



United States
of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE *105th* CONGRESS, FIRST SESSION

Vol. 143

WASHINGTON, SUNDAY, NOVEMBER 9, 1997

No. 157

House of Representatives

The House met at 2 p.m. and was called to order by the Speaker pro tempore [Mrs. EMERSON].

DESIGNATION OF THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore laid before the House the following communication from the Speaker:

WASHINGTON, DC,
November 9, 1997.

I hereby designate the Honorable JO ANN EMERSON to act as Speaker pro tempore on this day.

NEWT GINGRICH,
Speaker of the House of Representatives.

PRAYER

The Chaplain, Rev. James David Ford, D.D., offered the following prayer:

Let us pray using the words of St. Francis:

Lord, make us instruments of Your peace.
Where there is hatred, let us sow love;
where there is injury, pardon;
where there is discord, union;
where there is doubt, faith;
where there is despair, hope;
where there is darkness, light;
where there is sadness, joy.
Grant that we may not so much seek
to be consoled as to console;
to be understood as to understand;
to be loved as to love.
For it is in giving that we receive;
it is in pardoning that we are pardoned;
and
it is in dying that we are born to eternal
life. Amen.

THE JOURNAL

The SPEAKER pro tempore. The Chair has examined the Journal of the

last day's proceedings and announces to the House her approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

Mr. McNULTY. Madam Speaker, pursuant to clause 1, rule I, I demand a vote on agreeing to the Speaker's approval of the Journal.

The SPEAKER pro tempore. The question is on the Chair's approval of the Journal.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. McNULTY. Madam Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Pursuant to clause 5 of rule 1, further proceedings on this question are postponed.

NOTICE

Under the Rules for Publication of the Congressional Record, a final issue of the Congressional Record for the first session of the 105th Congress will be published on **(the 31st day after adjournment)**, in order to permit Members to revise and extend their remarks.

All material for insertion must be signed by the Member and delivered to the respective offices of the Official Reporters of Debates (Room HT-60 or ST-41 of the Capitol), no later than 10 days following adjournment. Office hours of the Official Reporters of Debates are 10:00 a.m. to 3:00 p.m. Monday through Friday through **(the 10th day after adjournment)**.

The final issue will be dated **(the 31st day after adjournment)** and will be delivered on **(the 33d day after adjournment)**.

None of the material printed in the final issue of the Congressional Record may contain subject matter, or relate to any event, that occurred after the adjournment date.

Members' statements also should be submitted electronically, either on a disk to accompany the signed statement, or by e-mail to the Official Reporters of Debates **(insert e-mail address for each office)**.

Members of Congress desiring to purchase reprints of material submitted for inclusion in the Congressional Record may do so by contacting the Congressional Printing Management Division, at the Government Printing Office, on 512-0224, between the hours of 8:00 a.m. and 4:00 p.m. daily.

By order of the Joint Committee on Printing.

JOHN WARNER, *Chairman.*

This symbol represents the time of day during the House proceedings, e.g., 1407 is 2:07 p.m.

Matter set in this typeface indicates words inserted or appended, rather than spoken, by a Member of the House on the floor.



Printed on recycled paper containing 100% post consumer waste

H110423

The point of order is considered withdrawn.

PLEDGE OF ALLEGIANCE

The SPEAKER pro tempore. Will the gentleman from New York [Mr. McNULTY] come forward and lead the House in the Pledge of Allegiance.

Mr. McNULTY led the Pledge of Allegiance as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

MESSAGE FROM THE SENATE

A message from the Senate by Mr. Lundregan, one of its clerks, announced that the Senate had passed without amendment bills of the House of the following titles:

H.R. 1086. An act to codify without substantive change laws related to transportation and to improve the United States Code;

H.R. 1787. An act to assist in the conservation of Asian elephants by supporting and providing financial resources for the conservation programs of nations within the range of Asian elephants and projects of persons with demonstrated expertise in the conservation of Asian elephants;

H.R. 2731. An act for the relief of Roy Desmond Moser; and

H.R. 2732. An act for the relief of John Andre Chalot.

The message also announced that the Senate had passed with amendments in which the concurrence of the House is requested, bills of the House of the following titles:

H.R. 497. An act to repeal the Federal charter of Group Hospitalization and Medical Services, Inc., and for other purposes; and

H.R. 867. An act to promote the adoption of children in foster care.

The message also announced that the Senate agrees to the report of the committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 1026) "An act to reauthorize the Export-Import Bank of the United States."

The message also announced that the Senate had passed bills and concurrent resolutions of the following titles, in which the concurrence of the House is requested:

S. 508. An act to provide for the relief of Mai Hoa "Jasmin" Salehi;

S. 759. An act to amend the State Department Basic Authorities Act of 1956 to require the Secretary of State to submit an annual report to Congress concerning diplomatic immunity;

S. 857. An act for the relief of Roma Salobrit;

S. 1193. An act to amend chapter 443 of title 49, United States Code, to extend the authorization of the aviation insurance program, and for other purposes;

S. 1258. An act to amend the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 to prohibit an alien who is not lawfully present in the United States from receiving assistance under that Act;

S. 1304. An act for the relief of Belinda McGregor;

S. 1347. An act to permit the city of Cleveland, Ohio, to convey certain lands that the United States conveyed to the city;

S. 1487. An act to establish a National Voluntary Mutual Reunion Registry;

S. Con. Res. 58. Concurrent resolution expressing the concern of Congress over Russia's newly passed religion law; and

S. Con. Res. 66. Concurrent resolution to correct the enrollment of S. 399.

ANNOUNCEMENT OF BILLS TO BE CONSIDERED UNDER SUSPENSION OF THE RULES TODAY

Mr. SOLOMON. Madam Speaker, I would like to announce the intentions to call up the following bills under suspension today:

S. 714, Homeless Veterans;

S. 1139, Small Business;

H.R. 1129, Microcredit;

H. Con. Res. 22, Scientology;

H. Con. Res. 239, Expo 2000;

H. Res. 245, Elections in Sahara;

H. Con. Res. 156, Afghanistan Women;

H.R. 1377, SAVER Act;

H.R. 2920, Immigration Deadline;

S. 1231, U.S. Fire Administration;

H.R. 112, Stanislaus County;

H.R. 1805, Auburn Indian Restoration;

H.R. 2402, Water-Related Technical Corrections;

H.R. 2283, Arches National Park;

S. 669, Jimmy Carter Historic Site;

H.R. 2834, Cleveland Airport Transfer;

H.R. 2626, Pilot Records Improvement;

H.R. 849, Uniform Relocation;

H.R. 2476, Foreign Irlene Family; and

H.R. 1502 James Foreman Courthouse.

Mr. TRAFICANT. Madam Speaker, reserving the right to object.

The SPEAKER pro tempore. The gentleman from New York is only making an announcement pursuant to House Resolution 305.

Mr. SOLOMON. Madam Speaker, if I might continue:

H.R. 861, Adoption;

S. 1026, Ex-Im Bank Conference Report;

H.R. 2472, EPCA; and

The FDA Commerce Report.

And one final bill, Madam Speaker, and one final bill, S. 1258.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. The Chair will recognize Members on each side for 1 minutes. There will be ten 1-minutes on each side.

LET US STICK TO THE DECLARATION OF INDEPENDENCE

(Mr. GUTKNECHT asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. GUTKNECHT. Madam Speaker, last week President Clinton told the voters of Virginia, the ones who supported repealing the car tax, that they were selfish.

Well, excuse me, Mr. President, but maybe you have forgotten what the Declaration of Independence says. It says that all men are created equal and they have certain inalienable rights, and among those rights are life, liberty, and the pursuit of happiness.

I find it remarkable that anyone would not notice that liberty and the pursuit of happiness both apply to the idea of who gets to decide what to do with their money. That is really the point. This is not a question of selfishness, but whether and who will decide how to spend their money.

Conservatives emphasize that people are the best judge of how their money should be spent, whereas liberals tend to think that politicians are a superior judge of how and where the money should be spent, especially if they, the liberals, are positively excited about spending the people's money to carry out social engineering plans.

As for me, I think I will stick with the original intent of the American Declaration of Independence.

STAND UP FOR AMERICA: DEFEAT FAST TRACK

(Mr. KUCINICH asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. KUCINICH. Madam Speaker, since the passage of NAFTA, NAFTA has contributed to numerous workplace, economic and environmental problems, including an increase in the import of contaminated food, downward pressure on United States wages, employer threats to move to Mexico, and a skyrocketing trade deficit.

Fast-track has failed to address any of those problems. First of all, with respect to our trade deficit growth and the loss of jobs, fast-track takes no action on that, no improvement, fails to address it.

Second, there is pressure to lower U.S. wages, and there is lowering of wages going on in this country in manufacturing because of NAFTA. Fast-track fails to address that.

Third, since NAFTA, we have had employer threats to move to NAFTA partner countries. The fast-track agreement fails to take action on that and fails to address it.

Unless we address these critical problems in fast-track, the NAFTA problems will spread like a virus through North America and the world. We need higher standards for our wages, for our workers and for our countries. Stand up for America; defeat fast-track.

TRIBUTE TO MAJOR GENERAL LANSFORD E. TRAPP

(Mr. THUNE asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. THUNE. Madam Speaker, today I rise to pay tribute to Maj. Gen. Lansford Trapp. Most know General

Trapp as the director of the Air Force's Legislative Liaison Office. I know the general as a fellow South Dakotan and a fine soldier.

The good news is that General Trapp has been selected as the next commander of the 12th Air Force. The bad news is that Congress is losing a great legislative liaison, not to mention another fine person from the Rushmore State.

Through the past 28 years, General Trapp has served in the Air Force with honor and distinction. He is a command pilot with over 3,000 flying hours. In Southeast Asia he flew over 700 combat hours and later commanded our air wing in Panama during Operation Just Cause. He has held 5 commanding positions, which is a real tribute to his leadership capabilities.

I would like to think that General Trapp's dedication to service and loyalty to his troops was instilled as a boy growing up in South Dakota. It was there where he attended South Dakota State on a ROTC scholarship, and where his parents and family still reside. I think he is also a product of the U.S. Air Force. The combination has produced an excellent commander that our Nation can be proud of.

I can think of no person more qualified to lead and care for our men and women than Gen. Lanny Trapp. To him, his wife Nancy and daughter Bethany, we wish God's blessing and Godspeed.

NEW TRADE POLICY FOR ALL AMERICANS

(Mr. DEFAZIO asked and was given permission to address the House for 1 minute.)

Mr. DEFAZIO. Madam Speaker, the proponents of fast track would have us believe today's legislative battle is about whether or not the United States will trade. This is not about a battle between protection as free traders, but rather a struggle over the conditions of that trade and who will benefit from that trade. On one side, the President, the entire administration, the Republican leadership, and a fleet of corporate CEO's who have actually been given office space right downstairs in the Capitol in violation of the House rules.

On our side, 80 percent of the Democrats and a small group of Republicans. We think it is time to overhaul our failing trade policy, a policy that has brought \$160 billion trade deficits, exported jobs, driven down wages, weakened our environmental and food safety laws, all in the name of free trade. A policy that undermines our values to encourage a race to the bottom; enriching a few multinational corporations and their CEO's at the expense of the majority of American workers and communities.

"No" to the threats, "no" to the silent promises, "no" to the legal campaign bribery, "no" to fast track, and "yes" to the beginnings of a new trade policy that benefits all Americans.

TIME FOR IRS REFORM

(Mr. FORBES asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. FORBES. Madam Speaker, the American people recently saw the IRS on trial. They saw a parade of witnesses come before the Congress to testify about the naked abuse of power over at the Internal Revenue Service. We saw current and former IRS agents who had to testify in secret because they feared for their lives. We saw ordinary citizens, taxpayers, who talked about how an audit turned their entire lives upside down, with some of them suffering great financial loss that will never be recovered. We saw a government agency totally out of control, lacking accountability, an agency where one is guilty until proven innocent.

Madam Speaker, the IRS needs radical reform. This House has taken great steps to begin that process, and we look forward to the other body and the White House to join us in this effort to reform the Internal Revenue Service, which is an agency of intimidation rather than enforcement.

STRAIGHT TALK ABOUT FAST TRACK

(Mr. TRAFICANT asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. TRAFICANT. Madam Speaker, let us tell it like it is. The last fast track traded Ma Bell for Taco Bell. Today's fast track will trade more American jobs and dollars and factories to all of Central America for a '48 Ford pickup truck, two loads of pinto beans and three ballplayers to be named later. Beam me up.

In addition, I predict we will get another 25 tons of heroin, another 35 tons of cocaine, and a lot more economic development in the form of prisons, I say to my colleagues. Let us have a little straight talk. "This dog don't hunt. Pull this turkey."

I yield back the balance of any jobs we have left.

FOREIGN OPERATIONS APPROPRIATION CONFERENCE REPORT

(Mr. PAUL asked and was given permission to address the House for 1 minute.)

Mr. PAUL. Madam Speaker, I rise to point out to the House a piece of legislation that I am sure will be passed tonight or in the morning in the wee hours when a lot of people are not paying much attention, and that is the foreign operations appropriations conference report.

I would like to point out that buried in this report is a \$3.5 billion new program called the new agreements to borrow, further funding for the IMF. These are the funds that will be used to bail

out Third World nations and also bail out bankers and industries that have invested in these nations such as in Mexico or Indonesia.

This is considered not to be expensive because of our special accounting procedure here, it is not on budget. It is supposed to be for free. But let me call my colleagues' attention to this: new agreements to borrow, IMF, new funding in the foreign operations bill report. This is inflationary, it is detrimental to the dollar, and it is subsidizing foreign interests as well as special banking and industrial interests here.

□ 1415

AMERICA NEEDS RECIPROCITY, NOT DUPLICITY, IN TRADE

(Mr. PASCRELL asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. PASCRELL. Madam Speaker, the supporters of fast track never discuss the massive trade imbalance which grows every year, never. This reflects job loss in America. The supporters are good, very good, at denigrating organized labor's efforts to defeat fast track. Organized labor has a vested interest. The jobs of members in various unions and the jobs in nonunion workplaces are at stake.

Why is their effort a special interest, and the expenditures of millions by multinational corporations simply "in the best interests of the American economy?" How can some Members of this House who vehemently defend the sovereignty of our Nation with foreign powers now surrender the oversight of the trade deal implementation to the World Trade Organization?

The WTO has just ruled in favor of Costa Rica and India on textile matters. What are we doing for our own sovereignty? Why sell us out again? Reciprocity, Mr. President, reciprocity, Mr. Speaker, not duplicity. Vote "no" on fast track.

