactures, distributes, or markets a drug, biological product, or device.

"(3) NEW USE.—The term 'new use' used with respect to a drug, biological product, or device means a use of a drug, biological product, or device not included in the approved labeling of such drug, biological product, or device.

"(4) REFERENCE TEXTBOOK.—The term 'reference textbook' means a reference publication that—

"(A) has not been written, edited, excerpted, or published specifically for, or at the request of a manufacturer of a drug, biological product, or device;

"(B) has not been edited or significantly influenced by a manufacturer of a drug, biological product, or device;

"(C) is not solely distributed through a manufacturer of a drug, biological product, or device but is generally available in bookstores or other distribution channels where medical textbooks are sold;

"(D) does not focus on any particular drug, biological product, or device of a manufacturer that disseminates information under subsection (a), and does not have a primary focus on new uses of drugs, biological products, or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

"(E) presents materials that are not false or misleading.

"(5) SCIENTIFIC OR MEDICAL JOURNAL.—The term 'scientific or medical journal' means a scientific or medical publication—

"(A) that is published by an organization—

"(i) that has an editorial board;

"(ii) that utilizes experts, who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles; and

"(iii) that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

"(B) whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

"(C) that is generally recognized to be of national scope and reputation;

"(D) that is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health;

"(E) that presents materials that are not false or misleading; and

"(F) that is not in the form of a special supplement that has been funded in whole or in part by 1 or more manufacturers.

"(d) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

"(e) STUDIES AND REPORTS.—

"(1) GENERAL ACCOUNTING OFFICE.—

"(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine the impact of this section on the resources of the Department of Health and Human Services.

"(B) REPORT.—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report of the results of the study.

"(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—

"(A) IN GENERAL.—In order to assist Congress in determining whether the provisions of this section should be extended beyond the termination date specified in section 811(e) of the Food and Drug Administration Modernization and Accountability Act of 1997,

the Secretary of Health and Human Services shall, in accordance with subparagraph (B), arrange for the conduct of a study of the scientific issues raised as a result of the enactment of this section, including issues relating to—

"(i) the effectiveness of this section with respect to the provision of useful scientific information to health care practitioners;

"(ii) the quality of the information being disseminated pursuant to the provisions of this section;

"(iii) the quality and usefulness of the information provided, in accordance with this section, by the Secretary or by the manufacturer at the request of the Secretary; and

"(iv) the impact of this section on research in the area of new uses, indications, or dosages, particularly the impact on pediatric indications and rare diseases.

"(3) PROCEDURE FOR STUDY.—

"(A) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (2), and to prepare and submit the report required by subparagraph (B), under an arrangement by which the actual expenses incurred by the Institute of Medicine in conducting the study and preparing the report will be paid by the Secretary. If the Institute of Medicine is unwilling to conduct the study under such an arrangement, the Secretary shall enter into a similar arrangement with another appropriate nonprofit private group or association under which the group or association will conduct the study and prepare and submit the report.

"(B) REPORT.—Not later than September 30, 2005, the Institute of Medicine, the group, or association, as appropriate, shall prepare and submit to the Committee on Labor and Human Resources of the Senate, the Committee on Commerce of the House of Representatives, and the Secretary a report of the results of the study required by paragraph (2). The Secretary, after the receipt of the report, shall make the report available to the public.

"(4) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated such sums as are necessary to carry out this subsection.

"SEC. 772. ESTABLISHMENT OF LIST OF ARTICLES AND TEXTBOOKS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE TEXTBOOKS.

"(a) IN GENERAL.—A manufacturer that disseminates information in the form of articles or reference textbooks under section 771 shall prepare and submit to the Secretary biannually—

"(1) a list containing the titles of the articles and reference textbooks relating to the new use of drugs, biological products, and devices that were disseminated by the manufacturer to a person described in section 771(a)(1) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

"(2) a list that identifies the categories of providers (as described in section 771(a)(1)) that received the articles and reference textbooks for the 6-month period described in paragraph (1).

"(b) RECORDS.—A manufacturer that disseminates information under section 771 shall keep records that identify the recipients of articles and textbooks provided pursuant to section 771. Such records are to be used by the manufacturer when, pursuant to section 771(a)(6), such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to paragraph (3), (5), or (6) of section 771(a).

"SEC. 773. CONSTRUCTION.

"(a) DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 771, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

"(b) PATENT PROTECTION.—Nothing in section 771 shall affect patent rights in any manner.

"(c) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 771 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 771(c)(5)) from requiring authorization from the entity to disseminate an article published by such entity and from charging fees for the purchase of reprints of published articles from such entity.".

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 205(b), is further amended by adding at the end the following:

"(y) The dissemination of information pursuant to section 771 by a manufacturer who fails to comply with the requirements of such section.".

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

(e) TERMINATION OF EFFECTIVENESS.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.

SEC. 812. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.

Section 2 of Public Law 102-222 (105 Stat. 1677) is amended—

(1) in subsection (a), by striking "a grant" and all that follows through "Such grant" and inserting the following: "grants for a pilot program for the training of individuals in clinical pharmacology at appropriate medical schools. Such grants"; and

(2) in subsection (b), by striking "to carry out this section" and inserting ", and for fiscal years 1998 through 2002 $3,000,000 for each fiscal year, to carry out this section".

SEC. 813. MONOGRAPH FOR SUNBURN PRODUCTS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final monograph for over-the-counter sunburn products for prevention or treatment of sunburn.

SEC. 814. SAFETY REPORT DISCLAIMERS.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 804, is further amended by adding at the end the following:

"SEC. 908. SAFETY REPORT DISCLAIMERS.

"With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product which is a food, drug, new drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report or information), such report or information shall not be construed to necessarily reflect a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, serious illness, or malfunction. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved caused or contributed to an adverse experience or caused or contributed to a death, serious injury, serious illness, or malfunction.".

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

Mr. COATS. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. JEFFORDS. Mr. President, I thank my colleagues and I thank them profusely for their vote, for their support in the committee, and all the work that has gone into this. But, as we all know, there are people who work behind the scenes, those who are probably more responsible for this vote than we on the floor are. I just want to take a moment to thank the staff.

In the office of Senate Legislative Counsel, Robin Bates, Elizabeth Aldridge, and Bill Baird worked tirelessly to produce countless bill drafts and amendments. And how they came out with them as expeditiously as they did, I'm not sure.

The staff at CRS, especially Donna Vogt, and at GAO, including Bernice Steinhardt deserve thanks for their willingness to provide essential information and documents on extremely short notice. We must always remember to appreciate these organizations that provide so much assistance to the Congress.

The staff to the members of the committee contributed greatly to the success of this bill. In particular, Vince Ventimiglia with Senator COATS' staff worked closely with ours in a true partnership on all aspects of S. 830.

In addition, Kimberly Spaulding with Senator GREGG, Sue Ramthun with Senator FRIST, Saira Sultan with Senator DEWINE, and Kate Lambrew-Hull with Senator HUTCHINSON all played important roles in fashioning compromises on key provisions of this bill. Also, Mark Smith with Senator MACK's staff worked very hard to make the agreement on off-label dissemination of information possible.

I would also like to thank the many staff of the administration who have worked on this legislation.

In particular, I want to thank Bill Schultz, Diane Thompson, and Peggy Dotzel, of the FDA.

Similarly, three staffers for members of the minority on the committee

played pivotal roles even before committee markup took place in making this bill a bipartisan success.

Lynne Lawrence with Senator MIKULSKI deserves special mention in recognition of her hard work in the last Congress on FDA reform and her willingness to put her future career plans on hold to commit herself again to the long hard job of bringing this bill to the floor this year. Jeanne Ireland with Senator DODD and Linda DeGutis, a fellow with Senator WELLSTONE also provided invaluable assistance.

Of course I would like to thank the Labor and Human Resources Committee majority and minority staffs who did the most work on this. In particular, I want to recognize Susan Hattan who stayed on with the committee after Senator Kassebaum's retirement.

She, and another Senator Kassebaum staffer, Jane Williams, who is now on the staff of Representative FRED UPTON, worked long hours last year to put FDA reform on the Senate agenda and brought a bill to successful committee markup in the last Congress—we stand here today in large part due to their hard work.

On the minority staff, I would like to thank Nick Littlefield and David Nexon and two minority fellows Diane Robertson and Debbie Kochever. Finally, I would like to thank the majority staff director Mark Powden, Jay Hawkins, and majority fellow Sean Donohue.

I want to take a moment to elaborate on my comments regarding one of the majority staff who has worked so diligently on this measure—Jay Hawkins. Jay joined my staff in January—literally hit the ground running—and I don't think he has stopped moving since.

He has set a new standard of dedication for professional staff to find the best solution in a difficult and controversial policy arena. He has been saluted by other Senators' staffs, from both majority and minority offices, for his willingness to include them in all aspects of this effort.

Mr. President, part of the job description for Senate staff is to take abuse. Jay unfortunately received more than his share, but it said more about his critics than him.

More recently—a little more than a month ago—Jay lost his mother to her 4-year battle with cancer. My friend, Senator HATCH, acknowledged on the floor just yesterday this hardship Jay faced and was eloquent in his praise for both Jay and for his mother—Donna Lotz Hawkins. Mrs. Hawkins was not unfamiliar with challenge and adversity. She was an experienced mountain climber and conquered some of the world's most difficult mountains in the Alaska range, the Tetons, the Alps, and the Himalayas. She was a dedicated ocean swimmer and conquered the white waters in Waikiki and Maui.

It is clear to us who know Jay that he too has the spirit of taking on the task when faced with adversity and challenge. We know the source of that sense of commitment and we cannot thank him enough for his efforts on this bill.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, in typical fashion, Senator JEFFORDS has given great credit where credit is due, and as I mentioned just before, the chairman of our committee really deserves credit for the passage of this very important bill. I commend him.

If I could, I will just take a moment of the Senate's time, but I think it is important to mention on our side David Nexon and Diane Robertson, who worked so closely with us; Jim Manly, Debbie Kochevar, Meg Archdeacon, Burt Cowgill, Susan Hammersten, Jonathan Halperin, and Danielle Drissel, Carrie Coberly and Addy Schmidt; Bonnie Hogue on Senator REED's staff and Deborah Walker on Senator BINGAMAN's staff; Sabrina Corlette with Senator HARKIN and Anne-Marie Murphy with Senator DURBIN.

I would like to believe the staffs have been helpful to all of us and don't work so much in a partisan way as in a common spirit, to try to advance the common interests. That has been, certainly, true on this legislation.

I thank all of those, and the majority staff as well, for all of their courtesies and for their cooperation. I think the record ought to show the dedication of, really, an outstanding group of men and women who have really served the Senate very, very well. I thank the chairman.

Mr. JEFFORDS. Mr. President, I thank the ranking minority member on my committee for his words. I commend him, also. We disagreed rather strongly on one issue here, but 19 out of 20 we were together and worked together, and certainly that's a pretty good average.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

DISTRICT OF COLUMBIA APPROPRIATIONS ACT, 1998

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the Senate now turn to consideration of Calendar No. 155, S. 1156, the District of Columbia appropriations bill.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

A bill (S. 1156) making appropriations for the government of the District of Columbia and other activities chargeable in whole or in part against the revenues of said District for the fiscal year ending September 30, 1998, and for other purposes.

The PRESIDING OFFICER. Without objection, the Senate will proceed to the consideration of the bill.

The Senator from North Carolina.

PRIVILEGE OF THE FLOOR

Mr. FAIRCLOTH. Mr. President, I send to the desk a list of staff. I ask unanimous consent they be allowed full privilege of the floor during the consideration of S. 1156, the D.C. appropriations bill.

The list follows:

Mary Beth Nethercutt; Jay Kimmitt; Terry Sauvain; Neyla Arnas;s Kate O'Malley; David Landers; Liz Tankersley; Quinn Dodd; and Jim Hyland.

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

Mr. FAIRCLOTH. Mr. President, I am pleased to present the fiscal year 1998 District of Columbia appropriations bill to the Senate.

This budget is the first I have had the opportunity to present to the Senate since becoming the chairman of the District of Columbia Appropriations Subcommittee. This is essentially a clean bill, with no new policy riders.

I am very pleased that this budget was reported favorably by the full Appropriations Committee by a vote of 27 to 1. This is a bipartisan bill, and a bill that reflects the consensus of both the Financial Control Board established by Congress and the city's elected leadership.

This budget of $4.2 billion is a smaller budget than last year's $5.1 billion budget for two reasons.

First, the Federal Government is providing the city with fewer Federal dollars. This past July, Congress enacted landmark legislation restructuring the city's budget, transferring some city functions to the Federal Government, and in exchange, cutting the Federal payment to the District.

That legislation also added some important management reforms at my urging. I'll have more to say about these structural changes and management reforms in a moment.

Second, this is a smaller budget because it is the first balanced budget submitted to the Congress by city officials since 1993. That one proved very unbalanced. This one will be balanced.

As many of my colleagues know, the law enacted by Congress in 1995 creating a Financial Control Board included a timetable requiring the city of Washington, DC to submit a balanced budget to Congress by next year.

Fortunately, the Control Board and the D.C. Council managed to agree on enough spending cuts to submit a balanced budget to Congress 1 year ahead of schedule. That is essentially the budget before the Senate today.

This balanced budget cuts roughly $85 million from last year's operating budget, not to mention a reduction of over $500 million in the direct Federal contribution to the city, from $712 million last year down to $190 million this year.

Most agencies in the District of Columbia government have been cut. One exception is the police department, which received a modest increase reflecting a citywide effort—and I might say a nationwide effort—to crack down on crime within the city.

Perhaps the most important point is that both the Control Board and the D.C. Council have agreed to these cuts.

The Control Board and the D.C. Council worked together to craft a consensus budget. That consensus has been incorporated into this bill.

I do not think it is necessary for the U.S. Senate to revisit every spending decision that has been agreed upon by both the council and the control board, especially since we have achieved a balanced budget 1 year ahead of time.

Such decisions are long overdue even if it took some prodding from the Congress to get. I think it is the responsibility of the Senate to ratify those decisions once they have been made.

In addition to being the first balanced budget in several years, this budget pays for many of the structural changes and management reforms, including the District of Columbia Revitalization Act, signed into law on August 5, 1997.

For example, the Revitalization Act transferred the city's prison system, the courts, and a huge unfunded pension liability of $5 billion to the Federal Government. In exchange, the Congress will no longer provide an annual Federal payment of $660 million or a $52 million annual payment on the pension liability. Instead, this bill provides a one-time Federal contribution of $190 million as authorized by the Revitalization Act. Of that $190 million, the bill directs that $30 million be applied to pay down on the city's debt.

The Revitalization Act has been called a rescue plan for the District of Columbia. I feel strongly that any rescue plan must first rescue the city from terrible mismanagement, waste, and unresponsive and irresponsible local government.

I insisted that the rescue plan, and the majority leader with me insisted that the rescue plan include the Management Reform Act of 1997 to begin the process of cleaning house in each of the major city agencies.

The Management Reform Act authorized the control board to hire professional consultants to conduct a top-to-bottom review of nine major city agencies to map out a plan for improving the quality of services.

This District of Columbia appropriations bill provides $8 million to pay for the consultants to go into the various city agencies.

The structural changes in the Revitalization Act provide the city with a one-time windfall of $200 million. I am pleased that the mayor, the council, and the Control Board agreed that this windfall should not be used for a spending spree and that none of the funds should go toward increasing the operating costs of the city.

Of the $200 million available, $160 million will be applied to pay down the city's accumulated deficit. The remaining $40 million will be used to make infrastructure repairs and the management changes and productivity improvements suggested by the management consultants. The infrastructure of the city is in dire need of much improvement.

The Management Reform Act also called for the immediate dismissal of the heads of nine major city agencies and called on the Mayor to either nominate new officials or renominate the current officials to head each of the agencies, with each nomination subject to the consent and approval of the Control Board. In other words, a final decision rests with the Control Board.

In order to preserve the checks and balances between the executive and the legislative branches and the District of Columbia, section 133 of this appropriations bill makes clear that the D.C. Council does have official responsibility for confirming the Mayor's nominations to head those agencies. But then again, I reiterate, the final decision rests with the Control Board.

Some Members expressed concern to me that funding for the homeless may be reduced by a consequence of this very tight budget. Section 146 of the bill directs the District government to maintain homeless services at the same level for fiscal year 1998 as the level for fiscal year 1997. I think this can be accomplished in a manner that is consistent with the spending restraints needed to maintain a balanced budget.

Perhaps no issue received more attention in recent weeks than the inability of the District's public schools to open on time. It was a local and a national embarrassment. As the new chairman of the D.C. subcommittee, I am going to make sure that such a delay does not happen again.

Section 147 of this bill directs the Control Board and General Becton, the CEO of the D.C. public schools, to report to the House and Senate appropriations and authorizing committees for the District of Columbia no later than April 1, 1998, of any and all necessary measures to ensure that the schools open on time in the fall of 1998.

Mr. President, I thank my colleagues on the subcommittee, Senator BOXER, the ranking member, and Senator HUTCHISON of Texas.

I also thank the chairman of the Committee on Appropriations, Senator STEVENS, and our distinguished ranking member, Senator BYRD, for their leadership and assistance on this bill.

In summary, as I said, this is a consensus bill and the first balanced budget the District has seen in some time. This one truly is balanced. This bill funds the tough medicine of management reforms as well as restructuring of courts and corrections enacted by the Congress and signed into law by the President. It is a good bill and it is a bipartisan bill.

With that, Mr. President, I yield to our ranking member, my good friend, Senator BOXER.

Mrs. BOXER addressed the Chair.

The PRESIDING OFFICER. The Senator from California.

Mrs. BOXER. Thank you very much, Mr. President.

I thank the chairman of the D.C. Appropriations Subcommittee, Senator FAIRCLOTH. I thank him for the hard work he has put into this bill. I thank his staff, and I thank the staff on our side. I think it is very fair to say they worked beautifully together.

We do have basically a consensus bill here. There are a couple of provisions that I am sure Senator FAIRCLOTH isn't enamored with and I am sure there are a couple of provisions that this Senator isn't enamored with. I do believe in local control —that cities and counties should be able to make their own policies in terms of how they spend their own health funds, how they spend funds that they raise.

There are a couple of problems in this bill. But Senator FAIRCLOTH is correct, there are no new riders here. The problems that I have with this bill this year were in this bill last year. So I just hope that as we take up this last appropriations bill—this is the 13th one—that we will have a relatively easy time of it.

I hope that any amendments that are offered here will be noncontroversial amendments that both sides can agree to. Unfortunately, I am hearing that may not be the case, that this bill may become the vehicle for some very controversial amendments.

If that happens, so be it. Senator FAIRCLOTH and I will be on our feet, and we will manage that in the best way we can with the cooperation of colleagues. But I really do hope that Senators from both sides would refrain from those kinds of amendments, because this bill was a long time in coming. This kind of consensus over the District of Columbia was a long time in coming. We put so much work into it, particularly the chairman.

I see that Congresswoman ELEANOR HOLMES NORTON has joined us to sit in on this debate. There was a tremendous amount of work on her part in getting us to reach this consensus.

I have heard that it is possible we are going to have an amendment on vouchers. I want to make the point right here as the minority ranking member

that I have discussed this amendment with my colleagues on this side. We are not going to look kindly upon any amendment that would look at helping 2 to 3 percent of the children in Washington, DC, while leaving 97 to 98 percent of those children without anything at all.

Ms. MOSELEY-BRAUN. Will the Senator yield for a question?

Mrs. BOXER. I will yield in a moment so I do not lose this track. I will absolutely yield.

I say to my colleagues who may or may not be listening to the opening of the debate, should we be faced with that, we will have an alternative that will help 100 percent of the children—that will help 100 percent of the children. We are working on that because we are here talking about people's lives, not about philosophy of education, not about trying somebody's pet idea. We should not be doing that. We should be in fact reaching out to all the children.

Again, I say to my colleagues, I could offer a number of amendments here that would be controversial. I do not really want to do that. I know other colleagues could as well. I know that I feel as strongly as any colleague on certain of these matters. But this is an appropriations bill. This isn't an authorization bill. This isn't the education authorization bill where we can debate, from morning till night, what helps kids most—making sure that our public schools are the best in the world or taking a small segment of children and saying, Well, if you draw the lucky straw, you can run away from a public school, instead of making that public school the greatest it could be.

I have to say that I went to public schools from kindergarten through college. Some of the people who like me could say, Well, look what great things public schools can do, and some who do not, could say, You see, those public schools aren't very good. But the bottom line is, whatever you think of an individual who did get that chance, we do know that we have the education in this country that we can give to our children so they can be the future Senators, they can be the future leaders of the world.

When we lose that because we decide we are going to abandon our children because of some political theory, I think it is a sad state for us. So I am very much hoping that we do not get into that debate. But if we do, as you can see, we are prepared for it.

I will be glad to yield to my friend from Illinois.

Ms. MOSELEY-BRAUN. Thank you.

I actually was prepared to put a question to the Senator from California.

I want to commend the Senator for her stewardship and working with the Senator from North Carolina on this issue because getting this appropriations passed for the District of Columbia is not only important but long overdue. It is unfortunate that the District winds up being a guinea pig of sorts for every kind of experiment that we have.

I just commend the Senator from California for the poignancy of her statement and her plea that amendments not be brought to this bill that would delay its passage.

It is kind of open knowledge that the schools in the District of Columbia, many of them, have been closed because they were crumbling and falling down. The courts would not allow children to attend schools in that kind of condition. And they have just recently reopened.

In fact, we had working in my office two young high schoolers from the District of Columbia. Pursuant to a project that Congresswoman ELEANOR HOLMES NORTON put together for all the displaced children of the District, we took two of them into our office as interns while the schools were closed down.

The schools have now reopened and those children are back where they ought to be, in a classroom, but it just seems to me to further displace all of those children because of a filibuster or an argument around an experiment with the District of Columbia schools would be cruel to say the least, and certainly an unfortunate development.

So I commend my colleague for her plea in the first instance that we not have this battle because there is so much at stake, but also to put the question to her whether or not it is her opinion that the District can afford to delay further to wait for this appropriation to be finalized?

Mrs. BOXER. I say to my friend, clearly, all the work that the chairman has done, along with Congresswoman NORTON, Senator HUTCHISON, myself, all of our staffs, this has been hard. As Senator FAIRCLOTH has said, we have a balanced budget submitted here. As a part of the agreement on the balanced budget plan of 1997, signed into law, the President forwarded to Congress a series of budget amendments to implement the Revitalization Act for Washington, DC.

So we are moving along. It has not been easy. I think every Member of the Senate—at least it is my feeling—would like to see us turn this Capital around. I think we have great pride in this Capital. We are very concerned about some of its problems. I think we are on the road to addressing them.

So my colleague, in asking her question, is implying that a delay would send the wrong signal to Washington, DC, residents, would send the wrong signal, frankly, to the whole country, that we are backing off, and here they go again, adding extraneous matters to a DC appropriations bill.

What I hear around is not very promising. I hear that these controversial amendments are coming. I make this plea to whoever might be listening to this opening debate on both sides: That we refrain from controversial amendments. This is the last bill we are getting together here. We should move it forward, keep it free of this controversy, move forward, do our business, do our work and get on with the Senate's business.

Mr. President, the fiscal year 1998 District of Columbia appropriations bill was reported by the Senate Appropriations Committee on September 9, 1997, by a vote of 26 to 1. I commend the chairman of the subcommittee, Mr. FAIRCLOTH, for his efforts to produce a bipartisan appropriations bill for the District of Columbia. While the bill contains a few provisions I do not support, in most respects, I think we succeeded in producing a consensus bill.

I will speak briefly about the three principal aspects of this bill: Federal funds in the bill; District of Columbia funds in the bill; and general provisions in the bill.

FEDERAL FUNDS

The bill includes $820 million in budget authority in Federal funds for the District of Columbia. These funds are to be used to implement the provisions of the National Capital Revitalization and Self-Government Improvement Act of 1997, which was incorporated into the Balanced Budget Act of 1997, and enacted into law on August 5, 1997.

Subsequently, on August 14, 1997, the President forwarded to Congress a series of budget amendments to implement the provisions of the Revitalization Act. The bill fully funds the President's revised budget and, in addition, provides $8 million for management reforms, $30 million for the full authorization of $190 million for the Federal contribution and $5 million for a reimbursement to the National Park Service for Park Police services.

DISTRICT OF COLUMBIA FUNDS

In response to the Revitalization Act, the District government, including the mayor and the city council, and the control board, submitted to Congress a consensus and balanced budget, incorporating the changes made by the Revitalization Act.

The revised District budget for fiscal year 1998 is $4,693,637,000. The committee adopted the consensus balanced budget without change.

GENERAL PROVISIONS

Most of the general provisions included in the bill have been included in previous years and restate existing law.

With regard to section 134, which restricts the use of funds for abortions, the bill states that no funds—Federal or local—may be used for this purpose.

As I said during committee markup, I believe this provision to be an unwarranted intrusion in the affairs of the

District of Columbia and I may offer an amendment at the appropriate time to allow the District of Columbia to use its own funds to pay for abortions for poor women.

Another general provision prohibits funds being used by the District to implement its domestic partners law. Again, I believe this is an unwarranted and inappropriate intrusion by the Federal Government into matters under local control.

One general provision was included in the bill at my request. It would provide that the D.C. initiative homeless services in the District of Columbia be maintained in fiscal year 1998 at the fiscal year 1997 level.

My amendment prevents a reduction in services to the homeless which had been recommended in the consensus budget from the District.

Again, I commend the chairman of the subcommittee, Senator FAIRCLOTH, for his efforts to produce a bipartisan bill. I would also like to express my thanks to the Appropriations Committee staff—Terry Sauvain of the Democratic staff and Mary Beth Nethercutt of the majority—for their assistance in helping us bring this bill to the floor today.

Finally, Mr. President, with respect to amendments that may be offered to this bill, I hope my colleagues will refrain from proposing amendments that are not germane to this measure. The new fiscal year begins in only a few days, and the District of Columbia desperately needs to have its new budget in place. So I hope we can quickly pass a bill with broad bipartisan support and send it to the President for signature.

Mr. DOMENICI. Mr. President, the pending measure is S. 1156, the fiscal year 1998 District of Columbia appropriations bill.

This appropriations bill provides Federal payments to the District of Columbia totaling $820.0 million. The bill provides $190 million for the Federal contribution to the District of Columbia, $169 million to operate the District's correctional facilities for felons, $302 million to build new correctional facilities to replace the Lorton facility, $146 million to operate the District Court System, $8 million to implement management reform initiatives, and $5 million to the National Park Service to support U.S. Park Police operations in the District.

This appropriation is in addition to the resources allocated to the District by the Balanced Budget Act and the Taxpayer Relief Act of 1997. Combined, the two laws provide tax breaks and mandatory spending worth $4.5 billion over 10 years. Because the cost of taking over the District's $5.8-billion pension liability is largely delayed until after this period, the total bailout is worth substantially more to the District.

This appropriation bill is at the subcommittee's revised 302(b) allocation for both budget authority and outlays.

Mr. President, I ask unanimous consent that a table displaying the Budget Committee scoring of the bill be printed in the RECORD.

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

D.C. APPROPRIATIONS, 1998, SPENDING COMPARISONS—SENATE-REPORTED BILL

[Fiscal year 1998, in millions of dollars]

	Defense	Nondefense	Crime	Mandatory	Total
Senate-reported bill:					
Budget authority		820			820
Outlays		500			500
Senate 302(b) allocation:					
Budget authority		820			820
Outlays		500			500
President's request:					
Budget authority		777			777
Outlays		479			479
House-passed bill:					
Budget authority					
Outlays					
Senate-Reported bill compared to:					
Senate 302(b) allocation:					
Budget authority					
Outlays					
President's request:					
Budget authority		43			43
Outlays		21			21
House-passed bill:					
Budget authority		820			820
Outlays		500			500

Note.—Details may not add to totals due to rounding. Totals adjusted for consistency with current scorekeeping conventions.

AMENDMENT NO. 1248

(Purpose: Technical amendments on the part of the managers of the bill)

Mr. FAIRCLOTH. Mr. President, I send an amendment to the desk, which is a series of technical amendments, on behalf of myself and Senator BOXER, and I ask they be considered en bloc.

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

The clerk will report.

The legislative clerk read as follows:

The Senator from North Carolina [Mr. FAIRCLOTH], for himself and Mrs. BOXER, proposes an amendment numbered 1248.

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent reading of the amendment be dispensed with.

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

The amendment is as follows:

On page 2, strike all after the word "Authority" on line 11, to the end of line 12.

On page 2, line 22, before the colon, insert: ", which shall be deposited into an escrow account held by the District of Columbia Financial Responsibility and Management Assistance Authority, which shall allocate the funds to the Mayor at such intervals and in accordance with such terms and conditions as it considers appropriate to implement the financial plan for the year".

On page 4, line 4, strike "$116,000,000" and insert in lieu thereof "$103,000,000".

On page 4, line 15, strike "$30,000,000" and insert in lieu thereof "$43,000,000".

On page 29, strike all after "the" on line 16, to the end of line 25, and insert: "District of Columbia Financial Responsibility and Management Assistance Authority (Authority). Appropriations made by this Act for such programs or functions are conditioned only on the approval by the Authority of the required reorganization plans.".

On page 33, strike all after "Financial" on line 19, and insert: "Responsibility and Management".

On page 41, strike all after "(B)" on line 24, through "$129,946,000" on line 25, and insert: "$4,811,906,000 (of which $118,269,000".

On page 42, line 16, after "Assistance," insert: "Authority".

On page 17, after the period on line 25, insert:

CORRECTIONAL INDUSTRIES FUND

For the Correctional Industries Fund, established by the District of Columbia Correctional Industries Establishment Act, approved October 3, 1964 (78 Stat. 1000; Public Law 88–622), $3,332,000 from other funds.

Mrs. BOXER. Mr. President, this amendment has been cleared, and I ask for its immediate adoption.

Mr. FAIRCLOTH. This has been cleared. We urge adoption.

The PRESIDING OFFICER. The question is on agreeing to the amendment.

The amendment (No. 1248) was agreed to.

Mr. FAIRCLOTH. Mr. President, we were expecting some other people to offer amendments and I assume they are coming down.

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

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

UNANIMOUS-CONSENT AGREEMENT—LEGISLATIVE BRANCH APPROPRIATIONS CONFERENCE REPORT

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent at 5:45 p.m. tonight the Senate proceed to the legislative branch appropriation conference report and at that time a vote occur on adoption of the conference report.

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

Mr. FAIRCLOTH. I ask that it be in order now to ask for the yeas and nays on the conference report.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The yeas and nays were ordered.

AMENDMENT NO. 1249

(Purpose: To provide scholarship assistance for District of Columbia elementary and secondary school students)

Mr. COATS. Mr. President, I send an amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Indiana [Mr. COATS], for himself, Mr. LIEBERMAN, Mr. BROWNBACK, Mr. ASHCROFT, Mr. COVERDELL and Mr. GREGG, proposes an amendment numbered 1249.

Mr. COATS. Mr. President, I ask unanimous consent reading of the amendment be dispensed with.

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

(The text of the amendment is printed in today's RECORD under "Amendments Submitted.")

Mr. COATS. Mr. President, I know the Senator from Oregon is waiting to bring forward an amendment and I will not take but just a few minutes. We have sent the amendment to the desk as the pending business. It will be debated tomorrow. Senator LIEBERMAN and I are joining as cosponsors in offering this amendment. I have a number of Senators, I think on both sides of the aisle, that wish to speak to it. There will be ample time for them to speak tomorrow on the amendments. They do not need to be concerned about rushing over here now. We did, however, want to have the amendment introduced so it is the pending business when we begin tomorrow.

In brief summary, the amendment provides opportunity scholarships for children in the District of Columbia in grades K through 12 whose family income is 185 percent or below the poverty level. The scholarships can be used for tuition costs of public or private scholarships in the District of Columbia, and adjacent counties in Virginia and Maryland. Scholarships are available for tutoring of students who attend public schools in the District.

The legislation creates a District of Columbia Scholarship Commission, a seven-member private, nonprofit corporation, to administer the scholarship program and certify institutions that will be eligible to participate in the scholarship program. One board member will be appointed by the mayor of Washington, DC, and the remaining six are to be appointed by the President, three from the list of nominees provided by the Speaker of the House of Representatives and three by a list of nominees provided by the majority leader of the Senate, both in consultation with the minority. Members must be residents of the District of Columbia and may not be Federal Government employees.

Students whose family incomes are below the poverty line may receive a scholarship of up to $3,200. Students whose family incomes are above the poverty line but below 185 percent of that level may receive the lesser of 75 percent of the cost of tuition, and mandatory fees for and transportation to attend an eligible institution, or $2,400. Students receiving tutoring assistance are eligible for up to $500. Both of these figures are indexed for inflation.

If there are not sufficient funds available for all of the eligible applicants, scholarships are to be awarded on a random basis by a lottery selection. The lottery is required to the extent practical to award an equal number of tuition scholarships and scholarships for fees. In other words, there will be no skimming of the green, there will be no biasing of the selection. If there are more scholarships than students, then, of course, every student would receive a scholarship that requested one. It is on a voluntary basis. If there are more students than scholarships, they will be awarded on a random basis. The amendment authorizes $7 million for spending in fiscal 1998 out of the Federal contribution earmarked to repay the cumulative Federal fund deficit for the District of Columbia. This total is $30 million. This $7 million earmark would leave $23 million remaining for that specific purpose of deficit fund reduction.

I point out that that is above the amount recommended by the administration. The administration requested a total Federal contribution for the District of Columbia of $160 million, and the bill before us, the D.C. Appropriations bill, contains $190 million.

In summary, then, we are not taking a dollar or a penny away from the D.C. public schools. We are not taking any money away from the current operating requirements of the District of Columbia that we are funding. In fact, we are adding $30 million for the purpose of reducing the general fund deficit. Of that additional $30 million, we are earmarking $7 million for these opportunity scholarships.

In the interest of time, I will not continue here. I will have much more to say about this tomorrow. I am looking forward to offering this amendment, together with my counterpart, Senator LIEBERMAN. This is a bipartisan effort. We are hopeful that we can begin the process of providing alternatives to students and their parents, who do not feel they are getting an adequate education. Our goal is not to undermine the school system of the District of Columbia; it is to improve it. Our goal is to move from the status quo, which is failing many, many students. We think this is an opportunity to do that. We look forward to debating this issue.

I yield the floor.

Mr. WYDEN addressed the Chair.

The PRESIDING OFFICER. The Senator from Oregon is recognized.

Mr. FAIRCLOTH. Mr. President, if the Senator from Oregon will yield, I would like to ask for a time agreement of 30 minutes for the discussion of the amendment Senator WYDEN has. Is that agreeable?

The PRESIDING OFFICER. The Senator from North Carolina is proposing a 30-minute time agreement.

Mr. WYDEN. Mr. President, I need 30 minutes on my side.

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that we have 30 minutes on each side.

The PRESIDING OFFICER. Is there objection to a 1-hour time limit equally divided?

Without objection, it is so ordered.

Mr. WYDEN. Mr. President, I ask that the pending amendment be temporarily set aside.

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

AMENDMENT NO. 1250

(Purpose: To eliminate secret Senate "holds")

Mr. WYDEN. Mr. President, I send an amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The bill clerk read as follows:

The Senator from Oregon [Mr. WYDEN], for himself and Mr. GRASSLEY, proposes an amendment numbered 1250.

The amendment is as follows:

At the appropriate place, insert:

SEC. . ELIMINATING SECRET SENATE "HOLDS."

(a) STANDING ORDER.—It is a standing order of the Senate that a Senator who provides notice to leadership of his or her intention to object to proceeding to a motion or matter shall disclose the objection (hold) in the Congressional Record not later than 2 session days after the date of said notice.

Mr. WYDEN. Mr. President, I offer this amendment today on behalf of myself and Senator GRASSLEY of Iowa. Mr. President, one of the most significant personal powers of a U.S. Senator is the power to effectively block the consideration of a bill or nomination from coming to the floor of the U.S. Senate. This power has become known as putting a "hold" on a measure or bill that a Senator opposes. It is a power that a U.S. Senator can exercise in secret. The name of the Senator placing a hold on Senate business is now held confidentially by party leadership.

This extraordinary power was once used rarely by Senators, usually as a matter of common courtesy. In the last 20 years, however, the hold has become a special tool for influence and leverage. It is especially valuable at this time—at a time when we are moving toward the end of the session—because it allows a Senator, secretly, to exercise an enormous amount of clout over a matter when time is short.

Mr. President, the record is replete with statements of Members of this body who have indicated that there have been abuses of the hold, and that this is a procedure that has completely gotten out of hand. Let me read from the words of Senator JOHN GLENN during the final hours of the 101st Congress. Senator GLENN said:

I find it deplorable that, suddenly, anonymously, a Senator or a combination of Senators on the Republican side can stand against the strong desire of the President and the Office of Management and Budget for this legislation.

Lest anyone think that this be a partisan matter, Senator THURMOND said:

I think abuse does arise out of that.

Senator HATCH said:

We get victimized by holds, especially at the end of a session.

Senator LEAHY of Vermont, another senior Member said:

There should not be any holds at all.

He said we just should not have any holds.