COALGATE IN UTAH

(Mr. GIBBONS asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. GIBBONS. Madam Speaker, today I rise to inform my Members about Coalgate; no, not the toothpaste or the university, but another campaign scandal. In the heat of the 1996 campaign, President Clinton created the Grand Staircase-Escalante National Monument in Utah, which consisted of more than 1.7 million acres of land, an area larger than the State of Delaware.

The White House claims this monument was needed to protect one of the most pristine areas in America. However, I would contend that 62 billion tons of low-sulfur coal reserve was the real reason for this designation. The

Lippo Group, very large donors of the President's campaign, had a large financial stake in this monument, because clean Utah coal would have competed with the imported coal from Indonesia.

It is a sad day when the President would deny schoolchildren in Utah the tax revenues of \$1.5 billion in coal or the royalties, to protect foreign interests and promote his own self-serving ambition. Madam Speaker, the definition of greed has truly been revealed to the American people. They deserve the truth.

PUT PEOPLE FIRST: VOTE "NO"
ON FAST TRACK

(Mr. LEVIN asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. LEVIN. Madam Speaker, the strategy of those of us opposing the present fast track proposal is not "America last," but putting people first. This is not mainly about the power of interest groups, but the power of issues.

In the last decade, more and more of U.S. trade has been with nations with low wages and tightly controlled labor and other markets, and with lax environmental conditions. Indeed, our imports from these nations like China, India, Brazil, Mexico rose by 25 percent in the last decade, and as an administration official said yesterday, 50 percent of all United States trade will be with these nations in the near future, increasingly changing from footwear to higher-tech ware.

Instead of moving forward towards new rules of competition to meet new patterns of expanding trade, the present fast track proposal goes backwards, limiting the President's authority in important areas of labor markets and the environment. There were no such limitations on Presidents Carter, Reagan, or Bush.

This fast-track proposal is wrong. Vote "no" and let us go back and do it right.

END IRS PRACTICE OF MEETING
QUOTAS

(Mr. HERGER asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. HERGER. Madam Speaker, I just cannot get over the shocking news about the IRS. It turns out that the IRS is not as bad as we thought. It is even worse. It turns out that when our friendly IRS agent appears at our door for an audit, he is not thinking about giving us a fair shake. He was not sent off from headquarters with instructions to do justice, no more, no less. No, of the things that is uppermost in his mind, the thing upon which his promotions will depend, is how much money he can extract from the poor taxpayer who is getting audited.

God help you if your friendly IRS agent is having a little trouble this month making his quota of fines. If you catch him a little behind in making his revenue quota, if his boss put a little pressure on his agents in the last weekly meeting, you may not want to expect to survive your audit without having to fork over money that you do not even have.

Madam Speaker, while the President and his friends at the Treasury Department are defending the evil ways of the IRS, this Congress is going to pass real change and put an end to this absolutely outrageous practice over at the IRS.

TRIBUTE TO HARRY M.
ROSENFELD

(Mr. McNULTY asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. McNULTY. Madam Speaker, I rise to pay tribute to Harry M. Rosenfeld, the editor-at-large of the Albany Times Union and one of this Nation's most highly respected journalists. Harry, who was one of my constituents, has enjoyed a long and illustrious career. He came to this country as an immigrant, was educated at Syracuse University, served his Nation proudly during the Korean war, and embarked on a career in newspaper work. He served as foreign editor of the New York Herald Tribune and then moved to the Washington Post, where he directed the coverage of the Watergate story that earned the Post a much-deserved Pulitzer Prize.

In 1979, Mr. Rosenfeld came to New York's capital district of serve as editor-in-chief of the Albany Times Union and Knickerbocker News. During his tenure as editor, the newspaper won countless awards for general excellence and community service.

Because of Harry Rosenfeld's commitment to honest courageous reporting as the foundation of responsible journalism, he leaves his community a better place.

Harry retired from journalism last week. For nearly half a century he has served as the living embodiment of the loftiest principles of his profession. In his community and in his industry, he enjoys a well-earned reputation for integrity and undying devotion to the highest standards of his craft. I am proud to salute my friend Harry for his distinguished journalistic service to the cause of democracy. Thanks, Harry.

SUPPORT RADIO FREE ASIA

(Ms. ROS-LEHTINEN asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. ROS-LEHTINEN. Madam Speaker, today the House will debate H.R. 2232, which will increase funding for Radio Free Asia and the Voice of America broadcasting into China. By passing this bill, we will then have con-

tinuous broadcasting to China in multiple dialects and languages.

Currently, only a few hours are broadcast and in only two languages. The increased funds will allow millions of Chinese citizens to hear the truth about their own country and the world around them. Listening to the words of truth, of freedom, of respect for human rights, of democracy is fundamental to making correct decisions.

There is no free press in China. Voice of America and Radio Free Asia tell the truth of today's news without the bias, the distortion, the lies of the Chinese propaganda machine. Our broadcast will serve as a surrogate free press in the dictators' Republic of China.

I know these broadcasts can be successful. Radio Marti, which is listened to by millions in my native homeland of Cuba, has been promoting justice and freedom, the hallmarks of our great country. Castro has tried and tried to jam its signal, but he has failed. An informed citizenry is needed for true political and economic freedom. Support Radio Free Asia today.

VOTE NO ON THE UPCOMING FAST
TRACK BILL

(Mr. BROWN of Ohio asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. BROWN of Ohio. Madam Speaker, we have heard numerous stories of dozens of deals between President Clinton and Speaker GINGRICH to ram fast-track legislation through this Congress. The killer deal was the very first deal the White House cut.

Instead of working with Democrats on positive legislation that looked to the future, the White House cozied up to the gentleman from Georgia [Mr. GINGRICH] and the gentleman from Texas [Mr. ARCHER] on a deal that betrays our values and our historic commitment to working American families and the environment.

The Archer-Gingrich bill not surprisingly would make the Republican hostility to labor and environment the U.S. agenda in international trade negotiations, a global race to the bottom. The Archer-Gingrich bill is a fast-track to the past, not to the future.

The vast majority of Democrats, 80 percent of them, oppose the Archer-Gingrich bill because we want sensible agreements that incorporate our values as Democrats, values such as clean air and clean water, values such as safe food, values such as worker rights and human rights.

As Democrats, we can do better. Vote no on the Gingrich-Archer fast-track bill.

THE LEGACY OF THIS
ADMINISTRATION

(Mr. BARTLETT of Maryland asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. BARTLETT of Maryland. Madam Speaker, we have really got to hand it to this administration. This is the first administration in history that has combined distinguishing characteristics and no controlling legal authority into a legal defense that the media are actually taking seriously, and then spends half the day talking about their legacy. Somehow, I think the legacy that they are likely to leave is not going to be the same legacy they have in mind.

Let us face it, when key witnesses keep turning up either dead, unwilling to testify, or hiding out in foreign countries, I do not think this is simply a question of partisan politics, despite the view repeated endlessly on ABC, NBC, and CBS that investigations into the 1996 Presidential campaign are much ado about nothing.

If there is nothing to hide, then I ask my fair-minded friends at ABC, NBC, and CBS, why are over 50 witnesses with critical information, why have they either fled the country or taken the fifth? The only scandal bigger than the Clinton-Gore campaign is the way the media have covered it since all these outrageous campaign finance violations have come to light. This, too, will be part of the legacy.

CONGRESS MUST MAINTAIN ITS INTEGRITY UP TO THE END OF THE SESSION

(Ms. JACKSON-LEE of Texas asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. JACKSON-LEE of Texas. Madam Speaker, as we bring this session of our responsibilities to the American people during this time of legislative activity to an end, I would ask this Congress to maintain its integrity.

There is a great deal of debate about legislation that is to be voted on and discussed this day, but I think that our Republican friends and certainly Democrats should understand that there are certain issues that need to be maintained separately from these discussions.

There is no doubt that sampling in the taking of the census in the year 2000 has been documented as the most accurate way of counting every human being. The homeless, people who are unhouseed, poor people, rich people, black people, Hispanic people, Anglo people, Asian people, anyone in this country needs to be counted in this Nation. So let us not play with the census.

Let us not play with the basic rights of women across the world to family plan and preserve their families.

Let us not play with the Haitians, who are the only group who are not being allowed to stay in this country to apply for their citizenship.

Maintain the integrity of this Congress, and allow these issues to go forward on their own merits. The census must have sampling, family planning

must exist, and leave the Haitians alone so they, too, have the rights of everybody else.

EDUCATION WOULD CHANGE IF WE HAD SCHOOL CHOICE

(Mr. PETERSON of Pennsylvania asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. PETERSON of Pennsylvania. Madam Speaker, there are schools in America that turn out more criminals than young people that will go out to attend college. Would Members like a choice if their child was attending that school? I believe they would.

Madam Speaker, wealthy Americans and many Congressmen and Senators make choices every day, and our President and Vice President, they send their child to the school of their choice. Many middle-class Americans choose where they live so their children can attend a school that they know is a good school. But what about poor Americans who are stuck in a bad neighborhood with a bad school?

Eighty percent of the schools in America are good and delivering a good product. Recently we had a bill that would allow choice for the poorest of Americans. What are the Democrats in the educational establishment afraid of, that it might work? We would have a chance to change education, and education would change, if we had choice. Bad schools would close, and the children would have a chance to go to a good school.

CALLING FOR BALANCED TRADE AGREEMENTS WHICH CONTAIN PROTECTIONS FOR WORKERS AND THE ENVIRONMENT

(Mr. NADLER asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. NADLER. Madam Speaker, since NAFTA we have converted a \$2 billion trade surplus with Mexico to a \$20 billion trade deficit. In 65 percent of union organizing elections, employers have threatened to move to Mexico or to another foreign country if workers have chosen the advantages of collective bargaining.

Working people have gotten almost none of the benefits of our expanding economy, as real wages for the middle class have remained static and, for lower-income workers, have actually declined. NAFTA and fast track quite properly protect American investors who invest abroad and protect intellectual property rights, but they do not protect labor and environmental rights. They are imbalanced.

We must have balanced trade agreements that protect not only investments and intellectual property, but also labor and environmental standards if trade is to serve all our people, and if our expanding trade is not to serve as a tool to be used to deny a fair share

of our economic gains from filtering down to working people and to the middle class. Reject the fast track agreement as imbalanced.

□ 1430

INVESTIGATION OF 1996 PRESIDENTIAL CAMPAIGN

(Mr. TIAHRT asked and was given permission to address the House for 1 minute.)

Mr. TIAHRT. Madam Speaker, investigations into crimes that may have been committed during the 1996 Presidential campaign are about a lot more than taking foreign money. They are a lot more than just the effort to secretly get around the rules that everyone else had to follow and then worry about explaining the misdeeds after the election.

No, Madam Speaker, the liberal media attempts to downplay this scandal. These investigations are also about compromising national security, about selling out American foreign policy to the highest bidder and acting in complicity with the Communist Government of China to subvert the democratic process in the United States.

I believe that I am correct, Madam Speaker, that both Democrats and Republicans would agree that these charges are truly alarming. In fact, all Americans who believe in democracy, who believe that America should decide who should rule over America and who believe that secret money laundering operations represent political corruption at its most disgraceful, all believe that we must find out the truth about these scandals. Democracy demands it.

IN TRIBUTE TO THE LATE CLARA BOSWELL

(Mrs. CLAYTON asked and was given permission to address the House for 1 minute.)

Mrs. CLAYTON. Madam Speaker, in less than an hour, legions of families and friends will gather in the historic town of Edenton, North Carolina, to mourn the death and celebrate the life of one of my staff members, Clara Boswell. This devoted mother and grandmother and former principal passed suddenly, without notice, on Thursday night.

Clara's life was personified by her two favorite symbols, the butterfly and the hat. While the grief of those who will gather is heavy, I know they will be comforted by acclaiming the life and celebrating the life of Clara.

I am confident she has left a lasting impression on those who came to know her, and the principles that guided her will now serve as guideposts for those she leaves behind. Like the butterfly, she brought a free spirit, bright colors, in every place she functioned. And like the hat, she brought peace and protection to everyone she encountered.

She has been called to rest and to reside in the place of total peace. God's

finger has gently touched her, and she now sleeps. May God comfort and help her family and friends to hold on to treasured yesterdays and to reach out with courage and hope to tomorrow, knowing that their beloved is with God.

Clara has labored long. She served well. She has made a difference. She loved the butterfly. She had a free spirit. Today we put her to rest.

PRIVILEGES OF THE HOUSE—DISMISSAL OF CONTEST IN 46TH DISTRICT OF CALIFORNIA

Mr. GEPHARDT. Madam Speaker, I rise to a question of the privileges of the House, and I send to the desk a privileged resolution (H. Res. 318) pursuant to rule IX and ask for its immediate consideration.

The Clerk read the resolution as follows:

H. RES. 318

Whereas, the election contest concerning the 46th District of California should be dismissed as there is no credible evidence to show that the outcome of the election is different than the election of Congresswoman Loretta Sanchez.

Whereas, State of California authorities should continue an investigation into any questionable registration activities; and

Whereas, the Committee on House Oversight should examine voter registration procedures; and now therefore be it

Resolved, That the contest in the 46th District of California is dismissed.

THE SPEAKER PRO TEMPORE (Mrs. EMERSON). The resolution presents a question of the privileges of the House.

MOTION TO TABLE OFFERED BY MR. BOEHNER

Mr. BOEHNER. Madam Speaker, I move to table the resolution.

The SPEAKER pro tempore. The question is on the motion to table offered by the gentleman from Ohio [Mr. BOEHNER].

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. OBEY. Madam Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Evidently a quorum is not present.

The Sergeant at Arms will notify absent Members.