Well, I am not proposing anything like that. But I do think that every Member of the U.S. Senate ought to be held publicly accountable. I think when one Member of the U.S. Senate moves to effectively block the consideration of a bill or a nomination, they ought to make it clear to their constituents that they are the individual blocking this matter.

Mr. President, as I have worked on this issue with Senator GRASSLEY, on a bipartisan basis, for a year and a half, I have found that very few Senators are aware of how extensive some of these abuses are until it happens to them. For example, I learned last year that, often, a member of the staff places a hold on a measure and the Senator whose name in which the hold is placed isn't even aware of it. So what you have are secret holds, not just by someone with an election certificate, but by someone who doesn't have an election certificate at all—a member of the staff.

So I believe that it is time to ensure that the rights of Senators and the rights under the Senate rules afford substantial opportunities for Senators to make sure that they are heard and, to represent their folks, are accompanied by responsibilities. I want to make it clear to each and every Senator that I, in no way, would limit the right to filibuster. I would, in no way, limit the right to ensure that they can speak at length on a motion to proceed. And, in fact, I am not even going so far as to put any limits on the right to place a hold on a measure or a matter, other than that a U.S. Senator be public about what they are doing.

As I have talked about it with my constituents, they raise serious questions about whether one Member of the U.S. Senate should be able to effectively block consideration of Senate business at all. So I think that the American people will consider this a very modest reform. I see no evidence that citizens want this kind of information held confidential, held secret. So I want to make clear to my colleagues that what I am against is the secrecy. It is the secrecy that is wrong, not the question of whether a Senator wants to exercise their rights.

Let me also say that I think it is particularly appropriate for the Senate to move now. I have discussed this, over the last 15 months, on a number of occasions with the majority leader, Senator LOTT. Senator LOTT, to his credit, has taken several steps to improve the procedures of the Senate and in dealing with the holds that I think are very constructive. But what has not been done is there has been no change in the Senate rules to deal with the issue that I bring up today. A hold can still be kept secret. A hold can still be kept confidential with the party leadership.

So, in my view, Senator LOTT's proposal and the proposal that he made on January 27 of this year is a constructive one. It puts in place a number of sensible changes, such as disallowing what are known as "block holds," where a Senator would put a hold on a block of bills. But it still keeps this procedure and the use of one of the most extensive personal powers a U.S. Senator has secret. So I hope that as the Senate considers this legislation—and it is only one sentence long, it is not a complicated amendment; it is only one sentence long. I hope that the Senators will see this for what it is, which is to bring sunlight to the debate over the Senate's rules.

I will be speaking for a few additional minutes, Mr. President, but I understand that the chairman of the subcommittee has asked to make a change in the time for the vote that he had arranged earlier. I am happy to yield to him at this time.

The PRESIDING OFFICER. The Senator from North Carolina.

UNANIMOUS CONSENT AGREEMENT—LEGISLATIVE BRANCH APPROPRIATIONS CONFERENCE REPORT

Mr. FAIRCLOTH. Mr. President, speaking for the leader, I ask unanimous consent that the vote on the legislative branch appropriations conference report now occur at 6 o'clock today, rather than 5:45.

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

The Senator from Oregon.

AMENDMENT NO. 1250

Mr. WYDEN. Mr. President, this effort that Senator GRASSLEY and I have pursued for many months has been endorsed by a number of groups that are seeking to try to make the U.S. Senate more open in the way it conducts its business. Common Cause, for example, is an organization that has sought to have public disclosure of this particular procedure.

What we are talking about here is if a Member of the U.S. Senate is going to exercise this extraordinary, unilateral power, there should be sunshine; sunshine, we all know, is the very best disinfectant. It is an opportunity for all Members of the U.S. Senate to have a chance to be part of the debate because at least they will know who they are debating with. What is the most ironic part of the use of the hold is that the Senate, in which every Member takes pride, an institution to foster debate about important issues, doesn't in many instances allow for a Member of the U.S. Senate to even know who they are debating with because one Member of the Senate has anonymously blocked the issue. So let me be clear with respect to what this legislation does. This applies to a Senator who is digging in and making it clear that they object to a measure or a nomination.

This is not an individual who perhaps needs to know when an amendment is coming up, or perhaps have an opportunity to come over to the Senate floor to speak on a measure or matter. That is not what is being discussed here. What is being discussed here is making sure that when there is a full court press to oppose a bill or a nomination that that kind of opposition be brought to light.

We had some recent experience with how influential polls can be. For example, we saw that in the last Congress, to quote USA Today on the matter, "A skulk of faceless Senators is using a series of parliamentary holds to dry gulch legislation extending health insurance to millions of Americans."

That wasn't 20 years ago. That wasn't 30 years ago. That was an anonymous hold that was used to influence an important piece of health care legislation in the last session of the U.S. Congress. The fact is, Mr. President, that this procedure, which was once a matter of common courtesy, is now so widely used that it has become one of the most frequent ways to prevent any public disclosure of Senate business.

I hope that as we look to these last few days of this session—I bring this to the floor now because I believe that the abuse of the hold is most likely during these last few days of the session—that we take this opportunity to make the U.S. Senate more open and more accountable.

Right now, if a Senator seeks to personally block a measure or matter, there is no cost to them. They face no disapproval because no one would know who they were disapproving of. The fact is that this is a process and a power, an enormous power, held by the U.S. Senate that is exercised in the dark. It seems to me that it carries the odor of back room deals, abuse of privilege, and a body that cares more about individual personal desires than those of the American people.

This isn't cutting off the right of any Member of the U.S. Senate. Every Senator can still filibuster. Every Senator can still exercise their rights with respect to a motion to proceed. It simply says that it has to be done publicly.

Let me also say that it has been the experience of Senator GRASSLEY and myself that you can do this, and, as Senator GRASSLEY has told me, it doesn't hurt. For example, just a week ago Senator SMITH and I felt strongly, on a bipartisan basis, about issues with respect to a C-130 crash that carried Oregonians who were reservists. At that time, because we were seeking answers from the military and given the fact that the appointment of the new head of the Joint Chiefs of Staff was forthcoming, I put a hold on that nomination for a brief period of time. I made it clear on the floor and in other forums that I was the Member of the Senate who did it. I published it in the CONGRESSIONAL RECORD, just as my amendment calls for.

So, during that period, there was, over a short few days, an effort to have

a public discussion about this matter. There were also bipartisan discussions with Senator THURMOND and Senator MCCAIN, and others were extremely helpful in the efforts that Senator SMITH and I made on this matter. And early the next week the hold that I had, which was public, I lifted. The needs of my constituents were addressed, and the American people saw a good man—a good man—General Shelton, confirmed to head the Joint Chiefs of Staff.

So, Mr. President, what we have done, Senator GRASSLEY and I, is we have practiced what we preach. We don't believe that it abridges our rights in any way. All we are saying is that there is no reasonable place for protracted ongoing anonymous delay. That is what we think is wrong. There is no place, as the New York Times recently said, for "the hold as currently practiced."

So I am not suggesting today, Mr. President and colleagues, that the hold be abolished. I am not suggesting that the filibuster be changed in any way. I am not suggesting that on the motion to proceed there be any change. All I am saying is when a hold is put on a matter so that a Senator digs in to personally effectively block the consideration of a measure or a matter, that within 2 days of that time they notify party leadership that they are the individual seeking to prevent consideration of that measure or matter on the floor of the U.S. Senate, and that they just put a little notice in the CONGRESSIONAL RECORD. No big procedure, no hassle, just a notice, just a notice identifying that Senator as the Senator who has put a hold on a measure or matter.

Mr. President, my guess is that if my amendment passes, there may be a variety of ways that Senators may still seek to vitiate the spirit of what Senator GRASSLEY and I are seeking to do. But I do think that passage of this amendment will put the U.S. Senate on record. We will be on record for sunshine. We will be on record as being opposed to secrecy, and especially we will be taking steps so that at this time of the session as the session moves into the last few weeks when history shows that you are most likely to have abuses of the hold, we will have shown that we are willing to make changes that hold the U.S. Senate and each Member here publicly accountable for their actions.

Mr. President, none of us got here easily. Like many other Senators, my campaign and my election was something of a trial by fire. No Member of this body lacks fortitude. I think we can stand some extra added light. I think we can stand some extra added sunshine. I think that we can take the secrecy out of the hold procedure and still make sure that each and every Senator is able to exercise their rights and protect their constituents.

I believe that the passage of this amendment, at a time when millions of Americans are especially cynical and skeptical about Government, will cause citizens to say that the Senate is doing the right thing, and we will see constituents have a bit more respect for this body as a result of Senators being willing to be held publicly accountable. This amendment is not about getting rid of the hold. It is not about doing anything to a hold other than saying that a Senator has to be publicly accountable when that one Senator effectively moves to block the consideration of a bill or a nomination.

Mr. President, I have not been here as long as some, but I read the statements of Senators who have been here for quite some time—Senator GLENN, who called it deplorable; Senator THURMOND, who said that there has been an abuse; Senator HATCH, who said that every Senator has been victimized by it; and, Senator LEAHY, who went far far farther than anything I would be talking about. He said there shouldn't be any holds at all.

In fact, in my conversations with Senators, I have been told that some Senators find this procedure so abhorrent that they will not exercise it at all, and they are especially frustrated by their colleagues who do.

So, in closing, Mr. President, let me go back to just how great the abuse is.

It is one thing if Chairman FAIRCLOTH or Senator BOXER or another Member of U.S. Senate puts a hold on a matter. All of the Senators are directly responsible to their constituents. What I found is a lot of Senators didn't even know that a hold had been placed on a bill in their name.

One senior Member of the U.S. Senate came to me last session, and said, "I am for your bill. I think it is a good idea. We need some public disclosure of these holds. And the reason I am for it is a few minutes ago a Senator came up to me and said, 'Why do you have a hold on my bill?' And the person who was sympathetic to what I have been trying to do said, 'I don't have a hold on your bill.'" It turned out that a staff person had done it in their name.

So what we have is a situation where not just are holds by Senators kept anonymous and kept confidential, but now we have staff that doesn't have an election certificate putting holds on these matters as well.

The hold started out many years ago. I gather from historians that it is well over 100 years old. It started out as a matter of common courtesy. It was something that Senators did to accommodate each other to make sure that an individual could be present to speak on an amendment, to ensure that they would have an opportunity to be heard if they had some sort of glitch in their time schedule. That is not what this amendment addresses. That is not what this amendment addresses at all.

This amendment is about ensuring that when a U.S. Senator uses all of their power, every bit of their power, to block a measure or a nomination, and they exercise those extraordinary rights that each of us has, that it be accompanied by a responsibility to the American people. That responsibility to the American people is to tell them, tell your constituents, when you exercise this extraordinary power that you are the one who did it. You are the one who blocked a bill or a nomination.

Let's bring some sunshine here.

I will tell leadership—let me say that Senator DASCHLE and Senator LOTT have talked with me about this. Both of them have been very gracious. Senator DASCHLE indicated that he is in support of this. I believe that what I am proposing in this amendment complements the useful changes that Senator LOTT, the majority leader, made this January.

The majority leader, Senator LOTT, implemented a number of changes that I think are constructive, but they still allow for the secrecy. They still allow for one Senator to effectively block consideration of a measure or matter.

I gather that the vote on this amendment will be tomorrow.

Mr. President, I ask unanimous consent at this time to be able, prior to the vote tomorrow, to speak on this amendment again for up to 10 minutes, to be able to ensure that Senators prior to the vote——

The PRESIDING OFFICER. Is there objection?

Mr. FAIRCLOTH. There is objection.

The PRESIDING OFFICER. Objection is heard.

Mr. WYDEN. Mr. President, reclaiming the floor, will the Senator from North Carolina be open to a question at this time?

Mr. FAIRCLOTH. Yes.

Mr. WYDEN. I am proposing that an amendment be accepted by the Senate that would modestly change one of a Senator's most extensive powers, the power to secretly block a measure or matter from coming to the Senate floor. Does the Senator believe that it is not appropriate to have 10 minutes of discussion of it tomorrow before it comes up?

Mr. FAIRCLOTH. It might be all right to have 10 minutes, but we will have to decide it tomorrow. I am not ready now to agree to it.

The PRESIDING OFFICER. Objection is heard.

Mr. JOHNSON addressed the Chair.

The PRESIDING OFFICER. The Senator from South Dakota is recognized.

Mr. JOHNSON. Mr. President, I ask unanimous consent that I may speak in morning business for up to 10 minutes.

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

Mr. JOHNSON. I will not use the full 10 minutes.

HONORING THE LIVES OF AIRMEN ANTHONY BEAT, CLAY CULVER, KIRK CAKERICE, AND GARY EVERETT

Mr. JOHNSON. Mr. President, a B-1 bomber from Ellsworth Air Force Base near Rapid City, SD, crashed last Friday killing all four of the flight crew members. All four men who lost their lives were highly decorated American airmen receiving such awards as the Meritorious Service Medal, the Air Force Commendation Medal, the Humanitarian Service Medal, the Combat Readiness Medal, and the National Defense Service Medal.

The four men were Col. Anthony Beat of the 28th Bomb Wing, vice commander. He was from Attica, OH, and is survived by his wife, Delores Ann, and sons, James and Alan. Maj. Clay Culver was the 37th Bomb Squadron assistant operations officer and weapons systems officer. He was from Sulfur, LA, and is survived by his wife, Cynthia, his daughter, Ann, and son, Parker, all of Rapid City. Maj. Kirk Cakerice, the 37th Bomb Squadron assistant operations officer and instructor pilot, was from Eldora, IA, and is survived by his wife, Myra, son, Brett, and daughter, Kendra, all of Rapid City. Capt. Gary Everett was the 37th Bomb Systems weapons systems officer from Brooklyn, NY, and is survived by his parents, Joseph and Dorthy Everett, of Glasgow, KY, and several brothers and sisters and fiance.

On Monday, over 1,500 friends, peers, colleagues, and family mourned the loss of these four brave men in a memorial service at Ellsworth Air Force Base. At this time of tragedy, thoughts and prayers and the attention of people of the Black Hills region and the State of South Dakota and our Nation are with the families and friends of these four crewmen.

This tragic incident underscores how quickly lives of even our bravest and most skilled military personnel can be lost. It is important that the legacy of these four men live on as dedicated airmen, proud parents, loving husbands, grateful sons, and honorable men. Our loss reflects the fact that in peacetime, as well as during conflict, the men and women of our military, our friends, our spouses, our children, put their lives on the line each and every day to preserve and protect our liberty as Americans.

Colonel Beat, Major Cakerice, Major Culver, and Captain Everett were decorated veterans and honorable men who approached their military service with extraordinary dedication, commitment, pride, and professionalism.

In this time of tragedy, we must also acknowledge that our Nation is stronger and our liberties more secure because of the willingness of these patriots to commit their talent, their leadership, and ultimately their lives to the defense of our Nation.

Colonel Beat, Major Cakerice, Major Culver, and Captain Everett were shining examples of the quality, the expertise and the talents of the men and women who put on the uniforms of our Armed Forces.

And so again, Mr. President, our prayers are with the families of these four great American airmen. We know that every day of the week others embark on similar training experiences and similar endeavors. Lives are always at risk in times of peace as well as in conflict in order to protect our liberties as Americans, including our ability in this Senate to gather, to debate, to discuss policy issues affecting our Nation.

So it is in the great effort of these airmen, and others like them in all of our branches of the military, that we owe great gratitude. All people in the State of South Dakota share the grief but also the pride of these families in the great contribution that these airmen have made to our Nation.

I yield back my time.

The PRESIDING OFFICER. Who yields time?

Mr. FAIRCLOTH. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

The PRESIDING OFFICER (Ms. COLLINS). Without objection, it is so ordered.

LEGISLATIVE BRANCH APPROPRIATIONS ACT, 1998—CONFERENCE REPORT

The PRESIDING OFFICER. The report will be stated.

The legislative clerk read as follows:

The committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 2209) having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses this report, signed by all of the conferees.

The Senate proceeded to consider the conference report.

(The conference report is printed in the House proceedings of the RECORD of September 18, 1997.)

Mr. BENNETT. Madam President, I am pleased to report that the House and Senate conferees reached an agreement on funding for the legislative branch for the fiscal year 1998. The agreement we reached provides for total spending of slightly under $2.5 billion—an increase of 2 percent over the fiscal year 1997 level and a decrease of 6 percent from the President's budget.

Before we begin, I would like to state for the record that the issue of pay for Members of Congress is not in this bill.

However, there were significant differences in the amount of funding in the House and Senate bills. The House wanted to limit the growth of the legislative branch to the fiscal year 1997 level exclusive of Senate items. The Senate had made a commitment to the General Accounting Office—a commitment which was made when Senator MACK chaired this subcommittee and oversaw a 25-percent reduction in GAO. This was a 25-percent reduction in their budget and a 33-percent reduction in staff. I participated in the decision to reduce the agency, and I was also a party to the Senate's commitment to stabilize the agency once it made the reduction. Senator DORGAN shared my desire to meet that commitment.

I want to thank Senator DORGAN for his hard work, and interest in the bill. It was only with his strong support that we were able to provide adequate funding—a $7 million increase in direct appropriations plus and increase of $1.5 million in offsetting receipts over the fiscal year 1997 level.

The Federal Government will spend almost $1.7 trillion next year. The legislative branch has the responsibility to oversee this budget and make sure that taxpayer funds are being spent wisely. GAO is responsible for identifying wasteful Federal spending and recommending ways in which we can save billions of dollars. This past year GAO has identified $6 billion in measurable savings in the Federal Government. That does not include other savings which cannot be measured in dollars—such as better organization, ways in which an agency can better serve taxpayers, etc. For every $1 appropriated to GAO, they have identified $50 savings. This is an agency which is worth the investment.

Maintenance was another issue in this bill. I believe strongly in the need to invest in maintenance. Saving a small amount of money now on maintenance will only result in higher costs in the future.

I learned in business that if you do not properly maintain your building and equipment you will soon find yourself spending much more money to replace those items which have crumbled or can no longer function. There are a number of maintenance and security items which the Senate identified as priorities such as, repairs to the Library of Congress roof, investment in the Capitol powerplant, and Capitol security.

Funding for the Joint Committee on Taxation was also an issue. The Senate conferees agreed at the strong urging of the House conferees to split the difference between the House and Senate bills resulting in an increase of $91,500 over the Senate bill. For many years now the Joint Committee on Taxation has operated as an extension of the Finance and Ways and Means committees. Members of Congress who are not members of those committees have not been able to get revenue estimates for

their proposals. Without the revenue estimates, it is almost impossible to go to the floor to offer an amendment to a tax bill.

We have been assured by the House that Congressman ARCHER—the current chairman of the Joint Committee on Taxation is committed to working harder to provide to Senators and Representatives revenue estimates in a timely fashion. It is our intent to ensure that the Joint Committee on Taxation assists all Members of Congress. Included in the statement of managers on page 26 of the conference report is language identifying the scope of the assistance we expect the Joint Committee to provide to Members.

During the course of the next year, I would like to hear from my colleagues if they are finding the Joint Committee to be helpful.

In reaching this agreement, the Senate came down $37 million in budget authority and the House went up $24 million. I am comfortable that the legislative branch will be able to meet its oversight responsibilities with the funding provided in this agreement.

Again, I would like to thank Senator DORGAN as the ranking member for his hard work on reaching this agreement. In addition, I would like to thank Senator STEVEN, Senator CRAIG and Senator BOXER for their assistance on the subcommittee as well as the following staff: Christine Ciccone, Jim English, Mary Dewald, Mary Hawkins, Chuck Turner, and Chip Yost, for their superior work.

I thank my colleagues in advance for their support of the conference report.

Mr. DORGAN. Madam President, I rise in support of the conference agreement to H.R. 2209, the fiscal year 1998 legislative branch appropriation bill. The conference agreement provides a total of $2.25 billion for fiscal year 1998 for the Congress and other legislative branch agencies. This represents a reduction of $144 million from the budget request.

All in all, this is a good conference agreement. I wish to take just a minute to point out the level of funding agreed to by the conferees with respect to the General Accounting Office [GAO]. As Members are aware, an agreement was reached last Congress between the GAO and appropriators to reduce the GAO's budget by a total of 25 percent over fiscal years 1996 and 1997. The GAO successfully implemented a plan for this reduction, without having to be dragged kicking and screaming. Our commitment to them, in return, was to stabilize their funding at that reduced level. Unfortunately, for fiscal year 1998, the House recommended an appropriation of only $323.5 million for the GAO, a reduction of $37.9 million below their budget request. The Senate bill, after thorough consideration and cooperation from the GAO itself, found that an appropriation of $346.8 million would be sufficient to maintain GAO's level of operations.

Madam President, this was the most difficult issue in the conference. Chairman BENNETT joined me in urging the House to come up substantially from their level. Ultimately, the conferees agreed to an appropriation of $339.5 million for fiscal year 1998, $7 million above the fiscal year 1997 appropriation and $16 million above the House-passed bill. While not providing GAO every last dollar that they would like to have had, this level of funding comes very close to fulfilling our commitment to the GAO.

I commend Senator BENNETT for his fairness and the leadership he showed during our conference with the House. I also compliment the House conferees, particularly the House subcommittee chairman, Congressman WALSH, and his minority counterpart, Congressman SERRANO, as well as their very capable staffs, Ed Lombard for the majority and Greg Dahlberg for the minority.

Madam President, I urge my colleagues to vote for this conference agreement.

Mr. MCCAIN. Madam President, as I said when this bill came before the Senate for consideration, this is, overall, a good bill. It contains very few of the types of earmarks and set-asides for pork-barrel spending that are included in most of the appropriations bills.

Of course, I don't believe I have ever had the pleasure of reading an appropriations bill that is completedly devoid of earmarks, and this bill is no exception.

When this bill came before the Senate, I applauded the Senate's decision to eliminate or reduce funding for several projects that did not appear to be high-priority projects. The Senate cut $50,000 for a study of electromagnetic fields in the Russell Senate Office Building, reduced funding for elevator modernization in the Hart Building by $200,000. Unfortunately, the Senate did include $100,000 for a new subway from the Russell Building to the Capitol.

Because of these and other reductions, the overall budget for Senate buildings was reduced by about $2 million. This conference agreement restores the full $52 million originally proposed for the Senate.

My staff was told by the Appropriations Subcommittee staff that this restored money will not be used for the projects noted above that the Senate explicitly cut. Instead, $2 million will be transferred and used for maintenance and repair projects and security improvements in the Capitol. Although I can find nothing in the conference agrement that would ensure this is the case, I trust that none of the restored funds will be used, for example, to study electromagnetic fields in the Russell Senate Office Building.

Finally, I am disappointed that the conferees chose to specifically reverse the direction in the Senate report that would require the General Accounting Office to place higher priority on Members' requests for audits, studies, and investigations. This has been a particular matter of concern to me, and I was pleased that the Senate Appropriations Committee chose to take the initiative to establish the proper priority for the GAO's work.

I am sure most of my colleagues have, at one time or another, been advised that the GAO cannot complete work we have requested in a timely fashion. But I don't know if my colleagues are aware that GAO does a great deal of work that is either self-initiated or requested informally by staff members. And often this work is placed ahead of work that is requested by Members in the GAO's assignment of staff and resources to complete the work. I don't believe most of my colleagues would think that is the proper prioritization for an agency that works for the Congress.

Frankly, I can see no good reason why the conferees took the unusual step of repudiating this very much-needed directive. Unfortunately, however, because this provision has been summarily reversed by the conferees, I will have to consider other appropriate means to ensure that GAO's prioritization of work reflects the needs of the Congress, not the GAO itself.

Madam President, these are not major problems. The total of the pork-barrel provisions in this bill is only slightly more than $1 million. However, again, I remind my colleagues that every taxpayer dollar we waste reinforces the disdain of the American people for the Congress and our way of doing business.

I ask unanimous consent that a list of objectionable provisions be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD.

OBJECTIONABLE PROVISIONS IN THE CONFERENCE REPORT ON THE FY 1998 LEGISLATIVE BRANCH APPROPRIATIONS BILL

BILL LANGUAGE

$100,000 from the Library of Congress budget for an International Copyright Institute.

$2,250 from the Library of Congress budget for official representational and reception expenses offor activities of the International Copyright Institute.

Earmark of unlimited amount of GAO's funds to finance an appropriate share of the expenses of: the Joint Financial Management Improvement Program, including the salary of the Executive Director and secretarial support; the National Intergovernmental Audit Forum or a Regional Intergovernmental Audit Forum, as determined by the respective forum, including necessary travel expenses of non-Federal participants; and the costs of the American Consortium on International Public Administration, including any expenses attributable to its membership in the International Institute of Administrative Sciences.

REPORT LANGUAGE

$300,000 for improved lighting in the Senate Chamber.

$100,000 to design a new subway from the Russell Building to the Capitol Building.

$550,000 to modernize elevators in the Hart Building.

Total Objectionable Provisions: $1.052 million.

Mr. DOMENICI. Madam President, I rise in support of the conference report on H.R. 2209, the legislative branch appropriations bill for fiscal year 1998.

The bill, as reported, provides $2.25 billion in new budget authority and $2 billion in outlays for the Congress and other legislative branch agencies, including the Library of Congress, the General Accounting Office, and the Government Printing Office, among others.

When outlays from prior year appropriations and other adjustments are taken into account, the bill totals $2.3 billion in budget authority and outlays. The bill is under the subcommittee's 302(b) allocation by $36 million in budget authority and $86 million in outlays.

I want to commend the distinguished chairman and ranking member of the Legislative Branch Subcommittee for producing a bill that is substantially within their 302(b) allocation. I am pleased that this bill continues to hold the line on congressional spending.

I ask unanimous consent to have printed in the RECORD a table displaying the Budget Committee scoring of H.R. 2209, as reported by the committee of conference. I urge the Senate to support this conference report.

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

H.R. 2209, LEGISLATIVE BRANCH APPROPRIATIONS, 1998 SPENDING COMPARISONS—CONFERENCE REPORT

[Fiscal year 1998, in millions of dollars]

	Defense	Nondefense	Crime	Mandatory	Total
Conference Report:					
Budget authority		2,251		92	2,343
Outlays		2,251		92	2,343
Senate 302(b) allocation:					
Budget authority		2,287		92	2,379
Outlays		2,337		92	2,429
President's request:					
Budget authority		2,386		92	2,478
Outlays		2,352		92	2,444
House-passed bill:					
Budget authority		2,261		92	2,353
Outlays		2,262		92	2,354
Senate-passed bill:					
Budget authority		2,286		92	2,378
Outlays		2,269		92	2,361
CONFERENCE REPORT COMPARED TO:					
Senate 302(b) allocation:					
Budget authority		−36			−36
Outlays		−86			−86
President's request:					
Budget authority		−135			−135
Outlays		−101			−101
House-passed bill:					
Budget authority		−10			−10
Outlays		−11			−11
Senate-passed bill:					
Budget authority		−35			−35
Outlays		−18			−18

Note.—Details may not add to totals due to rounding. Totals adjusted for consistency with current scorekeeping conventions.

The PRESIDING OFFICER. The question now occurs on agreeing to the conference report. The yeas and nays have been ordered. The clerk will call the roll.

The legislative clerk called the roll.

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 90, nays 10, as follows:

[Rollcall Vote No. 257 Leg.]

YEAS—90

Abraham	Domenici	Kempthorne
Akaka	Dorgan	Kennedy
Ashcroft	Durbin	Kerrey
Baucus	Enzi	Kerry
Bennett	Faircloth	Landrieu
Biden	Feingold	Lautenberg
Bingaman	Feinstein	Leahy
Bond	Ford	Levin
Boxer	Frist	Lieberman
Breaux	Glenn	Lott
Bryan	Gorton	Lugar
Bumpers	Graham	Mack
Byrd	Grams	McCain
Campbell	Grassley	McConnell
Chafee	Gregg	Mikulski
Cleland	Hagel	Moseley-Braun
Cochran	Harkin	Moynihan
Collins	Hatch	Murkowski
Conrad	Helms	Murray
Coverdell	Hollings	Nickles
Craig	Hutchinson	Reed
D'Amato	Hutchison	Reid
Daschle	Inouye	Robb
DeWine	Jeffords	Roberts
Dodd	Johnson	Rockefeller
Roth	Snowe	Thurmond
Santorum	Specter	Torricelli
Sarbanes	Stevens	Warner
Sessions	Thomas	Wellstone
Smith (OR)	Thompson	Wyden

NAYS—10

Allard	Gramm	Shelby
Brownback	Inhofe	Smith (NH)
Burns	Kohl	
Coats	Kyl	

The conference report was agreed to.

Mr. BENNETT. I move to reconsider the vote and I move to lay it on the table.

The motion to lay on the table was agreed to.

DISTRICT OF COLUMBIA APPROPRIATIONS ACT, 1998

The Senate continued with the consideration of the bill.

AMENDMENT NO. 1250

Mr. FAIRCLOTH. Madam President, I ask unanimous consent when the Senate resumes the Wyden amendment No. 1250, there be 20 minutes equally divided remaining, and following the conclusion or yielding back of time, the amendment be agreed to, and the motion to reconsider be laid upon the table, all without further action or debate.

Mr. WYDEN. Reserving the right to object.

The PRESIDING OFFICER. The Senator from Oregon is recognized.

Mr. WYDEN. Madam President, I do not intend to object. I have had a chance to discuss this with the majority leader who has been gracious in offering me his time on this matter.

I ask only that the further discussion of this amendment take place at a time when the majority leader could be on the floor and he and I could discuss this briefly. I believe the proposals he has made with respect to holds are constructive. This proposal goes one step further, to have public disclosure of holds.

I ask only that the majority leader, at a time convenient with his schedule, be allowed to participate in that 20-minute discussion so he and I could briefly discuss that.

With that, I have no objection.

The PRESIDING OFFICER. Is there further objection? If not, without objection, it is so ordered.

Mr. McCAIN. Madam President, I must applaud the actions of the chairman of the D.C. Appropriations Subcommittee, Senator FAIRCLOTH, for his restraint in putting together this bill.

The bill is the first step in implementing the National Capital Revitalization and Self-Government Improvement Act that Congress passed this

summer. This bill provides the funding necessary to carry out that act, and includes several provisions that will ensure fiscal responsibility and adherence to the act.

In reviewing this bill, I have found only one section in the report language that causes some concern. On page 31 of the report, the following language appears:

The Committee is aware of the need for an adult and pediatric heart transplant program at a not-for-profit academic medical center servicing this Nation's Capital. The D.C. metropolitan area is the only major metropolitan area that does not have an academic medical center with a heart transplant program. Since this not-for-profit medical center has recently enhanced its capabilities by the additional of a nationally and internationally renowned cardiovascular surgeon and a nationally known pediatric cardiologist, the Committee strongly recommends that the State health planning and development agency approve the certificate of need application for a nonprofit academic medical center in the District of Columbia that has an approved lung transplant program.

I am sure my colleagues are aware of the likely result of this type of language in an Appropriations Committee report. Although not bound to do so, I would expect that the State health planning and development agency will feel pressured to approve the application of this academic facility. Although that may not be an inappropriate decision, I continue to believe it is inappropriate for Congress to direct these types of decisions on a case-by-case basis, rather than assessing the broader requirements for health facilities in the District of Columbia. I would hope the committee would see fit to withdraw this near-directive and allow the agency to make decisions based on the criteria it has developed for all such matters.

Again, this bill is free of the types of earmarks that we have seen in virtually every other appropriations measure to come before the Senate this year.

As the last appropriations measure to come before the Senate for debate, perhaps this is a welcome sign of things to come as we turn to the appropriations conference reports.

Mr. FAIRCLOTH. Madam President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

UNANIMOUS-CONSENT AGREEMENT—AMENDMENT NO. 1249

Mr. FAIRCLOTH. Mr. President, on behalf of the leader, I ask unanimous consent that debate on amendment No. 1249 begin at 12 noon on Thursday and the time between noon and 5 p.m. be equally divided in the usual form. I further ask that at 5 p.m. the amendment be laid aside until Tuesday, September 30, and a cloture vote occur on the amendment at 11 a.m. on Tuesday, September 30, with the mandatory quorum under rule XXII being waived, and the time between 10 a.m. and 11 a.m. on Tuesday be equally divided between Senators COATS and KENNEDY. I further ask that no second-degree amendments be in order to amendment No. 1249 prior to the cloture vote.

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

CLOTURE MOTION

Mr. FAIRCLOTH. Mr. President, I send a cloture motion to the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The bill clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on the pending COATS amendment numbered 1249 to S. 1156:

Senators Trent Lott, Dan Coats, Richard Shelby, Mitch McConnell, Connie Mack, Lauch Faircloth, James Inhofe, Alfonse D'Amato, Rod Grams, John Warner, Pat Roberts, Chuck Hagel, Ted Stevens, John McCain, Susan Collins, and Sam Brownback.

MORNING BUSINESS

Mr. FAIRCLOTH. Mr. President, on behalf of the leader, I ask unanimous consent that there now be a period of morning business with Senators permitted to speak for up to 5 minutes each.

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

THE VERY BAD DEBT BOXSCORE

Mr. HELMS. Mr. President, at the close of business yesterday, Tuesday, September 23, 1997, the Federal debt stood at $5,382,650,076,978.81. (Five trillion, three hundred eighty-two billion, six hundred fifty million, seventy-six thousand, nine hundred seventy-eight dollars and eighty-one cents)

One year ago, September 23, 1996, the Federal debt stood at $5,192,406,000,000. (Five trillion, one hundred ninety-two billion, four hundred six million)

Five years ago, September 23, 1992, the Federal debt stood at $4,042,399,000,000. (Four trillion, forty-two billion, three hundred ninety-nine million)

Ten years ago, September 23, 1987, the Federal debt stood at $2,354,292,000,000. (Two trillion, three hundred fifty-four billion, two hundred ninety-two million)

Fifteen years ago, September 23, 1982, the Federal debt stood at $1,110,216,000,000 (One trillion, one hundred ten billion, two hundred sixteen million) which reflects a debt increase of more than $4 trillion—$4,272,434,076,978.81 (Four trillion, two hundred seventy-two billion, four hundred thirty-four million, seventy-six thousand, nine hundred seventy-eight dollars and eighty-one cents) during the past 15 years.

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Mr. Williams, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting a treaty and sundry nominations which were referred to the appropriate committees.

(The nominations received today are printed at the end of the Senate proceedings.)

REPORT OF THE NOTICE RELATIVE TO THE CONTINUATION OF THE EMERGENCY WITH RESPECT TO UNITA—MESSAGE FROM THE PRESIDENT—PM 68

The PRESIDING OFFICER laid before the Senate the following message from the President of the United States, together with an accompanying report; which was referred to the Committee on Banking, Housing, and Urban Affairs.

To the Congress of the United States:

Section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)) provides for the automatic termination of a national emergency unless, prior to the anniversary date of its declaration, the President publishes in the *Federal Register* and transmits to the Congress a notice stating that the emergency is to continue in effect beyond the anniversary date. In accordance with this provision, I have sent the enclosed notice, stating that the emergency declared with respect to the National Union for the Total Independence of Angola ("UNITA") is to continue in effect beyond September 26, 1997, to the *Federal Register* for publication.

The circumstances that led to the declaration on September 26, 1993, of a national emergency have not been resolved. The actions and policies of UNITA pose a continuing unusual and extraordinary threat to the foreign policy of the United States. United Nations Security Council Resolution 864 (1993) continues to oblige all Member States to maintain sanctions. Discontinuation of the sanctions would have a prejudicial effect on the Angolan peace process. For these reasons, I have determined that it is necessary to maintain in force the broad authorities necessary to apply economic pressure

to UNITA to reduce its ability to pursue its aggressive policies of territorial acquisition.

WILLIAM J. CLINTON.

THE WHITE HOUSE, *September 24, 1997.*

MESSAGES FROM THE HOUSE

At 12:02 p.m., a message from the House of Representatives, delivered by Mr. Hays, one of its reading clerks, announced that the House has passed the following bill, with an amendment, in which it requests the concurrence of the Senate:

S. 871. An act to establish the Oklahoma City National Memorial as a unit of the National Park System; to designate the Oklahoma City Memorial Trust, and for other purposes.

The message also announced that the House has passed the following bill, with amendments, in which it requests the concurrence of the Senate:

S. 996. An act to provide for the authorization of appropriations in each fiscal year for arbitration in United States district courts.

The message further announced that the House has passed the following bill, without amendment:

S. 1000. An act to designate the United States courthouse at 500 State Avenue in Kansas City, Kansas, as the "Robert J. Dole United States Courthouse."

The message further announced that the House agrees to the amendments of the Senate to the bill (H.R. 1420) to amend the National Wildlife Refuge System Administration Act of 1966 to improve the management of the National Wildlife Refuge System, and for other purposes.

The message also announced that the House disagrees to the amendments of the Senate to the bill (H.R. 2107) making appropriations for the Department of the Interior and related agencies for the fiscal year ending September 30, 1998, and for other purposes, and agrees to the conference asked by the Senate on the disagreeing votes of the two Houses thereon; and appoints Mr. REGULA, Mr. MCDADE, Mr. KOLBE, Mr. SKEEN, Mr. TAYLOR of North Carolina, Mr. NETHERCUTT, Mr. MILLER of Florida, Mr. WAMP, Mr. LIVINGSTON, Mr. YATES, Mr. MURTHA, Mr. DICKS, Mr. SKAGGS, Mr. MORAN of Virginia, and Mr. OBEY as the managers of the conference on the part of the House.