The vote was taken by electronic device, and there were—yeas 218, nays 194, answered “present” 1, not voting 20, as follows:

[Roll No. 622]
YEAS—218

Aderholt	Bereuter	Burton
Archer	Bilbray	Buyer
Armye	Bilirakis	Callahan
Bachus	Bliley	Calvert
Baker	Blunt	Camp
Ballenger	Boehlert	Campbell
Barr	Boehner	Canady
Barrett (NE)	Bonilla	Cannon
Bartlett	Brady	Castle
Barton	Bryant	Chabot
Bass	Bunning	Chambliss
Bateman	Burr	Chenoweth

Christensen	Hutchinson
Coble	Hyde
Coburn	Inglis
Collins	Istook
Combest	Jenkins
Cook	Johnson (CT)
Cooksey	Johnson, Sam
Cox	Jones
Crane	Kasich
Crapo	Kelly
Cunningham	Kim
Davis (VA)	King (NY)
Deal	Kingston
DeLay	Knollenberg
Diaz-Balart	Kolbe
Dickey	LaHood
Doolittle	Largent
Dreier	Latham
Duncan	LaTourette
Dunn	Lazio
Ehlers	Leach
Ehrlich	Lewis (CA)
Emerson	Lewis (KY)
English	Linder
Ensign	Livingston
Everett	LoBiondo
Ewing	Lucas
Fawell	Manzullo
Foley	Martinez
Fossella	McCollum
Fowler	McCraw
Fox	McDade
Franks (NJ)	McHugh
Frelinghuysen	McInnis
Galleghy	McIntosh
Ganske	McKeon
Gekas	Metcalfe
Gibbons	Mica
Gilchrist	Miller (FL)
Gilman	Moran (KS)
Goodlatte	Morella
Goodling	Myrick
Goss	Nethercutt
Graham	Neumann
Granger	Ney
Greenwood	Northup
Gutknecht	Norwood
Hansen	Norwood
Hastert	Nussle
Hastings (WA)	Oxley
Hayworth	Packard
Hefley	Pappas
Herger	Parker
Hill	Paul
Hilleary	Paxon
Hobson	Pease
Horn	Peterson (PA)
Hostettler	Petri
Houghton	Pickering
Hulshof	Pitts
Hunter	Pombo
	Porter

NAYS—194

Abercrombie	DeGette
Allen	Delahunt
Andrews	DeLauro
Baessler	Dellums
Baldacci	Deutsch
Barcia	Dicks
Barrett (WI)	Dingell
Becerra	Dixon
Bentsen	Doggett
Berman	Dooley
Berry	Doyle
Bishop	Edwards
Blagojevich	Engel
Blumenauer	Eshoo
Bonior	Etheridge
Borski	Evans
Boswell	Farr
Boucher	Fattah
Boyd	Fazio
Brown (CA)	Filner
Brown (FL)	Forbes
Brown (OH)	Ford
Cardin	Frank (MA)
Carson	Frost
Clay	Furse
Clayton	Gejdenson
Clement	Gephardt
Clyburn	Goode
Costello	Gordon
Coyne	Green
Cramer	Gutierrez
Cummings	Hall (OH)
Danner	Hall (TX)
Davis (FL)	Hamilton
Davis (IL)	Harman
DeFazio	Hastings (FL)

Portman
Pryce (OH)
Quinn
Radanovich
Ramstad
Redmond
Regula
Riggs
Rogan
Rogers
Rohrabacher
Ros-Lehtinen
Roukema
Royce
Ryun
Salmon
Sanford
Saxton
Scarborough
Schaefer, Dan
Schaffer, Bob
Sensenbrenner
Sessions
Shadegg
Shaw
Shays
Shimkus
Shuster
Skeen
Smith (MI)
Smith (NJ)
Smith (OR)
Smith (TX)
Smith, Linda
Snowbarger
Solomon
Souder
Spence
Stump
Sununu
Talent
Tauzin
Thomas
Thornberry
Thune
Tiahrt
Traficant
Upton
Walsh
Watkins
Watts (OK)
Weldon (FL)
Weldon (PA)
Weller
White
Whitfield
Wicker
Wolf
Young (AK)
Young (FL)

Markey
Mascara
Matsui
McCarthy (MO)
McCarthy (NY)
McGovern
McHale
McIntyre
McKinney
McNulty
Meehan
Meek
Menendez
Millender-McDonald
Miller (CA)
Minge
Mink
Moakley
Mollohan
Moran (VA)
Murtha
Nadler
Neal
Oberstar
Obey
Olver
Ortiz
Owens
Pallone

Pascrell
Pastor
Payne
Pelosi
Peterson (MN)
Pickett
Pomeroy
Poshard
Price (NC)
Roemer
Rothman
Roybal-Allard
Rush
Sabo
Sanchez
Sanders
Sandlin
Sawyer
Scott
Serrano
Sherman
Sisisky
Skaggs
Skelton
Slaughter

Smith, Adam
Snyder
Spratt
Stabenow
Stark
Stenholm
Strickland
Stupak
Tanner
Tauscher
Taylor (MS)
Thompson
Thurman
Tierney
Torres
Towns
Turner
Velazquez
Vento
Visclosky
Waters
Watt (NC)
Waxman
Wexler
Weygand
Wise
Woolsey
Wynn

ANSWERED “PRESENT”—1

Wamp

NOT VOTING—20

Ackerman	Gillmor	Schiff
Bono	Gonzalez	Schumer
Condit	Hoekstra	Stearns
Conyers	Klecza	Stokes
Cubin	Klug	Taylor (NC)
Flake	McDermott	Yates
Foglietta	Riley	

□ 1454

Ms. PELOSI and Mr. MURTHA changed their vote from “yea” to “nay.”

Mr. SHAYS and Mr. MCDADE changed their vote from “nay” to “yea.”

So the motion to table was agreed to. The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

CORRECTION OF ANNOUNCEMENT OF LEGISLATION TO BE CONSIDERED UNDER SUSPENSION OF THE RULES TODAY

Mr. BEREUTER. Madam Speaker, earlier today when announcing motions to suspend the rules, an incorrect number was announced for the adoption bill. The correct number is H.R. 867, not H.R. 861.

RADIO FREE ASIA ACT OF 1997

Mr. ROYCE. Madam Speaker, pursuant to House Resolution 302 and as the designee of the chairman of the Committee on Internal Relations, I call up the bill (H.R. 2232) to provide for increased international broadcasting activities to China, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore (Mrs. EMERSON). The bill is considered read for amendment.

The text of H.R. 2232 is as follows:

H.R. 2232

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 "Radio Free Asia Act of 1997".

SEC. 2. FINDINGS.

The Congress makes the following findings:
(1) The Government of the People's Republic of China systematically controls the flow of information to the Chinese people.

(2) The Government of the People's Republic of China demonstrated that maintaining its monopoly on political power is a higher priority than economic development by announcing in January 1996 that its official news agency Xinhua, will supervise wire services selling economic information, including Dow Jones-Telerate, Bloomberg, and Reuters Business, and in announcing in February of 1996 the "Interim Internet Management Rules", which have the effect of censoring computer networks.

(3) Under the May 30, 1997, order of Premier Li Peng, all organizations that engage in business activities related to international computer networking must now apply for a license, increasing still further government control over access to the internet.

(4) Both Radio Free Asia and the Voice of America, as a surrogate for a free press in the People's Republic of China, provide an invaluable source of uncensored information to the Chinese people, including objective and authoritative news of in-country and regional events, as well as accurate news about the United States and its policies.

(5) Radio Free Asia currently broadcasts only 5 hours a day in the Mandarin dialect and 2 hours a day in Tibetan.

(6) Voice of America currently broadcasts only 10 hours a day in Mandarin and 3½ hours a day in Tibetan.

(7) Radio Free Asia and the Voice of America should develop 24-hour-a-day service in Mandarin, Cantonese, and Tibetan, as well as further broadcasting capability in the dialects spoken in Xinjiang and other regions of the People's Republic of China.

(8) Radio Free Asia and Voice of America, in working toward continuously broadcasting the People's Republic of China in multiple languages, have the capability to immediately establish 24-hour-a-day Mandarin broadcasting to that nation by staggering the hours of Radio Free Asia and the Voice of America.

(9) Simultaneous broadcasting on Voice of America radio and Worldnet television 7 days a week in Mandarin are also important and needed capabilities.

SEC. 3. AUTHORIZATION OF APPROPRIATIONS FOR INCREASED FUNDING FOR RADIO FREE ASIA AND VOICE OF AMERICA.

(a) AUTHORIZATION OF APPROPRIATIONS FOR INTERNATIONAL BROADCASTING TO CHINA.—In addition to such sums as are otherwise authorized to be appropriated for "International Broadcasting Activities" for fiscal years 1998 and 1999, there are authorized to be appropriated for "International Broadcasting Activities" \$46,900,000 for fiscal years 1998 and \$31,200,000 for fiscal year 1999, which shall be available only for broadcasting to China.

(b) LIMITATIONS.—**(1) RADIO FREE ASIA.—**

(A) Of the funds authorized to be appropriated under subsection (a) \$26,900,000 is authorized to be appropriated for fiscal year 1998 and \$21,200,000 is authorized to be appropriated for fiscal year 1999 for Radio Free Asia.

(B) Of the funds under subparagraph (A), \$1,200,000 is authorized to be appropriated for each such fiscal year for additional personnel to staff Cantonese language broadcasting.

(C) Of the funds under subparagraph (A) authorized to be appropriated for fiscal year

1998, \$900,000 is authorized to be appropriated for additional advanced editing equipment.

(2) 1998.—

(A) Of the funds under subsection (a) authorized to be appropriated for fiscal year 1998, \$11,800,000 is authorized to be appropriated for capital expenditures for the purchase and construction of transmission facilities.

(B) Of the funds under subsection (a) authorized to be appropriated for fiscal year 1998, \$3,000,000 is authorized to be appropriated to facilitate the timely augmentation of transmitters at Tinian, Marshall Islands.

(c) ALLOCATION.—Of the amounts authorized to be appropriated under subsection (a), the Director of the United States Information Agency and the Board of Broadcasting Governors shall seek to ensure that the amounts made available for broadcasting to nations whose people do not fully enjoy freedom of expression do not decline in proportion to the amounts made available for broadcasting to other nations.

SEC. 4. REPORTING REQUIREMENT.

Not later than 90 days after the date of enactment of this Act, in consultation with the Board of Broadcasting Governors, the President shall prepare and transmit to Congress a report on a plan to achieve continuous broadcasting of Radio Free Asia and Voice of America to the People's Republic of China in multiple major dialects and languages.

SEC. 5. REDUCTION IN AUTHORIZATION OF APPROPRIATIONS FOR MIGRATION AND REFUGEE ASSISTANCE.

Notwithstanding any other provision of law, such amounts as are authorized to be appropriated for "Migration and Refugee Assistance" for fiscal year 1998 shall be reduced by \$21,900,000 and for fiscal year 1999 shall be reduced by \$6,200,000.

The SPEAKER pro tempore. Pursuant to House Resolution 302, the committee amendment in the nature of a substitute printed in the bill is adopted.

The text of the committee amendment in the nature of a substitute is as follows:

H.R. 2232

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 "Radio Free Asia Act of 1997".

SEC. 2. FINDINGS.

The Congress makes the following findings:
(1) The Government of the People's Republic of China systematically controls the flow of information to the Chinese people.

(2) The Government of the People's Republic of China demonstrated that maintaining its monopoly on political power is a higher priority than economic development by announcing in January 1996 that its official news agency Xinhua, will supervise wire services selling economic information, including Dow Jones-Telerate, Bloomberg, and Reuters Business, and in announcing in February of 1996 the "Interim Internet Management Rules", which have the effect of censoring computer networks.

(3) Under the May 30, 1997, order of Premier Li Peng, all organizations that engage in business activities related to international computer networking must now apply for a license, increasing still further government control over access to the internet.

(4) Both Radio Free Asia and the Voice of America, as a surrogate for a free press in the People's Republic of China, provide an invaluable source of uncensored information

to the Chinese people, including objective and authoritative news of in-country and regional events, as well as accurate news about the United States and its policies.

(5) Radio Free Asia currently broadcasts only 5 hours a day in the Mandarin dialect and 2 hours a day in Tibetan.

(6) Voice of America currently broadcasts only 10 hours a day in Mandarin and 3½ hours a day in Tibetan.

(7) Radio Free Asia and Voice of America should develop 24-hour-a-day service in Mandarin, Cantonese, and Tibetan, as well as further broadcasting capability in the dialects spoken in the People's Republic of China.

(8) Radio Free Asia and Voice of America, in working toward continuously broadcasting to the People's Republic of China in multiple languages, have the capability to immediately establish 24-hour-a-day Mandarin broadcasting to that nation by staggering the hours of Radio Free Asia and Voice of America.

(9) Simultaneous broadcasting on Voice of America radio and Worldnet television 7 days a week in Mandarin are also important and needed capabilities.

SEC. 3. AUTHORIZATION OF APPROPRIATIONS FOR INCREASED FUNDING FOR RADIO FREE ASIA AND VOICE OF AMERICA BROADCASTING TO CHINA.

(a) AUTHORIZATION OF APPROPRIATIONS FOR RADIO FREE ASIA.—

(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for "Radio Free Asia" \$30,000,000 for fiscal year 1998 and \$22,000,000 for fiscal year 1999.

(2) LIMITATIONS.—

(A) Of the funds under paragraph (1) authorized to be appropriated for fiscal year 1998, \$8,000,000 is authorized to be appropriated for one-time capital costs.

(B) Of the funds under paragraph (1), \$700,000 is authorized to be appropriated for each such fiscal year for additional personnel to staff Cantonese language broadcasting.

(b) AUTHORIZATION OF APPROPRIATIONS FOR INTERNATIONAL BROADCASTING TO CHINA AND NORTH KOREA.—In addition to such sums as are otherwise authorized to be appropriated for "International Broadcasting Activities" for fiscal years 1998 and 1999, there are authorized to be appropriated for "International Broadcasting Activities" \$10,000,000 for fiscal year 1998 and \$7,000,000 for fiscal year 1999, which shall be available only for enhanced Voice of America broadcasting to China and North Korea.

(c) AUTHORIZATION OF APPROPRIATIONS FOR RADIO CONSTRUCTION.—

(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to such sums as are otherwise authorized to be appropriated for "Radio Construction" for fiscal years 1998 and 1999, there are authorized to be appropriated for "Radio Construction" \$10,000,000 for fiscal year 1998 and \$3,000,000 for fiscal year 1999, which shall be available only for construction in support of enhanced broadcasting to China.

(2) LIMITATION.—Of the funds under paragraph (1) authorized to be appropriated for fiscal year 1998, \$3,000,000 is authorized to be appropriated to facilitate the timely augmentation of transmitters at Tinian, the Commonwealth of the Northern Mariana Islands.

(d) ALLOCATION.—Of the amounts authorized to be appropriated for "International Broadcasting Activities", the Director of the United States Information Agency and the Board of Broadcasting Governors shall seek to ensure that the amounts made available for broadcasting to nations whose people do not fully enjoy freedom of expression do not decline in proportion to the amounts made available for broadcasting to other nations.

(e) ALLOCATION OF FUNDS FOR NORTH KOREA.—Of the funds under subsection (b), \$2,000,000 is authorized to be appropriated for each fiscal year for additional personnel and broadcasting targeted at North Korea.

SEC. 4. REPORTING REQUIREMENT.

Not later than 90 days after the date of enactment of this Act, in consultation with the Board of Broadcasting Governors, the President shall prepare and transmit to Congress a report on a plan to achieve continuous broadcasting of Radio Free Asia and Voice of America to the People's Republic of China in multiple major dialects and languages.

SEC. 5. UTILIZATION OF UNITED STATES INTERNATIONAL BROADCASTING SERVICES FOR PUBLIC SERVICE ANNOUNCEMENTS REGARDING FUGITIVES FROM UNITED STATES JUSTICE.

United States international broadcasting services, particularly the Voice of America, shall produce and broadcast public service announcements, by radio, television, and Internet, regarding fugitives from the criminal justice system of the United States, including cases of international child abduction.

The SPEAKER pro tempore. Pursuant to House Resolution 302, the gentleman from California [Mr. ROYCE] and the gentleman from Indiana [Mr. HAMILTON] each will control 30 minutes.

The Chair recognizes the gentleman from California [Mr. ROYCE].

GENERAL LEAVE

Mr. ROYCE. Madam Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on this measure.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. ROYCE. Madam Speaker, I yield myself such time as I may consume. Madam Speaker, for the last few days, the House of Representatives has been debating policy for the most important bilateral relationship the United States has, and that is our relationship with the People's Republic of China. We have heard different views on how we should deal with this emerging power. It has been a good debate, a healthy debate for us to have. I have supported the initiatives that are part of that policy for freedom in China package, because together they contribute to a well-crafted China policy, a policy which positions the United States to stand up forcefully for our values and protect our national security. For certain our relationship with China is not easy. It will be the most challenging relationship we face in the next century. Moving forward, we must have principles to guide this relationship. For one, in all our dealings with the Beijing regime, it is essential that we do not shy away from our values. This means calling the Chinese leadership on democracy and on human rights, spotlighting the organ harvesting many Members have spoken against on this floor, and acting when we can. Standing up for our values also means promoting the free flow of uncensored information, which is the life-

blood of our values that Americans cherish and wish for the Chinese people.

□ 1500

That is why I am proud to be the author of the Radio Free Asia Act of 1997.

Everyone here has heard of Radio Free Europe; that is our effort which was so effective during the cold war in bringing information to those stuck behind the Iron Curtain. At that time we told the people of Eastern Europe what was happening in their own countries, but it was not really us telling them. It was the voices of Hungarians and Czechs and Poles broadcast on Radio Free Europe, telling their fellow countrymen about the politics and other developments in their home countries, and through this surrogate broadcasting Hungarians and Czechs and Poles and others were able to learn about human rights abuses and repression in their own countries and to ask why.

This information transmitted through the airwaves was tremendously effective in bringing about the demise of totalitarian regimes in these countries. How do we know that?

Lech Walesa of Poland and Vaclav Havel and Alexander Dubcek of Czechoslovakia, men who pulled the foundation out from communism, have said that Radio Free Europe did more than anything else to change those Communist regimes of Eastern Europe. It is clear, information is deadly to dictators. The Chinese people deserve no less of an effort from us.

Radio Free Asia has been up and running, breaking official silence in Asia for over a year now. It is patterned after Radio Free Europe. Radio Free Asia targets countries where Asians are unable to hear about developments in their own country, unable to hear about what is happening in their own capitals and even in their own cities and towns. Some 95 percent of Radio Free Asia's programming focuses on people and events within that targeted country. So while no Lech Walesa has emerged in China, I believe Radio Free Asia is one of the most powerful tools we have for promoting democracy and promoting human rights in China.

This bill will provide the means to broadcast 24 hours a day into China and Tibet and to expand broadcasting in North Korea. This round-the-clock broadcasting in Mandarin, Cantonese, Tibetan, and other dialects will be an invaluable source of uncensored information for the Chinese people, information they otherwise would be denied.

What do the Chinese people hear on Radio Free Asia? Weekly commentators, a discussion of topical issues with Chinese journalists. They hear China In Perspective, which deals with a range of issues, including the Chinese media; politics in the media; Tibet Today, a discussion of current issues in Tibet; "Voices of Current Party Members", which is a weekly discussion with current party members hosted by

a former editor of the People's Daily; and they have their own "Crossfire" show that they hear as well.

That sounds like pretty standard news and information, right? But it is not standard in a totalitarian country. And so the Beijing regime has complained. A Chinese Foreign Ministry spokesman recently denounced Radio Free Asia, saying it was using freedom of speech as an excuse to interfere in China's internal affairs. Freedom of speech and interference in internal affairs, and the Chinese Government has punished those caught listening to Radio Free Asia.

It also has tried to shut out these broadcasts through jamming. This jamming is not too effective though, and it will be less effective after the new transmitter approved by the Radio Free Asia Act of 1997 is built.

The fact is that there is no denying Radio Free Asia. Just look at this map of China. Each orange dot on this map represents a significant cluster of letters received by Radio Free Asia's Chinese listeners. Up and running only a little over a year, Radio Free Asia has received hundreds of these letters, many of them from students, which indicate that young people are listening as well, and let me just read sections of two.

This is from a worker in a labor union written this past September. He says, "every day in the past 8 months, 2 hours of my day belong to Radio Free Asia, which brings a fresh spring breeze to the stifling and repressed China and lets us see the hope for a free and democratic China."

Another letter written 2 months ago, quote: "Like most of my Chinese countrymen, I did not know what press freedom was and what human rights were, did not even know that Taiwan called itself the Republic of China and that the Dalai Lama even was awarded the Nobel Peace Prize. Then I bought a radio set, which made me hunger knowledge as I never have before."

I cannot imagine more powerful words, and I have nothing to add to those words.

Madam Speaker, I reserve the balance of my time.

Mr. HAMILTON. Madam Speaker, I yield myself such time as I may consume.

I rise in support of the bill. The bill authorizes \$30 million for Radio Free Asia for fiscal year 1998, \$22 million for fiscal year 1999. It authorizes an additional \$10 million for enhanced VOA broadcasting in China and North Korea for fiscal year 1998, and \$7 million for the same purpose in fiscal year 1999. The bill also authorizes an additional \$10 million in fiscal year 1998 and \$3 million for fiscal year 1999 for radio construction in support of enhanced broadcasting to China.

The bill requires that within 90 days the President and the Board of Broadcasting Governors submit to the Congress a plan to achieve 24-hour broadcasting of Radio Free Asia and Voice of

America to China in multiple dialects and languages.

The authorization funding for Radio Free Asia in this bill is identical to that provided in the State Department authorization conference language, so in a sense this is an issue that has already been agreed upon. There is additional authorization here for Voice of America broadcasting in China and North Korea and for radio construction that represents an increase in authorization levels from the State Department authorization conference language or the Commerce-Justice-State conference contemplated funding levels.

Insofar as I know, the administration has no objection to this bill. It did have some problems with the original bill. I think they have been addressed in the markup of the bill.

I totally agree with the sponsors of the bill that the promotion through Radio Free Asia of democracy and human rights is an extremely important element of U.S. foreign policy and one that we should support. I urge then the support for the bill.

Madam Speaker, I reserve the balance of my time.

Mr. ROYCE. Madam Speaker, I yield 3 minutes to the distinguished gentleman from New York [Mr. GILMAN], the chairman of the Committee on International Relations.

(Mr. GILMAN asked and was given permission to revise and extend his remarks.)

Mr. GILMAN. Madam Speaker, I am pleased to rise in support of H.R. 2322 sponsored by the gentleman from California [Mr. ROYCE]. This measure is an important enhancement to our international broadcasting to Asia.

Broadcasting to Asia, and particularly to China, is vital to the spread and support of democracy and the freedom of expression. I fully support the measure to expand broadcast capabilities of Radio Free Asia and the Voice of America through additional funding for personnel, for transmitters and for other broadcast requirements.

I commend the gentleman from California [Mr. ROYCE], the distinguished chairman of our Committee on International Relations Subcommittee on Africa for his foresight in drafting this bill. This additional funding that is supported by the Speaker and the President will increase the opportunity for the peoples living under communism in Asia to hear news and other programming untainted by State news services. Mr. ROYCE's worthy proposal will increase transmissions in Mandarin, Cantonese, Tibetan languages and other dialects. It is hoped that when we work with the Senate in conference on this proposal, we will not forget to add the Uygers in East Turkestan.

I commend the gentleman and urge our colleagues to support this measure.

Mr. HAMILTON. Madam Speaker, I reserve the balance of my time.

Mr. ROYCE. Madam Speaker, I yield 3½ minutes to the distinguished gen-

tleman from Nebraska [Mr. BEREUTER], chairman of the Subcommittee on Asia and the Pacific.

(Mr. BEREUTER asked and was given permission to revise and extend his remarks.)

Mr. BEREUTER. Madam Speaker, I would like to begin with an announcement. As some of the Members know, the Speaker appointed a bipartisan task force on the Hong Kong transition, were to give a quarterly report, and I want my colleagues to know that the first quarterly report or a summary thereof will be in the CONGRESSIONAL RECORD for today.

Madam Speaker, this legislation is very important. I rise in strong support of it and commend my distinguished colleague, the gentleman from California [Mr. ROYCE], for introducing this legislation. Madam Speaker, as mentioned this legislation authorizes appropriations specifically for broadcasting to China and North Korea and construction of broadcasting facilities. The purpose of this is to enhance America's ability to broadcast, increase the number of languages and dialects in which Radio Free Asia can broadcast.

As the chairman of the subcommittee, my colleagues might be interested in knowing that in order to assure that accurate, timely, uncensored news and information gets to China, Vietnam, Burma, Cambodia, North Korea and the rest of East Asia, that it is important to support the activities of Radio Free Asia and the Voice of America. Radio Free Asia can provide news to those who otherwise cannot obtain it because many of the governments in the region systematically control the flow of information to their own citizens.

Currently United States broadcasting in Chinese dialects totals only 7.5 hours daily by Radio Free Asia and 13 hours daily by Voice of America. This will permit expansion of broadcasting to 24 hours per day in Mandarin Chinese, plus expanded broadcasting in Cantonese, Tibetan, and other dialects. The combined Voice of America and Radio Free Asia broadcast to the region will provide listeners with a full-service broadcast covering local, national and international news, together with U.S. news and discussion of foreign policy. This would be the first around-the-clock broadcasting in Mandarin to China by any nation.

This resolution would also support one-time expenditures required to ensure reliable transmission of broadcasts to listeners in China and North Korea. This includes the purchase, modification, and operation of a transmission station in Saipan. Actually I think it is Tinian, an United States territory currently providing the strongest broadcast signal to China. The transmitter would also give Radio Free Asia a permanent transmission site, something it now lacks. The increased funds will also go to augment relay stations that carry the message on to China and other Asian countries.

Madam Speaker, in a world where Chinese military and diplomatic influence is growing, it is useful to remember the lessons of Radio Free Europe. Diplomats may have dismissed those broadcasts, but ordinary people listened. Eventually it was these ordinary people who were able to change those Communist systems.

The people of Asia who live under authoritarian regimes deserve no less of a commitment from the United States. If we are serious about spreading the voice of democracy to China, Vietnam, Cambodia, North Korea, Burma, and other authoritarian States in East Asia, this legislation assures that the message of democracy reaches the broadest possible audience.

In conclusion, Madam Speaker, this Member again would like to commend the distinguished gentleman from California [Mr. ROYCE] for his dedication and assistance in making this important increase in funding for Radio Free Asia and the Voice of America. It is an initiative which this Member has advocated in the House Committee on International Relations and elsewhere, and I thank this gentleman for bringing it to fruition.

Mr. HAMILTON. Madam Speaker, I yield 3 minutes to the distinguished gentleman from Indiana [Mr. ROEMER].

Mr. ROEMER. Madam Speaker, I thank my good friend and fellow Hoosier from Indiana for yielding this time to me, and I rise in strong support of this legislation.

I think this legislation has been explained very well by Members on both the Republican and the Democratic side. This bill authorizes \$30 million for Radio Free Asia for fiscal year 1998 and \$22 million for fiscal year 1999. As importantly, the bill authorizes an additional 10 million for enhanced VOA broadcasting in China and in North Korea for fiscal year 1998 and 7 million for the same purpose for fiscal year 1999.

As we have talked, Madam Speaker, this past week about American values, about human rights, about putting emphasis on these kinds of things in our very important bilateral relationship between the United States and China, this bill, I think, is at the crux of many of the things that the United States stands for.

□ 1515

We have engaged, I think, the past 2 weeks, when Jiang Zemin visited this country, in what the President has very appropriately called constructive engagement.

Now, there are some in this body that feel like we should not engage with the Chinese. I personally strongly support the President's constructive engagement. That means that you sit down and listen to one another, you meet with one another, and, at times, you strongly disagree with one another.

There is no better example, and I say to my colleagues on constructive engagement, there is no better example

of this than when the President was having a press conference with Jiang Zemin last week and a reporter asked them about Tiananmen Square. And Jiang Zemin said they did, in fact, what they had to do to restore economic and social stability.

And then the President had his turn, and the President very forcefully said, "I disagree, and you did the wrong thing. You did not do what was just, you did not stand up for human rights, and you will continue to be isolated in the world if you engage like that."

That is constructive engagement. I think in the most important bilateral relationship that our two countries will engage in, the Chinese and the American people in the next 20 and 30 and 50 years, the President's policy is right on the mark.

Now, I also think that we have engaged in some very constructive votes this past week. I personally have voted to stop the coerced abortions, and I applaud this body for that. I have voted to more prominently monitor human rights, and I applaud this body for that. I encourage more religious freedom in China. I think that these are the kinds of things we need to engage in with the Chinese, constructive engagement, and not destructive rhetoric.

I applaud the author of this bill, and I strongly encourage my colleagues to support it.

Mr. ROYCE. Madam Speaker, I yield 3 minutes to the gentleman from New York [Mr. SOLOMON], the distinguished chairman of the Committee on Rules.

Mr. SOLOMON. Madam Speaker, I certainly thank the gentleman from California for yielding me time.

Madam Speaker, as we bring this China package to a close, I would just once again like to thank all of these people who helped make this happen, the gentleman from California [Mr. COX], the gentleman from New York [Mr. GILMAN], the gentleman from New Jersey [Mr. SMITH], the gentlewoman from California [Ms. PELOSI], the gentleman from Missouri [Mr. GEPHARDT] on the other side of the aisle, and all of the rest of the Members and staff who have been so committed on this for such a long time.