The message further announced that the House disagrees to the amendment of the Senate to the bill (H.R. 2264) making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 1998, and for other purposes, and agrees to the conference asked by the Senate on the disagreeing votes of the two Houses thereon; and appoints Mr. PORTER, Mr. YOUNG of Florida, Mr. BONILLA, Mr. ISTOOK, Mr. MILLER of Florida, Mr. DICKEY, Mr. WICKER, Mrs. NORTHUP, Mr. LIVINGSTON, Mr. OBEY, Mr. STOKES, Mr. HOYER, Ms. PELOSI, Mrs. LOWEY, and Ms. DELAURO as the managers of the conference on the part of the House.

The message also announced that the House has passed the following bills, in which it requests the concurrence of the Senate:

H.R. 29. An act to designate the Federal building located at 290 Broadway in New York, New York, as the "Ronald H. Brown Federal Building."

H.R. 643. An act to designate the United States courthouse to be constructed at the corner of Superior and Huron Roads, in Cleveland, Ohio, as the "Carl B. Stokes United States Courthouse."

H.R. 824. An act to redesignate the Federal building located at 717 Madison Place, N.W., in the District of Columbia, as the "Howard T. Markey National Courts Building."

H.R. 994. An act to designate the United States border station located in Pharr, Texas, as the "Kika de la Garza United States Border Station."

H.R. 1460. An act to allow for election of the Delegate from Guam by other than separate ballot, and for other purposes.

H.R. 1683. An act to clarify the standards for State sex offender registration programs under the Jacob Wetterling Crimes Against Children and Sexually Violent Offender Registration Act.

H.R. 1948. An act to provide for the exchange of lands within Admiralty Island National Monument, and for other purposes.

H.R. 2027. An act to provide for the revision of the requirements for a Canadian border boat landing permit pursuant to section 235 of the Immigration and Nationality Act, and to require the Attorney General to report to the Congress on the impact on such revision.

H.R. 2343. An act to abolish the Thrift Depositor Protection Oversight Board, and for other purposes.

H.R. 2414. An act to provide for a 10-year circulating commemorative coin program to commemorate each of the 50 States, and for other purposes.

ENROLLED BILL SIGNED

The message further announced that the Speaker has signed the following enrolled bill:

H.R. 680. An act to amend the Federal Property and Administrative Services Act of 1949 to authorize the transfer of surplus personal property to States for donation to nonprofit providers of necessaries to impoverished families and individuals, and to authorize the transfer of surplus real property to States, political subdivisions and instrumentalities of States, and nonprofit organizations for providing housing or housing assistance for low-income individuals or families.

The enrolled bill was signed subsequently by the President pro tempore [Mr. THURMOND].

At 2:07 p.m., a message from the House of Representatives, delivered by Mr. Hays, one of its reading clerks, announced that the House agrees to the report of the committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 2209) making appropriations for the Legislative Branch for the fiscal year ending September 30, 1998, and for other purposes.

At 5:48 p.m., a message from the House of Representatives, delivered by Ms. Goetz, one of its reading clerks, announced that the House disagrees to the amendment of the Senate to the bill (H.R. 2378) making appropriations for the Treasury Department, the United States Postal Service, the Executive Office of the President, and certain Independent Agencies, for the fiscal year ending September 30, 1998, and for other purposes, and agrees to the conference asked by the Senate on the disagreeing votes of the two Houses thereon; and appoints the following Members as the managers of the conference on the part of the House:

For consideration of the House bill, and the Senate amendment, and modification committed to conference: Mr. KOLBE, Mr. WOLFE, Mr. LIVINGSTON, Mr. HOYER, and Mr. OBEY.

As additional conferees solely for consideration of titles I through IV of the House bill, and titles I through IV of the Senate amendment, and modifications committed to conference: Mr. ISTOOK, Mrs. NORTHUP, and Mrs. MEEK of Florida.

ENROLLED BILL SIGNED

The message also announced that the Speaker has signed the following enrolled bill:

H.R. 111. An act to provide for the conveyance of a parcel of unused agricultural land in Dos Palos, California, to the Dos Palos Ag boosters for use as a farm school.

The enrolled bill was signed subsequently by the President pro tempore [Mr. THURMOND].

MEASURES REFERRED

The following bills were read the first and second times by unanimous consent and referred as indicated:

H.R. 29. An act to designate the Federal building located at 290 Broadway in New York, NY, as the "Ronald H. Brown Federal Building"; to the Committee on Environment and Public Works.

H.R. 643. An act to designate the U.S. courthouse to be constructed at the corner of Superior and Huron Roads, in Cleveland, OH, as the "Carl B. Stokes United States Courthouse"; to the Committee on Environment and Public Works.

H.R. 824. An act to redesignate the Federal building located at 717 Madison Place NW., in the District of Columbia, as the "Howard T. Markey National Courts Building"; to the Committee on Environment and Public Works.

H.R. 994. An act to designate the U.S. border station located in Pharr, TX, as the "Kika de la Garza United States Border Station"; to the Committee on Environment and Public Works.

H.R. 1460. An act to allow for election of the Delegate from Guam by other than separate ballot, and for other purposes; to the Committee on Energy and Natural Resources.

H.R. 1683. An act to clarify the standards for State sex offender registration programs under the Jacob Wetterling Crimes Against Children and Sexually Violent Offender Registration Act; to the Committee on the Judiciary.

H.R. 2027. An act to provide for the revision of the requirements for a Canadian border boat landing permit pursuant to section 235 of the Immigration and Nationality Act, and to require the Attorney General to report to the Congress on the impact on such revision; to the Committee on the Judiciary.

H.R. 2343. An act to abolish the Thrift Depositor Protection Oversight Board, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

H.R. 2414. An act to provide for a 10-year circulating commemorative coin program to commemorate each of the 50 States, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

MEASURE PLACED ON THE CALENDAR

The following measure was read the first and second times by unanimous consent and placed on the calendar:

H.R. 1948. An act to provide for the exchange of lands within Admiralty Island National Monument, and for other purposes.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, which were referred as indicated:

EC–3026. A communication from the General Counsel of the Department of Transportation, transmitting, pursuant to law, five rules received on August 25, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3027. A communication from the General Counsel of the Department of Transportation, transmitting, pursuant to law, eighteen rules received on August 28, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3028. A communication from the General Counsel of the Department of Transportation, transmitting, pursuant to law, twelve rules received on September 4, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3029. A communication from the General Counsel of the Department of Transportation, transmitting, pursuant to law, five rules received on September 8, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3030. A communication from the General Counsel of the Department of Transportation, transmitting, pursuant to law, thirteen rules received on September 11, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3031. A communication from the General Counsel of the Department of Transportation, transmitting, pursuant to law, twelve rules received on September 15, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3032. A communication from the General Counsel of the Department of Transportation, transmitting, pursuant to law, three rules received on September 18, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3033. A communication from the General Counsel of the Department of Transportation, transmitting, pursuant to law, ten rules received on September 23, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3034. A communication from the Secretary of Defense, transmitting, pursuant to law, a notice regarding encryption policies; to the Committee on Commerce, Science, and Transportation.

EC–3035. A communication from the Secretary of the Federal Trade Commission, transmitting, pursuant to law, a rule concerning disclosures regarding energy consumption; to the Committee on Commerce, Science, and Transportation.

EC–3036. A communication from the Secretary of Transportation, transmitting, pursuant to law, a report relative to the National Transportation Safety Board for calendar year 1996; to the Committee on Commerce, Science, and Transportation.

EC–3037. A communication from the Secretary of Transportation, transmitting, a draft of proposed legislation entitled "The Motor Carrier Safety Act of 1997"; to the Committee on Commerce, Science, and Transportation.

EC–3038. A communication from the Chairman of the Surface Transportation Board, transmitting, pursuant to law, a rule received on September 8, 1997; to the Committee on Commerce, Science, and Transportation.

EC–3039. A communication from the Chairman of the Surface Transportation Board, transmitting, pursuant to law, a rule received on September 10, 1997; to the Committee on Commerce, Science, and Transportation.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. ROTH, from the Committee on Finance, without amendment:

S. 1216. An original bill to approve and implement the OECD Shipbuilding Trade Agreement (Rept. No. 105–84).

By Mr. McCAIN, from the Committee on Commerce, Science, and Transportation, with amendments:

S. 738. A bill to reform the statutes relating to Amtrak, to authorize appropriations for Amtrak, and for other purposes (Rept. No. 105–85).

By Mr. JEFFORDS, from the Committee on Labor and Human Resources, with an amendment in the nature of a substitute:

S. 1020. A bill to amend the National Foundation on the Arts and Humanities Act of 1965 and the Art and Artifacts Indemnity Act to improve and extend the Acts, and for other purposes (Rept. No. 105–86).

By Mr. CHAFEE, from the Committee on Environment and Public Works, without amendment:

H.R. 2443. A bill to designate the Federal building located at 601 Fourth Street, N.W., in the District of Columbia, as the "Federal Bureau of Investigation, Washington Field Office Memorial Building", in honor of William H. Christian, Jr., Martha Dixon Martinez, Michael J. Miller, Anthony Palmisano, and Edwin R. Woodriffe.

By Mr. HELMS, from the Committee on Foreign Relations, without amendment and with a preamble:

H. Con. Res. 99. A concurrent resolution expressing concern over recent events in the Republic of Sierra Leone in the wake of the recent military coup d'etat of that country's first democratically elected president.

By Mr. HELMS, from the Committee on Foreign Relations, without amendment and with a preamble:

S. Res. 123. An original resolution honoring the memory of former Peace Corps Director Loret Miller Ruppe.

By Mr. MURKOWSKI, from the Committee on Energy and Natural Resources, with an amendment in the nature of a substitute:

S. 1015. A bill to provide for the exchange of lands within Admiralty Island National Monument, and for other purposes.

By Mr. HELMS, from the Committee on Foreign Relations, without amendment:

S. 1211. An original bill to provide permanent authority for the administration of au pair programs.

By Mr. HELMS, from the Committee on Foreign Relations, without amendment and with a preamble:

S. Con. Res. 51. A concurrent resolution expressing the sense of Congress regarding elections for the legislature of the Hong Kong Special Administrative Region.

EXECUTIVE REPORTS OF COMMITTEES

The following executive reports of committees are submitted:

By Mr. MURKOWSKI, from the Committee on Energy and Natural Resources:

John C. Angell, of Maryland, to be an Assistant Secretary of Energy (Congressional and Intergovernmental Affairs).

Mary Anne Sullivan, of the District of Columbia, to be General Counsel of the Department of Energy.

Ernest J. Moniz, of Massachusetts, to be Under Secretary of Energy.

Michael Telson, of the District of Columbia, to be Chief Financial Officer, Department of Energy

Dan Reicher, of Maryland, to be an Assistant Secretary of Energy (Energy, Efficiency, and Renewable Energy).

Robert Wayne Gee, of Texas, to be an Assistant Secretary of Energy (Policy, Planning, and Program Evaluation).

(The above nominations were reported with the recommendation that they be confirmed, subject to the nominees' commitment to respond to requests to appear and testify before any duly constituted committee of the Senate.)

Mr. JEFFORDS. Mr. President, for the Committee on Labor and Human Resources, I report favorably two nomination lists in the Public Health Service which were printed in full in the CONGRESSIONAL RECORD of September 4 and 12, 1997, and ask unanimous consent, to save the cost of reprinting on the Executive Calendar, that this nominations lie at the Secretary's desk for the information of Senators.

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

(The nominations ordered to lie on the Secretary's desk were printed in the RECORDS of September 4 and 12, 1997, at the end of the Senate proceedings.)

The following candidates for personnel action in the regular component of the Public Health Service Commissioned Corps subject to qualifications therefor as provided by law and regulations:

1. FOR APPOINTMENT:

To be assistant surgeon

Jennifer L. Betts
Matthew A. Clark
Gretchen M. Esplund
Philip T. Farabough
Laurie E. Olnes
Susannah Q. Olnes
Melissa A. Sipe
Joanette A. Sorkin
Rebecca J. Werner

The following candidates for personnel action in the regular component of the Public Health Service Commissioned Corps subject to qualifications therfor as provided by law and regulations:

1. FOR APPOINTMENT:

To be medical director

William E. Halperin

To be senior surgeon

Diane L. Rowley

To be surgeon

Jay C. Butler
Robert H. Johnson

To be senior assistant surgeon

Joseph M. Chen
Susan A. Lippold
Carlos M. Rivera
Thomas J. Vangilder
Steven S. Wolf
Priscilla L. Young
Stephanie Zaza

To be dental surgeon

Richard M. Davidson

To be senior assistant dental surgeon

Glen A. Eisenhuth
Mark S. Elliott
Clay D. Henning
Steven A. Johnson
Michael J. Mindiola
Donald L. Ross
James H. Tennyson

To be nurse director

Susan P. Hubbard

To be senior nurse officer

Elizabeth J. McCarthy

To be nurse officer

Veronica G. Stephens

To be senior surgeon nurse officer

Brian P. Asay
Amy V. Buckanaga
Deborah K. Burkybile
Thomas L. Doss
Deann M. Eastman-Jansen
Edwin M. Galan
Louis J. Glass
Nelson Hernandez
Richard G. Hills
Leonard L. Howell
Lenora B. Jones
Joan F. Kelley
Eric A. Lasure
Patricaia A. Lawrence
Lucienne D. Nelson
Susan M. Nord
Martha T. Olone
Judy L. Pearce
Juliana M. Sadovich
Carmelita Sorrelman
Mary T. Vanieuven
Daniel J. Weskamp
Vernon L. Wilkie

To be Assistant Nurse Officer

Karen E. Bikowicz
Guadalupe R. Demske
Robert T. Edwards
William C. Guinn
Michael J. Lackey
Richard N. Leland
Mark J. Martineau
Edward A. Sexton

To be engineer director

Richard R. Truitt

To be senior assistant engineer officer

David M. Apanian
Charles S. Hayden, II
Lee C. Jackson
John W. Longstaff
Kathy M. Poneleit
Stephen P. Rhodes
Carol L. Rogers
Hung Trinh
Richard S. Wermers
Andrew J. Zajac

To be assistant engineer officer

Michael S. Coene
Paul J. Ritz

To be scientist

Susan M. Caviness

To be senior assistant scientist

Drue H. Barrett
Roy A. Blay
Ann M. Malarcher
Robert L. Williams

To be sanitarian

Edwin J. Fluette

To be senior assistant sanitarian

Clint R. Chamberlin
Jeffrey A. Church
Nancy J. Collins
Eric J. Esswein
Wendy L. Fanaselle
Michael G. Halko
Diana M. Kuklinski
Joseph D. Little
Gina L. Locklear
Joe L. Maloney
Michael A. Noska
David E. Robbins
Sarath B. Seneviratne
Daniel C. Strausbaugh
Jessilynn B. Taylor
Timothy Walker

To be veterinary officer

William S. Stokes

To be senior assistant pharmacist

Lisa A. Cohn
Alison R. Dion
Cindy P. Dougherty
Thomas P. Gammarano
Robert W. Griffith
Jill D. Mayes
Paul J. Na
Cheryl A. Namtvedt
William A. Russell, Jr.
Donna A. Shriner
Pamela J. West
Rochelle B. Young

To be assistant pharmacist

Christopher A. Bina

To be senior assistant dietitian

Jo Ann A. Holland
Marilyn A. Welschenbach

To be senior assistant therapist

Cindy R. Melanson

To be assistant therapist

Michelle Y. Jordan
Jean E. Marzen

To be health services officer

Eugene A. Migliaccio

To be senior assistant health services officer

Debora S. Descombes
Michael J. Flood
Donald H. Gabbert
Denis L. Goudelock
Jane Martin
Doreen M. Melling
David J. Miller
Peggy J. Roys
William Tool

To be assistant health services officer

James A. Gregory
Trinh K. Nguyen

(The above nominations were reported with the recommendation that they be confirmed, subject to the nominees' commitment to respond to requests to appear and testify before any duly constituted committee of the Senate.)

By Mr. HELMS, from the Committee on Foreign Relations:

Robin Lynn Raphel, of Washington, a Career Member of the Senior Foreign Service, Class of Minister-Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Tunisia.

Johnny Young, of Maryland, a Career Member of the Senior Foreign Service, Class of Minister-Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the State of Bahrain.

Susan E. Rice, of the District of Columbia, to be an Assistant Secretary of State.

Nancy Dorn, of the District of Columbia, to be Member of the Board of Directors of the Inter-American Foundation for a term expiring June 26, 2002.

Peter L. Scher, of the District of Columbia, for the rank of Ambassador during his tenure of service as Special Trade Negotiator.

Harold C. Pachios, of Maine, to be a Member of the United States Advisory Commission on Public Diplomacy for a term expiring July 1, 1999.

Paula Dobriansky, of Maryland, to be a Member of the United States Advisory Commission of Public Diplomacy for a term expiring July 1, 1998.

R. Nicholas Burns, of Virginia, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to Greece.

Nominee: R. Nicholas Burns.

Post: Greece.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self, R. Nicholas Burns, None.

2. Spouse, Elizabeth Allen Baylies, None.

3. Children and Spouses Names: Sarah; Elizabeth; Caroline, None.

4. Parents Names: Robert P. & Esther A. Burns—$25—1996—Newt Gingrich.

$100—1994—Romney for Senate in Massachusetts.

5. Grandparents Names: James & Delia Burns, deceased.

Richard & Helen Toomey, deceased.

6. Brothers and Spouses Names: Christopher & Nayla Burns, None; Jeffrey & Denise Burns, None.

7. Sisters and Spouses Names: Roberta Esther & Richard Hutchins, None; Stanton & Gigi Burns, None.

Barbara K. Bodine, of California, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Yemen.

Nominee: Barbara K. Bodine.

Post: The Republic of Yemen.

The following is a list of all members of my immediate family and their spouses. I have been able to ask only my father to inform me of the pertinent contributions made by him. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions	Amount	Date	Donee
1. Self	None	n/a	n/a
2. Spouse—none	n/a	n/a	n/a
3. Children None, spouses none.	n/a	n/a	n/a
4. Father: Robert J. Bodine	Low $100's each time.	Over several years.	Sen. Ashcroft Sen. Bond Sen. Mack Cong. Goss

Mother: Barbara Bode Bodine Red (NFI), Have not had any contact since Sept. 1982, Doubt any contributions of any note.

Step-mother: Joann Bodine—Have never met or spoken with my step-mother. Have no idea what donations/contributions she may have made.

Step-father: Alan (NFI)—Met once in summer '82. Do not recall surname; do not know address; do not know politics.

5. Grandparents: all deceased except maternal grandfather's fourth wife/widow. Does not make political contributions.

6. Half-brother: Jonathan B. Red (wife: Deborah Brockley), No contact since July, 1982.

7. Half-sister: Carol Bodine (married; husband's name unknown), No contact ever.

Half-sister: Gail Bodine (married; husband's name unknown), No contact ever.

Brian Dean Curran, of Florida, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Mozambique.

Nominee: Brian Dean Curran.

Post: Maputo, Mozambique.

The following is a list of all members of my immediate family and their spouses. I

have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self.
2. Spouse.
3. Children and Spouses Names.
4. Parents Names.
5. Grandparents Names.
6. Brothers and Spouses Names: Mr./Mrs. David Curran, $100, 1994, Harms for Congress.
7. Sisters and Spouses Names: Janice Curran, none.

[Brian Dean Curran, Post: Maputo, Mozambique]

Contributions	Amount	Date	Donee
1. Self	$50	3/3/92	Clinton for President.
	50	3/20/93	Democratic National Committee.
	50	8/8/93	Democratic National Committee.
	50	7/12/94	Citizens for Sarbanes.
	50	10/9/94	Friends of Tom Andrews.
	13	3/20/93	Human Rights Campaign Fund.
	155	9/29/94	Human Rights Campaign Fund.
	175	11/95	Human Rights Campaign Fund.
	50	10/96	Democratic National Committee.

5. Grandparents (all deceased) Wadsworth Harris Williams, none; Leila Williams, none; Winnefred Curran, none; Coleman Curran, none.

Corinne Claiborne Boggs, of Louisiana, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Holy See.

NOMINEE: Corinne Claiborne Boggs.

POST: Ambassador to the Holy See.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee.

1. Self: Corinne Claiborne Boggs.
2. Spouse: Thomas Hale Boggs (Deceased 1972).
3. Children and Spouses: Barbara Boggs Sigmund (Deceased 1990).

Thomas Hale Boggs Jr. m. Barbara Denechaud.

Corinne Boggs m. Steven V. Roberts. None.

4. Parents: Corinne Morrison (Deceased 1978), Roland Claiborne (Deceased 1918).
5. Grandparents: Rose Claiborne (Deceased 1935) m. Louis Claiborne (Deceased 1934), Eustatia Morrison (Deceased 1895) m. Edward S. Morrison (Deceased 1923).
6. Brothers and Spouses: None.
7. Sisters and Spouses: None.

LINDY BOGG'S FEDERAL CAMPAIGN CONTRIBUTIONS (JANUARY 1, 1993—PRESENT)

Date	Amount	Political organization	Name
Oct. 30, 1993	$250.00	Democratic Senatorial Campaign Committee	
Nov. 14, 1993	250.00	Catherine Baker Knoll	Catherine Baker Knoll.
May 28, 1994	250.00	Tom Foley	Tom Foley.
May 28, 1994	250.00	Jolene Unsoeld	Jolene Unsoeld.
July 27, 1994	1,000.00	Robb for the Senate	Charles Robb.
Aug. 5, 1994	250.00	Friends of Patrick Kennedy	Patrick Kennedy.
Aug. 23, 1994	200.00	D.C.C.C	
Oct. 9, 1994	250.00	Friends of Jim Cooper	Jim Cooper.
Oct. 22, 1994	500.00	Ted Kennedy	Ted Kennedy.
Oct. 24, 1994	250.00	Kathleen Townsend	Kathleen Townsend.
Oct. 24, 1994	100.00	Democratic National Committee	
Oct. 24, 1994	250.00	Diane Feinstein	Diane Feinstein.
Nov. 1, 1994	1,000.00	Democratic Leadership Council	
Jan. 30, 1995	500.00	Carol Moseley Braun for US Senate	Carol Moseley Braun.
Feb. 21, 1995	250.00	Feinstein for Senate '94	Diane Feinstein.
Dec. 29, 1995	250.00	President Clinton Dinner (D.N.C.)	
Dec. 31, 1995	240.00	Jim Chapman	Jim Chapman.
Dec. 31, 1995	500.00	Carol Moseley Braun for US Senate	Carol Moseley Braun.
Mar. 26, 1996	25.00	Joe Biden	Joe Biden.
Mar. 31, 1996	500.00	Mary Landrieu	Mary Landrieu.
May 6, 1996	500.00	Mary Landrieu	Mary Landrieu.
May 16, 1996	250.00	Barbara Kennelly	Barbara Kennelly.
May 28, 1996	250.00	D.C.C.C. of LA Federal	
June 6, 1996	200.00	D.C.C.C.	
Sept. 2, 1996	150.00	LA Democratic Victory Fund	
Feb. 16, 1997	200.00	D.C.C.C.	

THOMAS HALE BOGGS, JR.'S FEDERAL CAMPAIGN CONTRIBUTIONS (JANUARY 1, 1993–PRESENT)

Date	Amount	Political organization	Name
		1993	
Jan. 4, 1993	$500.00	Wilson for Chairman	John Wilson.
Feb. 2, 1993	1,000.00	Ed Markey for Congress Committee	Ed Markey.
Feb. 3, 1993	250.00	Friends of Paul McHale	Paul McHale.
Feb. 23, 1993	100.00	Epsy for Congress	Mike Epsy.
Mar. 9, 1993	250.00	Portman for Congress	Rob Portman.
Mar. 16, 1993	1,000.00	Bob Krueger Campaign	Bob Krueger.
Mar. 23, 1993	200.00	Simon for Senate	Paul Simon.
Mar. 24, 1993	1,000.00	The Jefferson Committee	William Jefferson.
Mar. 30, 1993	1,000.00	Citizens for Biden	Joseph Biden.
Mar. 30, 1993	500.00	Thornton for Congress	Ray Thornton.
Apr. 20, 1993	1,000.00	Murtha for Re-Election committee	John Murtha.
Apr. 28, 1993	500.00	Bliley for Congress Committee	Thomas Bliley.
Apr. 28, 1993	500.00	Jimmie Hayes for Congress	Jimmie Hayes.
May 14, 1993	1,000.00	DeConcini '94 Committee	Dennis DeConcini.
June 14, 1993	1,000.00	Committee to Re-elect Jack Brooks	Jack Brooks.
June 16, 1993	500.00	The Lautenberg Committee	Frank Lautenberg.
June 29, 1993	500.00	Wheat for Congress	Alan Wheat.
June 29, 1993	500.00	Kerrey for US Senate	Bob Kerrey.
July 20, 1993	1,000.00	Joseph M. McDade Legal Defense Fund	Joseph M. McDade.
Sep. 22, 1993	250.00	Paul Simon for Senate	Paul Simon.
Sep. 28, 1993	500.00	Friends of Neal Smith	Neal Smith.
Sep. 29, 1993	500.00	English for Congress Committee	Glenn English.
Oct. 13, 1993	500.00	Coloradans for David Skaggs	David Skaggs.
Oct. 14, 1993	310.51	Lieberman '94 Committee (in-kind)	Joseph Lieberman.
Oct. 27, 1993	250.00	Friends of Alan Wheat	Alan Wheat.
Oct. 27, 1993	1,000.00	Daniel K. Inouye in 98	Daniel K. Inouye.
Nov. 9, 1993	500.00	Citizens for David Mann	David Mann.
Nov. 10, 1993	500.00	Lynn Schenk for Congress Committee	Lynn Schenk.
Nov. 18, 1993	500.00	Citizens Committee for Ernest F. Hollings (aka the Citizens Committee)	Ernest Hollings.
Dec. 2, 1993	250.00	Sanford Bishop for Congress	Sanford Bishop.
Dec. 3, 1993	689.49	Lieberman '94 Committee	Joseph Lieberman.
Dec. 8, 1993	1,000.00	Jim Cooper for Congress Committee	Jim Cooper.
Dec. 9, 1993	1,000.00	The Lautenberg Committee/$500-Prim-500-Gen	Frank Lautenberg.
Dec. 16, 1993	500.00	Ed Markey for Congress	Ed Markey.
Dec. 16, 1993	500.00	Hoyer for Congress Committee	Steny Hoyer.
		1994	
Jan. 13, 1994	500.00	Hoyer for Congress	Steny Hoyer.
Jan. 25, 1994	1,000.00	Committee for Sam Gibbons	Sam Gibbons.
Jan. 26, 1994	11.60	The Lautenberg Committee (in-kind postage)	Frank Lautenberg.
Jan. 31, 1994	600.00	Mitchell for Senate Committee	George J. Mitchell.
Mar. 14, 1994	500.00	Moynihan Campaign	Daniel Moynihan.
Mar. 23, 1994	500.00	Hoyer for Congress Committee	Steny H. Hoyer.
Mar. 23, 1994	500.00	Hoagland for Congress Committee	Peter Hoagland.
Apr. 26, 1994	500.00	Friends of Congressman George Miller	George Miller.

THOMAS HALE BOGGS, JR.'S FEDERAL CAMPAIGN CONTRIBUTIONS (JANUARY 1, 1993–PRESENT)—Continued

Date	Amount	Political organization	Name
May 10, 1994	1,000.00	Laughlin for Congress	Greg Laughlin.
May 10, 1994	500.00	Committee for Congressman Charlie Rose	Charlie Rose.
May 17, 1994	350.00	Lancaster for Congress Committee	H. Martin Lancaster.
May 17, 1994	1,000.00	Robb for Senate Committee	Charles Robb.
May 18, 1994	100.00	Friends of Lem Chester	Lem Chester.
June 27, 1994	500.00	Friends of Patrick J. Kennedy for Congress	Patrick J. Kennedy.
July 7, 1994	250.00	Peter Deutsch for Congress	Peter Deutsch.
Aug. 11, 1994	500.00	Bill Wheeler for Congress	Bill Wheeler.
Sep. 20, 1994	50.00	Friends of Mark Takano for Congress	Mark Takano.
Sep. 26, 1994	1,000.00	Johnston Senate Committee	Bennet Johnston.
Nov. 30, 1994	1,000.00	Citizens for Harkin	Tom Harkin.
		1995	
Jan. 24, 1995	500.00	Friends of Senator Rockefeller	John D. Rockefeller.
Feb. 15, 1995	1,000.00	Nadler for Congress	Jerrold Nadler.
Feb. 28, 1995	1,000.00	Re-elect Senator Mark Hatfield	Mark O. Hatfield.
Feb. 28, 1995	1,000.00	Dole for President	Bob Dole.
Mar. 2, 1995	1,000.00	Friends of John Warner	John Warner.
Mar. 7, 1995	1,000.00	John D. Dingell for Congress Committee	John D. Dingell.
Mar. 8, 1995	500.00	Foglietta for Congress	Thomas M. Foglietta.
Mar. 8, 1995	500.00	Ackerman for Congress	Gary L. Ackerman.
Mar. 21, 1995	500.00	Louise Slaughter Re-election Committee	Louise Slaughter.
Mar. 28, 1995	500.00	Billy Tauzin Committee	W.J. (Billy) Tauzin.
Mar. 28, 1995	500.00	Ed Markey for Congress	Ed Markey.
Mar. 29, 1995	1,000.00	Arlen Specter '96	Arlen Specter.
Apr. 4, 1995	500.00	Martin Frost Campaign	Martin Frost.
Apr. 5, 1995	500.00	Greg Laughlin Campaign	Greg Laughlin.
Apr. 27, 1995	500.00	Friends of Chriss Dodd	Christopher J. Dodd.
May 2, 1995	1,000.00	The Kerry Committee	John F. Kerry.
May 31, 1995	1,000.00	Robb for Senate	Charles S. Robb.
June 13, 1995	250.00	Fazio for Congress	Vic Fazio.
June 19, 1995	300.00	Citizens Committee for Ernest Hollings	Ernest Hollings.
June 27, 1995	1,000.00	Matsui for Congress	Robert T. Matsui.
June 28, 1995	1,000.00	Friends of Joe Curran	Joe Curran.
June 29, 1995	500.00	Citizens for John Kasich	John Kasich.
June 29, 1995	500.00	Danner for Congress	Pat Danner.
July 15, 1995	1,000.00	Robb for Senate	Charles Robb.
July 18, 1995	1,000.00	Dick Molpus Campaign	Dick Molpus.
July 25, 1995	802.93	Richard Shelby Luncheon	Richard Shelby.
July 26, 1995	1,000.00	Friends of Barbara Boxer	Barbara Boxer.
Sep. 12, 1995	1,000.00	Clinton/Gore '96	Clinton/Gore.
Sep. 27, 1995	500.00	Riggs for Congress	Frank Riggs.
Sep. 28, 1995	1,000.00	Jesse Jackson Jr. for Congress	Jesse Jackson jr.
Oct. 2, 1995	1,000.00	The Freedom Project	Boehner Multi-Candidate PAC.
Oct. 10, 1995	500.00	Jesse Jackson Jr. for Congress	Jess Jackson Jr.
Oct. 20, 1995	700.00	Citizens Committee for Ernest Hollings $500-Gen, $200-Prim	Ernest Hollings.
Oct. 24, 1995	500.00	Glen D. Johnson	Glen D. Johnson.
Nov. 1, 1995	1,000.00	Citizens for Jim Hunt	Jim Hunt.
Nov. 9, 1995	500.00	Duncan for Congress	John J. Duncan, Jr.
Nov. 16, 1995	1,000.00	Wyden for Senate	Ron Wyden.
Nov. 16, 1995	1,000.00	The Kerry Committee	John Kerry.
Dec. 1, 1995	446.00	Nebraskans for Nelson	
Dec. 14, 1995	500.00	The Evan Bayh Committee	Evan Bayh.
		1996	
Jan. 31, 1996	1,000.00	Friends of Dick Durbin	Dick Durbin.
Feb. 6, 1995	1,000.00	Braun for US Senate	Carol Moseley-Braum.
Mar. 13, 1996	72.00	Coyne for Congress (in kind to La Brasserie)	William Coyne.
Mar. 20, 1996	1,000.00	Matsui for Congress Committee	Robert Matsui.
Mar. 28, 1996	129.75	Weiland for Congress (in kind to W. Millar & Co.)	Rick Weiland.
Apr. 17, 1996	154.00	Bryant for Congress (in kind to Le Bon)	John Bryant.
June 29, 1996	1,000.00	Gephardt's in Congress Committee	Richard Gephardt.
July 17, 1996	1,000.00	Citizens Committee for Ernest F. Hollings	Ernest Hollings.
Sep. 4, 1996	1,500.00	DNC Services Corporation/Democratic National Committee	
Oct. 18, 1996	(500.00)	Citizens Committee for Ernest F. Hollings	Ernest F. Hollings.
Oct. 18, 1996	562.74	Bedford for US Senate (in kind to Giant Food)	Roger Bedford.
Oct. 18, 1996	533.11	Tom Bruggere for US Senate (in kind to Giant Food)	Tom Bruggere.
Nov. 1, 1996	(600.00)	Johnston Senate Committee	Bennett Johnston.
Nov. 1, 1996	600.00	Jeff Coopersmith for Congress	Jeff Coopersmith.
Nov. 1, 1996	1,000.00	Congressman Bart Gordon Committee	Bart Gordon
Dec. 30, 1996	1,000.00	Leahy for U.S. Senator	Patrick Leahy.
		1997	
Jan. 14, 1997	400.00	DCCC	DCCC.
Feb. 11, 1997	1,000.00	Carol Mosely-Braun for US Senate	Carol Moseley-Braun.
Feb. 27, 1997	1,000.00	Shelby for Senate	Richard Shelby.
Feb. 27, 1997	5,000.00	DCCC	
Mar. 6, 1997	500.00	Alaskans for Don Young	Don Young.
Mar. 10, 1997	1,000.00	Friends of Kent Conrad	Kent Conrad.
Mar. 17, 1997	500.00	Friends of George Miller	George Miller.
Mar. 18, 1997	500.00	Frank Riggs for Congress	Frank Riggs.
Mar. 19, 1997	1,00.00	Friends of Barbara Boxer	Barbara Boxer.
Apr. 9, 1997	1,000.00	Gephardt in Congress Committee	Richard Gephardt.
Apr. 14, 1997	1,000.00	Murtha for Congress Committee	John Murtha.
May 7, 1997	1,000.00	Friends of Byron Dorgan	Byron Dorgan.
May 20, 1997	1,000.00	Hagle for Nebraska	Chuck Hagle.
June 4, 1997	500.00	Markey for Congress Committee	Ed Markey.
June 10, 1997	500.00	Pelosi for Congress	Nancy Pelosi.
June 10, 1997	250.00	Friends of Rosa DeLauro	Rose DeLauro.
June 10, 1997	250.00	Stenholm for Congress Committee	Charles Stenholm.
June 12, 1997	500.00	Luther for Congress	
June 24, 1997	500.00	Martin Frost Campaign	Martin Frost.

BARBARA DENECHAUD BOGGS'S FEDERAL CAMPAIGN CONTRIBUTION (JANUARY 1, 1994—PRESENT)

Date	Amount	Political organization	Name
		1994	
April 18, 1994	$1,000.00	Kerrey for U.S. Senate Committee	Bob Kerrey.
April 28, 1994	1,000.00	Citizens for Senator Wofford	Harris Wofford.
May 13, 1994	1,000.00	Laughlin for Congress	Greg Laughlin.
May 18, 1994	1,000.00	Murtha for Congress Committee	John Murtha.
June 14, 1994	1,000.00	Committee to Re-elect Jack Brooks	Jack Brooks.
June 21, 1994	1,000.00	Friends of Robert C. Byrd Committee	Robert C. Byrd.
June 28, 1994	500.00	Committee to Re-elect Tom Foley	Tom Foley.
June 29, 1994	1,000.00	Markey for Congress Committee	Ed Markey.