This has been a grueling process, yes, it has; several days on the floor, and months, even years of work, by the people that I have just mentioned.

But for those who are fatigued, and I certainly am, we must remember, what we endure is nothing compared to what the people of China have endured on a daily basis, every single day throughout the 48-year reign of the Communists in that unfortunate country, and they are the reason we have been here for the past several days with this very, very vital legislation, for we all know that when the people of China are free, America and China will develop a long-lasting friendship, and that is the way it ought to be, based on respect, based on trust and the mutual interests of 1.5 billion people.

That is why it is fitting that we end this process with the gentleman from

California [Mr. ROYCE], and I commend the gentleman from California [Mr. ROYCE] on this bill to enhance the capabilities of Radio Free Asia and the Voice of America to broadcast the truth to the Chinese people.

Madam Speaker, few things could be more heartening than to hear the stories from the victims of Communist repression in the former Soviet Union about how Radio Liberty about how Radio Free Europe and the Voice of America kept their hopes alive, gave them a beacon of hope during their darkest hours behind that Iron Curtain, and now they are free. Awareness of the truth and the knowledge that someone else really cared about them kept these people going under the worst of circumstances.

Madam Speaker, this is real engagement, engagement with the people of China, not with those Communist thugs who repress them, who imprison them, who beat them and give them a bad name abroad with their missile diplomacy and rogue activities. And we all know what we have been talking about for the last 3 weeks.

Radio Free Asia and the Voice of America are underfunded. They are only broadcasting a few hours a day and only a couple of dialects. This bill rectifies that by giving \$50 million for this year alone.

Madam Speaker, if the Committee on Appropriations sees fit to provide this money, and we all here will see they will, I can even suggest a perfect offset. Thursday night, this House approved my bill to oppose the World Bank's soft loans to the Communist Government of China by an overwhelming majority.

In 1996, the World Bank loaned about \$500 million to these thugs in Beijing. Since the United States owns about 15 percent of the World Bank, that means American taxpayers directly gave the Communist dictators in Beijing \$75 million of the taxpayers' money in interest-free, 35-year loans, and a 30-year grace period. We can put an end to that.

Madam Speaker, I thank the gentleman for yielding me this time. And this is perhaps the fitting end to these 10 bills that we have brought on this floor. The gentleman is to be commended. Let us come over here and vote unanimously for this vital piece of legislation.

Mr. ROYCE. Madam Speaker, I yield 2½ minutes to my colleague, the gentleman from California [Mr. ROHRBACHER].

Mr. ROHRBACHER. Madam Speaker, I rise in strong support of this amendment and Radio Free Asia. I would like to compliment the gentleman from California [Mr. ROYCE], my colleague and fellow Orange Countian, who has done so much over the years on this issue. He has made it real.

Ed, congratulations for a job well done.

There would not be a Radio Free Asia in the works and heading toward going

on the air if it was not for the fact that the gentleman from California [Mr. ROYCE] put in so much time and effort on this commendable piece of legislation.

During the cold war, we must remember that it was not our weapons and technology alone that won the day and ushered the world into a new era of peace and prosperity. And peace and prosperity is yet to prevail, but we have more opportunities for that than we have had during my entire lifetime.

While the courage of the Armed Forces and their technological edge was certainly an imperative that we needed during the cold war, our commitment to Radio Free Europe, the Voice of America, and Radio Liberty kept alive the flame of freedom in the hearts of people who were oppressed from the Balkans to the Baltics. This flame was in the hearts of America's greatest allies.

Our greatest allies in the cold war were those people who lived in Communist countries. And when they knew that we did not forget them, the flame lived on and eventually that conflagration brought down the Communist empire. With communism we were able to destroy the wills of the leadership by mustering support among the people they repressed.

The Good Book tells us that the truth will make you free. Today, with the Soviet collapse, it is our turn now; we must turn to finish the job. We must show the people of Asia that we have as great a commitment to their freedom as we had to the people of Europe.

Radio Free Asia will affirm to the good people throughout Asia that we are on their side, and they need this message when they can only see U.S. corporations exploiting their cheap labor, exploiting their environmental laws that permit corporations to come in and exploit the environment. When they see these, they need to be reaffirmed.

The people of Asia need a confirmation that we are on their side, and that is what Radio Free Asia will do. The Ughyurs, for example, in East Turkmenistan, now live under the heel of the Communist dictatorship in Beijing. We need to broadcast to those and other people, whether they be in Burma, Vietnam, or elsewhere, we believe in freedom, and if we hold firm to our principles in the United States of America, those principles of our Founding Fathers, we will finish the job of ending the cold war, and indeed the world will have a new era of peace and prosperity and freedom.

Mr. HAMILTON. Madam Speaker, I yield 3 minutes to the distinguished gentlewoman from Texas [Ms. JACKSON-LEE].

(Ms. JACKSON-LEE of Texas asked and was given permission to revise and extend her remarks.)

Ms. JACKSON-LEE of Texas. I, too, rise this afternoon to give my appreciation for the author of this legislation

and as well the ranking member of this committee for coming together around a very instructive and creative opportunity for us to recognize and to commemorate, if you will, the results of Radio Free Europe.

I can almost say to this House, need I say any more, all of us who have grown up in the World War era are aware of the impact of Radio Free Europe. In fact, it became the symbol of freedom. And as we listened ourselves, hearing about stories and reports on Radio Free Europe, needless to say, those voices that were being heard were impacting on smaller ears, younger people, people who thought that freedom now could be a reality for them.

Why not Radio Free Asia? In the time of child labor, religious persecution, and the denial of free thought, in one of the biggest markets in this world, do we not have the responsibility to say that economics is important but the free thought of those who live under those systems has to be of primary importance to those of us who claim capitalism on the economic side but freedom of thought and religion on the social justice side?

Yes, many of us have supported most favored-nation and we recognize through our corporate community that Southeast Asia is an attractive market. But can we stand by while the dollars flow in and out, while the markets increase, and yet there are people in these nations who cannot gather in their homes to worship their God?

There are people in these nations who cannot think freely for themselves to worship as they desire. And, yes, there are those who have been called to claim the message of whatever faith they believe in who cannot speak.

Radio Free Asia has to exist. We must use it responsibly, however. It cannot be accusatory. It cannot be threatening. It should not be where it is decisive. We simply have to let them hear the truth. We simply have to have them hear the voices of reason. We simply have to have those voices of free thought who can speak about the issues in a free and thoughtful manner be projected on those younger ears, those ears of those who have not heard.

I think Radio Free Asia will tell the real story. Once you hear and once you understand, then you will act. That is what this whole opportunity for Radio Free Asia will generate, and that is a hearing and understanding and an acting.

Madam Speaker, I would simply say that the dollar is not the almighty dollar as some of us have heard it claimed. It must be balanced with the freedom of speech and understanding, the freedom of religion, the freedom of thought. And out of that comes a real appreciation for where you live, and the value of the dollar diminishes when you have freedom for all.

I thank the author of the bill and encourage all of my colleagues to vote for this very timely legislation.

Mr. ROYCE. Madam Speaker, I yield 2 minutes to my colleague, the gentleman from Arizona, [Mr. SALMON], who speaks Mandarin and has spent time in China.

Mr. SALMON. Madam Speaker, I thank the gentleman for introducing this badly needed piece of legislation. In fact, I do not think I am alone in believing that this alone will probably go further than almost anything else that we have done this week or probably this year.

Mr. Rohrabacher made a comment, in fact quoted my favorite scripture from the New Testament, when he said, you shall know the truth and the truth shall make you free. Unfortunately, in China the truth does not find a way of filtering itself down to the common people on a daily basis.

I saw some footage last week when President Jiang Zemin visited these United States about the coverage in China, and it is interesting, because as we know, in watching our media, when Mr. Jiang went from place to place, there were numerous protests regarding various policies, regarding policies regarding Tibet, regarding policies regarding religious worship, regarding policies dealing with forced abortion. In fact, it was a very mixed bag of reviews. Most of the stops that he made had very, very angry people.

But none of that was filtered down to the common citizens in China. They never heard that information. They think everything is hunky-dory and we all love the guy.

That kind of information has to get down to the people so they do not give way to despondency, so they can keep some hope, some courage, that freedom is very much alive here in this country and we are still plugging for them.

When we continue with MFN, which a majority of Members in this body supported, sometimes I wonder if they get a mixed message, a wrong message. Many of us who support MFN also care deeply about human rights. We don't believe it is OK to turn a deaf ear to the human misery and suffering going on in China. We believe it is time for tough talk.

As the gentleman from Indiana [Mr. ROEMER] said, the President made some very tough statements last week, as he should have. That needs to be filtered down to the rank and file. They need to know that we care; they need to know we are with them, that we believe in freedom and that we believe it will happen if we persevere. That is what constructive engagement is all about.

Congratulations, Mr. ROYCE. This bill is going to go a long way to providing truth for the Chinese people.

Mr. ROYCE. Madam Speaker, I yield 2¼ minutes to the gentleman from Arkansas [Mr. HUTCHINSON].

□ 1530

Mr. HUTCHINSON. Madam Speaker, I rise in strong support of H.R. 2232, and I want to express my appreciation to the gentleman from California for

his leadership on this very important issue.

As a new Member of Congress, I believe this legislation involves one of the most important issues we have dealt with. My colleagues might ask why is that the case, and it is because it involves the fundamental issues of freedom and liberty.

I think about my father, who is now deceased, but when wartime came around, he was past draft age, he had 4 children, he did not need to go, but he went to serve in our Armed Forces. Why did he go, as so many others went? Because it was not necessarily what was happening in America, but it was about what America stood for; it was about liberty, it was about freedom, it was about supporting that voice around the world.

I think it is what America stands for. Today, the Voice of America, Radio Free Asia, needs to be strengthened in China. Madam Speaker, \$10 million for the Voice of America, \$20 million for Radio Free Asia. It is money well spent.

I think about Tiananmen Square and the images that that portrayed across America of those Chinese students, in their way, standing for freedom and speaking against a repressive regime. What can we do to help them?

Well, there are some things that we can do in these bills that we have passed, and China sanction legislation represents that. But there is one thing that government cannot stop and that is the Voice of America, it is the voice of freedom, the voice of liberty. Truth, truth cannot be shut out. If we can get that message in, then we can encourage those people who are still being repressed; we can raise the voice and awareness of democracy.

There is a temptation in America today that we should withdraw from world affairs, that we do not need to be concerned with what happens in China, and I reject that argument. I believe that we still need to be the leader of the free world. As Alexander Solzhenitsyn said, who is the Russian dissident who spent years in the gulag, "If America does not lead the free world, then the free world will not have a leader."

This is a small burden to pay for the price of liberty. We should support it enthusiastically. I urge my colleagues to support it.

Mr. HAMILTON. Madam Speaker, I yield 3 minutes to the distinguished gentleman from Illinois [Mr. PORTER].

Mr. PORTER. Madam Speaker, I thank the gentleman from Indiana for his graciousness in yielding me this time. I commend him and the gentleman from California [Mr. ROYCE] for their tremendous leadership in bringing this bill to the floor of the House of Representatives.

Madam Speaker, when we complete this series, we will have passed nine very significant bills designed to effect change in China. While I am biased on this matter, I believe this is the best of

the nine, and I believe that because I think it has more potential than any of the others in really providing for change in Chinese society.

We know this because of the record of Radio Liberty and Radio Free Europe during the cold war. Madam Speaker, surrogate radios are not propaganda, they are the beaming of truth and ideas and news into censored societies, societies where those ideas from outside are not permitted. And under Radio Free Asia, the concepts of freedom, of democracy, of free enterprise, of the rule of law, of an independent judiciary, the very values that we as Americans believe in so deeply, are reaching their way today into closed societies in Asia.

The ideas of Jefferson and Lincoln, the ideas that cannot be heard there, the ideas of their own people in believing in these values are getting through, and this legislation will cause that to be ramped up 3 times what we are doing today, and will affect not only China, but Burma, Vietnam, Tibet, North Korea, Laos, places where autocratic regimes hold sway.

Madam Speaker, this is cost-effective legislation and \$40 million will provide for construction of new antennae and broadcasting facilities and the broadcasts themselves. Through Voice of America and Radio Free Asia, and let me say, Madam Speaker, that Voice of America is equally important in doing a marvelous job for this country all across this world. It is simply a different approach than the surrogate radios. Both are needed. We will be able to broadcast 24 hours a day in Mandarin, more broadcasts in Cantonese. This is exactly what we need to be doing.

Madam Speaker, 3 years ago myself and Helen Bentley conceived Radio Free Asia. Senator BIDEN picked up this matter over in the Senate and came aboard, and we passed legislation into law, and today Dick Richter and his very able staff are making a real difference in that part of the world.

The concept of beaming truth and uncensored news and information and ideas and values will change these closed societies, will make a difference in the lives of the Chinese people and the people of Burma and Vietnam and other places in Europe. They will do so at a much less cost than any other approach, and with tremendous effectiveness. I commend the gentleman from California [Mr. ROYCE]; I commend the gentleman from New York [Mr. GILMAN]; the gentleman from Indiana [Mr. HAMILTON]; the gentleman from Nebraska [Mr. BEREUTER]. All of them have provided tremendous leadership in making this happen.

This is extremely important legislation that will make a true difference in this world, and I commend it to all Members.

Mr. ROYCE. Madam Speaker, I yield 4 minutes to the distinguished gentleman from California [Mr. COX], chairman of the Policy Committee, a

colleague who has spearheaded the Policy for Freedom package.

Mr. COX of California. Madam Speaker, I would like to thank especially the gentleman from California [Mr. ROYCE]. I want to commend the sponsor of this vital bill, my colleague from California, the chairman of the Committee on International Relations Subcommittee on Africa, for his leading role in policymaking. Prior to his committee chairmanship on the Subcommittee on Africa, he was the vice chairman of the Subcommittee on Asia and the Pacific. He went with the Speaker of the House this year to the People's Republic of China, to Taiwan and to Hong Kong, and today, after literally years of work, he is bringing to us this bill which is rightly praised by his colleagues on both sides of the aisle.

Radio Free Asia builds on Justice Louis Brandeis' great axiom of civil liberties, that sunshine is the best disinfectant. That is what this is all about. That is what in fact makes our system so wonderfully resilient.

Driving to the Capitol on a recent day, listening to our local news radio station, WTOP, I heard no fewer than 3 separate China Moments, China Moments paid for by government-owned firms in the People's Republic of China. They lionized President Jiang Zemin. They hyped Communist rule in China. They propagandized in the best Madison Avenue style that money can buy, and I listened to it, because I am an American.

The Government of the People's Republic of China can talk directly to us as Americans whenever they wish to do so, through their own magazines, which they do in this country, through the Internet, through talking heads on television and via authentic, unbiased, competitive news media in our country. Information, not just in America, but in the world, is the oxygen of freedom, and at the same time, censorship is the staff of life for a dictatorship. The People's Republic of China's Government knows this full well, and as a result, control and suppression of information is of paramount priority for them.

The PRC's oligarchy controls all newspapers, all radio, all television, through suffocating direct ownership or, just as stifling, censorship and regulation. It controls informal flows of information through the pervasive use of wiretapping, informants and surveillance, and it is even building an infrastructure so that the state in the 21st century can control the Internet. It is now seeking to jam broadcasts of Radio Free Asia and the Voice of America, an issue that our leadership raised directly with President Jiang when he was here in the Capitol just days ago.

The bill of the gentleman from California [Mr. ROYCE] is going to allow 24-hour-a-day broadcasts of Radio Free Asia in Mandarin, Cantonese and Tibetan as well as broadcasting in other major dialects. It will allow the cre-

ation of a Cantonese Language Service with 16 journalists. I strongly commend this bill which will let sunlight shine into every corner of China.

When Jiang Zemin visited the United States of America, he went to visit the Liberty Bell, and he read the Biblical verse on the Liberty Bell that reads: "Proclaim liberty throughout the land unto all the inhabitants thereof." That is what Radio Free Asia will do in Communist China.

Let freedom ring across the length and breadth of China, Madam Speaker. Pass this bill.

Mr. HAMILTON. Madam Speaker, I yield back the balance of my time.

Mr. ROYCE. Madam Speaker, I want to thank our colleague, the gentleman from California [Mr. COX] and his able staff, and I would like to thank the gentleman from Illinois [Mr. PORTER], who promoted Radio Free Asia over the years. A tremendous amount of work has gone into this effort. We have had a long and thorough debate throughout the last few days. There have been differences, but the Chinese people are yearning for information; not propaganda, but unbiased information, that is all. So I hope bolstering Radio Free Asia is something we can all support. This program has the opportunity to provide more than 1.4 billion, one-fourth of the world's population, with a daily dose of truth.

I would like to close my time by reading one last letter Radio Free Asia received from one of its Chinese listeners. "Congratulations on the first anniversary of your Mandarin broadcasts. I am one of your listeners writing to offer my thanks and congratulations. You have worked so hard and during this last year you have won some great victories. Here is hoping that your station in the future will gain a foothold in Asia and the world, and not fear cruelty and inhumanity."

Madam Speaker, in closing, let me yield 3 minutes to my distinguished colleague, the gentlewoman from San Francisco, CA [Ms. PELOSI].

Ms. PELOSI. Madam Speaker, I thank the gentleman for yielding me this time. I intend to yield back so that he can close, because he has worked so hard on this issue. But I will take a little bit of the time, if I may.

I thank my colleague the gentleman from California [Mr. ROYCE] for his leadership in bringing this important bill to the floor. It is appropriate that this piece of legislation be the last in this series of China bills, because it is a banner issue that we treat the people in Asia, Radio Free Asia in Asia and in China the way we conducted our approach to people in Eastern Europe throughout the cold war.

The gentleman from California [Mr. COX] was instrumental in putting a package together which had great consensus in this body. There were some of us who thought we could do more, but my colleague can prove us wrong by making these bills long, and then making these issues policy.

The leadership of the gentleman from California [Mr. COX] and the gentleman from California [Mr. ROYCE] and the gentleman from New York [Mr. GILMAN] and others enabled us to call to the attention of our colleagues and to our country the concerns that we have about the United States-China relationship. Most certainly we believe in engagement, but it must be effective engagement, that instead of contributing to an increased trade deficit and proliferation of weapons of mass destruction with impunity and ignoring of the repression in China, instead, that effective engagement would make the world safer, the trade fairer, and people freer. And Radio Free Asia, the Radio Free Asia part of this package is further to the point of making people freer.

So many people have told us, and I know that my colleagues have addressed this, that in the course of the cold war their consolation was Radio Free Europe, that people in the outside world had not forgotten them, that we did respect their aspirations to live in a freer society. It was true then in Europe, it is true now for Asia, and we reject the notion that democratic freedoms and individual human rights are Western values. Indeed, they are universal values written on the hearts of men. The people in China who aspire for a freer China have quoted Thomas Jefferson, really quoted Thomas Jefferson. They have lived his words, not mocked them, as President Jiang did when he came here.

□ 1545

They have fought, risked their personal lives, the security of their families, and, indeed, their lives for principles that we as a country have advocated.

We say that promoting democratic values is a cornerstone of our foreign policy. If indeed it is in the world, it must be also in China. Radio Free Asia is the mechanism for us to give some encouragement to those who take such risks for freedom. Those people are the legitimate heirs of our Founding Fathers. For that reason, I commend my colleague for his leadership.

Mr. ROYCE. Madam Speaker, I yield myself such time as I may consume.

Madam Speaker, for the sake of freedom in China and throughout Asia, I urge my colleagues to support H.R. 2232, as amended, the Radio Free Asia Act of 1997.

Mr. KIM. Madam Speaker, I rise in strong support of H.R. 2232, a bill to authorize additional funds for Voice of America broadcasts in Chinese and Korean.

As a young boy growing up in Seoul during the Communist invasion, I can remember huddling around the radio with my family listening to these Voice of America broadcasts. In occupied Seoul, VOA was a prime source of news and inspiration in desperate times by providing timely and accurate news, unfiltered by our North Korean oppressors.

Today, North Korea is the most isolated, closed society in the world. The Communist

regime maintains tight control of the dissemination of information within North Korea. Our VOA broadcasts are the people's lifeline to outside news and information, and otherwise available.

Several weeks ago, I had the opportunity to meet with two North Korean defectors who were visiting Washington. They told of how North Koreans—desperate for real news from the outside world—risk their lives to listen to VOA broadcasts. If found by North Korean authorities, they face certain execution on the spot. Yet thousands surround secret, miniature radios listening to our VOA broadcasts.

Madam Speaker, VOA broadcasts to China and North Korea provide those people with their primary source of accurate news and information about events in their country and around the world.

I urge my colleagues to support this bill.

Mrs. LINDA SMITH of Washington. Madam Speaker, I rise today in support of H.R. 2232, the Radio Free Asia Act authored by Congressman Ed ROYCE. I believe this legislation is one of the most important pieces of the China package that the House of Representatives has been considering this week because it gives people hope. It is the most tangible way for the Chinese people to learn about the democratic rule of law, human rights, and current events around the world. It will also audibly demonstrate the aspirations of the American people to have a positive relationship with China as we enter the 21st century.

The Radio Free Asia Act is a direct counterpoint to the oppressive policies of the Chinese Government. The lack of a free flow of information within China makes it all the more important that the broadcasts of Voice of America and Radio Free Asia are heard loud and clear. While the government of China can stifle their own press and attempt to jam our broadcasts, by increasing the number of hours on the air as well as the variety of dialects, a message of hope and freedom will be heard by countless millions.

My colleague, Congressman FRANK WOLF, recently came back from a trip to Tibet and he reported that the broadcasts of Radio Free Asia were a great source of encouragement to the Tibetan population. The least that we can do is to ensure that these broadcasts continue by providing the necessary funds to sustain and increase these broadcasts.

I urge my colleagues to join me in passing the Radio Free Asia Act.

Mr. ROYCE. Madam Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mrs. EMERSON). Pursuant to House Resolution 302, the previous question is ordered on the bill, as amended.

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

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

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. ROYCE. Madam Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 5(b) of rule I, further proceedings on this matter are postponed.

DESIGNATION OF THE HONORABLE CONSTANCE A. MORELLA TO ACT AS SPEAKER PRO TEMPORE TO SIGN ENROLLED BILLS AND JOINT RESOLUTIONS FOR REMAINDER OF FIRST SESSION OF 105TH CONGRESS

The SPEAKER pro tempore laid before the House the following communication from the Speaker:

WASHINGTON, DC,

November 9, 1997.

I hereby designate the Honorable CONSTANCE A. MORELLA to act as Speaker pro tempore to sign enrolled bills and joint resolutions for the remainder of the first session of the One Hundred Fifth Congress.

NEWT GINGRICH,

Speaker of the House of Representatives.

The SPEAKER pro tempore. Without objection, the designation is agreed to. There was no objection.

COMMUNICATION FROM CHAIRMAN OF THE COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE

The Speaker pro tempore laid before the House the following communication from the chairman of the Committee on Transportation and Infrastructure; which was read and, without objection, referred to the Committee on Appropriations and ordered to be printed.

Washington, DC, November 4, 1997.

Hon. NEWT GINGRICH,

Speaker, United States House of Representatives, Capitol Building, Washington, DC.

DEAR SPEAKER GINGRICH: On Wednesday, October 29, 1997, the Committee on Transportation and Infrastructure, pursuant to 40 U.S.C. § 606, approved fifteen resolutions authorizing appropriations for federal buildings and leased space. Please find enclosed copies of these resolutions.

With warm regards, I remain,

Sincerely,

BUD SHUSTER,

Chairman.

There was no objection.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to the provisions of clause 5 of rule I, the Chair announces that she will postpone further proceedings today on each motion to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote is objected to under clause 4 of rule XV.

Such rollcall votes, if postponed, will be taken later today.

VETERANS' BENEFITS ACT OF 1997

Mr. STUMP. Madam Speaker, I move to suspend the rules and pass the Senate bill (S. 714) to extend and improve the Native American Veteran Housing Loan Pilot Program of the Department of Veterans Affairs, to extend certain authorities of the Secretary of Veterans Affairs relating to services for homeless veterans, to extend certain other authorities of the Secretary, and for other purposes, as amended.

The Clerk read as follows:

S. 714

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the ‘‘Veterans’ Benefits Act of 1997’’.

(b) **TABLE OF CONTENTS.**—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. References to title 38, United States Code.

TITLE I—EQUAL EMPLOYMENT OPPORTUNITY PROCESS IN THE DEPARTMENT OF VETERANS AFFAIRS

Sec. 101. Equal employment responsibilities.
Sec. 102. Discrimination complaint adjudication authority.
Sec. 103. Assessment and review of Department of Veterans Affairs employment discrimination complaint resolution system.

TITLE II—EXTENSION AND IMPROVEMENT OF AUTHORITIES

Sec. 201. Native American Veteran Housing Loan Program.
Sec. 202. Treatment and rehabilitation for seriously mentally ill and homeless veterans.
Sec. 203. Extension of certain authorities relating to homeless veterans.
Sec. 204. Annual report on assistance to homeless veterans.
Sec. 205. Expansion of authority for enhanced-use leases of Department of Veterans Affairs real property.
Sec. 206. Permanent authority to furnish noninstitutional alternatives to nursing home care.
Sec. 207. Extension of Health Professional Scholarship Program.
Sec. 208. Policy on breast cancer mammography.
Sec. 209. Persian Gulf War veterans.
Sec. 210. Presidential report on preparations for a national response to medical emergencies arising from the terrorist use of weapons of mass destruction.

TITLE III—MAJOR MEDICAL FACILITY PROJECTS CONSTRUCTION AUTHORIZATION

Sec. 301. Authorization of major medical facility projects.
Sec. 302. Authorization of major medical facility leases.
Sec. 303. Authorization of appropriations.

TITLE IV—TECHNICAL AND CLARIFYING AMENDMENTS

Sec. 401. Technical amendments.
Sec. 402. Clarification of certain health care authorities.
Sec. 403. Correction of name of medical center.
Sec. 404. Improvement to spina bifida benefits for children of Vietnam veterans.

SEC. 2. REFERENCES TO TITLE 38, UNITED STATES CODE.

Except as otherwise expressly provided, whenever 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 title 38, United States Code.

TITLE I—EQUAL EMPLOYMENT OPPORTUNITY PROCESS IN THE DEPARTMENT OF VETERANS AFFAIRS

SEC. 101. EQUAL EMPLOYMENT RESPONSIBILITIES.

(a) **IN GENERAL.**—(1) Chapter 5 is amended by inserting at the end of subchapter I the following new section:

‘‘§ 516. Equal employment responsibilities

‘‘(a) The Secretary shall provide that the employment discrimination complaint resolution system within the Department be established and administered so as to encourage timely and fair resolution of concerns and complaints. The Secretary shall take steps to ensure that the system is administered in an objective, fair, and effective manner and in a manner that is perceived by employees and other interested parties as being objective, fair, and effective.

‘‘(b) The Secretary shall provide—

‘‘(1) that employees responsible for counseling functions associated with employment discrimination and for receiving, investigating, and processing complaints of employment discrimination shall be supervised in those functions by, and report to, an Assistant Secretary or a Deputy Assistant Secretary for complaint resolution management; and

‘‘(2) that employees performing employment discrimination complaint resolution functions at a facility of the Department shall not be subject to the authority, direction, and control of the Director of the facility with respect to those functions.

‘‘(c) The Secretary shall ensure that all employees of the Department receive adequate education and training for the purposes of this section and section 319 of this title.

‘‘(d) The Secretary shall, when appropriate, impose disciplinary measures, as authorized by law, in the case of employees of the Department who engage in unlawful employment discrimination, including retaliation against an employee asserting rights under an equal employment opportunity law.

‘‘(e)(1)(A) Not later than 30 days after the end of each calendar quarter, the Assistant Secretary for Human Resources and Administration shall submit to the Committees on Veterans’ Affairs of the Senate and House of Representatives a report summarizing the employment discrimination complaints filed against the individuals referred to in paragraph (2) during such quarter.

‘‘(B) Subparagraph (A) shall apply in the case of complaints filed against individuals on the basis of such individuals’ personal conduct and shall not apply in the case of complaints filed solely on the basis of such individuals’ positions as officials of the Department.

‘‘(2) Paragraph (1) applies to the following officers and employees of the Department:

‘‘(A) The Secretary.

‘‘(B) The Deputy Secretary of Veterans Affairs.

‘‘(C) The Under Secretary for Health and the Under Secretary for Benefits.

‘‘(D) Each Assistant Secretary of Veterans Affairs and each Deputy Assistant Secretary of Veterans Affairs.