BARBARA DENECHAUD BOGGS'S FEDERAL CAMPAIGN CONTRIBUTION (JANUARY 1, 1994—PRESENT)—Continued

Date	Amount	Political organization	Name
July 25, 1994	1,000.00	Friends of Jim Sasser	Jim Sasser.
September 29, 1994	500.00	Friends of Sherrod Brown	Sherrod Brown.
September 29, 1994	1,000.00	Oberly Senate Committee	
September 30, 1994	250.00	Thurman for Congress	Karen Thurman.
October 6, 1994	500.00	New Mexicans for Bill Richardson	Bill Richardson.
October 7, 1994	1,000.00	Effective Government Committee	
October 7, 1994	500.00	Lancaster for Congress Committee	
October 7, 1994	1,000.00	Friends of Jerry Kleczka	Jerry Kleczka.
October 13, 1994	1,000.00	Akaka in 94	Daniel Akaka.
November 15, 1994	(380)	DeConcini '94 Committee	Dennis DeConcini.
		1995.	
March 31, 1995	500.00	Friends of Jane Harman	Jane Harman.
April 10, 1995	500.00	Laughlin for Congress	Greg Laughlin.
December 6, 1995	500.00	Friends of Rosa DeLauro	Rosa DeLauro.
		1996	
March 4, 1996	1,000.00	Friends of Jerry Kleczka	Jerry Kleczka.
April 18, 1996	1,000.00	Bonior for Congress	Daniel Bonior.
October 24, 1996	500.00	Friends of Senator Rockefeller	Rockefeller.
April 29, 1996	1,000.00	Gephardt in Congress Committee	Richard Gephardt.
May 1, 1996	250.00	Susan B. Anthony List Pac, Inc.	
May 23, 1996	1,000.00	Murtha for Congress Committee	John Murtha.
May 20, 1996	250.00	People for Weiland	
May 29, 1996	500.00	Peter Deutsch for Congress	Peter Deutsch.
May 31, 1996	1,000.00	Harvey Gantt for Senate Campaign Committee	Harvey Gantt.
June 27, 1996	1,000.00	Levin for Congress Committee	Sander Levin.
July 3, 1996	500.00	Friends of Congressman George Miller	George Miller.
September 13, 1996	250.00	Friends of John Warner 1996 Committee	John Warner.
September 25, 1996	1,000.00	Don Mooers for Congress Committee Inc.	Don Mooers.
September 26, 1996	1,000.00	Clinton/Gore '96 Gen Election Legal & Accounting Compliance	Clinton/Gore.
September 30, 1996	250.00	Friends of John Warner 1996 Committee	John Warner.
October 5, 1996	1,000.00	Friends of Max Cleland for the U.S. Senate Inc.	Max Cleland.
November 4, 1996	1,000.00	Kerry Committee	John Kerry.

Timberlake Foster, of California, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Islamic Republic of Mauritania.

Nominee: Timberlake Foster.

Post: Mauritania.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, and donee:

1. Self, none.

2. Spouse, Pamela Biolley, none.

3. Children and spouses names, Noel Foster (age 11), none.

4. Parents names, Lang and Clarice foster, none.

5. Grandparents names, Ira and Lillian Jones, deceased; Charles and Elberta Foster, deceased.

6. Brothers and spouses names, Lang Foster, Jr., none.

7. Sisters and spouses names, no sisters.

Thomas J. Dodd, of the District of Columbia, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Costa Rica.

Nominee: Thomas J. Dodd.

Post: U.S. Ambassador to Costa Rica.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, and donee:

1. Self, none.

2. Spouse, N/A.

3. Children and spouses names, none.

4. Parents names, none.

5. Grandparents names, none.

6. Brothers and spouses names, Senator Christopher J. Dodd, none.

7. Sisters and spouses names, Martha Dodd Buonanno/Bernard V. Buonanno (see attached), $4,700, 1989–1997, Sen. Jack Reed; $2,000, 1989–1997, Sen. John Chafee.

BUONANNO CONTRIBUTIONS—1989–1997

Year	Reed	Chafee	Total
1989	$500.00	$200.00	$700.00
1990	100.00	—	100.00
1991	750.00	375.00	1,125.00
1992	500.00	—	500.00
1993	700.00	1,000.00	1,700.00
1994	550.00	425.00	975.00
1995	1,600.00	—	1,600.00
1996	—	—	—
1997	—	—	—
Total	4,700.00	2,000.00	6,700.00

Thomas M. Foglietta, of Pennsylvania, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to Italy.

Nominee: Thomas M. Foglietta.

Post: Ambassador.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, and donee:

1. Self, no personal contributions. See attached schedule of campaign contributions.

2. Spouse, none.

3. Children and spouses names, none.

4. Parents names, Rosaria and Michael Foglietta, deceased.

5. Grandparents names, deceased.

6. Brothers and spouses names, Theodore Michael Foglietta, deceased.

7. Sisters and spouses names, Bertha Foglietta Bruentti, Margaret Jacqueline Foglietta, none.

Federal Campaign Contributions Reporting—Foglietta for Congress

Candidate or Organization	Date	Amount
DCCC	4/7/92	$5,000.00
America 500	7/6/92	1,000.00
Russo for Congress	11/24/92	1,000.00
Kostmayer for Congress	1/14/93	1,000.00
Hayes for Congress	2/1/93	500.00
DCCC	2/3/93	5,000.00
Dem. Campaign Comm.	4/27/93	1,250.00
Gejdensen Re-Elect	9/21/94	1,000.00
Tucker for Congress	9/23/94	500.00
Mezvinsky for Congress	11/1/94	1,000.00
DCCC	4/10/95	5,000.00
DCCC	7/24/96	5,000.00
Hefner for Congress	8/7/96	1,000.00

Federal Campaign Contributions Reporting—Foglietta for Congress—Continued

Candidate or Organization	Date	Amount
Coles for Congress	8/7/96	500.00
Ruth Rudy for Congress	9/20/96	1,000.00
Hinchey for Congress	9/20/96	500.00
Price for Congress	9/20/96	500.00
Blagojevich for Congress	9/20/96	500.00
Turney for Congress	9/20/96	500.00
Carolyn McCarthy for Congress	9/20/96	500.00
Owens for Congress	9/20/96	500.00
McKinney for Congress	9/20/96	500.00
Coles for Congress	9/20/96	500.00
Peter Navarro for Congress	9/20/96	500.00
Gejdensen for Congress	9/20/96	500.00
Tauscher for Congress	9/20/96	500.00
George Brown for Congress	9/20/96	500.00
Capps for Congress	9/20/96	500.00
McHale for Congress	9/20/96	1,000.00
Ron DiNicola for Congress	9/20/96	500.00
Kucinich for Congress	10/1/96	500.00
Bentsen for Congress	10/1/96	500.00
Julia Carson for Congress	10/1/96	500.00
Michela Alioto for Congress	10/1/96	1,000.00
Loretta Sanchez for Congress	10/1/96	500.00
Bentsen for Congress	11/20/96	1,000.00
Lampson for Congress	11/20/96	1,000.00

Donna Jean Hrinak, of Virginia, a Career Member of the Senior Foreign Service, Class of Minister-Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Bolivia.

Nominee: Donna Jean Hrinak.

Post: Ambassador to La Paz.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, and donee:

1. Self, none.

2. Spouse, Gabino M. Flores, none.

3. Children and spouses names, Wyatt A. Flores, none.

4. Parents names, John and Mary Hrinak, none.

5. Grandparents names, John and Anna Hrinak, Joseph and Julia Pukach, deceased.

6. Brothers and spouses names, David J. Hrinak, none.

7. Sisters and spouses names, none.

Curtis Warren Kamman, of the District of Columbia, a Career Member of the Senior

Foreign Service, Class of Career Minister, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Colombia.

Nominee: Curtis Warren Kamman.

Post: Ambassador to Colombia.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, and donee:

1. Self, none.

2. Spouse, Mary Curtis Kamman, none.

3. Children and spouses names, Edward Kamman and spouse Esta Kamman, John Kamman, W. Stephen Kamman, none.

4. Parents names, father Glenn Kamman (deceased), mother Mildred Kamman (deceased), none.

5. Grandparents names, Horace and Bertha Kamman (deceased), Warren and Ella Merry (deceased), none.

6. Brothers and spouses names, Robert E. Kamman, Jon Kamman and spouse Beverly Medlyn, none.

7. Sisters and spouses names, no sisters.

Nancy Jo Powell, of Iowa, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Uganda.

Nominee: Nancy Jo Powell.

Post: Kampala.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self.

2. Spouse.

3. Children and spouses, names.

4. Parents, names, Joseph William Powell, Jennie Maxine Powell.

5. Grandparents, names (deceased).

6. Brothers and spouses, names William Craig Powell.

7. Sisters and spouses names.

Tom McDonald, of Ohio, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Zimbabwe.

Nominee: Tom McDonald.

Post: Ambassador to Zimbabwe.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self (see attached list).

2. Spouse, $1,000, 1994, Sherrod Brown for Congress Comm.; $1,000, 1996, Sherrod Brown for Congress Comm.

3. Children and spouses names.

4. Parents, names.

5. Grandparents, names.

6. Brothers and spouses, names.

7. Sisters and spouses, names.

POLITICAL CONTRIBUTIONS OF TOM McDONALD

Federal contributions	Year	Contribution
Louis Stokes for Congress Committee	1993	$1,000
Rob Portman for Congress Committee	1993	500

POLITICAL CONTRIBUTIONS OF TOM McDONALD—Continued

Federal contributions	Year	Contribution
Sherrod Brown for Congress Committee	1993	250
Judy Hancock for Congress Committee	1993	500
Deborah Pryce for Congress Committee	1993	500
Deborah Pryce for Congress Committee	1993	250
Democratic National Committee	1993	1,000
Fingerhut for Congress	1993	350
Helen Smith for Congress	1994	250
11th Congressional District Caucus PAC	1994	70
Ted Strickland for Congress Committee	1994	500
Patrick Moynihan for U.S. Senate Committee	1994	1,000
Friends of John Glenn (Paying off 1984 Presidential debt)	1994	1,000
Friends of John Glenn (Paying off 1984 Presidential debt)	1994	1,000
The Hyatt Committee (Primary election contribution)	1994	1,000
The Hyatt Committee (General election contribution)	1994	1,000
Louis Stokes for Congress Committee	1994	1,000
Robert Matsui for Congress Committee	1994	1,000
Rob Portman for Congress Committee	1994	1,000
Friends of Eric Fingerhut	1994	1,000
Kennedy for Senate Committee	1994	1,000
Judy Hancock for Congress	1994	1,000
Democratic National Committee	1994	5,000
Rob Portman for Congress Committee	1995	100
Clinton/Gore '96	1995	1,000
Democratic National Committee	1996	5,000
Dennis Kucinich for Congress	1996	500
Kucinich for Congress	1996	250
Ted Strickland for Congress Committee	1996	250
Bill Richardson for Congress Committee	1996	200
Bob Torricelli for Senate Committee	1996	500
Tom Coyne for Congress Committee	1996	250
Stokes for Congress Committee	1996	250
Gephardt for Congress Committee	1996	1,000
Sherrod Brown for Congress	1996	1,000
Tom Sawyer for Congress Committee	1996	1,000
Democratic National Committee	1996	5,000
Judy Hancock for Congress Committee	1996	1,000
Rangel for Congress Committee	1996	1,000
Sherrod Brown for Congress Committee	1997	500
The Gephardt Committee	1997	1,000

Mark Robert Parris, of Virginia, a Career Member of the Senior Foreign Service, Class of Minister-Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Turkey.

Nominee: Mark R. Parris.

Post: Ambassador to Turkey.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self, Mark Robert Parris, (none).

2. Spouse, Joan Gardner Parris, $25, 1992, DNC.

3. Children and Spouses, Names, Katherine Parris, (Not available—Peace Corps in Gabon), Christopher Parris (none).

4. Parents, Names, Robert L. Parris, (none), Anita M. Parris, (none).

5. Grandparents, Names, Ernest Parris (deceased), Warren Rutter (deceased), Lucille Parris (deceased), Mildred Rutter (deceased).

6. Brothers and Spouses, Names, See attached continuation sheet.

7. Sisters and Spouses, Names, no sisters.

Continuation sheet:

(A) Kevin Scott Parris, (none), m. Peggy Parris (none).

(B) Paul Ernest Parris, small amounts, up to $200 total, 1992–1996, DNC, m. Susan Parris, (none).

(C) Eric Warren Parris (none).

Nominee: Robin Lynn Raphel.

Post: Tunis, Tunisia.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self, Robin Lynn Raphel.

2. Spouse, Leonard Arthur Ashton, none.

3. Children and Spouses, Names, Alexandra Raphel, none, Anna Ashton, none.

4. Parents, Names, Vera Johnson, My mother has over the years made very modest contributions (less than $50) on occasion to Washington state Congressional candidates. In 1996 she made no such contribution.

5. Grandparents, Names, deceased.

6. Brothers and Spouses, Names, I do not have any brothers.

7. Sisters and Spouses, Names, Karen Freeze, none, Deborah Johnson, none.

Amerlia Ellen Shippy, of Washington, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Malawi.

Nominee: Amelia Ellen Shippy.

Post: American Embassy, Lilongwe.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self, Amelia Ellen Shippy—see attached.

2. Spouse, none.

3. Children and spouses, names, none.

4. Parents, names, Homer Charles Shippy, none, Amelia Giles Shippy, deceased.

5. Grandparents, names, Leroy and Harriet Shippy, deceased, James Tandy and Sophia Amelia Giles, deceased.

6. Brothers and spouses, names, none.

7. Sisters and spouses, names, Jean Ann and Phil Witherspoon—see attached.

Amelia Ellen Shippy:

$100, February 15, 1993, Americans for Democratic Action (ADA).

$100, February 15, 1993, Democratic Senatorial Campaign Committee (DSCC).

$50, February 15, 1993, Schroeder for Congress Committee.

$100, February 28, 1993, National Committee for an Effective Congress (NCEC).

$100, March 13, 1993, Emily's List.

$100, March 13, 1993, Shipnuck for Congress.

$100, March 13, 1993, Blackwell for Congress.

$100, May 2, 1993, NCEC.

$10, May 31, 1993, Lynn Yeakel for U.S. Senate, Debt Retirement.

$100, September 20, 1993, NCEC.

$100, October 11, 1993, DSCC.

$100, December 5, 1993, Margolies-Mezvinsky for Congress.

$100, December 5, 1993, English for Congress.

$100, December 5, 1993, Clayton for Congress.

$100, December 20, 1993, DSCC.

$100, December 20, 1993, Emily's List.

$100, January 5, 1994, Schroeder for Congress Committee.

$100, January 18, 1994, Center for National Independence in Politics/Project Vote Smart (CNIP).

$100, January 23, 1994, ADA.

$100, March 8, 1994, NCEC.

$100, March 12, 1994, CNIP.

$100, September 26, 1994, NCEC.

$100, January 11, 1995, NCEC.

$50, October 15, 1995, Emily's List.

$50, November 12, 1995, CNIP.

$100, January 9, 1996, ADA.

$100, February 4, 1996, NCEC.

$100, September 15, 1996, McKinney for Congress.

$100, September 15, 1996, Rivers for Congress.

$50, November 14, 1996, CNIP.

$100, December 16, 1996, Emily's List.

Jean and Phil Witherspoon (sister and her spouse):

$15, April 1993, $10, June 1993, Jeff Bingaman Reelection Fund.

$30, June 1993, Kerry for Senate.

$10, September 1993, Jeff Bingaman Reelection Fund.

$50, September 1993, Democratic Campaign.

$10, December 1993, Jeff Bingaman Reelection Fund.

$40, January 1994, $10, March 1994, Kerry for Senate.

$50, June 1994, Jeff Bingaman Reelection Fund.

$50, July 1994, Democratic Party.

$25, August 1994, $25, October 1994, Kerry for Senate.

$50, October 1994, Jeff Bingaman Reelection Fund.

$50, October 1994, Bill Richardson Campaign.

$55, January 1995, Democratic Campaign Fund.

$30, February 1995, Democratic National Committee.

$30, April 1995, Jeff Bingaman Reelection Fund.

$30, June 1995, Democratic National Committee.

$100, June 1995, Clinton-Gore Campaign.

$10, October 1995, $35, November 1995, Jeff Bingaman Reelection Fund.

$25, November 1995, Clinton-Gore Media Campaign..

$10/month, March 1996 to the present, Democratic National Committee.

$10/quarter, April 1996 to the present, People for Bingaman.

$100, October 1996, Democratic Senatorial Campaign.

$100, October 1996, Clinton-Gore '96 GELAC.

Edward E. Shumaker, III, of New Hampshire, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Trinidad and Tobago.

Nominee: Edward E. Shumaker, III.

Post: Ambassador to Trinidad and Tobago.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self, $20.00, 01/03/94, Verge for Congress, $500.00, 03/29/94, Swett for Congress, $500.00, 04/09/94, Citizens for Biden, $250.00, 07/01/94, Friends of Dave McCurdy, $250.00, 10/15/94, McCurdy for Senate, $100.00, 06/22/95, Wilhelm for Senate, $1,000.00, 11/08/95, Clinton/Gore '96, $250.00, 11/16/95, Jack Reed for Senate, $500.00, 12/22/95, Biden for Senate, $250.00, 06/03/96, Keefe for Congress, $250.00, 06/21/96, Arnesen for Congress, $100.00, 09/17/96, Keefe for Congress, $250.00, 09/19/96, Swett for Senate, $500.00, 10/28/96, Keefe for Congress.

2. Spouse, Polly D. Shumaker, none.

3. Children, Nathan D. Shumaker, none, Daniel E. Shumaker, none, Michael D. Shumaker, none.

4. Parents, Edward E. Shumaker, Jr. (deceased), Marie G. Shumaker, none.

5. Grandparents, Edward E. Shumaker (deceased), Josephine Mary Shumaker (deceased), John F. Gilliams (deceased), Mary E. Gilliams (deceased).

6. Brothers, John G. Shumaker (deceased).

7. Sisters, Linda M. (Shumaker) Vasso, none, George Vasso, none.

Nominee: Johnny Young.

Post: State of Bahrain.

The following is a list of all members of my immediate family and their spouses. I have asked each of these persons to inform me of the pertinent contributions made by them. To the best of my knowledge, the information contained in this report is complete and accurate.

Contributions, amount, date, donee:

1. Self, Johnny Young, N/A.

2. Spouse, Angelena V. Young, N/A.

3. Children and spouses, names, David J. Young, Michelle J. Young, N/A.

4. Parents names, Eva Grant, deceased, N/A, Lucille Pressy (adoptive) deceased, N/A, John Young, deceased, N/A.

5. Grandparents, names, Alice Young, deceased, N/A, Louis Young, deceased, N/A.

6. Brothers and spouses, names, N/A.

7. Sisters and spouses, names, Lottie Mae Young, deceased, N/A, Loretta Young, N/A.

Mr. HELMS. Mr. President, for the Committee on Foreign Relations, I also report favorably one nomination list in the Foreign Service which was printed in full in the CONGRESSIONAL RECORD of September 4, 1997, and ask unanimous consent, to save the expense of reprinting on the Executive Calendar, that this nomination lie at the Secretary's desk for the information of Senators.

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

(The nominations ordered to lie on the Secretary's desk were printed in the RECORD of September 4, 1997, at the end of the Senate proceedings.)

The following-named persons of the agencies indicated for appointment as Foreign Service Officers of the classes stated, and also for the other appointments indicated herewith:

For appointment as Foreign Service Officers of Class One, Consular Officers and Secretaries in the Diplomatic Service of the United States of America:

AGENCY FOR INTERNATIONAL DEVELOPMENT

Dominic Alfred D'Antonio, of Connecticut
Joseph J. Pastic, of Virginia

UNITED STATES INFORMATION AGENCY

Nancy R. LeRoy, of Florida

DEPARTMENT OF STATE

David F. Davidson, of Virginia

For appointment as Foreign Service Officers of Class Two, Consular Officers and Secretaries in the Diplomatic Service of the United States of America:

AGENCY FOR INTERNATIONAL DEVELOPMENT

Earell Edwin Kissinger III, of Colorado
Michael James Yates, of Virginia

For appointment as Foreign Service Officers of Class Three, Consular Officers and Secretaries in the Diplomatic Service of the United States of America:

AGENCY FOR INTERNATIONAL DEVELOPMENT

Charles S. Morgan, of Virginia
Susan Mutijima Page, of Illinois

UNITED STATES INFORMATION AGENCY

Frank J. Whitaker, of Virginia

For appointment as Foreign Service Officers of Class Four, Consular Officer and Secretaries in the Diplomatic Service of the United States of America:

U.S. INFORMATION AGENCY

Mary Jane Wolansky Bushnaq, of Virginia
Thomas E. Cooney, of Michigan
Nida A. Emmons, of Florida
Sheila R. Parkman, of Pennsylvania
Karyn Allison Posner-Mullen, of Florida
Aleta Fay Wenger, of Washington

DEPARTMENT OF STATE

Christopher D. Berlew, of Virginia
Betty A. Bernstein-Zabza, of the District of Columbia
Janine R. Boiarsky, of California
Russel John Brown, of Montana
Kelly Colleen Degnan, of California
Leslie Stephen deFraffenried, of Texas
Cynthia Ras Doell, of Nebraska
Mark Christopher Elliott, of Maryland
Karen Lynn Enstrom, of Pennsylvania
Gabriel Escobar, of Texas
Jonathan David Fritz, of Florida
J. Robert Garverick, of Ohio
Jonathan Hanick, of California
Barbara A.P. Hibben, of Maryland
Jan Krc, of the District of Columbia
Patricia J. Koetelancik, of Illinois
Margaret U. Kurtz-Randall, of Illinois
Adam Duane Lamoreaux, of Utah
Timothy A. Lenderking, of New Hampshire
Cheryl S. Lester, of Virginia
Brian R. Naranjo, of New Mexico
Helen Patricia Reed-Rowe, of Maryland
Joan Marie Richard, of California
Elizabeth Helen Rood, of Maryland
William Johann August Schmonsees III, of South Carolina
David Jonathan Schwartz, of Florida
Kenneth A. Thomas, of Oregon

For appointment as Foreign Service Officer of Class Four, Consular Officer and Secretary in the Diplomatic Service of the United States of America, effective May 29, 1997:

DEPARTMENT OF STATE

Christine Anne Harold, of Maryland

The following-named Members of the Foreign Service of the Department of Commerce and the Departmetof State and the U.S. Information Agency to be Consular Officers and/or Secretaries in the Diplomatic Service of the U.S. of America, as indicated:

Consular Officers and Secretaries in the Diplomatic Service of the United States of America:

Abigail Kessler Aronson, of New Jersey
Mark Andrew Assur, of Virginia
Brian S. Austin, of Virginia
Martha L. Austin, of Virginia
Alan M. Browning, of Virginia
Richard C. Bulman, Jr., of Florida
Don L. Brown, of Texas
Elaine A. Byers, of Virginia
Peter Callamari, of Virginia
John M. Cardwell, of Virginia
Florence Carson, of Virginia
Marc Walter Carson, of Virginia
Cheryl D. Comfort-Carter, of Virginia
Erin Crowe, of Michigan
Linda Elisa Daetwyler, of California
Gary A. Dziedzic, of Virginia
Cheryl L. Eichorn, of Virginia
Albert Elgamil, of Virginia
Jose M. Estevez, of Puerto Rico
Randolph Francis Fagan, Jr., of Virginia
Robert L. Farris, of Virginia
David Eric Fass, of Virginia
John Edward Friberg, Jr., of Virginia
Daniel T. Froats, of California
Stephen C. Galloway, of Virginia
Russell C. Gilger, of Virginia
Terry Arthur Ginsburg, of Virginia
Joshua D. Glazeroff, of New York
Caren F. Gordon, of Virginia
Christopher J. Green, of Virginia
Giselle C. Griggs, of Maryland
George K. Hale, of Washington

Sabina Ann Hasmi, of Virginia
James W. Hentschel, of Virginia
David Alan Higdon, of Texas
John J. Hill, of Alabama
Michelle M. Hopkins, of California
James C. Hsu, of Texas
Anthony N. Ieronimo, of New Jersey
S. George Imredy, of the District of Columbia
Christopher Lee Jaeger, of Maryland
Thomas T. Kim, of Virginia
Douglas Alan Kriesel, of the District of Columbia
Sanjai Kumar, of Virginia
Julie Lange, of Virginia
Betty Jo Little, of the District of Columbia
LizaBeth Lowell, of Florida
Kathleen A. Lundy, of Virginia
George W. Lynn, of Virginia
Jose Elias Merrero, of Florida
Jacques L. Massengill, of Virginia
Robert Peter McCarthy, of New York
John M. McCaslin, of Ohio
Francis M. McGuinness, of Virginia
Mitzi M. McNamara, of Virginia
Theresa M. Michaud, of Virginia
William L. Moyer, of Virginia
Barbara Beth Morrison, of New Jersey
Susan V. Naraine, of the District of Columbia
Martin A. Newell, of Maryland
David Roy O'Connor, of the District of Columbia
Darin K. Olson, of Virginia
Michael Andrew Ordonez, of Washington
Douglas L. Padget, of Virginia
Kenneth L. Parson, of Virginia
Rebecca Ann Pasine, of Indiana
Troy Eric Pederson, of Virginia
Rosetta Perri, of Pennsylvania
J. Philip Plowman, of Virginia
David B. Ponsar, of California
John David Radel, of Virginia
Hope C. Rawding, of Virginia
Scott Michael Renner, of Colorado
Deborah Carrie Rhea, of Virginia
Nicholas E. Reynolds, of Virginia
John P. Richardson, of Virginia
John C. Roberts, of Mississippi
Abigail Elizabeth Rupp, of Virginia
Cynthia M. Saddy, of Virginia
Luis A. Santos, of Maryland
Amy Wing Schedlbauer, of Texas
Michael B. Schneider, of Virginia
Brian G. Scott, of Virginia
James Semivan, of Virginia
Janet E. Seng, of Pennsylvania
Kathleen F. Seroskie, of Virginia
Scott A. Shaw, of Illinois
Rita M. Sheehan, of Virginia
Vincent P. Shugrue, of Virginia
David J. Smith, of Maryland
Lyn R. Sumner, of Virginia
Gavin Alexander Sundwall, of North Carolina
Andrew J. Tichava, of Virginia
Nancy E. Totten, of Virginia
William M. Totten, of Virginia
Dee B. White, of Virginia
Teresa Wilkin, of the District of Columbia
Sean Michael Wiswesser, of Virginia
Charles M. Wolf, Jr., of Virginia
Kristin Marie Wood, of Virginia
David Michael Zimov, of Ohio

(The above nominations were reported with the recommendation that they be confirmed, subject to the nominees' commitment to respond to requests to appear and testify before any duly constituted committee of the Senate.)

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second time by unanimous consent, and referred as indicated:

By Mr. BINGAMAN:

S. 1210. A bill to authorize the acquisition of the geologic formation known as the Valles Caldera currently managed by the Baca Land and Cattle Company, and to provide for an effective management program for this resource within the Department of Agriculture, and consistent land management to protect the watershed of the Bandelier National Monument; to the Committee on Energy and Natural Resources.

By Mr. HELMS:

S. 1211. An original bill to provide permanent authority for the administration of au pair programs; from the Committee on Foreign Relations; placed on the calendar.

By Mr. DORGAN:

S. 1212. A bill to amend the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 to clarify that records of arrival or departure are not required to be collected for purposes of the automated entry-exit control system developed under 110 of such Act for Canadians who are not otherwise required to possess a visa, passport, or border crossing identification card; to the Committee on the Judiciary.

By Mr. HOLLINGS (for himself, Mr. STEVENS, Mr. KERRY, Ms. SNOWE, Mr. INOUYE, Mr. BREAUX, Mr. MCCAIN, Mr. KENNEDY, Mrs. BOXER, Mr. BIDEN, Mr. LAUTENBERG, Mr. AKAKA, and Mr. MURKOWSKI):

S. 1213. A bill to establish a National Ocean Council, a Commission on Ocean Policy, and for other purposes; to the Committee on Commerce, Science, and Transportation.

By Mr. ALLARD:

S. 1214. A bill to amend the Line Item Veto Act of 1996 to eliminate the requirement that a Federal budget deficit must exist in order for the President to use the line-item veto authority; to the Committee on the Budget and the Committee on Governmental Affairs, jointly, pursuant to the order of August 4, 1977, as modified by the order of April 11, 1986, with instructions that if one Committee reports, the other Committee have thirty days to report or be discharged.

By Mr. ASHCROFT:

S. 1215. A bill to prohibit spending Federal education funds on national testing; to the Committee on Labor and Human Resources.

By Mr. ROTH:

S. 1216. An original bill to approve and implement the OECD Shipbuilding Trade Agreement; from the Committee on Finance; placed on the calendar.

By Mr. HOLLINGS:

S. 1217. A bill for the relief of Olga Gorgiladze; to the Committee on the Judiciary.

By Mr. KERREY:

S. 1218. A bill to assure the integrity of information, transportation and telecommunications upon the arrival of the year 2000; to the Committee on Commerce, Science, and Transportation.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. HELMS:

S. Res. 123. An original resolution honoring the memory of former Peace Corps Director Loret Miller Ruppe; from the Committee on Foreign Relations; placed on the calendar.

By Mr. ROTH (for himself, Mr. THOMAS, Mrs. FEINSTEIN, and Mr. GRAMS):

S. Res. 124. A resolution to state the sense of the Senate that members of the Khmer Rouge who participated in the Cambodian genocide should be brought to justice before an international tribunal for crimes against humanity; to the Committee on Foreign Relations.

By Mr. MURKOWSKI:

S. Res. 125. A resolution commending Dr. Jason C. Hu, Representative of the Taipei Economic and Cultural Representative Office in the United States; considered and agreed to.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. BINGAMAN:

S. 1210. A bill to authorize the acquisition of the geologic formation known as the Valles Caldera currently managed by the Baca Land and Cattle Co., and to provide for an effective management program for this resource within the Department of Agriculture, and consistent land management to protect the watershed of the Bandelier National Monument; to the Committee on Energy and Natural Resources.

VALLE GRANDE VALLES CALDERA PRESERVATION LEGISLATION

Mr. BINGAMAN. Mr. President, this bill that I have just sent to the desk, in my view, gives us a chance in this Congress to grasp a historic opportunity to make a real difference for the American people for generations to come.

Most Americans can name various geologic treasures and places of wonder within our land. Places like Diamond Head in Hawaii, the Sawtooth Mountains in Idaho, the Grand Canyon in Arizona, and Rocky Mountain National Park in Colorado readily come to mind because our people have access to them. However, there is a place in New Mexico that rivals these areas in splendor and yet, few people know about, or fully appreciate its significance. It is called the Valles Caldera.

The Valles Caldera is one of the world's greatest volcanic features. A large circular crater 12–15 miles in diameter, the views from the rim are awe inspiring. As one looks across the vast green valleys and mountains that now sit within the ring of the caldera, and realizes that they are all merely the cooled workings of a resurgent lava dome, one is struck by the sheer magnitude of the natural forces that created the Jemez Mountains in north central New Mexico.

The explosions that created the caldera, some 1.2 million years ago, ejected over 100 cubic miles of earth, rock, and lava. It is estimated that if the original mountain had come to a peak that it would have been taller than Mount Everest.

However very few people, even in New Mexico, have ever been on this land. Since 1860, it has been in private

ownership. At that time it was granted by the United States to the heirs of Don Luis Maria Cabeza de Vaca as part of a settlement of Spanish land grant claims under the Treaty of Guadalupe Hidalgo, and has since been known as the Baca Land & Cattle Company.

It has passed through several owners since 1860, and about once in a generation the United States has tried to purchase the land. The first time was in the 1930's. Again, in the 1960's the late former Senator from New Mexico, Clinton P. Anderson tried to negotiate a deal for the land. Finally in 1980, the owner of the land, James "Pat" Dunigan, was in negotiations with the Government to sell the land when he died a premature death. Now, his family has come forward and said they would like to fulfill his dream of seeing this land move into public ownership.

Mr. President, this is an opportunity that we cannot let pass us by. In 1993, the Forest Service completed a study of this land which lays out the tremendous value it could have within public ownership:

First, the Valles Caldera is the classic example of a resurgent lava dome. The study of its features has helped geologists to understand volcanic processes throughout the world;

Second, the recreation potential is enormous. Hiking, camping, cross-country skiing, photography, horse back riding, hunting, and fishing are obvious possibilities.

The headwaters of the Jemez and San Antonio rivers are located on this land, and represent some of the best trout fishing streams in New Mexico. There are nearly 27 miles of trout streams on the ranch, most of which meander through grass meadows perfect for fly fishing.

Also over 6,000 elk live on this land, making it ideal for hunting.

Perhaps the most unique features of this land are the seven enormous open grassland valleys that are tailor made for horseback riding.

Third, finally, and perhaps most important, this land has been well preserved. Through careful management of their grazing land, selective timbering, and the use of proscribed fire, the current owners have maintained the caldera as an ecological jewel. With over 65,000 acres of conifer forests mixed with aspen, gamble oak, and broken rock known as felsenmeer, and 30,000 acres of lush grasslands, the Caldera supports an abundance of wildlife, including black bears and cougars.

Mr. President, words are a poor substitute for seeing this land, and although pictures cannot convey its grandeur, they may provide my colleagues with a sense of it:

First, to give people a sense of location, here is a map of north central New Mexico. To the south is Albuquerque and then Santa Fe above it. You'll notice that the Baca Ranch is nestled between the Santa Fe National Forest, and Bandelier National Monument, which many members of the public have visited.

Second, here is a satellite photo of the volcano. The black outline represents the Baca Ranch, approximately 95,000 acres. For perspective, on the right side of this photo is Los Alamos, NM, and just below it is the Bandelier National Monument. This large yellow spot on the bottom right corner of the caldera rim is known as the Valle Grande. It is the only part of the Ranch that most people have seen because state highway 4 comes through on the side, but it is only one of seven valleys on the property.

Third, here's a picture of the Valle Grande, it's about 4 miles wide and 6 miles long covering over 17,000 acres.

Fourth, and here is the upper Jemez river which originates and meanders through the Valle Grande.

Fifth, finally, here is a picture of the Valle Toledo the third largest valley on the property, about 4,000 acres.

Mr. President, the legislation I'm introducing today does two things: it gives the Forest Service the authority to start negotiating for the purchase of this land in good faith by authorizing appropriations, land exchanges, and the acceptance of donations; and it rationalizes the boundaries between the Santa Fe National Forest and Bandelier National Monument for consistent management of their respective watersheds.

Acquiring land of this quality and magnitude will not be cheap or easy. It will take a lot of work on the part of this body and our counterparts on the House, and on the part of the administration. However, if we don't close this deal this time, I'm not sure the American people will ever forgive us. Although the Dunigan's have been great stewards of the land, they want to sell it. Who knows how future owners may use this land.

When Senator Anderson tried to acquire this land for the United States 35 years ago, we could have bought this land for less than $5 million. Now the costs will be much, much greater, and if it is ever subdivided, the costs will go up exponentially.

Mr. President, I know that many people will want to argue about the management of this land. There are many, many uses that this land could be put to, but I would caution my colleagues that now is not the time to argue over future use. Let's worry about how we will acquire the land first. Management options can be worked out later.

I think it will take additional time before a full management plan can be put in place for the property. It would be an exercise in futility for us to try to work all of that out before we move to take advantage of this historic opportunity.

Mr. President, I understand that there is support for this effort to bring this property into public ownership by others in the delegation. I very much want to work with them and with people in the administration to see this happen. It is a very important initiative and a very important goal for us to pursue in the second session of this Congress. So I hope very much that we can make progress on it.

By Mr. DORGAN:

S. 1212. A bill to amend the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 to clarify that records of arrival or departure are not required to be collected for purposes of the automated entry-exit control system developed under 110 of such act for Canadians who are not otherwise required to possess a visa, passport, or border crossing identification card; to the Committee on the Judiciary.

THE ILLEGAL IMMIGRATION REFORM AND IMMIGRANT RESPONSIBILITY ACT CLARIFICATION AMENDMENT ACT OF 1997

Mr. DORGAN. Mr. President, approximately 1 year ago the Illegal Immigration Reform and Immigrant Responsibility Act became law.

Next year at this time, September 30, 1998, section 110 of this act will be implemented and will adversely—and unintentionally—affect our neighbors in Canada. Section 110 requires the Immigration and Naturalization Service [INS] to develop an automated entry and exit system for the purpose of documenting the entry and departure of every alien arriving and leaving the United States. The United States has never had such an alien departure management system.

Unfortunately, section 110 as enacted fails to recognize the decades-long practice of not requiring most Canadian nationals to fill out INS documents—referred to as "I-94s" at the border.

In a December 18, 1996 letter to the Ambassador of Canada at the time, Raymond Chretien, Senator Alan Simpson, and Representative LAMAR SMITH, the chairmen of the Senate and the House Judiciary Subcommittees on Immigration, respectively, indicated to Ambassador Chretien that it was not the intention of the Judiciary Committee to impose any new requirements for border crossing cards—so-called I-94's—on Canadians who are not presently required to possess such documents.

The legislation which I am introducing today—which was introduced in the House on September 16 by Congressman JOHN LAFALCE of New York—would simply clarify the intent of Congress by exempting from the section 110 provisions of the act Canadian nationals who are not now required by law to possess a visa, passport, or border-crossing identification card to enter the United States.

There is no logical reason to inhibit the flow of traffic between the United

States and Canada. If the committee's intention is not clarified, and section 110 is implemented at the Canadian border, congestion would become intolerable.

According to U.S. Customs, the port in Pembina, ND, saw 963,665 individuals cross into North Dakota in fiscal year 1996, averaging 2,640 people a day. Customs estimates that if the entry/exit system had to be implemented on the Canadian border, providing the agent to spend just 1 minute per person entering it would take two customs workers a nonstop daily shift of 22 hours to process them.

An estimated 116 million persons cross into the United States at all land points on the Canadian border. Of these, 76 million are Canadian or United States permanent residents. More than $1 billion in goods and services trade crosses the United States/Canadian border each day. I urge the Judiciary Committee to consider soon mine or other legislation to clarify the intent of the 1996 act.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1212

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. EXEMPTION FOR CERTAIN ALIENS FROM ENTRY-EXIT CONTROL SYSTEM.

(a) IN GENERAL.—Section 110(a) of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (8 U.S.C. 1221 note) is amended to read as follows:

"(a) SYSTEM.—

"(1) IN GENERAL.—Subject to paragraph (2), not later than 2 years after the date of the enactment of this Act, the Attorney General shall develop an automated entry and exit control system that will—

"(A) collect a record of departure for every alien departing the United States and match the records of departure with the record of the alien's arrival in the United States; and

"(B) enable the Attorney General to identify, through on-line searching procedures, lawfully admitted nonimmigrants who remain in the United States beyond the period authorized by the Attorney General.

"(2) EXEMPTION FOR CERTAIN ALIENS.—The system under paragraph (1) shall not collect a record of arrival or departure for an alien—

"(A) who is—

"(i) a Canadian national; or

"(ii) an alien having a common nationality with Canadian nationals and who has his or her residence in Canada; and

"(B) who is not otherwise required by law to be in possession, for purposes of establishing eligibility for admission into the United States, of—

"(i) a visa;

"(ii) a passport; or

"(iii) a border crossing identification card.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the enactment of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (Public Law 104-208; 110 Stat. 3009-546).

By Mr. HOLLINGS (for himself, Mr. STEVENS, Mr. KERRY, Ms. SNOWE, Mr. INOUYE, Mr. BREAUX, Mr. MCCAIN, Mr. KENNEDY, Mrs. BOXER, Mr. BIDEN, Mr. LAUTENBERG, Mr. AKAKA, and Mr. MURKOWSKI):

S. 1213. A bill to establish a National Ocean Council, a Commission on Ocean Policy, and for other purposes; to the Committee on Commerce, Science, and Transportation.

THE OCEANS ACT OF 1997

Mr. HOLLINGS. Mr. President, I rise today to introduce the Oceans Act of 1997. I am pleased to be joined in this endeavor by Senators STEVENS, KERRY, SNOWE, BREAUX, MCCAIN, INOUYE, KENNEDY, BOXER, BIDEN, LAUTENBERG, AKAKA, and MURKOWSKI. Mr. President, plainly and simply, this bill calls for a plan of action for the 21st century to explore, protect, and use our oceans and coasts.

This is not the first time we have faced the need for a national ocean policy. Three decades ago, our Nation roared into space, investing tens of billions of dollars to investigate the Moon and the Sea of Tranquility. During that golden era of science, some of us also recognized the importance of exploring the seas on our own planet. In 1966, Congress enacted the Marine Resources and Engineering Development Act in order to define national objectives and programs with respect to the oceans. That legislation laid the foundation for U.S. ocean and coastal policy and programs and has guided their development for three decades. I was elected to the Senate just 3 months after the 1966 act was enacted into law, but I am pleased that both Senators INOUYE and KENNEDY, the two cosponsors of the 1966 act still serving in the Senate, have agreed to join me today in introducing the Oceans Act.

One of the central elements of the 1966 act was establishment of a Presidential commission to develop a plan for national action in the oceans and atmosphere. Dr. Julius A. Stratton, a former president of the Massachusetts Institute of Technology and then-chairman of the Ford Foundation, led the Commission on an unprecedented, and since unrepeated, investigation of this Nation's relationship with the oceans and the atmosphere. The Stratton Commission and its congressional advisers—including Senators Warren G. Magnuson and Norris Cotton—worked together in a bipartisan fashion. In fact, the Commission was established and carried out its mandate in the Democratic administration of Lyndon Johnson and saw its findings implemented by the Republicans under President Richard Nixon. With a staff of 35 people, the commissioners heard and consulted over 1,000 people, visited every coastal area of this country, and submitted some 126 recommendations in a 1969 report to Congress entitled "Our Nation and the Sea." Those recommendations led directly to the creation of the National Oceanic and Atmospheric Administration in 1970, laid the groundwork for enactment of the Coastal Zone Management Act [CZMA] in 1972, and established priorities for Federal ocean activities that have guided this Nation for almost 30 years.

While the Stratton Commission performed its job with vision and integrity, the world has changed since 1966. Today, half of the U.S. population lives within 50 miles of our shores and more than 30 percent of the gross domestic product is generated in the coastal zone. Ocean and coastal resources once considered inexhaustible are severely depleted, and wetlands and other marine habitats are threatened by pollution and human activities. In addition, the U.S. regulatory and legal framework has developed over the years with the passage of a number of statutes in addition to CZMA. These include the Endangered Species Act, the Marine Mammal Protection Act, the Marine Protection, Research, and Sanctuaries Act, the Magnuson-Stevens Fishery Conservation and Management Act, the Coastal Barrier Resources Act, and the Oil Pollution Act. Finally, the United Nations has declared 1998 to be the International Year of the Ocean, focusing global attention on the state of the world's oceans. In short, it is time to reexamine our Nation's relationship to the sea.

The Oceans Act is vital to the continued health of the oceans and prosperity of our coasts. It is patterned after and would replace the 1966 act. Like that act, it is comprised of three major elements:

First, the bill calls for development and implementation of a coherent national ocean and coastal policy to conserve and sustainably use fisheries and other ocean and coastal resources, protect the marine environment and human safety, explore ocean frontiers, create marine technologies and economic opportunities, and preserve U.S. leadership on ocean and coastal issues.

Second, the bill establishes a 15-member Commission, similar to the Stratton Commission, to examine ocean and coastal activities and report within 18 months on recommendations for a national policy. Commission members would be appointed by the President and the Congress. In developing its recommendations, the Commission would assess Federal programs and funding priorities, ocean-related infrastructure requirements, conflicts among marine users, and technological opportunities. The bill authorizes appropriations of $6 million over 2 years to support Commission activities.

Third, the bill creates a high-level Federal interagency Council that is chaired by the Secretary of Commerce and includes the heads of the Departments of Navy, State, Transportation,

and the Interior, the Environmental Protection Agency, the National Science Foundation, the Office of Science and Technology Policy, the Office of Management and Budget, the Council on Environmental Quality, and the National Economic Council. This new Council will advise the President and serve as a forum for developing and implementing an ocean and coastal policy, will provide for coordination of Federal budgets and programs, and will work with non-Federal and international organizations.

By establishing an action plan for ocean and coastal activities, the Oceans Act should contribute substantially to national goals and objectives in the areas of education and research, economic development, and public safety. With respect to education and research, our view of the oceans 30 years ago was based on a remarkably small amount of information. When Jack Kennedy was in the White House, we were just beginning to develop the capability for exploring the oceans, and the driving factor was the military need to hide our submarines from the Soviets during the cold war. What we knew of the oceans at that time was based as much on what fishermen brought up in their nets as it was on reliable scientific investigation.

Today, we still have explored only a tiny fraction of the sea, but with the use of new technologies what we have found is truly incredible. For example, hydrothermal vents, hot water geysers on the deep ocean floor, were discovered just 20 years ago by oceanographers trying to understand the formation of the Earth's crust. Now this discovery has led to the identification of nearly 300 new types of marine animals with untold pharmaceutical and biomedical potential.

Many of our marine research efforts could have profound impacts on our economic well-being. For example, research on coastal ocean currents and other processes that affect shoreline erosion is critical to effective management of the shoreline. Oceanographers are working with Federal, State, and local managers to use this new understanding in protecting beachfront property and the lives of those who reside and work in coastal communities.

Development of underwater cameras and sonar, begun in the 1940's for the U.S. Navy, has led to major strides not only for military uses, but for marine archaeologists and scientists exploring unknown stretches of sea floor. Consumers have benefited from the technology now used in video cameras. Sonar has broad applications in both the military and commercial sector.

Finally, marine biotechnology research is thought to be one of the greatest remaining technological and industrial frontiers. Among the opportunities which it may offer are to: restore and protect marine ecosystems; monitor human health and treat disease; increase food supplies through aquaculture; enhance seafood safety and quality; provide new types and sources of industrial materials and processes; and understand biological and geochemical processes in the world ocean.

In addition to the economic opportunities offered by our marine research investment, traditional marine activities play an important role in our national economic outlook. Ninety-five percent of our international trade is shipped on the ocean and each year products valued at more than $220 billion are shipped within the United States via the water. In 1996, commercial fishermen in the United States landed almost 10 billion pounds of fish with a value of $3.5 billion. Their fishing-related activities contributed over $42 billion to the U.S. economy. During the same period, marine anglers contributed another $20 billion. Travel and tourism also contribute over $700 billion to our economy, much of which is generated in coastal areas. Last year, in South Carolina alone, the total impact of tourism in coastal areas was almost $6 billion. With a sound national ocean and coastal policy and effective marine resource management, these numbers have nowhere to go but up.

With respect to public safety, it is particularly important to develop ocean and coastal priorities that reflect the changes we have seen in recent years. Before World War II, most of the U.S. shoreline was sparsely populated. There were long, wild stretches of coast, dotted with an occasional port city, fishing village, or sleepy resort. Most barrier islands had few residents or were uninhabited. After the war, people began pouring in, and coastal development began a period of explosive growth. In my State of South Carolina, our beaches attract millions of visitors every year, and more and more people are choosing to move to the coast—making the coastal counties the fastest growing ones in the State. Seventeen of the 20 fastest growing States in the Nation are coastal States—which compounds the situation that the most densely populated regions already border the ocean. With population growth comes the demand for highways, shopping centers, schools, and sewers that permanently alter the landscape. If people are to continue to live and work on the coast, we must do a better job of planning how we impact the very regions in which we all want to live.

There is no better example of how our ocean and coastal policies affect public safety, than to look at the effects of hurricanes. Throughout the 1920's, hurricanes killed 2,122 Americans while causing about $1.8 billion in property damages. By contrast, in the first 5 years of the 1990's, hurricanes killed 111 Americans, and resulted in damages of about $35 billion. While we have made notable advances in early warning and evacuation systems to protect human lives, the risk of property loss continues to escalate and coastal inhabitants are more vulnerable to major storms than they ever have been. In 1989, Hurricane Hugo came ashore in South Carolina, leaving more than $6 billion in damages. Of that total from Hugo, the Federal Government paid out more than $2.8 billion in disaster assistance and more than $400 million from the National Flood Insurance Program. The payments from private insurance companies were equally staggering. In 1992, Hurricane Andrew struck southern Florida and slammed into low-lying areas of Louisiana, forever changing the lives of more than a quarter of a million people and causing an estimated $25 to $30 billion in damage. Hurricanes demonstrate that the human desire to live near the oceans and along the coast comes with both a responsibility and a cost.

The oceans are part of our culture, part of our heritage, part of our economy, and part of our future. Therefore, we need to be smart about ocean policy—we need the best minds to come together and take a look at what the real challenges are. It is not enough to sit back and assume the role of caretakers. We must be proactive and develop a plan for the future.

Mr. President, Members who doubt the need for this legislation need only pick up a newspaper and they will be face to face with pressing ocean and coastal issues: fish covered with lesions in the Chesapeake Bay and North Carolina; a powerful El Nino brewing in the Pacific; condemnation of vacation homes as the beaches beneath them erode; U.S. ships held hostage over fishing disputes; and the list could go on. Deciding how to manage these problems and use the seas is one of the most complicated tasks we can tackle. There are no boundaries at sea, no national borders with fences and checkpoints. The resources of the sea are a common heritage, shared by all. While our coastal waters are governed by the United States for all of us, there are few rules on the high seas and progress relies primarily on international cooperation.

The United Nations has declared 1998 to be the Year of the Ocean. One reason for launching the International Year of the Ocean is to wake up the governments and the public so we pay adequate attention to the need to protect the marine environment and to ensure a healthy ocean. This is an unprecedented opportunity to celebrate and enhance what has been accomplished in understanding and managing the ocean.

The Stratton Commission stated in 1969: "How fully and wisely the United States uses the sea in the decades

ahead will affect profoundly its security, its economy, its ability to meet increasing demands for food and raw materials, its position and influence in the world community, and the quality of the environment in which its people live." Those words are as true today as they were 30 years ago.

Mr. President, it is time to look toward the next 30 years. This bill offers us the vision and understanding needed to establish sound ocean and coastal policies for the 21st century. I thank the cosponsors of the legislation for joining with me in recognizing its significance and trust that this body will work quickly to enact it into law. I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1213

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Ocean Act of 1997".

SEC. 2. CONGRESSIONAL FINDINGS; PURPOSE AND OBJECTIVES.

(a) FINDINGS.—The Congress makes the following findings:

(1) Covering more than two-thirds of the Earth's surface, the oceans and Great Lakes play a critical role in the global water cycle and in regulating climate, sustain a large part of Earth's biodiversity, provide an important source of food and a wealth of other natural products, act as a frontier to scientific exploration, are critical to national security, and provide a vital means of transportation. The coasts, transition between land and open ocean, are regions of remarkably high biological productivity, contribute more than 30 percent of the Gross Domestic Product, and are of considerable importance for recreation, waste disposal, and mineral exploration.

(2) Ocean and coastal resources are susceptible to change as a direct and indirect result of human activities, and such changes can significantly impact the ability of the oceans and Great Lakes to provide the benefits upon which the Nation depends. Changes in ocean and coastal processes could affect global climate patterns, marine productivity and biodiversity, environmental quality, national security, economic competitiveness, availability of energy, vulnerability to natural hazards, and transportation safety and efficiency.

(3) Ocean and coastal resources are not infinite, and human pressure on them is increasing. One half of the Nation's population lives within 50 miles of the coast, ocean and coastal resources once considered inexhaustible are now threatened with depletion, and if population trends continue as expected, pressure on and conflicting demands for ocean and coastal resources will increase further as will vulnerability to coastal hazards.

(4) Marine technologies hold tremendous promise for expanding the range and increasing the utility of products from the oceans and Great Lakes, improving the stewardship of ocean and coastal resources, and contributing to business and manufacturing innovations and the creation of new jobs.

(5) Marine research has uncovered the link between oceanic and atmospheric processes and improved understanding of world climate patterns and forecasts. Important new advances, including availability of military technology, have made feasible the exploration of large areas of the ocean which were inaccessible several years ago. In designating 1998 as "The Year of the Ocean", the United Nations highlights the value of increasing our knowledge of the oceans.

(6) It has been 30 years since the Commission on Marine Science, Engineering, and Resources (known as the Stratton Commission) conducted a comprehensive examination of ocean and coastal activities that led to enactment of major legislation and the establishment of key oceanic and atmospheric institutions.

(7) A review of existing activities is essential to respond to the changes that have occurred over the past three decades and to develop an effective new policy for the twenty-first century to conserve and use sustainable ocean and coastal resources, protect the marine environment, explore ocean frontiers, protect human safety, and create marine technologies and economic opportunities.

(8) While significant Federal ocean and coastal programs are underway, those programs would benefit from a coherent national ocean and coastal policy that reflects the need for cost-effective allocation of fiscal resources, improved interagency coordination, and strengthened partnerships with State, private, and international entities engaged in ocean and coastal activities.

(b) PURPOSE AND OBJECTIVES.—The purpose of this Act is to develop and maintain a coordinated, comprehensive, and long-range national policy with respect to ocean and coastal activities that will assist the Nation in meeting the following objectives:

(1) The protection of life and property against natural and manmade hazards.

(2) Responsible stewardship, including use, of fishery resources and other ocean and coastal resources.

(3) The protection of the marine environment and prevention of marine pollution.

(4) The enhancement of marine-related commerce, transportation, and national security, and the resolution of conflicts among users of the marine environment.

(5) The expansion of human knowledge of the marine environment including the role of the oceans in climate and global environmental change and the advancement of education and training in fields related to ocean and coastal activities.

(6) The continued investment in and development and improvement of the capabilities, performance, use, and efficiency of technologies for use in ocean and coastal activities.

(7) Close cooperation among all government agencies and departments to ensure—

(A) coherent regulation of ocean and coastal activities;

(B) availability and appropriate allocation of Federal funding, personnel, facilities, and equipment for such activities; and

(C) cost-effective and efficient operation of Federal departments, agencies, and programs involved in ocean and coastal activities.

(8) The preservation of the role of the United States as a leader in ocean and coastal activities, and, when it is in the national interest, the cooperation by the United States with other nations and international organizations in ocean and coastal activities.

SEC. 3. DEFINITIONS.

As used in this Act—

(1) The term "Commission" means the Commission on Ocean Policy.

(2) The term "Council" means the National Ocean Council.

(3) The term "marine research" means scientific exploration, including basic science, engineering, mapping, surveying, monitoring, assessment, and information management, of the oceans, coasts, and Great Lakes—

(A) to describe and advance understanding of—

(i) the role of the oceans, coasts and Great Lakes in weather and climate, natural hazards, and the processes that regulate the marine environment; and

(ii) the manner in which such role, processes, and environment are affected by human actions;

(B) for the conservation, management and sustainable use of living and nonliving resources; and

(C) to develop and implement new technologies related to sustainable use of the marine environment.

(4) The term "marine environment" includes—

(A) the oceans, including coastal and offshore waters and the adjacent shore lands;

(B) the continental shelf;

(C) the Great Lakes; and

(D) the ocean and coastal resources thereof.

(5) The term "ocean and coastal activities" includes activities related to marine research, fisheries and other ocean and coastal resource stewardship and use, marine aquaculture, energy and mineral resource extraction, national security, marine transportation, recreation and tourism, waste management, pollution mitigation and prevention, and natural hazard reduction.

(6) The term "ocean and coastal resource" means, with respect to the oceans, coasts, and Great Lakes, any living or non-living natural resource (including all forms of animal and plant life found in the marine environment, habitat, biodiversity, water quality, minerals, oil, and gas) and any significant historic, cultural or aesthetic resource.

SEC. 4. NATIONAL OCEAN AND COASTAL POLICY.

(a) EXECUTIVE RESPONSIBILITIES.—The President, with the assistance of the Council and the advice of the Commission, shall—

(1) develop and maintain a coordinated, comprehensive, and long-range national policy with respect to ocean and coastal activities; and

(2) with regard to Federal agencies and departments—

(A) review significant ocean and coastal activities, including plans, priorities, accomplishments, and infrastructure requirements;

(B) plan and implement an integrated and cost-effective program of ocean and coastal activities including, but not limited to, marine research, stewardship of ocean and coastal resources, protection of the marine environment, maritime transportation safety and efficiency, the marine aspects of national security, marine recreation and tourism, and marine aspects of weather, climate, and natural hazards;

(C) designate responsibility for funding and conducting ocean and coastal activities; and

(D) ensure cooperation and resolve differences arising from laws and regulations applicable to ocean and coastal activities which result in conflicts among participants in such activities.

(b) COOPERATION AND CONSULTATION.—In carrying out responsibilities under this Act, the President and the Council may use such staff, interagency, and advisory arrangements as they find necessary and appropriate and shall consult with non-Federal organizations and individuals involved in ocean and coastal activities.

SEC. 5. NATIONAL OCEAN COUNCIL.

(a) ESTABLISHMENT.—The President shall establish a National Ocean Council which shall consist of—

(1) the Secretary of Commerce, who shall be Chairman of the Council;

(2) the Secretary of the Navy;

(3) the Secretary of State;

(4) the Secretary of Transportation;

(5) the Secretary of the Interior;

(6) the Administrator of the Environmental Protection Agency;

(7) the Director of the National Science Foundation;

(8) the Director of the Office of Science and Technology Policy;

(9) the Chairman of the Council on Environmental Quality;

(10) the Chairman of the National Economic Council;

(11) the Director of the Office of Management and Budget; and

(12) such other Federal officers and officials as the President considers appropriate.

(b) ADMINISTRATION.—

(1) The President or the Chairman of the Council may from time to time designate one of the members of the Council to preside over meetings of the Council during the absence or unavailability of such Chairman.

(2) Each member of the Council may designate an officer of his or her agency or department appointed with the advice and consent of the Senate to serve on the Council as an alternate in the event of the unavoidable absence of such member.

(3) An executive secretary shall be appointed by the Chairman of the Council, with the approval of the Council. The executive secretary shall be a permanent employee of one of the agencies or departments represented on the Council and shall remain in the employ of such agency or department.

(4) For the purpose of carrying out the functions of the Council, each Federal agency or department represented on the Council shall furnish necessary assistance to the Council. Such assistance may include—

(A) detailing employees to the Council to perform such functions, consistent with the purposes of this section, as the Chairman of the Council may assign to them; and

(B) undertaking, upon request of the Chairman of the Council, such special studies for the Council as are necessary to carry out its functions.

(5) The Chairman of the Council shall have the authority to make personnel decisions regarding any employees detailed to the Council.

(c) FUNCTIONS.—The Council shall—

(1) serve as the forum for developing an ocean and coastal policy and program, taking into consideration the Commission report, and for overseeing implementation of such policy and program;

(2) improve coordination and cooperation, and eliminate duplication, among Federal agencies and departments with respect to ocean and coastal activities;

(3) work with academic, State, industry, public interest, and other groups involved in ocean and coastal activities to provide for periodic review of the Nation's ocean and coastal policy;

(4) cooperate with the Secretary of State in—

(A) providing representation at international meetings and conferences on ocean and coastal activities in which the United States participates; and

(B) coordinating the Federal activities of the United States with programs of other nations; and

(5) report at least biennially on Federal ocean and coastal programs, priorities, and accomplishments and provide budgetary advice as specified in section 7.

SEC. 6. COMMISSION ON OCEAN POLICY.

(a) ESTABLISHMENT.—

(1) The President shall, within 90 days of the enactment of this Act, establish a Commission on Ocean Policy. The Commission shall be composed of 15 members including individuals drawn from Federal and State governments, industry, academic and technical institutions, and public interest organizations involved with ocean and coastal activities. Members shall be appointed for the life of the Commission as follows:

(A) 7 shall be appointed by the President of the United States, no more than 3 of whom may be from the executive branch of the Government.

(B) 2 shall be appointed by the Majority Leader of the Senate in consultation with the Chairman of the Senate Committee on Commerce, Science, and Transportation.

(C) 2 shall be appointed by the Minority Leader of the Senate in consultation with the Ranking Member of the Senate Committee on Commerce, Science, and Transportation.

(D) 2 shall be appointed by the Speaker of the House of Representatives in consultation with the Chairman of the House Committee on Resources and the Chairman of the House Committee on Science.

(E) 2 shall be appointed by the Minority Leader of the House of Representatives in consultation with the Ranking Member of the House Committee on Resources and the Ranking Member of the House Committee on Science.

(2) CHAIRMAN.—The President shall select a Chairman and Vice Chairman from Among such 15 members.

(3) ADVISORY MEMBERS TO THE COMMISSION.—The President shall appoint 4 advisory members from among the Members of the Senate and House of Representatives as follows:

(A) Two Members, one from each party, selected from the Senate.

(B) Two Members, one from each party, selected from the House of Representatives.

(b) FINDINGS AND RECOMMENDATIONS.—The Commission shall report to the President and the Congress on a comprehensive national ocean and coastal policy to carry out the purpose and objectives of this Act. In developing the findings and recommendations of the report, the Commission shall—

(1) review and suggest any necessary modifications to United States laws, regulations, and practices necessary to define and implement such policy;

(2) assess the condition and adequacy of investment in existing and planned facilities and equipment associated with ocean and coastal activities including human resources, vessels, computers, satellites, and other appropriate technologies and platforms;

(3) review existing and planned ocean and coastal activities of Federal agencies and departments, assess the contribution of such activities to development of an integrated long-range program for marine research, ocean and coastal resource management, and protection of the marine environment, and identify any such activities in need of reform to improve efficiency and effectiveness;

(4) examine and suggest mechanisms to address the interrelationships among ocean and coastal activities, the legal and regulatory framework in which they occur, and their inter-connected and cumulative effects on the marine environment, ocean and coastal resources, and marine productivity and biodiversity;

(5) review the known and anticipated demands for ocean and coastal resources, including an examination of opportunities and limitations with respect to the use of ocean and coastal resources within the exclusive economic zone, projected impacts in coastal areas, and the adequacy of existing efforts to manage such use and minimize user conflicts;

(6) evaluate relationships among Federal, State, and local governments and the private sector for planning and carrying out ocean and coastal activities and address the most appropriate division of responsibility for such activities;

(7) identify opportunities for the development of or investment in new products, technologies, or markets that could contribute to the objectives of this Act;

(8) consider the relationship of the ocean and coastal policy of the United States to the United Nations Convention on the Law of the Sea and other international agreements, and actions available to the United States to effect collaborations between the United States and other nations, including the development of cooperative international programs for marine research, protection of the marine environment, and ocean and coastal resource management; and

(9) engage in any other preparatory work deemed necessary to carry out the duties of the Commission pursuant to this Act.

(c) DUTIES OF CHAIRMAN.—In carrying out the provisions of this subsection, the Chairman of the Commission shall be responsible for—

(1) the assignment of duties and responsibilities among staff personnel and their continuing supervision; and

(2) the use and expenditures of funds available to the Commission.

(d) COMPENSATION OF MEMBERS.—Each member of the Commission who is not an officer or employee of the Federal Government, or whose compensation is not precluded by a State, local, or Native American tribal government position, shall be compensated at a rate equal to the daily equivalent of the annual rate payable for Level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Commission. All members of the Commission who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(e) STAFF.—

(1) The Chairman of the Commission may, without regard to the civil service laws and regulations, appoint and terminate an executive director who is knowledgeable in administrative management and ocean and coastal policy and such other additional personnel as may be necessary to enable the Commission to perform its duties. The employment and termination of an executive director shall be subject to confirmation by a majority of the members of the Commission.

(2) The executive director shall be compensated at a rate not to exceed the rate payable for Level V of the Executive Schedule under section 5316 of title 5, United States Code. The Chairman may fix the compensation of other personnel without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, relating to classification of positions and General Schedule pay rates, except that the rate of pay for such personnel

may not exceed the rate payable for GS–15, step 7, of the General Schedule under section 5332 of such title.

(3) Upon request of the Chairman of the Commission, the head of any Federal Agency shall detail appropriate personnel of the agency to the Commission to assist the Commission in carrying out its functions under this Act. Federal Government employees detailed to the Commission shall serve without reimbursement from the Commission, and such detailee shall retain the rights, status, and privileges of his or her regular employment without interruption.

(4) The Commission may accept and use the services of volunteers serving without compensation, and to reimburse volunteers for travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code. Except for the purposes of chapter 81 of title 5, United States Code, relating to compensation for work injuries, and chapter 171 of title 28, United States Code, relating to tort claims, a volunteer under this section may not be considered to be an employee of the United States for any purpose.

(5) The Commission is authorized to procure the temporary and intermittent services of experts and consultants in accordance with section 3109 of title 5, United States Code, but at rates not to exceed the daily rate payable for GS–15, step 7, of the General Schedule under section 5332 of title 5, United States Code.

(f) ADMINISTRATION.—

(1) All meetings of the Commission shall be open to the public, except when the Chairman of the Commission or a majority of the members of the Commission determine that the meeting or any portion of it may be closed to the public. Interested persons shall be permitted to appear at open meetings and present oral or written statements on the subject matter of the meeting. The Commission may administer oaths or affirmations to any person appearing before it.

(2) All open meetings of the Commission shall be preceded by timely public notice in the Federal Register of the time, place, and subject to the meeting.

(3) Minutes of each meeting shall be kept and shall contain a record of the people present, a description of the discussion that occurred, and copies of all statements filed. Subject to section 552 of title 5, United States Code, the minutes and records of all meetings and other documents that were made available to or prepared for the Commission shall be available for public inspection and copying at a single location in the offices of the Commission.

(4) The Federal Advisory Committee Act (5 U.S.C. App.) does not apply to the Commission.

(g) COOPERATION WITH OTHER AGENCIES.—

(1) The Commission is authorized to secure directly from any Federal agency or department any information it deems necessary to carry out its functions under this Act. Each such agency or department is authorized to cooperate with the Commission and, to the extent permitted by law, to furnish such information to the Commission, upon the request of the Chairman of the Commission.

(2) The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

(3) The General Services Administration shall provide to the Commission on a reimbursable basis the administrative support services that the Commission may request.

(4) The Commission may enter into contracts with Federal and State agencies, private firms, institutions, and individuals to assist the Commission in carrying out its duties. The Commission may purchase and contract without regard to section 303 of the Federal Property and Administration Services Act of 1949 (41 U.S.C. 253), section 18 of the Office of Federal Procurement Policy Act (41 U.S.C. 416), and section 8 of the Small Business Act (15 U.S.C. 637), pertaining to competition and publication requirements, and may arrange for printing without regard to the provisions of title 44, United States Code. The contracting authority of the Commission under this Act is effective only to the extent that appropriations are available for contracting purposes.

(h) REPORT.—The Commission shall submit to the President, via the Council, and to the Congress not later than 18 months after the establishment of the Commission, a final report of its findings and recommendations. The Commission shall cease to exist 30 days after it has submitted its final report.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to support the activities of the Commission a total of $6,000,000 for fiscal years 1998 and 1999. Any sums appropriated shall remain available without fiscal year limitation until expended.

SEC. 7. REPORT AND BUDGET COORDINATION.

(a) BIENNIAL REPORT.—Beginning in January, 1999, the President, through the Council, shall transmit to the Congress biennially a report, which shall include—

(1) a comprehensive description of the ocean and coastal activities and related accomplishments of all agencies and departments of the United States during the preceding two fiscal years; and

(2) an evaluation of such activities and accomplishments in terms of the purpose and objectives of this Act. Reports made under this section shall contain such recommendations for legislation as the President may consider necessary or desirable.

(b) BUDGET COORDINATION.—

(1) Each year the Council shall provide general guidance to each Federal agency or department involved in ocean or coastal activities with respect to the preparation of requests for appropriations.

(2) Working in conjunction with the Council, each agency or department involved in such activities shall include with its annual request for appropriations a report which—

(A) identifies significant elements of the proposed agency or department budget relating to ocean and coastal activities; and

(B) specifies how each such element contributes to the implementation of a national ocean and coastal policy.

(3) Each agency or department that submits a report under paragraph (1) shall submit such report simultaneously to the Council.

(4) The President shall, in a timely fashion, provide the Council with an opportunity to review and comment on the budget estimate of each such agency or department.

(5) The President shall identify in each annual budget submitted to the Congress under section 1105 of title 31, United States Code, those elements of agency or department budget that contribute to the implementation of a national ocean and coastal policy.

SEC. 8. REPEAL OR 1966 STATUTE.

The Marine Resources and Engineering Development Act of 1966 (33 U.S.C. 1101 et seq.) is repealed.

Mr. STEVENS. Madam President, I am pleased to be an original cosponsor of Senator HOLLINGS' bill to require a wholesale review of the Nation's oceans and coastal policies to prepare for the 21st century. We have not done this since the 1960's, and the time has come.

The bill has three important components: First, it calls for the development of a coherent national ocean and coastal policy; second, it establishes a 15-member commission similar to the Stratton Commission to make recommendations within 18 months on this national ocean and coastal policy; and third, it creates an interagency council of all the Federal agencies involved in oceans and coastal matters, chaired by the Secretary of Commerce, to coordinate the implementation of the national policy.

I applaud Senator HOLLINGS for developing this legislation. As has been pointed out, over half of the U.S. population lives within 50 miles of our shores. In my State, the oceans employ more people in the private sector than any other industry. The demands on our oceans and coastal resources continues to grow, and we must be prepared to meet these demands in the 21st century.

Mr. KERRY. Mr. President, I rise today to support the efforts of my esteemed colleagues, particularly the ranking member of the Commerce Committee, Senator HOLLINGS, and the chairman of the Appropriations Committee, Senator STEVENS, and to cosponsor the Oceans Act of 1997. I have great respect for Senators HOLLINGS and STEVENS and their stewardship of our ocean and coastal resources.

Since the day I first arrived in the Senate nearly 12 years ago, I have worked hard to address the many challenges confronting our common ocean and coastal resources. I have led this effort principally through my participation and leadership on the Commerce, Science, and Transportation Committee, and particularly as ranking member on the Oceans and Fisheries Subcommittee and as cochair of its predecessor, the national ocean policy study [NOPS].

Over the last 25 years, Congress has worked to develop innovative policy solutions to enable the long-term protection, conservation, utilization, and management of our vulnerable marine resources. We have acted to ensure strong coastal economies in Massachusetts and a clean, healthy coastal environment from the Gulf of Maine to the Gulf of Alaska.

In that vein therefore, I believe that it is time for us, like the Stratton Commission did over 30 years ago, to take an inventory of where our Nation has been and where we are going regarding the great responsibility of stewardship of our coastal resources. The Oceans Act of 1997 will provide the framework for that effort.

The bill contains three major provisions. First, it calls for development of a national ocean and coastal policy to

provide for protection from natural hazards, stewardship of fisheries and coastal resources, protection of the marine environment, enhanced marine transportation and security, continued investment in marine technologies, ocean monitoring and exploration, Government cooperation and coordination, and continued U.S. international leadership. Second, it establishes a Commission on Ocean Policy to complete an 18-month examination and evaluation of ocean and coastal activities and provide recommendations for national policy. Third, it creates an interagency National Ocean Council, headed by the Secretary of Commerce to advise the President and serve as a forum for developing and implementing ocean and coastal policy programs, designate funding responsibilities, provide coordination of Federal budgets, and work with non-Federal organizations to periodically review the Nation's ocean and coastal policy.

The time for this legislation is now, the world population will double to over 10 billion by the middle of the next century. Today over 50 percent of world population resides in coastal areas. The United States and its insular areas have more than 95,000 miles of coastline and the offshore U.S. Exclusive Economic Zone [EEZ] encompasses more than 3.4 million square miles, nearly equal to the land area of the United States.

Over the last 30 years the coastal area populations have increased from 80 to over 110 million and is projected to reach 127 million by 2010. If these trends continue, much heavier demands will be placed on ocean and coastal resources, that is, need for food from the sea for world protein requirements and energy and mineral production from offshore deposits. Ocean threats from this vast expansion include; sewage, chemical, and garbage disposal, runoff from agricultural and forested lands, exploitation of fisheries resources, development of energy and mineral resources, and coastal infrastructure development. Moreover, recent years have yielded a degradation of coastal water quality, loss of wetlands, closure of beach and recreational areas, pollution of fishery and shellfish management resources that diminish the resource base, contaminate seafood, and endanger human health. In fact over 70 percent of U.S. commercial and recreational fish and shellfish depend on estuaries at some point in their life cycle.

Toxic chemicals and sewage dumped have contaminated the Nation's harbors and waterways. More than 20,000 combined sewer overflows [CSO's], sewers that combine storm water and sanitary flows empty directly into rivers and coastal waters. In 1992 heavy rains and flooding caused severe CSO overflows in Los Angeles which forced the temporary closing of over 70 miles of adjacent coastal areas. Coastal area real estate development has accelerated to the point that over 50 percent of annual U.S. residential construction during the past two decades has occurred in coastal areas. This trend is expected to continue and is expected to stress coastal ecosystems even further mostly in California and Florida, two of the Nation's most productive coastal areas. This also increases risk to life and property due to hurricanes and other major storms. For example the price tag for Hurricane Andrew, one of the largest storms in history, was estimated to be $25 to $30 billion. Further sea level rise from global warming will exacerbate this already growing problem.

Further, as the world population grows, we will become more and more dependent on food from the sea. Since 1977 total fish harvest from the EEZ increased more than 325 percent to a peak of 6.65 billion pounds annually in 1986–88, but has subsequently declined—only 6.32 in 1993. Alaska pollock and Gulf of Mexico shrimp were the leading fisheries in 1993. Imported seafood comprised 57 percent of U.S. consumption during 1996, a 3 percent increase from 1995.

Many problems exist however in the way we manage the world's fisheries. A Time magazine article of August 11, 1997, on the world overfishing problem, stated that "fish of all kinds are being hauled from the sea faster than they can reproduce." We addressed many of those concerns with the passage of "Sustainable Fisheries Act" last year. With a focus on overfishing, we established National goals to rebuild most currently overfished stocks in 10 years, provided for the protection of fish habitats and Pacific Insular Areas, established a by-catch reduction program, and encouraged the development of underutilized species.

However, more can be done, particularly on an international level. Fish stocks migrate across jurisdictions. Nations approach fisheries conservation and manage differently. Development of conversation objectives of nations harvesting common fish stocks often clash, and overcapitalized fleets are over-harvesting the available resources in many areas.

Again, much work remains and we must be vigilant in our duty to preserve and protect the oceans and coastal resources as we start the next century.

Ms. SNOWE. Mr. President, I am pleased to join the ranking member of the Commerce Committee, Senator HOLLINGS, in the introduction of the Oceans Act of 1997. This bill will establish a commission like the Stratton Commission of 1966 to review the many ocean and coastal issues facing the United States, and to develop a comprehensive, coordinated, national ocean and coastal policy.

Prior to introduction, I raised a few concerns with Senator HOLLINGS on some provisions of the draft bill. Basically, I had recommended some language that made it clear that as we develop a new ocean and coastal policy for the Nation, we keep in mind the facts that our fiscal resources are limited, and that our Federal investments in ocean and coastal resources must be spent efficiently and wisely. I also raised some concerns about the fact that the original draft had the President appointing all of the members of this important commission.

Mr. President, Senator HOLLINGS has graciously agreed to make some changes to the bill pursuant to my recommendations. For instance, the bill now authorizes the Congress to appoint more than half of the commission members, and the commission is directed to identify opportunities to reform Federal ocean programs to improve efficiency and effectiveness. I commend Senator HOLLINGS for his willingness to work with me and other Republican Senators before introduction of the bill. After introduction, I look forward to working with the distinguished Senator from South Carolina, a Senator who worked on the original Stratton Commission bill 30 years ago and who is a true champion of ocean protection, in the Oceans and Fisheries Subcommittee on any further refinements along these lines that might be constructive.