‘‘(E) The Director of the National Cemetery System.

‘‘(F) The General Counsel of the Department.

‘‘(G) The Chairman of the Board of Veterans’ Appeals.

‘‘(H) The Chairman of the Board of Contract Appeals of the Department.

‘‘(I) The director and the chief of staff of each medical center of the Department.

‘‘(J) The director of each Veterans Integrated Services Network.

‘‘(K) The director of each regional office of the Department.

‘‘(L) Each program director of the Central Office of the Department.

‘‘(3) Each report under this subsection—

‘‘(A) may not disclose information which identifies the individuals filing, or the individuals who are the subject of, the complaints concerned or the facilities at which

the discrimination identified in such complaints is alleged to have occurred;

‘‘(B) shall summarize such complaints by type and by equal employment opportunity field office area in which filed; and

‘‘(C) shall include copies of such complaints, with the information described in subparagraph (A) redacted.

‘‘(4) Not later than April 1 each year, the Assistant Secretary shall submit to the committees referred to in paragraph (1)(A) a report on the complaints covered by paragraph (1) during the preceding year, including the number of such complaints filed during that year and the status and resolution of the investigation of such complaints.

‘‘(f) The Secretary shall ensure that an employee of the Department who seeks counseling relating to employment discrimination may elect to receive such counseling from an employee of the Department who carries out equal employment opportunity counseling functions on a full-time basis rather than from an employee of the Department who carries out such functions on a part-time basis.

‘‘(g) The number of employees of the Department whose duties include equal employment opportunity counseling functions as well as other, unrelated functions may not exceed 40 full-time equivalent employees. Any such employee may be assigned equal employment opportunity counseling functions only at Department facilities in remote geographic locations (as determined by the Secretary). The Secretary may waive the limitation in the preceding sentence in specific cases.

‘‘(h) The provisions of this section shall be implemented in a manner consistent with procedures applicable under regulations prescribed by the Equal Employment Opportunity Commission.’’

(2) The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 515 the following new item:

‘‘516. Equal employment responsibilities.’’

(b) **REPORTS.**—(1) The Secretary of Veterans Affairs shall submit to Congress reports on the implementation and operation of the equal employment opportunity system within the Department of Veterans Affairs. The first such report shall be submitted not later than April 1, 1998, and subsequent reports shall be submitted not later than January 1, 1999, and January 1, 2000.

(2) The first report under paragraph (1) shall set forth the actions taken by the Secretary to implement section 516 of title 38, United States Code, as added by subsection (a), and other actions taken by the Secretary in relation to the equal employment opportunity system within the Department of Veterans Affairs.

(3) The subsequent reports under paragraph (1) shall set forth, for each equal employment opportunity field office of the Department and for the Department as a whole, the following:

(A) Any information to supplement the information submitted in the report under paragraph (2) that the Secretary considers appropriate.

(B) The number of requests for counseling relating to employment discrimination received during the one-year period ending on the date of the report concerned.

(C) The number of employment discrimination complaints received during such period.

(D) The status of each complaint described in subparagraph (C), including whether or not the complaint was resolved and, if resolved, whether the employee concerned sought review of the resolution by the Equal Employment Opportunity Commission or by Federal court.

(E) The number of employment discrimination complaints that were settled during such period, including—

(i) the type of such complaints; and

(ii) the terms of settlement (including any settlement amount) of each such complaint.

(c) **EFFECTIVE DATE.**—Section 516 of title 38, United States Code, as added by subsection (a), shall take effect 90 days after the date of enactment of this Act. Subsection (e) of that section shall take effect with respect to the first quarter of calendar year 1998.

SEC. 102. DISCRIMINATION COMPLAINT ADJUDICATION AUTHORITY.

(a) **IN GENERAL.**—(1) Chapter 3 is amended by adding at the end the following new section:

“§319. Office of Employment Discrimination Complaint Adjudication

“(a)(1) There is in the Department an Office of Employment Discrimination Complaint Adjudication. There is at the head of the Office a Director.

“(2) The Director shall be a career appointee in the Senior Executive Service.

“(3) The Director reports directly to the Secretary or the Deputy Secretary concerning tribal matters within the responsibility of the Office.

“(b)(1) The Director is responsible for making the final agency decision within the Department on the merits of any employment discrimination complaint filed by an employee, or an applicant for employment, with the Department. The Director shall make such decisions in an impartial and objective manner.

“(2) No person may make any ex parte communication to the Director or to any employee of the Office with respect to a matter on which the Director has responsibility for making a final agency decision.

“(c) Whenever the Director has reason to believe that there has been retaliation against an employee by reason of the employee asserting rights under an equal employment opportunity law, the Director shall report the suspected retaliatory action directly to the Secretary or Deputy Secretary, who shall take appropriate action thereon.

“(d)(1) The Office shall employ a sufficient number of attorneys and other personnel as are necessary to carry out the functions of the Office. Attorneys shall be compensated at a level commensurate with attorneys employed by the Office of the General Counsel.

“(2) The Secretary shall ensure that the Director is furnished sufficient resources in addition to personnel under paragraph (1) to enable the Director to carry out the functions of the Office in a timely manner.

“(3) The Secretary shall ensure that any performance appraisal of the Director of the Office of Employment Discrimination Complaint Adjudication or of any employee of the Office does not take into consideration the record of the Director or employee in deciding cases for or against the Department.”.

(2) The table of sections at the beginning of such chapter is amended by adding at the end the following new item:

“319. Office of Employment Discrimination Complaint Adjudication.”.

(b) **REPORTS ON IMPLEMENTATION.**—The Director of the Office of Employment Discrimination Complaint Adjudication of the Department of Veterans Affairs (established by section 319 of title 38, United States Code, as added by subsection (a)) shall submit to the Secretary of Veterans Affairs and to Congress reports on the implementation and the operation of that office. The first such report shall be submitted not later than April 1, 1998, and subsequent reports shall be submitted not later than January 1, 1999, and January 1, 2000.

(c) **EFFECTIVE DATE.**—Section 319 of title 38, United States Code, as added by sub-

section (a), shall take effect 90 days after the date of enactment of this Act.

SEC. 103. ASSESSMENT AND REVIEW OF DEPARTMENT OF VETERANS AFFAIRS EMPLOYMENT DISCRIMINATION COMPLAINT RESOLUTION SYSTEM.

(a) **AGREEMENT FOR ASSESSMENT AND REVIEW.**—(1) The Secretary of Veterans Affairs shall seek to enter into an agreement with a qualified private entity under which agreement the entity shall carry out the assessment described in subsection (b) and the review described in subsection (c).

(2) The Secretary shall include in the agreement provisions necessary to ensure that the entity carries out its responsibilities under the agreement (including the exercise of its judgments concerning the assessment and review) in a manner free of influence from any source, including the officials and employees of the Department of Veterans Affairs.

(3) The Secretary may not enter into the agreement until 15 days after the date on which the Secretary notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the entity with which the Secretary proposes to enter into the agreement.

(b) **INITIAL ASSESSMENT OF SYSTEM.**—(1) Under the agreement under subsection (a), the entity shall conduct an assessment of the employment discrimination complaint resolution system administered within the Department of Veterans Affairs, including the extent to which the system meets the objectives set forth in section 516(a) of title 38, United States Code, as added by section 101. The assessment shall include a comprehensive description of the system as of the time of the assessment.

(2) Under the agreement, the entity shall submit the assessment to the committees referred to in subsection (a)(3) and to the Secretary not later than June 1, 1998.

(c) **REVIEW OF ADMINISTRATION OF SYSTEM.**—(1) Under the agreement under subsection (a), the entity shall monitor and review the administration by the Secretary of the employment discrimination complaint resolution system administered within the Department.

(2) Under the agreement, the entity shall submit to the committees referred to in subsection (a)(3) and to the Secretary a report on the results of the review under paragraph (1) not later than June 1, 1999. The report shall include an assessment of the administration of the system, including the extent to which the system meets the objectives referred to in subsection (b)(1), and the effectiveness of the following:

(A) Programs to train and maintain a cadre of individuals who are competent to investigate claims relating to employment discrimination.

(B) Programs to train and maintain a cadre of individuals who are competent to provide counseling to individuals who submit such claims.

(C) Programs to provide education and training to Department employees regarding their rights and obligations under the equal employment opportunity laws.

(D) Programs to oversee the administration of the system.

(E) Programs to evaluate the effectiveness of the system in meeting its objectives.

(F) Other programs, procedures, or activities of the Department relating to the equal employment opportunity laws, including any alternative dispute resolution procedures and informal dispute resolution and settlement procedures.

(G) Any disciplinary measures imposed by the Secretary on employees determined to have violated the equal employment opportunity laws in preventing or deterring viola-

tions of such laws by other employees of the Department.

TITLE II—EXTENSION AND IMPROVEMENT OF AUTHORITIES

SEC. 201. NATIVE AMERICAN VETERAN HOUSING LOAN PROGRAM.

(a) **EXTENSION OF PILOT PROGRAM.**—Section 3761(c) is amended by striking out “September 30, 1997” and inserting in lieu thereof “December 31, 2001”.

(b) **OUTREACH.**—Section 3762(i) is amended—

(1) by inserting “(1)” after “(i)”;

(2) by inserting “, in consultation with tribal organizations (including the National Congress of American Indians and the National American Indian Housing Council),” after “The Secretary shall”;

(3) by striking out “tribal organizations and”;

(4) by adding at the end the following:

“(2) Activities under the outreach program shall include the following:

“(A) Attending conferences and conventions conducted by the National Congress of American Indians in order to work with the National Congress in providing information and training to tribal organizations and Native American veterans regarding the availability of housing benefits under the pilot program and in assisting such organizations and veterans in participating in the pilot program.

“(B) Attending conferences and conventions conducted by the National American Indian Housing Council in order to work with the Housing Council in providing information and training to tribal organizations and tribal housing entities regarding the availability of such benefits.

“(C) Attending conferences and conventions conducted by the Department of Hawaiian Homelands in order to work with the Department of Hawaiian Homelands in providing information and training to tribal housing entities in Hawaii regarding the availability of such benefits.

“(D) Producing and disseminating information to tribal governments, tribal veterans service organizations, and tribal organizations regarding the availability of such benefits.

“(E) Assisting tribal organizations and Native American veterans in participating in the pilot program.

“(F) Outstationing loan guarantee specialists in tribal facilities on a part-time basis if requested by the tribal government.”.

(c) **ANNUAL REPORTS.**—Section 3762 is further amended by adding at the end the following new subsection:

“(j) Not later than February 1 of each year through 2002, the Secretary shall transmit to the Committees on Veterans' Affairs of the Senate and House of Representatives a report relating to the implementation of the pilot program under this subchapter during the fiscal year preceding the date of the report. Each such report shall include the following:

“(1) The Secretary's exercise during such fiscal year of the authority provided under subsection (c)(1)(B) to make loans exceeding the maximum loan amount.

“(2) The appraisals performed for the Secretary during such fiscal year under the authority of subsection (d)(2), including a description of—

“(A) the manner in which such appraisals were performed;

“(B) the qualifications of the appraisers who performed such appraisals; and

“(C) the actions taken by the Secretary with respect to such appraisals to protect the interests of veterans and the United States.

“(3) The outreach activities undertaken under subsection (i) during such fiscal year, including—

“(A) a description of such activities on a region-by-region basis; and

“(B) an assessment of the effectiveness of such activities in encouraging the participation of Native American veterans in the pilot program.

“(4) The pool of Native American veterans who are eligible for participation in the pilot program, including—

“(A) a description and analysis of the pool, including income demographics;

“(B) a description and assessment of the impediments, if any, to full participation in the pilot program of the Native American veterans in the pool; and

“(C) the impact of low-cost housing programs operated by the Department of Housing and Urban Development and other Federal or State agencies on the demand for direct loans under this section.

“(5) The Secretary's recommendations, if any, for additional legislation regarding the pilot program.”.

SEC. 202. TREATMENT AND REHABILITATION FOR SERIOUSLY MENTALLY ILL AND HOMELESS VETERANS.

(a) CODIFICATION AND REVISION OF PROGRAMS.—Chapter 17 is amended by adding at the end the following new subchapter:

“SUBCHAPTER VII—TREATMENT AND REHABILITATION FOR SERIOUSLY MENTALLY ILL AND HOMELESS VETERANS

“§ 1771. General treatment

“(a) In providing care and services under section 1710 of this title to veterans suffering from serious mental illness, including veterans who are homeless, the Secretary may provide (directly or in conjunction with a governmental or other entity)—

“(1) outreach services;

“(2) care, treatment, and rehabilitative services (directly or by contract in community-based treatment facilities, including halfway houses); and

“(3) therapeutic transitional housing assistance under section 1772 of this title, in conjunction with work therapy under subsection (a) or (b) of section 1718 of this title and outpatient care.

“(b) The authority of the Secretary under subsection (a) expires on December 31, 2001.

“§ 1772. Therapeutic housing

“(a) The Secretary, in connection with the conduct of compensated work therapy programs, may operate residences and facilities as therapeutic housing.

“(b) The Secretary may use such procurement procedures for the purchase, lease, or other acquisition of residential housing for purposes of this section as the Secretary considers appropriate to expedite the opening and operation of transitional housing and to protect the interests of the United States.

“(c) A residence or other facility may be operated as transitional housing for veterans described in paragraphs (1) and (2) of section 1710(a) of this title under the following conditions:

“(1) Only veterans described in those paragraphs and a house manager may reside in the residence or facility.

“(2) Each resident, other than the house manager, shall be required to make payments that contribute to covering the expenses of board and the operational costs of the residence or facility for the period of residence in such housing.

“(3) In order to foster the therapeutic and rehabilitative objectives of such housing (A) residents shall be prohibited from using alcohol or any controlled substance or item, (B)

any resident violating that prohibition may be expelled from the residence or facility, and (C) each resident shall agree to undergo drug testing or such other measures as the Secretary shall prescribe to ensure compliance with that prohibition.

“(4) In the establishment and operation of housing under this section, the Secretary shall consult with appropriate representatives of the community in which the housing is established and shall comply with zoning requirements, building permit requirements, and other similar requirements applicable to other real property used for similar purposes in the community.

“(5) The residence or facility shall meet State and community fire and safety requirements applicable to other real property used for similar purposes in the community in which the transitional housing is located, but fire and safety requirements applicable to buildings of the Federal Government shall not apply to such property.

“(d) The Secretary shall prescribe the qualifications for house managers for transitional housing units operated under this section. The Secretary may provide for free room and subsistence for a house manager in addition to, or instead of payment of, a fee for the services provided by the manager.