Again, I thank Senator HOLLINGS and commend him upon introduction of this bill.

Mr. KENNEDY. Mr. President, it is an honor for me to join as a sponsor of the Oceans Act of 1997. Our goal in this legislation is to deal more effectively with one of the most important aspects of our overall policy for the environment—our efforts to preserve and protect our magnificent ocean and coastal resources.

I commend Senator HOLLINGS for his leadership on this important legislation.

By Mr. ALLARD:

S. 1214. A bill to amend the Line-Item Veto Act of 1996 to eliminate the requirement that a Federal budget deficit must exist in order for the President to use the line-item veto authority; to the Committee on the Budget and the Committee on Governmental Affairs, jointly, pursuant to the order of August 4, 1977, as modified by the order of April 11, 1986, with instructions that if one committee reports, the other committee have 30 days to report or be discharged.

LEGISLATION TO STRENGTHEN THE LINE-ITEM VETO

Mr. ALLARD. Mr. President, today I am pleased to introduce legislation that will strengthen the recently enacted line-item veto.

Currently, the line-item veto can only be exercised by the President

when there is a deficit. This legislation would eliminate that restriction and provide for line-item veto authority whether there is a deficit or a surplus.

Mr. President, the purpose of the line-item veto should be to reduce wasteful Government programs, as well as reduce deficits.

Last year the Congress approved legislation that granted the President line-item veto authority beginning in 1997. The Congress did this out of principle. Members did not wait to see which candidate won the election before deciding whether to grant the new authority, and in August history was made when President Clinton became the first President to exercise the line-item veto.

While some Members of Congress may not agree with the specific provisions that the President selected to line-item veto, the important point is that any President should have this power as a check on narrow special interest spending and tax provisions. If Congress wishes to restore a vetoed provision it can do so with the requisite two-thirds vote.

I have long been a supporter of line-item veto authority for the President. In my view it will serve as a powerful check on Congress' ability to load up bills with wasteful provisions.

I think it is safe to say that the President's use of the line-item veto has created an environment in which narrow spending and tax provisions are going to be scrutinized much more carefully before they are loaded onto legislation.

I recognize that there have been court challenges concerning the constitutionality of the statutory line-item veto. I believe that this authority is constitutional and I certainly hope that the Supreme Court comes down on that side. However, this issue is important enough that we should amend the Constitution if necessary. That is why earlier this year I introduced a line-item veto constitutional amendment.

Today, however we should focus on the line-item veto that is before us and look for ways to improve that law. That is the purpose of this legislation.

In the last several years our economy has been very healthy and tax revenues have come in at much higher levels than previously forecast. This has created a situation where we may actually see a budget surplus at some point in the next several years. Does this mean we should rescind the line-item veto authority we have given the President? Of course not, but that would be the result as the law was drafted in 1996.

My view is that the line-item veto should be used in both deficit and surplus times. While we may have some surplus years on the horizon, it is clear that without entitlement reform massive deficits will return just after the turn of the century. This means that we must be constantly working to eliminate wasteful Government programs. A line-item veto is one way to help do that.

Mr. President, I cast my vote for a permanent line-item veto. The President and Congress cannot afford to take a vacation from the battle against wasteful Government programs.

By Mr. ASHCROFT:

S. 1215. A bill to prohibit spending Federal education funds on national testing; to the Committee on Labor and Human Resources.

NATIONAL TESTING LEGISLATION

Mr. ASHCROFT. Mr. President, I rise today to introduce legislation to prohibit the Federal Government from developing and/or imposing new national individualized tests on students across the country.

During his State of the Union Address this year, President Clinton announced his intentions to establish national tests for students in fourth grade reading and eighth grade mathematics. Without waiting for congressional authority, the Department of Education surged ahead and began development of uniform national tests, with plans to administer them starting in 1999. In August, the Department announced the award of a $13 million contract for its national testing initiative, and plans to spend an estimated $50.6 million under the contract from fiscal year 1998 through fiscal year 2001, including $12.3 million for fiscal year 1998.

In response, Representative BILL GOODLING, chairman of the Committee on Education and the Workforce, offered an amendment in the House which prohibits the expenditure of fiscal year 1998 funds for a new national testing program. While the Senate failed to consider fully and vote on the Goodling approach during its debate of the Labor-HHS appropriations bill, the House embraced the Goodling amendment, approving it by a resounding vote of 295 to 125.

The House vote sends a clear and strong signal that Congress should prohibit Federal funds for national testing in education. In fact, the alliance of members from both sides of the political spectrum demonstrates the universal concern that the administration's proposal is besieged by problems. Here are just a few of the many reasons why national tests should be opposed:

First, education experts such as Dr. Donald J. Senese, former Assistant Secretary for Educational Research and Improvement during the Reagan administration, warn that national testing will lead to a national curriculum.

Second, Lynne Cheney, former chairperson of the National Endowment for the Humanities, reminds us that Federal efforts to set standards and tests have been disastrous. She points to the politically correct Federal history standards and the English-language arts standards, which were such an ill-considered muddle that even the Clinton Department of Education cut off funding for them after having spent more than $1 million in taxpayer funds.

Third, the proposed math test is steeped in the new, unproven whole math or fuzzy math philosophy, which encourages students to rely on calculators, discourages basic math skills, and has resulted in declines in math performance. For example, the median percentile computation scores on the Comprehensive Test of Basic Skills taken by more than 37,000 DODDS students one year after the Defense Department introduced whole math dropped 9 points for third graders, 12 for fourth graders, 11 for fifth graders, 10 for sixth graders, 10 for seventh graders, and 4 for eighth graders.

Finally, Federal testing takes away local control and parental involvement. The Federal Government should not impose its will on school boards, parents, and teachers about the education of their children. Rather, education should be controlled by school boards in local communities, where parents have the greatest opportunity to be involved in the education of their child, by participating in the development of school curriculum and testing. After all, research confirms that parental involvement is the single most important element in educating our children.

Mr. President, the big losers from national tests will be students, parents, teachers, and local school boards. Once Federal exams are in place, teachers and schools will teach the test. In other words, they will change their classes to fit the Federal tests, in order to get higher scores. Textbooks and instructional materials will follow suit, even in areas that attempt to avoid national tests. As a result, Washington bureaucrats who design the tests will shape local curriculum decisions. National control of curriculum is absolutely unacceptable to me. Once the Federal Government is using tests to shape curriculum, parental control through local school boards will be doomed.

Who should control local education? I believe our schools should remain under the control of parents, teachers, and school boards, in cooperation with the States. The flawed whole math approach which brought major losses in computation test scores demonstrates the central threat in national control: When the bureaucrats make a mistake, everybody pays, from coast to coast.

Parents are looking to Congress to protect their right and their ability to shape the education of their children. A national testing system would deprive parents of this vital opportunity. As Members of Congress, we can show our support for education by saying "no" to national testing and "yes" to

parental control of their children's learning.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1215

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PROHIBITION ON NATIONAL TESTING.

Part C of the General Education Provision Act (20 U.S.C. 1231 et seq.) is amended by adding at the end the following:

"SEC. 447. PROHIBITION ON NATIONAL TESTING.

"(a) GENERAL PROHIBITION.—Notwithstanding any other provision of Federal law, funds provided to the Department or for an applicable program may not be used to develop, plan, implement, or administer any national testing program.

"(b) EXCEPTION.—Subsection (a) shall not apply to the following:

"(1) The National Assessment of Educational Progress carried out under section 411 of the National Education Statistics Act of 1994 (20 U.S.C. 9010).

"(2) The Third International Mathematics and Science Study (TIMSS).".

By Mr. HOLLINGS:

S. 1217. A bill for the relief of Olga Gorgiladze; to the Committee on the Judiciary.

PRIVATE RELIEF LEGISLATION

Mr. HOLLINGS. Mr. President, I am introducing a bill today that will grant permanent residency in the United States to Olga Gorgiladze.

I serve as the ranking member of the Appropriations Subcommittee that has jurisdiction and oversight over both the Immigration and Naturalization Service and the Executive Office for Immigration Review. I can tell you that with respect to Mrs. Gorgiladze's case—they have missed the mark. They have done this woman an injustice. It is a wrong that this Senate and this Congress should make right.

Olga Gorgiladze's case is a special situation that involves the turmoil and changes that came with the fall of the Berlin Wall and the collapse of the Soviet Union. In September 1991, Mrs. Gorgiladze came to the United States to stay with her lifelong friend, Merilyn Hodgson. Three months later the Soviet Union was dissolved and civil and ethnic war broke out in Georgia, the Soviet Republic where Mrs. Gorgiladze's husband was from. She applied for asylum in this country in March 1992. INS and the Executive Office of Immigration Review finally got to her case in late 1995 and turned down her request. They instructed Mrs. Gorgiladze to obtain Georgian citizenship and to leave for that country. The irony, of course, is that Olga Gorgiladze is not now and never has been a Georgian citizen. In fact, quite the contrary she fears for her safety should she be forced to go to that nation. She loves the United States. She loves our democratic society that protects freedom of speech and religion. Most importantly, she feels safe in a nation that has racial and ethnic diversity. The reality is that Olga Gorgiladze wants to become an American, not a Georgian citizen.

Olga Gorgiladze is not even ethnically Georgian. She is half Chinese and half Russian. She was born in China in 1940 to a Russian father and a Chinese mother. Her father was a naval officer in the Tsarist navy and fought against the Bolsheviks during the Russian Revolution. Her mother met Mrs. Gorgiladze's father in Shanghai where he had fled after the war. Olga grew up in China, speaking Chinese. But, once again in 1954, her family had to flee another violent Communist takeover—and her father moved the family back to the Soviet Union. They were sent to work on the undeveloped desert lands of Kazakhstan. In 1959, after her father died of cancer she was given permission by the Soviet authorities to move to Sukhami, Georgia, near the Russian border.

In 1971, Olga graduated from the Teachers College of Foreign Languages where she majored in English. However, she was denied a teaching position because preference was given to Georgians. She finally got a job as a part-time teacher at the college from which she graduated, but was later fired when all classes for Russian speaking groups were terminated. Despite her advanced education—equivalent to a masters degree in this country—she has continually been forced to take low-paying clerk positions because of discrimination against her as a non-Georgian. Other discriminations displayed against her included housing which is controlled by the state and purchasing of food and supplies.

Since 1991, the Caucasus nations have been plagued by ethnic strife and warfare. We have all watched the violence and bloodshed in the Abkhaszia region of Georgia, between Armenia and Azerbaijan in Nagorno-Karabakh, and the war in Chechneya. Less well televised is the hostility and persecution of outsiders and ethnic minorities. In Georgia, there is hostility to anything or anyone affiliated with Russia. As a woman who looks Chinese, speaks only Russian and English, Olga Gorgiladze has been subject to countless incidents of verbal, physical, and mental abuse. Mrs. Gorgiladze does not and cannot blend into the Georgian population. She has been beaten, spit on, verbally and physically abused. Her safety and livelihood have always felt threatened every minute of every day while living in Georgia. For example, while riding the bus, Mrs. Gorgiladze has been beaten and threatened with knifes, chains, and various other weapons.

Her husband of 25 years, Malkhaz Gorgiladze, stayed in Georgia and warned Olga of the dangers posed to her if she returned to that country. He encouraged her to seek asylum in the United States and collected evidence for her hearing. He especially worked to document police inactivity and the Georgian officials' complicity in attacks on non-Georgians by violent nationalist groups. The police warned him to stop his efforts. Malkhaz Gorgiladze began to receive anonymous phone calls and threats and warnings to stop criticizing the police. In 1996, while returning home from a New Year's Eve gathering, his car was rammed by a Georgian police car and Olga's husband was killed.

When asked by the immigration judges at Justice, our State Department reported that Georgia is in a state of cease-fire and everybody is getting along with each other. Further, the Justice Department conjectured that if the Georgian police wanted Olga's husband killed, the would have used means other than an auto accident involving a police car. The INS and immigration judges down there at the Justice Department have used this information and conclusions to deny Mrs. Gorgiladze's request for asylum. Yet, there were numerous letters and affidavits by witnesses regarding Malkhaz Gorgiladze's murder. And, in Georgia, the ultranationalists blame non-Georgians, and in particular blame Russians, for all their misfortunes and lack of economic development. Friends and relatives of Olga Gorgiladze have warned her that she should not return. They tell her that she will never be able to get a job and always will be an outcast. They say she will be considered a traitor. And, Malkhaz will not be there to try and defend her as in the past. In short, they fear for her safety, as do I.

Mrs. Gorgiladze's case is truly heartwrenching. And, here is a woman I might add—that has worked for the last 5 years at MCI Customer Service Representative International Department and turned around and paid her taxes to the State of Virginia and the U.S. Government. In my view, she has been an outstanding resident in our Nation who serves as an example of the American dream. She has never broken any law and has never been on welfare or asked the Government for handouts. She has followed the immigration rules every step of the way. She is what America is all about. What astonishes me is why the Justice Department would want to deport this 57-year-old woman.

Mr. President, I have served in the U.S. Senate over 30 years. Every now and then we get an opportunity to stand up for someone who the Federal bureaucracy has mistreated. This is one of those times. Olga Gorgiladze's situation has touched me. Since her friend brought the case to my attention, I can't stop thinking about how

unfair it seems. I've sat in Senate hearing after hearing on the Immigration and Naturalization Service asking why action is not taken to deport illegal aliens who got into this country through deception. I have listened to this administration try to explain how in 1996 they naturalized thousands of aliens with criminal backgrounds. And, I find it astonishing, these very same Justice immigration judges have ruled in separate cases that homosexuality per se does constitute a legitimate claim for asylum. But, in this case we have a woman who came to the United States legally, who is not and never has been a citizen of Georgia, who had her husband killed by Georgian authorities, who legitimately fears for her safety if sent there, who has complied with all the United States immigration laws, and who has paid her own way and has not been a burden to taxpayers in this country—and this is who the Justice Department wants to deny asylum and deport? Maybe I should forgo this bill and simply tell Olga to pretend that she is homosexual. This is injustice. This is just simply wrong.

Mr. President, I am introducing this bill today because the system is not working. I believe that Olga Gorgiladze has legitimate reasons to fear being deported to Georgia. She is not Georgian and does not belong in that country. It is ludicrous for the United States Government to be ordering her to apply for Georgian citizenship. What she has demonstrated is that she does belong in this country. In her case the system has failed and I think it is incumbent upon the United States Senate to put things right. I am pleased to sponsor this bill. I intend to work with the Judiciary Committee, with Senators ABRAHAM, KENNEDY, HATCH, and LEAHY, to ensure that Mrs. Olga Gorgiladze is permitted to remain in the United States.

By Mr. KERREY.

S. 1218. A bill to assure the integrity of information, transportation, and telecommunications upon the arrival of the year 2000; to the Committee on Commerce, Science, and Transportation.

THE MILLENNIUM ACT

Mr. KERREY. Mr. President, one of the challenges of the 21st century is already upon us. It is commonly known as the year 2000 computer problem or the millennium bug. At issue is a programming technique that could lead to the malfunction of computer systems worldwide on January 1, 2000. It is essential that government, business, and personal computer users take adequate steps to fix this problem in advance of December 31, 1999, to ensure that cyberspace enters the next millennium without a hitch.

During the early years of computing, computer storage space was incredibly expensive. Storage space that costs only 10 cents per megabyte today, cost $36 per megabyte in 1972. In an effort to reduce storage costs, computer programmers commonly programmed date information using only two digits to indicate the year. For example, 1999 would be programmed as 99. This clever space saving trick saved computer users millions of dollars and became industry practice because programmers believed that by the time the year 2000 arrived any code they were working on would be obsolete and out of service. Unfortunately, the conventional wisdom was wrong and many computer systems still use these programs. Computers and computer software programmed in this fashion may misinterpret the year 2000 as 1900. This electronic confusion could lead to serious malfunction or collapse of computers and computer networks around the world.

Date information plays a significant role in almost all computer applications developed over the last 30 years. The year 2000 problem has many practical implications from the relatively benign to the very serious. Credit cards may be read as invalid, traffic lights may not operate, 99 years of bank records could be destroyed or the Nation's air traffic control systems could fail. The list of possible failures is nearly endless and can be found in systems used by the government, the business community, and personal computer users worldwide. Personal computers are less susceptible to the problem and in most cases can be quickly fixed. However, business and government leaders should be working night and day to ensure that the computer systems the country depends on are reprogrammed to correctly recognize the date in time for the arrival of New Year's Day 2000.

The time and financial commitment necessary to replace the problematic date code is stunning. The Gartner Group estimates that costs could exceed $600 billion. Newsweek magazine points out that this sum is enough to fund a year's worth of education costs, preschool through graduate school. Correcting the problem is technically simple, however in order to find the date information the entire program must be manually scanned line for line. Often, the programs are written in the outdated COBAL programming language and finding programmers skilled in older languages to solve the problem is very difficult because the demand for their services is sky rocketing. After a competent technician is hired and they have analyzed the code and made the necessary changes, the programs must go through a time consuming testing phase. In sum, it is a very complex task and it is quickly becoming too late to begin the reprogramming process.

Many companies and government offices have already taken steps to avert this problem and are well on their way to making their systems year 2000 compliant. Unfortunately, many others have not addressed the problem and the time needed to analyze, modify, and test the code used by these entities is quickly slipping away. I am very concerned that further delays will leave the government and many private companies unprepared to carry out normal transactions in the early days of the next century. In order to address this problem, I have joined Senator MOYNIHAN as a cosponsor of S. 22. S. 22 would create a commission that would be required to report to the President, by July 3, 1997, with proposals for new procedures or regulations to address the year 2000 computer problem for systems of Federal, State, and local governments and would make recommendations for funding levels that might be needed to address this problem.

In addition I am introducing a bill today that would instruct the Federal Communications Commission to initiate a proceeding to determine the integrity of the telecommunications networks as the year 2000 arrives. It also requires the National Institute of Standards and Technology to review the risks to personal computers and requires the Department of Transportation to assure that transportation safety is not compromised.

Inconvenience can be tolerated, but every effort must be taken to assure that the health and safety of humans and the security and integrity of networks and data are not compromised by what we know to be a significant weakness in our computer networks and software.

In conclusion, I am also very concerned by reports that small and midsize businesses are experiencing difficulty in determining if their computer systems are year 2000 compliant because some third-party systems vendors are not forthcoming with information about their products. An already difficult task is further complicated by uncooperative third party vendors who fail to help these companies understand how the year 2000 problem could affect their businesses. These companies have a responsibility to provide their customers with the information they need to make their systems year 2000 compliant.

There is still time to act and prevent dangerous disruptions in computer, transportation and computer networks and the loss of valuable data. If the private and public sector does that, then Americans can party, and not panic when the clock strikes midnight on New Year's eve 1999. Mr. President I ask unanimous consent that the text of my bill be printed in the RECORD.

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

S. 1218

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be referred to as the "Millennium Act."

SEC. 101. TELECOMMUNICATIONS NETWORKS.

(a) The Federal Communications Commission shall initiate a proceeding to evaluate the potential dangers to the nation's telecommunications networks from to software and systems which are unable to effectively toll the passage of time from December 31, 1999 to January 1, 2000.

(b) The Commission shall make necessary and appropriate regulatory changes within their jurisdiction to ensure the integrity of the nation's telecommunications networks.

SEC. 102. PERSONAL COMPUTERS.

The National Institute of Standards and Technology shall evaluate the potential risks to information stored on personal computers from to software and systems which are unable to effectively toll the passage of time from December 31, 1999 to January 1, 2000 and shall take necessary and appropriate actions within its jurisdiction to propose solutions and inform the public.

SEC. 103. TRANSPORTATION NETWORKS.

The Secretary of Transportation shall initiate a comprehensive plan to assure that computer hardware and software in transportation systems which are unable to effectively toll the passage of time from December 31, 1999 to January 1, 2000 do not create a safety risk to transportation workers and the general public. Should a risk to safety be identified, the Department shall take necessary and appropriate measures to assure safety and inform the public of such risks.

ADDITIONAL COSPONSORS

S. 22

At the request of Mr. MOYNIHAN, the names of the Senator from Oregon [Mr. WYDEN] and the Senator from South Dakota [Mr. DASCHLE] were added as cosponsors of S. 22, a bill to establish a bipartisan national commission to address the year 2000 computer problem.

S. 67

At the request of Ms. SNOWE, the name of the Senator from New York [Mr. D'AMATO] was added as a cosponsor of S. 67, a bill to amend the Public Health Service Act to extend the program of research on breast cancer.

S. 489

At the request of Mr. KYL, the name of the Senator from Missouri [Mr. BOND] was added as a cosponsor of S. 489, a bill to improve the criminal law relating to fraud against consumers.

S. 830

At the request of Mr. JEFFORDS, the name of the Senator from Michigan [Mr. ABRAHAM] was added as a cosponsor of S. 830, a bill to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

S. 850

At the request of Mr. AKAKA, the name of the Senator from California [Mrs. FEINSTEIN] was added as a cosponsor of S. 850, a bill to amend the Packers and Stockyards Act, 1921, to make it unlawful for any stockyard owner, market agency, or dealer to transfer or market nonambulatory livestock, and for other purposes.

S. 852

At the request of Mr. LOTT, the name of the Senator from South Dakota [Mr. DASCHLE] was added as a cosponsor of S. 852, a bill to establish nationally uniform requirements regarding the titling and registration of salvage, nonrepairable, and rebuilt vehicles.

S. 941

At the request of Mr. INOUYE, the name of the Senator from South Carolina [Mr. HOLLINGS] was added as a cosponsor of S. 941, a bill to promote the utilization of marine ferry and high-speed marine ferry services.

S. 1069

At the request of Mr. MURKOWSKI, the names of the Senator from Utah [Mr. HATCH], the Senator from Illinois [Ms. MOSELEY-BRAUN], the Senator from Virginia [Mr. ROBB], and the Senator from Rhode Island [Mr. REED] were added as cosponsors of S. 1069, a bill entitled the "National Discovery Trails Act of 1997".

S. 1100

At the request of Mr. AKAKA, the name of the Senator from Hawaii [Mr. INOUYE] was added as a cosponsor of S. 1100, a bill to amend the Covenant to Establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America, the legislation approving such covenant, and for other purposes.

S. 1105

At the request of Mr. COCHRAN, the name of the Senator from Texas [Mrs. HUTCHISON] was added as a cosponsor of S. 1105, a bill to amend the Internal Revenue Code of 1986 to provide a sound budgetary mechanism for financing health and death benefits of retired coal miners while ensuring the long-term fiscal health and solvency of such benefits, and for other purposes.

S. 1106

At the request of Mr. COATS, the name of the Senator from Iowa [Mr. HARKIN] was added as a cosponsor of S. 1106, a bill to provide for the establishment of demonstration projects designed to determine the social, civic, psychological, and economic effects of providing to individuals and families with limited means an opportunity to accumulate assets, and to determine the extent to which an asset based policy may be used to enable individuals and families with limited means to achieve economic self-sufficiency.

S. 1115

At the request of Mr. LOTT, the names of the Senator from Arkansas [Mr. HUTCHINSON], the Senator from Louisiana [Mr. BREAUX], the Senator from Nevada [Mr. BRYAN], and the Senator from North Dakota [Mr. DORGAN] were added as cosponsors of S. 1115, a bill to amend title 49, United States Code, to improve one-call notification process, and for other purposes.

S. 1180

At the request of Mr. KEMPTHORNE, the names of the Senator from Oregon [Mr. SMITH], the Senator from Alaska [Mr. STEVENS], and the Senator from Utah [Mr. BENNETT] were added as cosponsors of S. 1180, a bill to reauthorize the Endangered Species Act.

S. 1194

At the request of Mr. KYL, the names of the Senator from Montana [Mr. BURNS], the Senator from Idaho [Mr. KEMPTHORNE], and the Senator from Iowa [Mr. GRASSLEY] were added as cosponsors of S. 1194, a bill to amend title XVIII of the Social Security Act to clarify the right of Medicare beneficiaries to enter into private contracts with physicians and other health care professionals for the provision of health services for which no payment is sought under the Medicare program.

SENATE CONCURRENT RESOLUTION 51

At the request of Mr. HELMS, the names of the Senator from Tennessee [Mr. FRIST], and the Senator from Connecticut [Mr. DODD] were added as cosponsors of Senate Concurrent Resolution 51, a concurrent resolution expressing the sense of Congress regarding elections for the legislature of the Hong Kong Special Administrative Region.

SENATE RESOLUTION 96

At the request of Mr. CRAIG, the names of the Senator from Utah [Mr. BENNETT], the Senator from California [Mrs. BOXER], the Senator from Georgia [Mr. CLELAND], the Senator from Indiana [Mr. COATS], the Senator from California [Mrs. FEINSTEIN], the Senator from Arkansas [Mr. HUTCHINSON], and the Senator from Alabama [Mr. SHELBY] were added as cosponsors of Senate Resolution 96, a resolution proclaiming the week of March 15 through March 21, 1998, as "National Safe Place Week."

SENATE RESOLUTION 123—HONORING THE MEMORY OF FORMER PEACE CORPS DIRECTOR LORET MILLER RUPPE

Mr. HELMS, from the Committee on Foreign Relations, reported the following original resolution; which was placed on the calendar:

S. RES. 123

Whereas the Members of the Senate were greatly saddened by the death of Loret Miller Ruppe, the longest-serving Director of the Peace Corps; and

Whereas Loret Miller Ruppe's inspirational vision, dedication, and leadership (1) revitalized the Peace Corps as she began or revived programs in Sri Lanka, Haiti, Burundi, Guinea-Bissau, Chad, Equatorial Guinea, and the Cape Verde Islands; (2) energized a new generation of Americans to accept the challenge of serving in the Corps; (3) refocused

the Corps on its mission of development to achieve world peace; and (4) did a great service to America and to the millions of the world's citizens touched by her efforts: Now, therefore, be it

Resolved, That (a) the Senate recognizes and acknowledges the achievements and contributions of the longest-serving Director of the Peace Corps, Loret Miller Ruppe, and the volunteers she inspired, not only for their service in other countries but also in their own communities.

(b) It is the sense of the Senate that the President should honor the memory of the Peace Corps' great leader Loret Miller Ruppe and reaffirm the commitment of the United States to international peace and understanding.

SENATE RESOLUTION 124—RELATIVE TO AN INTERNATIONAL TRIBUNAL FOR CRIMES AGAINST HUMANITY

Mr. ROTH (for himself, Mr. THOMAS, Mrs. FEINSTEIN and Mr. GRAMS) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 124

Whereas, the Khmer Rouge recently staged a show trial of Pol Pot, the reputed leader of the Khmer Rouge during the Cambodian genocide;

Whereas, the Khmer Rouge have been promoting their National Solidarity Party and proclaiming their support for "liberal democracy" as a means to legitimate their role in Cambodian politics;

Whereas, while the Khmer Rouge have been weakened since the Paris Peace Accords of 1991, they remain a key source of violence in Cambodia;

Whereas, Cambodian People's Party leader and Second Prime Minister Hun Sen staged a bloody and illegal coup against the First Prime Minister and leader of the FUNCINPEC Party, Norodom Ranaridhh;

Whereas, Hun Sen maintains that the coup was necessary because elements of FUNCINPEC were on the verge of consummating a deal to bring the Khmer Rouge military and political organization into the legitimate political arena;

Whereas, Norodom Ranaridhh, by contrast, has argued that FUNCINPEC had no plan to form an alliance with the Khmer Rouge and that this allegation was used as a pretext by Hun Sen for the coup;

Whereas, Norodom Ranaridhh asserts instead that he was on the verge of finally destroying the Khmer Rouge and bringing them to justice;

Whereas, Norodom Ranaridhh further asserts that the real reason for the coup was that Hun Sen fears that convening an international tribunal to bring the Khmer Rouge to justice would implicate Hun Sen in genocidal atrocities;

Whereas, Hun Sen has consistently argued that the top Khmer Rouge leadership—including, but not limited to Pol Pot—must be brought to justice before an international criminal tribunal;

Whereas, earlier this year, Norodom Ranaridhh and Hun Sen wrote to United Nations Secretary-General Kofi Annan asking for "the assistance of the United Nations and the international community in bringing to justice those persons responsible for genocide and crimes against humanity during the rule of the Khmer Rouge from 1975 to 1979";

Whereas, after the coup, troops loyal to Norodom Ranaridhh appear to have formed a military alliance with troops loyal to the Khmer Rouge leadership, thus reinforcing the fears of the Cambodia people that the Khmer Rouge will use any means necessary to regain power;

Whereas, peace, democracy, stability, the rule of law and national reconciliation in Cambodia are unlikely to be achieved until the Khmer Rouge are brought to justice;

Whereas, the Cambodian Genocide Justice Act states that it is the policy of the United States to support efforts to bring to justice members of the Khmer Rouge for their crimes against humanity, and in circumstances which the President deems appropriate, to encourage the establishment of an international criminal tribunal for the prosecution of those accused of genocide in Cambodia and provide such tribunal with relevant information;

Resolved, That it is the sense of the Senate that:

(1) a primary objective of U.S. policy toward Cambodia should be the establishment of an international tribunal for the prosecution those responsible for the Cambodian genocide;

(2) in compliance with the Cambodian Genocide Justice Act and the objectives stated above, the President should immediately deem it appropriate to encourage the establishment of an international criminal tribunal for the prosecution of such members of the Khmer Rouge;

(3) in further compliance with the Cambodian Genocide Justice Act, the United States should support efforts to bring members of the Khmer Rouge—including Pol Pot—to justice for their crimes against humanity before an international tribunal, including providing that tribunal with any information available on such members' involvement in the Cambodian genocide;

(4) the Secretary of State should encourage all Member countries of the Association of Southeast Asian Nations, the People's Republic of China, Japan and other interested countries to support such a tribunal.

Mr. ROTH. Mr. President, I rise today on behalf of myself, Mr. THOMAS, Mrs. FEINSTEIN, and Mr. GRAMS to a sense-of-the-Senate resolution that the Khmer Rouge and other participants in the Cambodian genocide should be brought to justice before an international tribunal.

Just a couple of months ago, we witnessed the grotesque spectacle of a Khmer Rouge show trial of Pol Pot, the leader of the Khmer Rouge during its genocidal reign in the 1970's. In July, Cambodian People's Party leader and Second Prime Minister Hun Sen staged a bloody coup against the First Prime Minister and leader of the FUNCINPEC Party, Norodom Ranaridhh.

Hun Sen has claimed the coup was necessary because Norodom Ranaridhh was attempting to gain Khmer Rouge support for his party.

Norodom Ranaridhh, on the other hand, has labeled Hun Sen's allegations a false pretext for the coup. Norodom Ranaridhh has also asserted that Hun Sen fears an international tribunal on the Cambodian genocide would implicate Hun Sen for atrocities he committed during his tenure as a senior Khmer Rouge official.

Finally, troops loyal to Norodom Ranaridhh now appear to have formed a military alliance with troops loyal to the Khmer Rouge leadership, thus reinforcing the fears of the Cambodia people that the Khmer Rouge will use any means necessary to regain power.

These events and the assertions of the two Prime Ministers demonstrate that while the Khmer Rouge have been weakened since the Paris Peace Accords of 1991, they remain central to the continuing conflict in Cambodia. Recent events also demonstrate that the objectives of bringing peace, democracy, national reconciliation, and the rule of law to Cambodia are likely to remain out of reach until the Khmer Rouge are brought to justice.

What this resolution does, Mr. President, is make it clear that an international tribunal is essential if we are to achieve these objectives. It also points out that before the coup and before their allegations against one another about their respective involvement with the Khmer Rouge, Norodom Ranaridhh and Hun Sen wrote a joint letter to U.N. Secretary-General Kofi Annan asking for U.N. assistance in convening such a tribunal.

We should take them up on their request because removing the Khmer Rouge as a military and political force in Cambodia is essential if we are to avoid another slide toward authoritarianism and war. I believe an international tribunal will also prevent the Khmer Rouge from succeeding in their transparent attempt to emerge as a legitimate political force in Cambodia. Indeed, at the show trial of Pol Pol they staged, the Khmer Rouge loudly proclaimed their support for liberal democracy. Other members of the Khmer Rouge have been promoting the National Solidarity Party to give Khmer Rouge a legitimate voice in Cambodian politics.

According to the Yale Cambodian Genocide project, the principal organization documenting atrocities committed by the Khmer Rouge, such a tribunal "would soon return indictments against all or most of the current Khmer Rouge leadership.

Mr. President, the Cambodian tragedy will never end until the Khmer Rouge are brought to justice. I offer this resolution to move us closer to that goal and to demonstrate this body's continued interest in the development of a free, democratic, and peaceful Cambodia.

SENATE RESOLUTION 125—COMMENDING THE REPRESENTATIVE OF THE TAIPEI ECONOMIC AND CULTURAL REPRESENTATIVES OFFICE IN THE UNITED STATES

Mr. MURKOWSKI (for himself and Mr. LOTT) submitted the following resolution; which was considered and agreed to:

S. RES. 125

Whereas Dr. Jason C. Hu has served with distinction as Representative of the Taipei Economic and Cultural Representatives Office (TECRO) since June 1996, and has ably represented the interests of the Republic of China on Taiwan;

Whereas Dr. Hu has been a firm and consistent advocate to democratic principles throughout his distinguished career;

Whereas Dr. Hu has established many deep friendships with Members of Congress and other Americans during his tenure in Washington: and

Whereas Dr. Hu has been asked to return to Taiwan to serve as the Minister of Foreign Affairs of the Republic of China: Now, therefore, be it

Resolved by the Senate, That the Senate hereby—

(1) commends Dr. Jason C. Hu for his service as Representative of the TECRO office; and

(2) expresses to Dr. Hu and his family its best wishes for his continued success in the future.

AMENDMENTS SUBMITTED

THE DISTRICT OF COLUMBIA APPROPRIATIONS ACT, 1998

FAIRCLOTH (AND BOXER) AMENDMENT NO. 1248

Mr. FAIRCLOTH (for himself and Mrs. BOXER) proposed an amendment to the bill (S. 1156) making appropriations for the Government of the District of Columbia and other activities chargeable in whole or in part against the revenues of said District for the fiscal year ending September 30, 1998, and for other purposes; as follows:

On page 2, strike all after the word "Authority" on line 11, to the end of line 12.

On page 2, line 22, before the colon, insert: ", which shall be deposited into an escrow account held by the District of Columbia Financial Responsibility and Management Assistance Authority, which shall allocate the funds to the Mayor at such intervals and in accordance with such terms and conditions as it considers appropriate to implement the financial plan for the year".

On page 4, line 4, strike "$116,000,000" and insert in lieu thereof "$103,000,000".

On page 4, line 15, strike "$30,000,000" and insert in lieu thereof "$43,000,000".

On page 29, strike all after "the" on line 16, to the end of line 25, and insert: "District of Columbia Financial Responsibility and Management Assistance Authority (Authority). Appropriations made by this Act for such programs or functions are conditioned only on the approval by the Authority of the required reorganization plans."

On page 33, strike all after "Financial" on line 19, and insert: "Responsibility and Management".

On page 41, strike all after "(B)" on line 24, through "$129,946,000" on line 25, and insert: "$4,811,906,000 (of which $118,269,000".

On page 42, line 16, after "Assistance," insert: "Authority".

On page 17, after the period on line 25, insert:

CORRECTIONAL INDUSTRIES FUND

For the Correctional Industries Fund, established by the District of Columbia Correctional Industries Establishment Act, approved October 3, 1964 (78 Stat. 1000; Public Law 88-622), $3,332,000 from other funds.

COATS (AND OTHERS) AMENDMENT NO. 1249

Mr. COATS, for himself, Mr. LIEBERMAN, Mr. BROWNBACK, Mr. ASHCROFT, Mr. COVERDELL, and Mr. GREGG) proposed an amendment to the bill, S. 1156, supra; as follows:

At the end, insert the following:

TITLE ___—STUDENT OPPORTUNITY SCHOLARSHIPS

SEC. ___01. SHORT TITLE; FINDINGS; PRECEDENTS.

(a) SHORT TITLE.—This title may be cited as the "District of Columbia Student Opportunity Scholarship Act of 1997".

(b) FINDINGS.—Congress makes the following findings:

(1) Public education in the District of Columbia is in a crisis, as evidenced by the following:

(A) The District of Columbia schools have the lowest average of any school system in the Nation on the National Assessment of Education Progress.

(B) 72 percent of fourth graders in the District of Columbia tested below basic proficiency on the National Assessment of Education Progress in 1994.

(C) Since 1991, there has been a net decline in the reading skills of District of Columbia students as measured in scores on the standardized Comprehensive Test of Basic Skills.

(D) At least 40 percent of District of Columbia students drop out of or leave the school system before graduation.

(E) The National Education Goals Panel reported in 1996 that both students and teachers in District of Columbia schools are subjected to levels of violence that are twice the national average.

(F) Nearly two-thirds of District of Columbia teachers reported that violent student behavior is a serious impediment to teaching.

(G) Many of the District of Columbia's 152 schools are in a state of terrible disrepair, including leaking roofs, bitterly cold classrooms, and numerous fire code violations.

(2) Significant improvements in the education of educationally deprived children in the District of Columbia can be accomplished by—

(A) increasing educational opportunities for the children by expanding the range of educational choices that best meet the needs of the children;

(B) fostering diversity and competition among school programs for the children;

(C) providing the families of the children more of the educational choices already available to affluent families; and

(D) enhancing the overall quality of education in the District of Columbia by increasing parental involvement in the direction of the education of the children.

(3) The 350 private schools in the District of Columbia and the surrounding area offer a more safe and stable learning environment than many of the public schools.

(4) Costs are often much lower in private schools than corresponding costs in public schools.

(5) Not all children are alike and therefore there is no one school or program that fits the needs of all children.

(6) The formation of sound values and moral character is crucial to helping young people escape from lives of poverty, family break-up, drug abuse, crime, and school failure.

(7) In addition to offering knowledge and skills, education should contribute positively to the formation of the internal norms and values which are vital to a child's success in life and to the well-being of society.

(8) Schools should help to provide young people with a sound moral foundation which is consistent with the values of their parents. To find such a school, parents need a full range of choice to determine where their children can best be educated.

(c) PRECEDENTS.—The United States Supreme Court has determined that programs giving parents choice and increased input in their children's education, including the choice of a religious education, do not violate the Constitution. The Supreme Court has held that as long as the beneficiary decides where education funds will be spent on such individual's behalf, public funds can be used for education in a religious institution because the public entity has neither advanced nor hindered a particular religion and therefore has not violated the establishment clause of the first amendment to the Constitution. Supreme Court precedents include—

(1) Wisconsin v. Yoder, 406 U.S. 205 (1972); Pierce v. Society of Sisters, 268 U.S. 510 (1925); and Meyer v. Nebraska, 262 U.S. 390 (1923) which held that parents have the primary role in and are the primary decision makers in all areas regarding the education and upbringing of their children;

(2) Mueller v. Allen, 463 U.S. 388 (1983) which declared a Minnesota tax deduction program that provided State income tax benefits for educational expenditures by parents, including tuition in religiously affiliated schools, does not violate the Constitution;

(3) Witters v. Department of Services for the Blind, 474 U.S. 481 (1986) in which the Supreme Court ruled unanimously that public funds for the vocational training of the blind could be used at a Bible college for ministry training; and

(4) Zobrest v. Catalina Foothills School District, 509 U.S. 1 (1993) which held that a deaf child could receive an interpreter, paid for by the public, in a private religiously affiliated school under the Individual with Disabilities Education Act (20 U.S.C. 1400 et seq.). The case held that providing an interpreter in a religiously affiliated school did not violate the establishment clause of the first amendment of the Constitution.

SEC. ___02. DEFINITIONS.

As used in this title—

(1) the term "Board" means the Board of Directors of the Corporation established under section ___03(b)(1);

(2) the term "Corporation" means the District of Columbia Scholarship Corporation established under section ___03(a);

(3) the term "eligible institution"—

(A) in the case of an eligible institution serving a student who receives a tuition scholarship under section ___04(c)(1), means a public, private, or independent elementary or secondary school; and

(B) in the case of an eligible institution serving a student who receives an enhanced achievement scholarship under section ___04(c)(2), means an elementary or secondary school, or an entity that provides services to a student enrolled in an elementary or secondary school to enhance such student's achievement through instruction described in section ___04(c)(2);

(4) the term "parent" includes a legal guardian or other person standing in loco parentis; and

(5) the term "poverty line" means the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)) applicable to a family of the size involved.

SEC. 03. DISTRICT OF COLUMBIA SCHOLARSHIP CORPORATION.

(a) GENERAL REQUIREMENTS.—

(1) IN GENERAL.—There is authorized to be established a private, nonprofit corporation, to be known as the "District of Columbia Scholarship Corporation", which is neither an agency nor establishment of the United States Government or the District of Columbia Government.

(2) DUTIES.—The Corporation shall have the responsibility and authority to administer, publicize, and evaluate the scholarship program in accordance with this title, and to determine student and school eligibility for participation in such program.

(3) CONSULTATION.—The Corporation shall exercise its authority—

(A) in a manner consistent with maximizing educational opportunities for the maximum number of interested families; and

(B) in consultation with the District of Columbia Board of Education or entity exercising administrative jurisdiction over the District of Columbia Public Schools, the Superintendent of the District of Columbia Public Schools, and other school scholarship programs in the District of Columbia.

(4) APPLICATION OF PROVISIONS.—The Corporation shall be subject to the provisions of this title, and, to the extent consistent with this title, to the District of Columbia Nonprofit Corporation Act (D.C. Code, sec. 29–501 et seq.).

(5) RESIDENCE.—The Corporation shall have its place of business in the District of Columbia and shall be considered, for purposes of venue in civil actions, to be a resident of the District of Columbia.

(6) FUND.—There is established in the Treasury a fund that shall be known as the District of Columbia Scholarship Fund, to be administered by the Secretary of the Treasury.

(7) DISBURSEMENT.—The Secretary of the Treasury shall make available and disburse to the Corporation, before October 15 of each fiscal year or not later than 15 days after the date of enactment of an Act making appropriations for the District of Columbia for such year, whichever occurs later, such funds as have been appropriated to the District of Columbia Scholarship Fund for the fiscal year in which such disbursement is made.

(8) AVAILABILITY.—Funds authorized to be appropriated under this title shall remain available until expended.

(9) USES.—Funds authorized to be appropriated under this title shall be used by the Corporation in a prudent and financially responsible manner, solely for scholarships, contracts, and administrative costs.

(10) AUTHORIZATION.—

(A) IN GENERAL.—There are authorized to be appropriated to the District of Columbia Scholarship Fund—

(i) $7,000,000 for fiscal year 1998;

(ii) $8,000,000 for fiscal year 1999; and

(iii) $10,000,000 for each of fiscal years 2000 through 2002.

(B) LIMITATION.—Not more than 7.5 percent of the amount appropriated to carry out this title for any fiscal year may be used by the Corporation for salaries and administrative costs.

(b) ORGANIZATION AND MANAGEMENT; BOARD OF DIRECTORS.—

(1) BOARD OF DIRECTORS; MEMBERSHIP.—

(A) IN GENERAL.—The Corporation shall have a Board of Directors (referred to in this title as the "Board"), comprised of 7 members with 6 members of the Board appointed by the President not later than 30 days after receipt of nominations from the Speaker of the House of Representatives and the Majority Leader of the Senate.

(B) HOUSE NOMINATIONS.—The President shall appoint 3 of the members from a list of 9 individuals nominated by the Speaker of the House of Representatives in consultation with the Minority Leader of the House of Representatives.

(C) SENATE NOMINATIONS.—The President shall appoint 3 members from a list of 9 individuals nominated by the Majority Leader of the Senate in consultation with the Minority Leader of the Senate.

(D) DEADLINE.—The Speaker of the House of Representatives and Majority Leader of the Senate shall submit their nominations to the President not later than 30 days after the date of the enactment of this Act.

(E) APPOINTEE OF MAYOR.—The Mayor shall appoint 1 member of the Board not later than 60 days after the date of the enactment of this Act.

(F) POSSIBLE INTERIM MEMBERS.—If the President does not appoint the 6 members of the Board in the 30-day period described in subparagraph (A), then the Speaker of the House of Representatives and the Majority Leader of the Senate shall each appoint 2 members of the Board, and the Minority Leader of the House of Representatives and the Minority Leader of the Senate shall each appoint 1 member of the Board, from among the individuals nominated pursuant to subparagraphs (A) and (B), as the case may be. The appointees under the preceding sentence together with the appointee of the Mayor, shall serve as an interim Board with all the powers and other duties of the Board described in this title, until the President makes the appointments as described in this subsection.

(2) POWERS.—All powers of the Corporation shall vest in and be exercised under the authority of the Board.

(3) ELECTIONS.—Members of the Board annually shall elect 1 of the members of the Board to be the Chairperson of the Board.

(4) RESIDENCY.—All members appointed to the Board shall be residents of the District of Columbia at the time of appointment and while serving on the Board.

(5) NONEMPLOYEE.—No member of the Board may be an employee of the United States Government or the District of Columbia Government when appointed to or during tenure on the Board, unless the individual is on a leave of absence from such a position while serving on the Board.

(6) INCORPORATION.—The members of the initial Board shall serve as incorporators and shall take whatever steps are necessary to establish the Corporation under the District of Columbia Nonprofit Corporation Act (D.C. Code, sec. 29–501 et seq.).

(7) GENERAL TERM.—The term of office of each member of the Board shall be 5 years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor was appointed shall be appointed for the remainder of such term.

(8) CONSECUTIVE TERM.—No member of the Board shall be eligible to serve in excess of 2 consecutive terms of 5 years each. A partial term shall be considered as 1 full term. Any vacancy on the Board shall not affect the Board's power, but shall be filled in a manner consistent with this title.

(9) NO BENEFIT.—No part of the income or assets of the Corporation shall inure to the benefit of any Director, officer, or employee of the Corporation, except as salary or reasonable compensation for services.

(10) POLITICAL ACTIVITY.—The Corporation may not contribute to or otherwise support any political party or candidate for elective public office.

(11) NO OFFICERS OR EMPLOYEES.—The members of the Board shall not, by reason of such membership, be considered to be officers or employees of the United States Government or of the District of Columbia Government.

(12) STIPENDS.—The members of the Board, while attending meetings of the Board or while engaged in duties related to such meetings or other activities of the Board pursuant to this title, shall be provided a stipend. Such stipend shall be at the rate of $150 per day for which the member of the Board is officially recorded as having worked, except that no member may be paid a total stipend amount in any calendar year in excess of $5,000.

(c) OFFICERS AND STAFF.—

(1) EXECUTIVE DIRECTOR.—The Corporation shall have an Executive Director, and such other staff, as may be appointed by the Board for terms and at rates of compensation, not to exceed level EG–16 of the Educational Service of the District of Columbia, to be fixed by the Board.

(2) STAFF.—With the approval of the Board, the Executive Director may appoint and fix the salary of such additional personnel as the Executive Director considers appropriate.

(3) ANNUAL RATE.—No staff of the Corporation may be compensated by the Corporation at an annual rate of pay greater than the annual rate of pay of the Executive Director.

(4) SERVICE.—All officers and employees of the Corporation shall serve at the pleasure of the Board.

(5) QUALIFICATION.—No political test or qualification may be used in selecting, appointing, promoting, or taking other personnel actions with respect to officers, agents, or employees of the Corporation.

(d) POWERS OF THE CORPORATION.—

(1) GENERALLY.—The Corporation is authorized to obtain grants from, and make contracts with, individuals and with private, State, and Federal agencies, organizations, and institutions.

(2) HIRING AUTHORITY.—The Corporation may hire, or accept the voluntary services of, consultants, experts, advisory boards, and panels to aid the Corporation in carrying out this title.

(e) FINANCIAL MANAGEMENT AND RECORDS.—

(1) AUDITS.—The financial statements of the Corporation shall be—

(A) maintained in accordance with generally accepted accounting principles for nonprofit corporations; and

(B) audited annually by independent certified public accountants.

(2) REPORT.—The report for each such audit shall be included in the annual report to Congress required by section 11(c).

(f) ADMINISTRATIVE RESPONSIBILITIES.—

(1) SCHOLARSHIP APPLICATION SCHEDULE AND PROCEDURES.—Not later than 30 days after the initial Board is appointed and the first Executive Director of the Corporation is hired under this title, the Corporation shall implement a schedule and procedures for processing applications for, and awarding, student scholarships under this title. The schedule and procedures shall include establishing a list of certified eligible institutions, distributing scholarship information

to parents and the general public (including through a newspaper of general circulation), and establishing deadlines for steps in the scholarship application and award process.

(2) INSTITUTIONAL APPLICATIONS AND ELIGIBILITY.—

(A) IN GENERAL.—An eligible institution that desires to participate in the scholarship program under this title shall file an application with the Corporation for certification for participation in the scholarship program under this title that shall—

(i) demonstrate that the eligible institution has operated with not less than 25 students during the 3 years preceding the year for which the determination is made unless the eligible institution is applying for certification as a new eligible institution under subparagraph (C);

(ii) contain an assurance that the eligible institution will comply with all applicable requirements of this title;

(iii) contain an annual statement of the eligible institution's budget; and

(iv) describe the eligible institution's proposed program, including personnel qualifications and fees.

(B) CERTIFICATION.—

(i) IN GENERAL.—Except as provided in subparagraph (C), not later than 60 days after receipt of an application in accordance with subparagraph (A), the Corporation shall certify an eligible institution to participate in the scholarship program under this title.

(ii) CONTINUATION.—An eligible institution's certification to participate in the scholarship program shall continue unless such eligible institution's certification is revoked in accordance with subparagraph (D).

(C) NEW ELIGIBLE INSTITUTION.—

(i) IN GENERAL.—An eligible institution that did not operate with at least 25 students in the 3 years preceding the year for which the determination is made may apply for a 1-year provisional certification to participate in the scholarship program under this title for a single year by providing to the Corporation not later than July 1 of the year preceding the year for which the determination is made—

(I) a list of the eligible institution's board of directors;

(II) letters of support from not less than 10 members of the community served by such eligible institution;

(III) a business plan;

(IV) an intended course of study;

(V) assurances that the eligible institution will begin operations with not less than 25 students;

(VI) assurances that the eligible institution will comply with all applicable requirements of this title; and

(VII) a statement that satisfies the requirements of clauses (ii) and (iv) of subparagraph (A).

(ii) CERTIFICATION.—Not later than 60 days after the date of receipt of an application described in clause (i), the Corporation shall certify in writing the eligible institution's provisional certification to participate in the scholarship program under this title unless the Corporation determines that good cause exists to deny certification.

(iii) RENEWAL OF PROVISIONAL CERTIFICATION.—After receipt of an application under clause (i) from an eligible institution that includes a statement of the eligible institution's budget completed not earlier than 12 months before the date such application is filed, the Corporation shall renew an eligible institution's provisional certification for the second and third years of the school's participation in the scholarship program under this title unless the Corporation finds—

(I) good cause to deny the renewal, including a finding of a pattern of violation of requirements described in paragraph (3)(A); or

(II) consistent failure of 25 percent or more of the students receiving scholarships under this title and attending such school to make appropriate progress (as determined by the Corporation) in academic achievement.

(iv) DENIAL OF CERTIFICATION.—If provisional certification or renewal of provisional certification under this subsection is denied, then the Corporation shall provide a written explanation to the eligible institution of the reasons for such denial.

(D) REVOCATION OF ELIGIBILITY.—

(i) IN GENERAL.—The Corporation, after notice and hearing, may revoke an eligible institution's certification to participate in the scholarship program under this title for a year succeeding the year for which the determination is made for—

(I) good cause, including a finding of a pattern of violation of program requirements described in paragraph (3)(A); or

(II) consistent failure of 25 percent or more of the students receiving scholarships under this title and attending such school to make appropriate progress (as determined by the Corporation) in academic achievement.

(ii) EXPLANATION.—If the certification of an eligible institution is revoked, the Corporation shall provide a written explanation of the Corporation's decision to such eligible institution and require a pro rata refund of the proceeds of the scholarship funds received under this title.

(3) PARTICIPATION REQUIREMENTS FOR ELIGIBLE INSTITUTIONS.—

(A) REQUIREMENTS.—Each eligible institution participating in the scholarship program under this title shall—

(i) provide to the Corporation not later than June 30 of each year the most recent annual statement of the eligible institution's budget; and

(ii) charge a student that receives a scholarship under this title not more than the cost of tuition and mandatory fees for, and transportation to attend, such eligible institution as other students who are residents of the District of Columbia and enrolled in such eligible institution.

(B) COMPLIANCE.—The Corporation may require documentation of compliance with the requirements of subparagraph (A), but neither the Corporation nor any governmental entity may impose requirements upon an eligible institution as a condition for participation in the scholarship program under this title, other than requirements established under this title.

SEC. ___04. SCHOLARSHIPS AUTHORIZED.

(a) ELIGIBLE STUDENTS.—The Corporation is authorized to award tuition scholarships under subsection (c)(1) and enhanced achievement scholarships under subsection (c)(2) to students in kindergarten through grade 12—

(1) who are residents of the District of Columbia; and

(2) whose family income does not exceed 185 percent of the poverty line.

(b) SCHOLARSHIP PRIORITY.—

(1) FIRST.—The Corporation first shall award scholarships to students described in subsection (a) who—

(A) are enrolled in a District of Columbia public school or preparing to enter a District of Columbia public kindergarten, except that this subparagraph shall apply only for academic years 1997–1998, 1998–1999, and 1999–2000; or

(B) have received a scholarship from the Corporation for the academic year preceding the academic year for which the scholarship is awarded.

(2) SECOND.—If funds remain for a fiscal year for awarding scholarships after awarding scholarships under paragraph (1), the Corporation shall award scholarships to students who are described in subsection (a), not described in paragraph (1), and otherwise eligible for a scholarship under this title.

(3) LOTTERY SELECTION.—The Corporation shall award scholarships to students under this subsection using a lottery selection process whenever the amount made available to carry out this title for a fiscal year is insufficient to award a scholarship to each student who is eligible to receive a scholarship under this title for the fiscal year.

(c) USE OF SCHOLARSHIP.—

(1) TUITION SCHOLARSHIPS.—A tuition scholarship may be used for the payment of the cost of the tuition and mandatory fees for, and transportation to attend, an eligible institution located within the geographic boundaries of the District of Columbia; Montgomery County, Maryland; Prince Georges County, Maryland; Arlington County, Virginia; Alexandria City, Virginia; Falls Church City, Virginia; Fairfax City, Virginia; or Fairfax County, Virginia.

(2) ENHANCED ACHIEVEMENT SCHOLARSHIP.—An enhanced achievement scholarship may be used only for the payment of the costs of tuition and mandatory fees for, and transportation to attend, a program of instruction provided by an eligible institution which enhances student achievement of the core curriculum and is operated outside of regular school hours to supplement the regular school program.

(e) NOT SCHOOL AID.—A scholarship under this title shall be considered assistance to the student and shall not be considered assistance to an eligible institution.

SEC. ___05. SCHOLARSHIP AWARDS.

(a) AWARDS.—From the funds made available under this title, the Corporation shall award a scholarship to a student and make scholarship payments in accordance with section ___06.

(b) NOTIFICATION.—Each eligible institution that receives the proceeds of a scholarship payment under subsection (a) shall notify the Corporation not later than 10 days after—

(1) the date that a student receiving a scholarship under this title is enrolled, of the name, address, and grade level of such student;

(2) the date of the withdrawal or expulsion of any student receiving a scholarship under this title, of the withdrawal or expulsion; and

(3) the date that a student receiving a scholarship under this title is refused admission, of the reasons for such a refusal.

(c) TUITION SCHOLARSHIP.—

(1) EQUAL TO OR BELOW POVERTY LINE.—For a student whose family income is equal to or below the poverty line, a tuition scholarship may not exceed the lesser of—

(A) the cost of tuition and mandatory fees for, and transportation to attend, an eligible institution; or

(B) $3,200 for fiscal year 1998, with such amount adjusted in proportion to changes in the Consumer Price Index for all urban consumers published by the Department of Labor for each of fiscal years 1999 through 2002.

(2) ABOVE POVERTY LINE.—For a student whose family income is greater than the poverty line, but not more than 185 percent of the poverty line, a tuition scholarship may not exceed the lesser of—

(A) 75 percent of the cost of tuition and mandatory fees for, and transportation to attend, an eligible institution; or

(B) $2,400 for fiscal year 1998, with such amount adjusted in proportion to changes in the Consumer Price Index for all urban consumers published by the Department of Labor for each of fiscal years 1999 through 2002.

(d) ENHANCED ACHIEVEMENT SCHOLARSHIP.—An enhanced achievement scholarship may not exceed the lesser of—

(1) the costs of tuition and mandatory fees for, and transportation to attend, a program of instruction at an eligible institution; or

(2) $500 for 1998, with such amount adjusted in proportion to changes in the Consumer Price Index for all urban consumers published by the Department of Labor for each of fiscal years 1999 through 2002.

SEC. __06. SCHOLARSHIP PAYMENTS.

(a) PAYMENTS.—The Corporation shall make scholarship payments to the parent of a student awarded a scholarship under this title.

(b) DISTRIBUTION OF SCHOLARSHIP FUNDS.—Scholarship funds may be distributed by check, or another form of disbursement, issued by the Corporation and made payable directly to a parent of a student awarded a scholarship under this title. The parent may use the scholarship funds only for payment of tuition, mandatory fees, and transportation costs as described in this title.

(c) PRO RATA AMOUNTS FOR STUDENT WITHDRAWAL.—If a student receiving a scholarship under this title withdraws or is expelled from an eligible institution after the proceeds of a scholarship is paid to the eligible institution, then the eligible institution shall refund to the Corporation on a pro rata basis the proportion of any such proceeds received for the remaining days of the school year. Such refund shall occur not later than 30 days after the date of the withdrawal or expulsion of the student.

SEC. __07. CIVIL RIGHTS.

(a) IN GENERAL.—An eligible institution participating in the scholarship program under this title shall not discriminate on the basis of race, color, national origin, or sex in carrying out the provisions of this title.

(b) APPLICABILITY AND CONSTRUCTION WITH RESPECT TO DISCRIMINATION ON THE BASIS OF SEX.—

(1) APPLICABILITY.—With respect to discrimination on the basis of sex, subsection (a) shall not apply to an eligible institution that is controlled by a religious organization if the application of subsection (a) is inconsistent with the religious tenets of the eligible institution.

(2) CONSTRUCTION.—With respect to discrimination on the basis of sex, nothing in subsection (a) shall be construed to require any person, or public or private entity to provide or pay, or to prohibit any such person or entity from providing or paying, for any benefit or service, including the use of facilities, related to an abortion. Nothing in the preceding sentence shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.

(3) SINGLE-SEX SCHOOLS, CLASSES, OR ACTIVITIES.—With respect to discrimination on the basis of sex, nothing in subsection (a) shall be construed to prevent a parent from choosing, or an eligible institution from offering, a single-sex school, class, or activity.

(c) REVOCATION.—Notwithstanding section __03(f)(2)(D), if the Corporation determines that an eligible institution participating in the scholarship program under this title is in violation of subsection (a), then the Corporation shall revoke such eligible institution's certification to participate in the program.

SEC. __08. CHILDREN WITH DISABILITIES.

Nothing in this title shall affect the rights of students, or the obligations of the District of Columbia public schools, under the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

SEC. __09. RULE OF CONSTRUCTION.

(a) IN GENERAL.—Nothing in this title shall be construed to prevent any eligible institution which is operated by, supervised by, controlled by, or connected to, a religious organization from employing, admitting, or giving preference to, persons of the same religion to the extent determined by such institution to promote the religious purpose for which the eligible institution is established or maintained.

(b) SECTARIAN PURPOSES.—Nothing in this title shall be construed to prohibit the use of funds made available under this title for sectarian educational purposes, or to require an eligible institution to remove religious art, icons, scripture, or other symbols.

SEC. __10. REPORTING REQUIREMENTS.

(a) IN GENERAL.—An eligible institution participating in the scholarship program under this title shall report to the Corporation not later than July 30 of each year in a manner prescribed by the Corporation, the following data:

(1) Student achievement in the eligible institution's programs.

(2) Grade advancement for scholarship students.

(3) Disciplinary actions taken with respect to scholarship students.

(4) Graduation, college admission test scores, and college admission rates, if applicable for scholarship students.

(5) Types and amounts of parental involvement required for all families of scholarship students.

(6) Student attendance for scholarship and nonscholarship students.

(7) General information on curriculum, programs, facilities, credentials of personnel, and disciplinary rules at the eligible institution.

(8) Number of scholarship students enrolled.

(9) Such other information as may be required by the Corporation for program appraisal.

(b) CONFIDENTIALITY.—No personal identifiers may be used in such report, except that the Corporation may request such personal identifiers solely for the purpose of verification.

SEC. __11. PROGRAM APPRAISAL.

(a) STUDY.—Not later than 4 years after the date of enactment of this Act, the Comptroller General shall enter into a contract, with an evaluating agency that has demonstrated experience in conducting evaluations, for an independent evaluation of the scholarship program under this title, including—

(1) a comparison of test scores between scholarship students and District of Columbia public school students of similar backgrounds, taking into account the students' academic achievement at the time of the award of their scholarships and the students' family income level;

(2) a comparison of graduation rates between scholarship students and District of Columbia public school students of similar backgrounds, taking into account the students' academic achievement at the time of the award of their scholarships and the students' family income level;

(3) the satisfaction of parents of scholarship students with the scholarship program; and

(4) the impact of the scholarship program on the District of Columbia public schools, including changes in the public school enrollment, and any improvement in the academic performance of the public schools.

(b) PUBLIC REVIEW OF DATA.—All data gathered in the course of the study described in subsection (a) shall be made available to the public upon request except that no personal identifiers shall be made public.

(c) REPORT TO CONGRESS.—Not later than September 1 of each year, the Corporation shall submit a progress report on the scholarship program to the appropriate committees of Congress. Such report shall include a review of how scholarship funds were expended, including the initial academic achievement levels of students who have participated in the scholarship program.

(d) AUTHORIZATION.—There are authorized to be appropriated for the study described in subsection (a), $250,000, which shall remain available until expended.

SEC. __12. JUDICIAL REVIEW.

(a) JURISDICTION.—

(1) IN GENERAL.—The United States District Court for the District of Columbia shall have jurisdiction in any action challenging the constitutionality of the scholarship program under this title and shall provide expedited review.

(2) STANDING.—The parent of any student eligible to receive a scholarship under this title shall have standing in an action challenging the constitutionality of the scholarship program under this title.

(b) APPEAL TO SUPREME COURT.—Notwithstanding any other provision of law, any order of the United States District Court for the District of Columbia which is issued pursuant to an action brought under subsection (a) shall be reviewable by appeal directly to the Supreme Court of the United States.

SEC. __13. EFFECTIVE DATE.

This title shall be effective for each of the fiscal years 1998 through 2002.

On page 3, line 3, strike "$30,000,000" and insert "$23,000,000".

On page 3, line 4, before the period insert ": *Provided further*, That $7,000,000 of the funds made available under this heading shall be used to carry out the District of Columbia Student Opportunity Scholarship Act of 1997".

WYDEN (AND GRASSLEY) AMENDMENT NO. 1250

Mr. WYDEN (for himself and Mr. GRASSLEY) proposed an amendment to the bill, S. 1156, supra; as follows:

At the appropriate place, insert:

SEC. . ELIMINATING SECRET SENATE "HOLDS."

(a) STANDING ORDER.—It is a standing order of the Senate that a Senator who provides notice to leadership of his or her intention to object to proceeding to a motion or matter shall disclose the objection (hold) in the Congressional Record not later than 2 session days after the date of said notice.

NOTICES OF HEARINGS

COMMITTEE ON ENERGY AND NATURAL RESOURCES, SUBCOMMITTEE ON NATIONAL PARKS, HISTORIC PRESERVATION AND RECREATION

Mr. THOMAS. Mr. President, I would like to announce for the information of

the Senate and the public that a hearing has been scheduled before the Subcommittee on National Parks, Historic Preservation and Recreation of the Committee on Energy and Natural Resources.

The hearing will take place on Wednesday, October 1, 1997, a 2 p.m., in room SD-366 of the Dirksen Senate Office Building in Washington, DC.

The purpose of this hearing is to receive testimony on S. 940 to provide for a study of the establishment of Midway Atoll as a national memorial to the Battle of Midway; and H.R. 765 to ensure the maintenance of a herd of wild horses in Cape Lookout National Seashore.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send two copies of their testimony to the Subcommittee on National Parks, Historic Preservation and Recreation, Committee on Energy and Natural Resources, U.S. Senate, 364 Dirksen Senate Office Building, Washington, DC 20510-6150.

For further information, please contact Jim O'Toole of the subcommittee staff at (202) 224-5161.

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. MURKOWSKI. Mr. President, I would like to announce for the information of the Senate and the public that a full committee hearing has been scheduled before the Committee on Energy and Natural Resources.

The hearing will take place on Wednesday, October 8, 1997, at 9:30 a.m., in room SD-366 of the Dirksen Senate Office Building in Washington, DC.

The purpose of this hearing is to receive testimony on S. 1064 to amend the Alaska National Interest Lands Conservation Act to more effectively manage visitor service and fishing activity in Glacier Bay National Park and for other purposes.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send two copies of their testimony to the Committee on Energy and Natural Resources, U.S. Senate, 364 Dirksen Senate Office Building, Washington, DC 20510-6150.

For further information, please contact Jim O'Toole of the committee staff at (202) 224-5161.

COMMITTEE ON ENERGY AND NATURAL RESOURCES, SUBCOMMITTEE ON NATIONAL PARKS, HISTORIC PRESERVATION AND RECREATION

Mr. THOMAS. Mr. President, I would like to announce for the information of the Senate and the public that an oversight hearing has been scheduled before the Subcommittee on National Parks, Historic Preservation and Recreation of the Committee on Energy and Natural Resources.

The hearing will take place on Thursday, October 9, 1997, at 2 p.m., in room SD-366 of the Dirksen Senate Office Building in Washington, DC.

The purpose of this hearing is to receive testimony on the feasibility of using bonding techniques to finance large-scale capital projects in the National Park System.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send two copies of their testimony to the Subcommittee on National Parks, Historic Preservation and Recreation, Committee on Energy and Natural Resources, U.S. Senate, 364 Dirksen Senate Office Building, Washington, DC 20510-6150.

For further information, please contact Jim O'Toole of the subcommittee staff at (202) 224-5161.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON FINANCE

Mr. JEFFORDS. Mr. President, the Finance Committee requests unanimous consent to conduct a hearing on Wednesday, September 24, 1997, beginning at 9 a.m., in room 106 Dirksen.

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

COMMITTEE ON FOREIGN RELATIONS

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, September 24, 1997, at 10 a.m., to hold a hearing, and at 2:15 p.m., to hold a business meeting.

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

COMMITTEE ON GOVERNMENTAL AFFAIRS

Mr. JEFFORDS. Mr. President, I ask unanimous consent on behalf of the Governmental Affairs Committee Special Investigation to meet on Wednesday, September 24, at 10 a.m., for a hearing on campaign financing issues.

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

ADDITIONAL STATEMENTS

TRIBUTE TO LT. COL. THOMAS R. MILLER

• Mr. SANTORUM. Mr. President, I would like to take this opportunity to recognize an outstanding citizen from Allison Park, PA. On October 3, Lt. Col. Thomas Miller will retire from his position as the joint program office site director at the Software Engineering Institute [SEI] of Carnegie Mellon University.

Thomas was born in Valley View, PA. He earned an undergraduate degree in computer science from Utah State University. Later, Thomas received a M.S. degree in systems management from the Florida Institute of Technology.

In 1974, Thomas received his Air Force Commission from the Reserve Officer Training Corps. Since then, he has had an exemplary military career. Lieutenant Colonel Miller has served as a computer systems acquisition engineer at the Air Force Electronic Systems Division for the Joint Tactical Information Distribution System Joint Program Office; the computer systems acquisition manager for the seismic portion of the Atomic Energy Detection System; the software division chief at the Joint Surveillance Target Attack Radar Systems [JSTARS] Joint Program Office; and the chief of the Advanced Medium Range Air-to-Air Missile Systems Division at Eglin AFB.

Lieutenant Colonel Miller became the joint program office site director at the Software Engineering Institute in 1992. During his tenure at SEI, Lieutenant Colonel Miller earned the respect and admiration of his colleagues. A proven leader, Thomas will be sincerely missed.

Mr. President, after many years of service to his country, Lieutenant Colonel Miller is retiring to private life. In honor of his service, I ask my colleagues to join me in extending the Senate's best wishes to Lt. Col. Thomas Miller, his wife Colleen, and their three children.•

FRANK LLOYD WRIGHT BUILDING CONSERVANCY ANNUAL CONFERENCE

• Mr. MOYNIHAN. Mr. President, this past weekend I was invited to speak at the annual conference of the Frank Lloyd Wright Building Conservancy which took place in Buffalo, NY. I promised some of the attendees that I would enter my keynote address in the CONGRESSIONAL RECORD. I ask that the full text of my address be printed in the RECORD.

The text follows:

KEYNOTE ADDRESS BY SENATOR DANIEL PATRICK MOYNIHAN

Not long ago I happened to be in Phoenix and took the opportunity to visit Taliesin West, Frank Lloyd Wright's desert commune. I was most generously received and shown everywhere, including the atelier where the plans were being drawn for Wright's splendid Monona Terrace Community and Convention Center, just now completed in Milwaukee. At length, I was shown the splendid, terraced dining room where, in the manner of the Englishman in the jungle, all communards, faithful to the Master's edict, dress for dinner on Saturday night.

We are less formal here in Buffalo, but no less welcoming, and greatly honored to be at the site of this year's Frank Lloyd Wright Building Conservancy Annual Conference.

Each of us, I cannot doubt, has a personal story of an encounter with the spiritual and physical force of architecture. As Americans, we tend to begin in Europe, but with time, more and more we return to our own.

I have two tales to tell.

The first is simple enough. In 1992, I was asked to address the convention of the American Sociological Association then meeting in Pittsburgh. I arrived in a fine new hotel in the Golden Triangle expecting all manner of posters and pronouncements as had been the fashion of a few decades earlier. Instead, I was greeted by a large sign announcing the times of departure for the tour of Fallingwater. American sociologists are finally getting their priorities straight.

My second tale, more personal and specific to Buffalo, took place some twenty-one years ago. I was then in a five-way primary contest for the Democratic nomination for United States Senator. In the manner of such campaigns, most of one's time is spent in strategy sessions in hotel rooms. One August day, having spent the morning and afternoon at the Statler Hotel in a seemingly endless succession of these consultations, I announced I was going out for a walk. An economist would call it a random walk. I had no direction in mind, save any that would get me away from that hotel room.

And so I wandered westerly to Church Street and reached Pearl. Glancing south along Church Street, of a sudden I saw something that did not exist. Couldn't exist. Certainly something I for certain had not known to exist. A Sullivan skyscraper. The Guaranty Building. The beginning of an American architecture that would come to be known as the International Style. Sure enough, on the east side of the street there were three tall skyscrapers (an American term, incidentally, the topmost sail of a clippership, save when the moonraker is rigged). One was by an old friend, Minoru Yamasaki. Each was an exact copy, if you would just look at the essentials, of Sullivan's building across the street, built fifty or sixty years earlier. (On closer examination, there had been a fire of sorts, and the building was all but abandoned.)

I then and there resolved to win the Democratic primary, become a United States Senator and save the Sullivan building.

My first task was to get the City of Buffalo interested. One day the Mayor agreed to walk over with me from City Hall. He was a fine new Mayor; if he had any weakness, it was that he agreed with you on everything. I mean everything. Well, most things. "Mr. Mayor," I proclaimed, "if we can save that building, the time will come when people will get on airplanes and fly to Buffalo just to see it." "Bull," said His Honor.

May I say, it was a special pleasure to see in Thursday's Buffalo News a picture of Eugenio De Anzorena of Alexandria, Virginia, one of your conferees, making videotapes of the designs on the wall of the Guaranty Building. "Appreciating Architecture" was the caption, although I should have preferred, "The Mayor Refuted!"

No matter. The Buffalo "Evening News," as it then was, got the point. I began to learn the history of this great achievement of the Prairie School, the first American architecture, soon to be seen world-wide.

We begin in middle of the 19th Century, in the village of Stockton in nearby Chautauqua, County. It was in Stockton where one Hascal L. Taylor, a carriage maker, had grown up. Taylor would in time make a great deal of money in the oil fields of western Pennsylvania. His vision was to build a monument, the largest office building in the city, in downtown Buffalo. Taylor immediately sought the prestigious Chicago firm of Dankmar Adler and Louis Sullivan, who had of course built the Wainright Building in St. Louis four years earlier—in 1892.

Adler, the engineer, and Sullivan, the designer, had created a new form. A form based on function. Taylor got it. He, however, died in 1894. Fortunately the Guaranty Company bought the plans for the building and the site. Note the brevity of the subsequent succession: The Guaranty purchased the land and plans in December of 1894. The constructors began laying the foundation for the new building in February of 1895. By July of 1895, the steel frame was complete, and in March of 1896, barely a year after laying the foundation, the first occupants were moving in. Incredible.

Using his "organic" philosophy, Sullivan, had created a 'sister' work to St. Louis's Wainwright Building. The new, taller building, a 13 story, 140,000 square foot structure was called the nation's second skyscraper. An ornate masterpiece, embellished with a warm terra cotta exterior but forceful in its verticality, was the new "American skyscraper." Let me say, that I would rather see Mount Vernon torn down, or even the White House. They are fine buildings, but they are copies. Copies of European buildings, which in turn were copies of Greek and Roman buildings. The skyscraper is ours. Invented by this man of singular American genius, Louis Sullivan. In architecture, as in much else, we had followed the rest of the world. Then came Sullivan, and ever since the world has followed us. Indeed, the Guaranty is our treasure, and yet remarkably it has not always been appreciated as such.

By the 1940s the building had already changed owners. In the 1950s the owners were concerned about the accumulation of dirt on the facade. They chose an unfortunately destructive solution: they hired sandblasters to clean the terra cotta on the first two stories. Other "improvements" included adding suspended acoustical ceilings and tile flooring, thereby altering the perspectives of Sullivan's rooms and hiding some of the exquisite interior decorations.

Even though it was located downtown, its facilities became "outmoded" and its rental space was in very little demand. Even though it was listed on the National Register of Historic Places in 1973 and designated a national historic landmark in 1975, a fire in 1974 forced much of the building to close, and placed the building's future in jeopardy.

In June of 1977, Progressive Architecture, reported: "Discreet inquiries have been made by owners of Louis Sullivan's Prudential Building (formerly Guaranty) in Buffalo, NY about steps to demolish a historic landmark." Thus by 1977, architects were speaking of the building in terms of how best to demolish it. In April of 1977 the City threatened to destroy the building.

In September of 1977, the Greater Buffalo Development Foundation established a volunteer task force of business and community leaders to study the possible renovation of the building. After concluding that it should be done, they came up with new financial strategies that included tax exempt financing rates, partial property tax abatement, and private loans. The cost was estimated to be around $12.4 million.

I wrote to the Secretaries of Housing and Urban Development, Commerce, and Interior seeking funds for the building. In October of 1977, I convinced Vice President Mondale to tour the building whilst visiting here. (He needed no persuading, having the Owatonna Bank back home.) In November of 1978, we got our first grant, small but symbolic—$50,000 from The Department of Interior's Historic Preservation Program. And in April of 1981, we secured a $2.4 million Urban Development Action Grant (UDAG) from the US Department of Housing and Urban Development (HUD). In addition, as a site on the National Register of Historic Places, the building was qualified to receive a 25 percent tax credit on the entire investment under the Economic Recovery Tax Act of 1981.

After a majestic renovation by the architectural and engineering firm Canon, the building re-opened in December of 1983.

But there is a lesson to be learned here. Fortunately, throughout the process of renovating the Guaranty building there were those of us, spurred on by the Buffalo News, who began to recover the memory, if you will, of one of the greatest tragedies of architecture in this nation—the demolition of Frank Lloyd Wright's Larkin building. An examination of that misguided chain of events tells us a little more about the dangers of neglect, and introduces New York to the mind of Louis Sullivan's greatest pupil.

As all of you know, Sullivan was Frank Lloyd Wright's "Lieber meister". In his book largely on Sullivan, Genius and the Mobocrocy, Wright wrote of his early days with Sullivan:

"'Wright,' the young draughtsman nineteen, he would often say to me with undisguised contempt: 'Wright! I have no respect at all for a draughtsman!' . . . His haughty disregard had already offended most of the Adler and Sullivan employees. His contempt may have been due to the fact that he was so marvelous a draughtsman himself. But I knew what he really meant . . . He taught me nothing nor did he ever pretend to do so except as he was himself the thing he did and as I could see it for myself. He ('the designing partner') was the educational document in evidence."

Wright then clarified Sullivan's genius and its relationship to the 'mobocrocy':

"Do you realize, that here in his [Sullivan's] own way, is no body of culture evolving through centuries of time but a scheme and 'style' of plastic expression which an individual, working away in the poetry crushing environment of a more cruel materialism than any seen since the days of the brutal Roman, has made out of himself? Here was a sentient individual who evoked the goddess whole civilizations strove in vain for centuries to win, and wooed her with this charming interior style—all on his own in one lifetime all too brief . . . [Sullivan's] language of self expression was as complete in itself" as that "of any of the great style which time took so many ages to perfect."

Yet, I do not want to mislead. They had their disagreements.

By 1902, Wright had perfected some of his outside commissions in the form of the Prairie house. On September 11, 1902, Darwin Martin—Secretary of the successful Larkin Company of Buffalo—visited his brother William in Chicago. William was looking for a site for a new home, and as they toured Oak Park they became intrigued with Wright's designs there. William met with Wright a month later and wrote his brother that he was most favorably impressed. William wrote:

"He would be pleased to design your house - & further he is the man to build your office - he has had large experience in the large office buildings with Adler and Sullivan . . . he says it is strange that he is only known as a residence architect - when his best and largest experience was in large buildings."

Meryle Secrest in his biography of Wright, A House Divided, wrote that Wright saw the Larkin Project as his chance to "break into the world of large building commissions,"

but that he "shamelessly exaggerated the importance of his role at Adler and Sullivan." For Martin later told Larkin that: "the $500,000 Wainwright Building and the Union Trust Building and the Union Trust Building of St. Louis; the Schiller Theater and the Stock Exchange in Chicago; the Seattle and Pueblo Opera Houses, all Adler and Sullivan's work, were, I inferred from Mr. Wright, largely his creations.'"

The Larkin Company of Buffalo commissioned him (at Mr. Darwin Martin's recommendation) to design its administrative building across from the soap factory and warehouse. For Wright, it was an opportunity to develop complex spatial ideas. His exterior was an expression of almost pure geometric form, with no ornamentation save for two piers topped by sculptures supporting globes to symbolize the company's international aspirations. Wright intended the reductive form to be a "genuine and constructive affirmation of the new Order of the Machine Age."

The Larkin Building was not at first widely praised in architectural circles. It began to exert a great deal of influence on European architects with the publication of Wright's work by Ernst Wasmuth in Berlin in 1910. By the mid-1920s the European appreciation of the Larkin Building had crossed the Atlantic. The building gained prominence in American surveys of modern architecture and does so to this day.

Yet, the proliferation of chain stores in small towns began to cut into the Larkin Company's mail order business. The Depression caused further problems. Assets were liquidated to pay creditors. By 1943 the Larkin Company had no assets other than the building, on which it owed $85,000 in back taxes.

In August, 1949 the Western Trading Corporation offered the Common Council $5,000 and promised to raze the Larkin Building and replace it with something that would improve the tax base. Two months later Mayor Dowd accepted the offer. The building was demolished to make way for a truck terminal, but Western Trading then petitioned to move the terminal to a larger lot. A vacant lot exists on the site today.

So too in downtown Chicago, one of Sullivan's first buildings was replaced by a multistory parking garage. Wright had warned of the "poetry crushing environment of a more cruel materialism" and both his and Sullivan's works were victims of this environment. The burden falls on men and women like you to remind us all of the value of these works.

It was just such a reminder that opened my eyes to the wonder, and neglect of the Darwin Martin House. It was Saint Patrick's Day, 1991, and Jason Aronoff, the head of the Landmark Society of the Niagara Frontier's Martin House Task Force had asked me to look into the condition of the Darwin Martin House. I was not prepared.

We first visited the splendidly maintained Heath House with its gracious young family. We then went across to see the Darwin Martin House, which was quite simply a ruin. The concrete was running away like sand. Two of the great ornamental urns were missing from the front step and were only later found discarded in the yard. On the front door and side windows thereof there was a printed sign which read:

NOTICE

"New York State's Current fiscal condition has caused the closing of the Darwin D. Martin House to the public until further notice. Queries about future opening date and restoration plans for the House should be Mailed to . . ."

I immediately wrote to the Buffalo News in an effort to alert all to the horrid state of this wonderful House. What had become of this masterpiece? Who was to blame? How can we avoid such a tragedy in the future?

In the Martin House, Wright showed what he could do with what became an almost unlimited budget. Construction on the Martin House began in early 1904 and ended in 1906 with 20 rooms and 11,000 square feet, at a cost of $160,000.

Because of, perhaps in spite of, their numerous dialogues over the plans for and the cost of the house, Martin and Wright became fast friends. Martin helped Wright get many other commissions through the years. Late in life Martin offered Wright one last commission, a monument for the family plot in the Forest Lawn Cemetery. Martin wanted a design to cover only the space for one grave. Typically, Wright produced a much larger design with a flight of marble steps climbing the slope of the lot to a single headstone bearing the family names. The stock market crash prevented the commission from being realized. On learning of Martin's death in 1935, Wright referred to him as "My best friend."

After Darwin Martin died the house stood vacant for the next 17 years. There is no clear explanation for his son's lack of appreciation for the house, no clear answer to why Darwin Jr. began to strip the house of its doors, lighting, wiring, moldings, heating, and plumbing systems and installing them in other buildings he owned. When he finally vacated the house, he left the doors unlocked. Neighborhood children would come in for roller skating, or to smash some windows or some of the remaining mosaic tiles over the fireplace. Eventually part of the roof fell in from the weight of snow.

In 1946 the City was the sole bidder on the Martin House at the foreclosure sale. In 1954 Buffalo architect Sebastian Tauriello bought the house, the pergola, the conservatory, and the garage for $22,000. He wrote to Wright for the original plans and received the following reply: "Dear Tauriello: Hope you treat the opus according to its merits. When we return to Wisconsin May first I will look up the plans and send you a set of prints with a bill for the prints. Frank Lloyd Wright."

Fearing an exorbitant fee, Tauriello proceeded without them. The doors, heating, and plumbing systems were replaced by August and the Tauriello's moved in. Part of his plan for financing the restoration of the house was the sale of a portion of the property. The pergola, conservatory, and garage were in varying stages of decay. They were demolished and the apartments you see today were built to Mr. Tauriello's design.

Mr. Tauriello was not wealthy, and was not in a position to restore the house to its 1908 condition. He also wanted to add modern conveniences and some individual touches. As he did not need a 20 room house and did need restoration funds, he created two five-room apartments inside. But regardless of the changes he made, he saved the house. Tauriello died in 1965. The next year his wife sold the house to SUNY Buffalo at the request of new president Martin Meyerson, a Wright aficionado. He left Buffalo in 1970. Several university offices were located in the house until 1980, when it again stood unused, as it was on the day of our visit in 1991.

There was a restoration plan in place, but next to no money. I went to ROBERT C. BYRD, chairman of the subcommittee that funds Federal historic preservation programs, and asked for his help. While there was no program that provides specific funds to restore specific buildings, he saw to it that the Darwin Martin House got $500,000 that year. In 1995 we were able to reprogram another $500,000, this time in funds from the Department of Housing and Urban Development, for the house. Last spring, at the urging of Stan Lipsey, I asked Senator GORTON of Washington State for another $500,000 in historic preservation funds, and the Senate bill, HR 2107, which we passed on Thursday night, includes that amount.

I should warn you not to look at these appropriations and think any deserving preservation project, even a Wright house, can count on Federal funds. None can. The $40 million we provide each year for preservation goes directly to the State Preservation offices. There is no "Save This Building" account. Is there support for one? I quote the Senate bill we just passed: "This will be the final year of appropriations to the National Trust for Historic Preservation." That is a battle for next year, but we have all we can do to keep what programs we have.

Thus on a couple of last notes, I hope you have had a chance to visit Kleinhans Music Hall, another of Buffalo's wonders. It is one of the great later works of Eliel Saarinen. It is also one of the first commissions on which son Eero worked side by side with him. The building's sense of balance is representative of, in Eliel's words, the structure's "masculine" and "feminine" traits as exhibited by "strongly indicative line" in the former and a "playful pattern of wall space" in the latter. But function was certainly important to the Saarinens; Kleinhans is a splendid hall in which to hear a concert. It is also one of but three examples of Eliel's work in the East.

In 1984 I secured a tax provision—a "sale-leaseback" provision, that could have been worth millions to the upkeep and restoration of Kleinhans. But one of the investors backed out at the last minute before the legal deadline and the deal fell through. A decade later the need for restoration funds had not diminished. I got $1.5 million for the effort in 1994.

Then, of course, there are the buildings by H. H. Richardson. Wright disclosed that Sullivan had a respect for Richardson, that he (Richardson) had for few others. Again from, Genius and the Mobocrocy: "Later I [Wright] discovered his [Sullivan's] secret respect, leaning toward envy (I am ashamed to suspect), for H.H. Richardson."

Eight of the original eleven buildings designed for the Buffalo State Hospital stand today. The most splendid being the twin towered centerpiece buildings. In 1990, the state spent $4.5 million to restore one of the seven remaining patient pavilions. However, these buildings were vacated in 1993 and 1995. Ominously, the state has designated the buildings "surplus property" and is looking to sell them on the open market. Thus our battle continues.

We restored the Guaranty—the soul of this city. We are on our way to restoring Darwin Martin—the treasure of scale, of form and of relationship of interior to exterior. Kleinhans Music Hall and the Roycroft Inn are also to be included in a tablet of success. However, Federal support is waning. As you state in the opening of the conference, Wright wrote that the "Prairie begins west of Buffalo." We must do our best to see that our treasures do not become dust on the prairie. It happened to the Larkin building. It may yet happen to those of Richardson. So again I say the burden is unduly forced on

men and women like you to remind us of the symphony that continues to play around us, like this great symphonic interplay we have here in Buffalo.•

NATIONAL UNDERGROUND RAILROAD NETWORK TO FREEDOM ACT, S. 887

• Mr. D'AMATO. Mr. President, I rise today to urge my colleagues to join me in cosponsoring legislation that will commemorate the physical as well as spiritual triumph over one of our Nation's most tragic legacies. This legislation is designed to help the National Park Service present a dramatic chapter in American history; the perseverance of the quest for liberty that saw hundreds of thousands risk their lives so that they might live free. The National Underground Railroad Network to Freedom Act, S. 887, will give, for the first time, Federal recognition and acknowledgment to this avenue of hope for those who sought freedom from tyranny and oppression.

The Underground Railroad was a loosely organized system of escape routes for hundreds of thousands of enslaved African-Americans. Average men and women, who shared a love of freedom and a hatred of the institution of slavery, committed themselves to help free a people by offering food, shelter, clothing, money, or whatever would assist passengers along the Underground Railroad. Typically, a stop along the Underground Railroad would be a farmhouse or a church where passengers would be hidden in the attic or the basement, or behind false walls or even under floorboards. A person on the railroad would be concealed until it was determined that it was safe to travel to the next site. This scenario was repeated over and over again until the passenger reached safety in the North or in Canada, Mexico, or the Caribbean.

Although largely clandestine, the Underground Railroad is a tangible example of the extent that resistance to slavery existed during the 18th and 19th centuries. Indeed, some 380 sites—28 of which are in New York—have been documented in a National Park Service study as sites potentially significant to the Underground Railroad movement. It is likely that there are more sites about which we will never know. Of the sites that do exist, it is important to highlight their role in abetting the elimination of the shameful practice of slavery.

It is important to our national heritage that we recognize and remember the bravery of those who risked their lives to make the journey along the Underground Railroad and those who provided sanctuary to them. This legislation will help raise awareness about these locations along the Underground Railroad, enhancing the chances that the sites will be maintained or restored. We must recognize and preserve these historic sites, which represent the extraordinary efforts, perils, sacrifices, and triumphs of those who risked their lives so that they might taste freedom. I urge my colleagues to join me in cosponsoring this important measure.•

TRIBUTE TO ENTREPRENEUR WALLY AMOS

• Mr. CLELAND. Mr. President, I come to the floor today to pay tribute to my good friend Wally Amos. "Famous Amos" known to many Americans as the founder of Famous Amos Cookies and the father of the gourmet chocolate chip cookie industry, is an example to all of us. He is an example because of his dedication to our country as a veteran of the U.S. Air Force, and for what he has accomplished as an entrepreneur and businessman. He is a citizen of this country who has reaped great success but has not neglected his responsibilities to the community. And even more than that, Mr. President, Wally Amos brings a powerful and inspirational message to people in all walks of life.

I have said over and over that I believe that small businesses and entrepreneurship are the foundation of the economic engine of this country. Wally Amos has for some time now written a monthly column subtitled "Grow Your Business," and I would like to take just a few moments to highlight several principals that he has offered as a result of good and bad experiences he has lived though: First, effort doesn't always equal results. You grow a business by assessing your personal strengths and contributing them to the efforts of the team. Second, some of the greatest personal growth comes as a result of some of the most challenging experiences. What you give attention to grows. Rather than give attention to what you don't have, focus on what you do have. Third, fear creates anger, resentment, anxiety, frustration, and worry, none of which will help you succeed in business. Fourth, be passionate about your business. Demonstrate that you care for your employees and business associates. People are your most important asset. Fifth, your employees have a vested interest in your success. Sixth, dogmatic behavior and stubbornness have not created long-term success. The quickest way to failure is to believe that your way is the only way.

Mr. President, in every job Wally Amos has had, he always started at the bottom and worked his way to the top. I hope that others will look to the example of citizenship and entrepreneurship of Wally Amos and be inspired as I am.•

ST. MONICA CATHOLIC CHURCH

• Mr. BOND. Mr. President, today I stand before you to pay tribute to the Saint Monica Catholic Church in Creve Coeur, Missouri. On Sunday, September 28, 1997, the St. Monica Catholic Church will celebrate its 125th anniversary with Archbishop Justin Rigali.

Among the several outstanding aspects of St. Monica Catholic Church is a school which has contributed to the community in service and education. The St. Monica Parish Family is the center of the Creve Coeur community and has always prided themselves in their family oriented approach in faith.

I commend the St. Monica Catholic Church staff and members for their spirit and energy throughout their many years of existence and hope they continue to enrich the Creve Coeur community for years to come.•

TRIBUTE TO SUSAN M. WOODWARD, OUTSTANDING TEACHER

• Mr. SMITH of New Hampshire. Mr. President, I rise today to honor Susan M. Woodward, the New Hampshire winner of the Sallie Mae First Class Teacher's Award, which recognizes the Nation's outstanding elementary and secondary school teachers in their first year of teaching. Susan was selected for her outstanding dedication to teaching and her love for her students in her first year at Mastricola Middle School in Merrimack, NH.

Ms. Woodward received her bachelor of arts degree from Rivier College in Nashua, NH, in 1995. She graduated summa cum laude and was valedictorian of her class. Ms. Woodward joined the staff of the Merrimack School District as a substitute, and is currently employed as a full-time French teacher at Mastricola Middle School.

Dedicated, creative, hard-working and inspirational are all words which describe Ms. Woodward. A perfectionist by nature, Susan uses a variety of instructional techniques, auditory and visual, so her students are always active participants in their learning. She makes her classes fun, employing a marvelous sense of humor, fairness and compassion. Ms. Woodward believes every student has potential, every student is special, and makes every effort to be available for her students.

Active inside and outside the classroom, Ms. Woodward is a good role model for her students. Whether staying after school helping her students or dancing at a school dance, Ms. Woodward is always available for advice and support.

The mark of a great teacher is one who cares, unconditionally, about the success and well-being of students. Mr. President, as a former teacher myself, I understand the challenges, responsibilities and dedication involved with teaching. I admire and respect Ms.

Woodward for establishing herself as an irreplaceable teacher in the school district of Merrimack. Most importantly, she is helping to shape the lives of the young students who are the future of New Hampshire and the country. I am very honored to have Ms. Woodward as a teacher in the Granite State. The Sallie Mae Award has indeed gone to a first-class teacher.●

REMOVAL OF INJUNCTION OF SECRECY—TREATY DOCUMENT NO. 105–31

Mr. FAIRCLOTH. As in executive session, I ask unanimous consent that the Injunction of Secrecy be removed from the following treaty transmitted to the Senate on September 4 by the President of the United States:

Tax Convention with Ireland (Treaty Document No. 105–31.)

I further ask that the treaty be considered as having been read the first time, that it be referred with accompanying papers to the Committee on Foreign Relations and ordered to be printed and that the President's message be printed in the RECORD.

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

The message of the President is as follows:

To the Senate of the United States:

I transmit herewith for Senate advice and consent to ratification the Convention Between the Government of the United States of America and the Government of Ireland for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital Gains, signed at Dublin on July 28, 1997, (the "Convention") together with a Protocol and an exchange of notes done on the same date. Also transmitted is the report of the Department of State concerning the Convention.

This Convention, which is similar to tax treaties between the United States and other OECD nations, provides maximum rates of tax to be applied to various types of income and protection from double taxation of income. The Convention also provides for resolution of disputes and sets forth rules making its benefits unavailable to residents that are engaged in treaty shopping.

I recommend that the Senate give early and favorable consideration to this Convention, with its Protocol and exchange of notes, and that the Senate give its advice and consent to ratification.

WILLIAM J. CLINTON.

THE WHITE HOUSE, *September 24, 1997.*

THE CALENDAR

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the Senate now proceed to the consideration of the following bills en bloc: Calendar No. 147, S. 542; Calendar No. 148, S. 662; and Calendar No. 149, S. 880.

Mr. President, I further ask unanimous consent that any committee amendment be considered as agreed to, the bills be considered read a third time and passed, the motions to reconsider be laid upon the table, and that any statement relating to the bills be printed at the appropriate point in the RECORD and that the proceedings all occur en bloc.

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

CERTIFICATE OF DOCUMENTATION FOR THE VESSEL "FAR HORIZONS"

The Senate proceeded to consider the bill (S. 542) to authorize the Secretary of Transportation to issue a certificate of documentation with appropriate endorsement for employment in the coastwise trade for the vessel *Far Horizons*.

The bill was considered, ordered to be engrossed for a third reading, read the third time, and passed; as follows:

S. 542

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CERTIFICATE OF DOCUMENTATION.

Notwithstanding section 27 of the Merchant Marine Act, 1920 (46 U.S.C. App. 883), section 8 of the Act of June 19, 1886 (24 Stat. 81, chapter 421; 46 U.S.C. App. 289), and sections 12106 through 12108 of title 46, United States Code, the Secretary of Transportation may issue a certificate of documentation with appropriate endorsement for employment in the coastwise trade for the vessel FAR HORIZONS, United States official number 1044011.

CERTIFICATE OF DOCUMENTATION FOR THE VESSEL "VORTICE"

The Senate proceeded to consider the bill (S. 662) to authorize the Secretary of Transportation issue a certificate of documentation with appropriate endorsement for employment in the coastwise trade for the vessel *Vortice*, which had been reported from the Committee on Commerce, Science, and Transportation, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

S. 662

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That notwithstanding sections 12106 and 12108 of title 46, United States Code, section 8 of the Act of June 19, 1886 (46 U.S.C. App. 289), and section 27 of the Merchant Marine Act, 1920 (46 U.S.C. App. 883), the Secretary of Transportation may issue a certificate of documentation with appropriate endorsement for employment in the coastwise trade for the vessel VORTICE (Bari, Italy, registration number 256), if the vessel meets the ownership requirements of section 2 of the Shipping Act, 1916 (46 U.S.C. App. 802).

The bill (S. 662), as amended, was passed.

CERTIFICATE OF DOCUMENTATION FOR THE VESSEL "DUSKEN IV"

The Senate proceeded to consider the bill (S. 880) to authorize the Secretary of Transportation to issue a certificate of documentation with appropriate endorsement for employment in the coastwise trade for the vessel *Dusken IV*, which had been reported from the Committee on Commerce, Science, and Transportation, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

S. 880

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That notwithstanding sections 12106 and 12108 of title 46, United States Code, section 8 of the Act of June 19, 1886 (24 Stat. 81, chapter 421; 46 U.S.C. App. 289), and section 27 of the Merchant Marine Act, 1920 (46 U.S.C. App. 883), the Secretary of Transportation may issue a certificate of documentation with appropriate endorsement for employment in the coastwise trade for the vessel DUSKEN IV (United States official number 952645).

The bill (S. 880), as amended, was passed.

COMMENDING OF DR. JASON C. HU

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of S. Res. 125 submitted earlier today by Senator MURKOWSKI.

The PRESIDING OFFICER. The clerk will report the resolution by title.

The bill clerk read as follows:

A resolution (S. Res. 125) commending Dr. Jason C. Hu, Representative of the Taipei Economic and Cultural Representative Office in the United States.

The PRESIDING OFFICER. Is there objection to the immediate consideration of the resolution?

There being no objection, the Senate proceeded to consider the resolution.

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motion to reconsider be laid upon the table, and that any statement relating to the resolution appear at this point in the RECORD.

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

The resolution was agreed to.

The preamble was agreed to.

The resolution (S. Res. 125), with its preamble, read as follows:

S. RES. 125

Whereas Dr. Jason C. Hu has served with distinction as Representative of the Taipei Economic and Cultural Representative Office (TECRO) since June 1996, and has ably represented the interests of the Republic of China on Taiwan;

Whereas Dr. Hu has been a firm and consistent advocate of democratic principles throughout his distinguished career;

Whereas Dr. Hu has established many deep friendships with Members of Congress and other Americans during his tenure in Washington; and

Whereas Dr. Hu has been asked to return to Taiwan to serve as the Minister of Foreign Affairs of the Republic of China: Now, therefore, be it

Resolved by the Senate, That the Senate hereby—

(1) commends Dr. Jason C. Hu for his service as Representative of the TECRO office; and

(2) expresses to Dr. Hu and his family its best wishes for his continued success in the future.

EXECUTIVE SESSION

EXECUTIVE CALENDAR

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the Senate immediately proceed to executive session to consider the following nominations on the Executive Calendar: No. 246 and No. 258.

I further ask unanimous consent that the nominations be confirmed, the motions to reconsider be laid upon the table, any statements relating to the nominations appear at this point in the RECORD, the President be immediately notified of the Senate's action, and the Senate then return to legislative session.

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

The nominations considered and confirmed en bloc are as follows:

FEDERAL TRADE COMMISSION

Sheila Foster Anthony, of Arkansas, to be a Federal Trade Commissioner for the term of seven years from September 26, 1995.

AIR FORCE

The following named officer for appointment in the United States Air Force to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601 and to be appointed as Chief of Staff, United States Air Force under the provisions of title 10, U.S.C., section 8033:

To be general

Gen. Michael E. Ryan, 9889.

STATEMENT ON THE NOMINATION OF MS. SHEILA ANTHONY TO BE FEDERAL TRADE COMMISSIONER

Mr. HOLLINGS. Mr. President, as the ranking Democratic member of the Senate Commerce Committee, I am proud to support the nomination of Ms. Sheila F. Anthony to serve as a Commissioner of the Federal Trade Commission [FTC]. The FTC is now functioning with only four Commissioners. Because of the Commission's myriad of responsibilities, it is imperative the agency operates with maximum participation of its designated Commissioners to ensure its efficiency.

The primary duties of the Federal Trade Commission are: First, to protect consumers from unfair and deceptive practices, and second to ensure the operation of an efficient and competitive market-place. As part of its administrative responsibilities, the Commission administers a number of Federal statutes, including the Federal Trade Commission Act, which provides the Commission its consumer protection authority, and the Sherman, Clayton & Robinson-Patman antitrust statutes, as well as the Fair Credit Reporting, Fair Debt Collection Practices, and Truth in Lending Acts. A few of the Commission's specific duties include safeguarding the public from false advertisement of goods and services, telemarketing fraud, unfair pricing of products, unfair mergers and acquisitions, illegal boycotts, and other unfair methods of competition.

Ms. Anthony's record reveals she is well qualified to serve as a Commissioner on the FTC. Her past experience includes serving as an Assistant Attorney General with the U.S. Department of Justice, as well as working as a private practice attorney on matters such as copyright, trademark, and antitrust.

Ms. Anthony has stated she is ready to take on the many present challenges of the FTC. I look forward to working with her and urge my colleagues to support her nomination.

LEGISLATIVE SESSION

The PRESIDING OFFICER. Under the previous order, the Senate will return to legislative session.

AUTHORIZING THE PRESIDENT TO AWARD A GOLD MEDAL

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 2248 which was received from the House.

The PRESIDING OFFICER. The clerk will report the bill by title.

The bill clerk read as follows:

A bill (H.R. 2248) to authorize the President to award a gold medal on behalf of the Congress to Ecumenical Patriarch Bartholomew in recognition of his outstanding and enduring contributions toward religious understanding and peace, and for other purposes.

The PRESIDING OFFICER. Is there objection to the immediate consideration of the bill?

There being no objection, the Senate proceeded to consider the bill.

Mr. D'AMATO. Mr. President, I rise today to urge my colleagues to support swift passage of H.R. 2248. This bill is identical to the bill that I introduced along with Senator SARBANES as original cosponsor. Both bills authorize the presentation of the Congressional Gold Medal to His All Holiness, the Ecumenical Patriarch Bartholomew, leader of the Orthodox Christian Church.

It is fitting that we recognize the tremendous leadership this religious figure provides to nearly 300 million people worldwide during his upcoming visit to our country.

While many consider countries such as Russia and Greece to be Orthodox Christian strongholds, the fact is that nearly 5 million United States citizens of Greek, Russian, Ukrainian, and Serbian descent are Orthodox Christians. The contributions of these Americans to our rich history and culture exemplify the values, ideals, and dreams of this great Nation.

The Patriarch Bartholomew has followed a calling in his life—to selflessly serve not only people of Greek origin, but millions of believers from all over the world, through his strong faith.

Patriarch Bartholomew was enthroned as the 270th spiritual leader of the Orthodox Christians in 1991. This new title came with enormous responsibilities and burdens. But, the Patriarch Bartholomew was prepared to meet the task. Not only has he fulfilled the demanding role as preeminent leader of Orthodox Christians, he has dedicated himself and used his station to promote worthy, noble causes.

Mr. President, in the name of religious unity and cooperation, Patriarch Bartholomew is working to promote interfaith dialog between the Orthodox Church, and the Roman Catholic Church, leading Protestant denominations, Muslim leaders, and various other faiths.

He has also sought to strengthen the bonds between Judaism and Orthodox Christianity. In 1994, the Patriarch worked side by side with Rabbi David Schneier and the Appeal of Conscience Foundation to cosponsor the Peace and Tolerance Conference, bringing together Christians, Jews, and Muslims for human and religious freedom.

And Patriarch Bartholomew's compassion is far-reaching. In the war-torn countries of the Balkans, he has helped to advance reconciliation among Catholic, Muslim, and Orthodox communities.

As a citizen of Turkey, Patriarch Bartholomew is deeply concerned about the need to sustain the cause of peace. He has been a dynamic leader in efforts to ease Greek-Turkish tensions and to promote international cooperation, adherence to international law, and respect for human rights of victims of aggression.

Mr. President, Patriarch Bartholomew, also referred to as the "Green Patriarch" has a sincere commitment to the environmental legacy we will one day leave to our children. Together with global leaders, he convened an international environmental symposium emphasizing the health and well-being of the world's oceans. The Patriarch is also a cosponsor of an annual conference addressing the protection of our global environment.

Mr. President, in October of this year, Patriarch Bartholomew will visit the United States to offer his spiritual message of unity, compassion, and brotherhood. It is my belief that Congress should honor the work of this great leader in recognition of his outstanding and enduring contributions to religious freedom, tolerance, world

peace, environmental protection, and human rights.

In closing, Mr. President, I call upon my colleagues to support bestowing the Congressional Gold Medal upon a visionary for our times, Ecumenical Patriarch Bartholomew. I would also like to take the opportunity to extend thanks to my 48 colleagues in the Senate who have lent their bipartisan support to this effort.

Mr. SARBANES. Mr. President, I am pleased to join Senator D'AMATO, chairman of the Senate Committee on Banking, Housing, and Urban Affairs, in urging immediate passage of H.R. 2248.

Patriarch Bartholomew will be visiting the United States from October 19 through November 17, 1997. This bill awards the Congressional Gold Medal to Ecumenical Patriarch Bartholomew, the spiritual leader of approximately 300 million Orthodox Christians worldwide. The occasion of this legislation is to recognize Patriarch Bartholomew's outstanding contributions to world peace and understanding during his tenure as head of this ancient branch of Christianity and to honor Patriarch Bartholomew's first visit to the United States as Patriarch. As a Greek-Orthodox American and member of the Greek Orthodox Cathedral of the Annunciation in Baltimore, I am particularly gratified to join in this tribute.

During his American visit Patriarch Bartholomew will meet with thousands of Orthodox faithful and will take the opportunity to convey his message of reconciliation to Americans of all backgrounds and beliefs. His All Holiness has been a leader in ecumenical understanding and has convened important meetings which have brought together participants of all religious backgrounds. In 1994, in cooperation with Rabbi David Schneier and the Appeal of Conscience Foundation, he cosponsored a Peace and Tolerance Conference in Istanbul where Christians, Jews, and Muslims joined together to discuss important and pressing issues.

As spiritual head of world Orthodoxy, Patriarch Bartholomew has been a leader in the quest for peace throughout the world, particularly in Eastern Europe, the Balkans, and the Middle East. He has vigorously spoken out against extremists and those who would use violence to achieve their ends and has counseled respect for all peoples, irrespective of their nationality and religion; his ministry has been a call to our best virtues.

From his historical seat in Istanbul, Turkey, Patriarch Bartholomew has served as a mediator between East and West, Christians and Muslims, and as a force for openness and tolerance in the newly emerging independent countries of Eastern Europe.

As he pursues the goal of peace, Patriarch Bartholomew is equally vigorous in his desire to preserve and promote the Earth's environment as a reflection of God's creation. Working with the European Commission, the Worldwide Fund for Nature, and his Royal Highness Prince Philip, he has cosponsored significant international conferences on the environment, including one scheduled for this month on the future ecological health of the Black Sea.

I believe it is most fitting that the visit and the accomplishments of Patriarch Bartholomew should be recognized and honored by this Gold Medal as it will reflect the appreciation of the American people for his ministry of peace and reconciliation.

Mr. FAIRCLOTH. I ask unanimous consent that the bill be considered read a third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed at the appropriate place in the RECORD.

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

The bill (H.R. 2248) was passed.

FEDERAL BUREAU OF INVESTIGATION, WASHINGTON FIELD OFFICE MEMORIAL BUILDING

Mr. FAIRCLOTH. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 2443, which was reported by the Environment and Public Works Committee today.

The PRESIDING OFFICER. The clerk will report.

The bill clerk read as follows:

A bill (H.R. 2443) to designate the Federal building located at 601 Fourth Street, N.W., in the District of Columbia, as the "Federal Bureau of Investigation, Washington Field Office Memorial Building", in honor of William H. Christian, Jr., Martha Dixon Martinez, Michael J. Miller, Anthony Palmisano, and Edwin R. Woodriffe.

The Senate proceeded to consider the bill.

Mr. FAIRCLOTH. I ask unanimous consent the bill be considered read a third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed at the appropriate place in the RECORD.

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

The bill (H.R. 2443) was considered read the third time, and passed.

ORDERS FOR THURSDAY, SEPTEMBER 25, 1997

Mr. FAIRCLOTH. Mr. President, on behalf of the leader, I ask unanimous consent that when the Senate completes its business today, it stand in adjournment until the hour of 12 noon on Thursday, September 25. I further ask that on Thursday, immediately following the prayer, the routine requests through the morning hour be granted and the Senate immediately resume consideration of S. 1156, the District of Columbia appropriations bill.

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

PROGRAM

Mr. FAIRCLOTH. Mr. President, tomorrow the Senate will resume consideration of S. 1156, the District of Columbia appropriations bill. Under the previous order, the Senate will debate the Coats amendment, No. 1249, regarding school vouchers, from 12 noon until 5 p.m.

As a reminder, a cloture motion was filed this evening on the Coats amendment with the cloture vote scheduled to occur Tuesday, September 30, at 11 a.m., with the mandatory quorum under rule XXII being waived. Following the debate tomorrow on the Coats amendment, the Senate will continue debating amendments to the D.C. appropriations bill. As Members are aware, this is the last of the 13 appropriations bills the Senate will consider. Therefore, all Members' cooperation is appreciated in notifying the managers of the legislation of their intent to offer amendments so we can have timely consideration of this legislation. In addition, the Senate may consider any other legislative or executive business that can be cleared for action.

ADJOURNMENT

Mr. FAIRCLOTH. Mr. President, I now ask unanimous consent that the Senate stand in adjournment under the previous order.

There being no objection, the Senate, at 7:10 p.m, adjourned until Thursday, September 25, 1997 at 12 noon.

NOMINATIONS

Executive nominations received by the Senate September 24, 1997:

THE JUDICIARY

ARTHUR J. TARNOW, OF MICHIGAN, TO BE U.S. DISTRICT JUDGE FOR THE EASTERN DISTRICT OF MICHIGAN, VICE JULIAN A. COOK, JR., RETIRED.

GEORGE CARAM STEEH III, OF MICHIGAN, TO BE U.S. DISTRICT JUDGE FOR THE EASTERN DISTRICT OF MICHIGAN, VICE BARBARA K. HACKETT, RETIRED.

DEPARTMENT OF STATE

SHAUN EDWARD DONNELLY, OF INDIANA, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF MINISTER-COUNSELOR, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA, AND TO SERVE CONCURRENTLY AND WITHOUT ADDITIONAL COMPENSATION AS AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE REPUBLIC OF MALDIVES.

EDWARD S. WALKER, JR., OF MARYLAND, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF CAREER MINISTER, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO ISRAEL.

CONFIRMATIONS

Executive nominations confirmed by the Senate September 24, 1997:

FEDERAL TRADE COMMISSION

SHEILA FOSTER ANTHONY, OF ARKANSAS, TO BE A FEDERAL TRADE COMMISSIONER FOR THE TERM OF 7 YEARS FROM SEPTEMBER 26, 1995.

THE ABOVE NOMINATION WAS APPROVED SUBJECT TO THE NOMINEE'S COMMITMENT TO RESPOND TO REQUESTS TO APPEAR AND TESTIFY BEFORE ANY DULY CONSTITUTED COMMITTEE OF THE SENATE.

IN THE AIR FORCE

THE FOLLOWING-NAMED OFFICER FOR APPOINTMENT IN THE U.S. AIR FORCE TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, UNITED STATES CODE, SECTION 601, AND TO BE APPOINTED AS CHIEF OF STAFF, U.S. AIR FORCE, UNDER THE PROVISIONS OF TITLE 10, UNITED STATES CODE, SECTION 8033:

To be general

GEN. MICHAEL E. RYAN, 9689