“(e)(i) The Secretary may operate as transitional housing under this section—

“(A) any suitable residential property acquired by the Secretary as the result of a default on a loan made, guaranteed, or insured under chapter 37 of this title;

“(B) any suitable space in a facility under the jurisdiction of the Secretary that is no longer being used (i) to provide acute hospital care, or (ii) as housing for medical center employees; and

“(C) any other suitable residential property purchased, leased, or otherwise acquired by the Secretary.

“(2) In the case of any property referred to in paragraph (1)(A), the Secretary shall—

“(A) transfer administrative jurisdiction over such property within the Department from the Veterans Benefits Administration to the Veterans Health Administration; and

“(B) transfer from the General Post Fund to the Loan Guaranty Revolving Fund under chapter 37 of this title an amount (not to exceed the amount the Secretary paid for the property) representing the amount the Secretary considers could be obtained by sale of such property to a nonprofit organization or a State for use as a shelter for homeless veterans.

“(3) In the case of any residential property obtained by the Secretary from the Department of Housing and Urban Development under this section, the amount paid by the Secretary to that Department for that property may not exceed the amount that the Secretary of Housing and Urban Development would charge for the sale of that property to a nonprofit organization or a State for use as a shelter for homeless persons. Funds for such charge shall be derived from the General Post Fund.

“(f) The Secretary shall prescribe—

“(1) a procedure for establishing reasonable payment rates for persons residing in transitional housing; and

“(2) appropriate limits on the period for which such persons may reside in transitional housing.

“(g) The Secretary may dispose of any property acquired for the purpose of this section. The proceeds of any such disposal shall be credited to the General Post Fund.

“(h) Funds received by the Department under this section shall be deposited in the General Post Fund. The Secretary may distribute out of the fund such amounts as necessary for the acquisition, management, maintenance, and disposition of real prop-

erty for the purpose of carrying out such program. The Secretary shall manage the operation of this section so as to ensure that expenditures under this subsection for any fiscal year shall not exceed by more than \$500,000 proceeds credited to the General Post Fund under this section. The operation of the program and funds received shall be separately accounted for, and shall be stated in the documents accompanying the President's budget for each fiscal year.

“§ 1773. Additional services at certain locations

“(a) Subject to the availability of appropriations, the Secretary shall operate a program under this section to expand and improve the provision of benefits and services by the Department to homeless veterans.

“(b) The program shall include the establishment of not fewer than eight programs (in addition to any existing programs providing similar services) at sites under the jurisdiction of the Secretary to be centers for the provision of comprehensive services to homeless veterans. The services to be provided at each site shall include a comprehensive and coordinated array of those specialized services which may be provided under existing law.

“(c) The program shall include the services of such employees of the Veterans Benefits Administration as the Secretary determines appropriate at sites under the jurisdiction of the Secretary at which services are provided to homeless veterans.

“(d) The program under this section shall terminate on December 31, 2001.

“§ 1774. Coordination with other agencies and organizations

“(a) In assisting homeless veterans, the Secretary shall coordinate with, and may provide services authorized under this title in conjunction with, State and local governments, other appropriate departments and agencies of the Federal Government, and nongovernmental organizations.

“(b)(1) The Secretary shall require the director of each medical center or the director of each regional benefits office to make an assessment of the needs of homeless veterans living within the area served by the medical center or regional office, as the case may be.

“(2) Each such assessment shall be made in coordination with representatives of State and local governments, other appropriate departments and agencies of the Federal Government, and nongovernmental organizations that have experience working with homeless persons in that area.

“(3) Each such assessment shall identify the needs of homeless veterans with respect to the following:

“(A) Health care.

“(B) Education and training.

“(C) Employment.

“(D) Shelter.

“(E) Counseling.

“(F) Outreach services.

“(4) Each assessment shall also indicate the extent to which the needs referred to in paragraph (3) are being met adequately by the programs of the Department, of other departments and agencies of the Federal Government, of State and local governments, and of nongovernmental organizations.

“(5) Each assessment shall be carried out in accordance with uniform procedures and guidelines prescribed by the Secretary.

“(c) In furtherance of subsection (a), the Secretary shall require the director of each medical center and the director of each regional benefits office, in coordination with representatives of State and local governments, other Federal officials, and nongovernmental organizations that have experience working with homeless persons in the areas served by such facility or office, to—

“(1) develop a list of all public and private programs that provide assistance to homeless persons or homeless veterans in the area concerned, together with a description of the services offered by those programs;

“(2) seek to encourage the development by the representatives of such entities, in coordination with the director, of a plan to coordinate among such public and private programs the provision of services to homeless veterans;

“(3) take appropriate action to meet, to the maximum extent practicable through existing programs and available resources, the needs of homeless veterans that are identified in the assessment conducted under subsection (b); and

“(4) attempt to inform homeless veterans whose needs the director cannot meet under paragraph (3) of the services available to such veterans within the area served by such center or office.”

(b) CONFORMING AMENDMENTS.—(1) Section 1720A is amended—

(A) by striking out subsections (a), (e), (f), and (g); and

(B) by redesignating subsections (b), (c), and (d) as subsections (a), (b), and (c), respectively.

(2) The heading of such section is amended to read as follows:

“§ 1720A. Treatment and rehabilitative services for persons with drug or alcohol dependency”.

(c) CONFORMING REPEALS.—The following provisions are repealed:

(1) Section 7 of Public Law 102-54 (38 U.S.C. 1718 note).

(2) Section 107 of the Veterans' Medical Programs Amendments of 1992 (38 U.S.C. 527 note).

(3) Section 2 of the Homeless Veterans Comprehensive Service Programs Act of 1992 (38 U.S.C. 7721 note).

(4) Section 115 of the Veterans' Benefits and Services Act of 1988 (38 U.S.C. 1712 note).

(d) CLERICAL AMENDMENTS.—The table of sections at the beginning of chapter 17 is amended—

(1) by striking out the item relating to section 1720A and inserting in lieu thereof the following:

“1720A. Treatment and rehabilitative services for persons with drug or alcohol dependency.”; and

(2) by adding at the end the following:

“SUBCHAPTER VII—TREATMENT AND REHABILITATION FOR SERIOUSLY MENTALLY ILL AND HOMELESS VETERANS

“1771. General treatment.

“1772. Therapeutic housing.

“1773. Additional services at certain locations.

“1774. Coordination with other agencies and organizations.”.

SEC. 203. EXTENSION OF CERTAIN AUTHORITIES RELATING TO HOMELESS VETERANS.

(a) AGREEMENTS FOR HOUSING ASSISTANCE FOR HOMELESS VETERANS.—Section 3735(c) is amended by striking out “December 31, 1997” and inserting in lieu thereof “December 31, 1999”.

(b) EXTENSION OF HOMELESS VETERANS COMPREHENSIVE SERVICE GRANT PROGRAM.—Section 3(a)(2) of the Homeless Veterans Comprehensive Service Programs Act of 1992 (38 U.S.C. 7721 note) is amended by striking out “September 30, 1997” and inserting in lieu thereof “September 30, 1999”.

(c) HOMELESS VETERANS' REINTEGRATION PROJECTS.—The Stewart B. McKinney Homeless Assistance Act is amended as follows:

(1) Section 738(e)(1) (42 U.S.C. 11448(e)(1)) is amended by adding at the end the following new subparagraph:

“(G) \$10,000,000 for fiscal year 1999.”.

(2) Section 741 (42 U.S.C. 11450) is amended by striking out “December 31, 1997” and inserting in lieu thereof “December 31, 1999”.

SEC. 204. ANNUAL REPORT ON ASSISTANCE TO HOMELESS VETERANS.

Section 1001 of the Veterans' Benefits Improvements Act of 1994 (38 U.S.C. 7721 note) is amended—

(1) in subsection (a)(2)—

(A) by striking out “and” at the end of subparagraph (B);

(B) by striking out the period at the end of subparagraph (C) and inserting in lieu thereof “; and”; and

(C) by adding at the end the following new subparagraphs:

“(D) evaluate the effectiveness of the programs of the Department (including residential work-therapy programs, programs combining outreach, community-based residential treatment, and case-management, and contract care programs for alcohol and drug-dependence or abuse disabilities) in providing assistance to homeless veterans; and

“(E) evaluate the effectiveness of programs established by recipients of grants under section 3 of the Homeless Veterans Comprehensive Service Programs Act of 1992 (38 U.S.C. 7721 note), and describe the experience of such recipients in applying for and receiving grants from the Secretary of Housing and Urban Development to serve primarily homeless persons who are veterans.”; and

(2) by striking out subsection (b).

SEC. 205. EXPANSION OF AUTHORITY FOR ENHANCED-USE LEASES OF DEPARTMENT OF VETERANS AFFAIRS REAL PROPERTY.

(a) FOUR-YEAR EXTENSION OF AUTHORITY.—Section 8169 is amended by striking out “December 31, 1997” and inserting in lieu thereof “December 31, 2001”.

(b) REPEAL OF LIMITATION ON NUMBER OF AGREEMENTS.—(1) Section 8168 is repealed.

(2) The table of sections at the beginning of chapter 81 is amended by striking out the item relating to section 8168.

SEC. 206. PERMANENT AUTHORITY TO FURNISH NONINSTITUTIONAL ALTERNATIVES TO NURSING HOME CARE.

(a) PERMANENT AUTHORITY.—Subsection (a) of section 1720C is amended by striking out “During” and all that follows through “furnishing of” and inserting in lieu thereof “The Secretary may furnish”.

(b) CONFORMING AMENDMENTS.—(1) Subsections (b)(1) and (d) of such section are amended by striking out “pilot”.

(2) The heading for such section is amended to read as follows:

“§ 1720C. Noninstitutional alternatives to nursing home care”.

(3) The item relating to such section in the table of sections at the beginning of chapter 17 is amended to read as follows:

“1720C. Noninstitutional alternatives to nursing home care.”.

SEC. 207. EXTENSION OF HEALTH PROFESSIONAL SCHOLARSHIP PROGRAM.

(a) EXTENSION.—Section 7618 is amended by striking out “December 31, 1997” and inserting in lieu thereof “December 31, 1998”.

(b) SUBMISSION OF OVERDUE REPORT.—The Secretary of Veterans Affairs shall submit to Congress not later than 180 days after the date of the enactment of this Act the report evaluating the operation of the health professional scholarship program required to be submitted not later than March 31, 1997, under section 202(b) of Public Law 104-110 (110 Stat. 770).

SEC. 208. POLICY ON BREAST CANCER MAMMOGRAPHY.

(a) IN GENERAL.—(1) Subchapter II of chapter 73 is amended by adding at the end the following new section:

“§ 7322. Breast cancer mammography policy

“(a) The Under Secretary for Health shall develop a national policy for the Veterans Health Administration on mammography screening for veterans.

“(b) The policy developed under subsection (a) shall—

“(1) specify standards of mammography screening;

“(2) provide recommendations with respect to screening, and the frequency of screening, for—

“(A) women veterans who are over the age of 39; and

“(B) veterans, without regard to age, who have clinical symptoms, risk factors, or family history of breast cancer; and

“(3) provide for clinician discretion.”.

(2) The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 7321 the following new item:

“7322. Breast cancer mammography policy.”.

(b) EFFECTIVE DATE.—The Secretary of Veterans Affairs shall develop the national policy on mammography screening required by section 7322 of title 38, United States Code, as added by subsection (a), and shall furnish such policy in a report to the Committees on Veterans' Affairs of the Senate and House of Representatives, not later than 60 days after the date of the enactment of this Act. Such policy shall not take effect before the expiration of 30 days after the date of its submission to those committees.

(c) SENSE OF CONGRESS.—It is the sense of Congress that the policy developed under section 7322 of title 38, United States Code, as added by subsection (a), shall be in accordance with the guidelines endorsed by the Secretary of Health and Human Services and the Director of the National Institutes of Health.

SEC. 209. PERSIAN GULF WAR VETERANS.

(a) CRITERIA FOR PRIORITY HEALTH CARE.—(1) Subsection (a)(2)(F) of section 1710 is amended by striking out “environmental hazard” and inserting in lieu thereof “other conditions”.

(2) Subsection (e)(1)(C) of such section is amended—

(A) by striking out “the Secretary finds may have been exposed while serving” and inserting in lieu thereof “served”;

(B) by striking out “to a toxic substance or environmental hazard”; and

(C) by striking out “exposure” and inserting in lieu thereof “service”.

(3) Subsection (e)(2)(B) of such section is amended by striking out “an exposure” and inserting in lieu thereof “the service”.

(b) DEMONSTRATION PROJECTS FOR TREATMENT OF PERSIAN GULF ILLNESS.—(1) The Secretary of Veterans Affairs shall carry out a program of demonstration projects to test new approaches to treating, and improving the satisfaction with such treatment of, Persian Gulf veterans who suffer from undiagnosed and ill-defined disabilities. The program shall be established not later than July 1, 1998, and shall be carried out at up to 10 geographically dispersed medical centers of the Department of Veterans Affairs.

(2) At least one of each of the following models shall be used at no less than two of the demonstration projects:

(A) A specialized clinic which serves Persian Gulf veterans.

(B) Multidisciplinary treatment aimed at managing symptoms.

(C) Use of case managers.

(3) A demonstration project under this subsection may be undertaken in conjunction with another funding entity, including agreements under section 8111 of title 38, United States Code.

(4) The Secretary shall make available from appropriated funds (which have been retained for contingent funding) \$5,000,000 to carry out the demonstration projects.

(5) The Secretary may not approve a medical center as a location for a demonstration project under this subsection unless a peer review panel has determined that the proposal submitted by that medical center is among those proposals that have met the highest competitive standards of clinical merit and the Secretary has determined that the facility has the ability to—

(A) attract the participation of clinicians of outstanding caliber and innovation to the project; and

(B) effectively evaluate the activities of the project.

(6) In determining which medical centers to select as locations for demonstration projects under this subsection, the Secretary shall give special priority to medical centers that have demonstrated a capability to compete successfully for extramural funding support for research into the effectiveness and cost-effectiveness of the care provided under the demonstration project.

SEC. 210. PRESIDENTIAL REPORT ON PREPARATIONS FOR A NATIONAL RESPONSE TO MEDICAL EMERGENCIES ARISING FROM THE TERRORIST USE OF WEAPONS OF MASS DESTRUCTION.

(a) REPORT.—(1) Not later than March 1, 1998, the President shall submit to Congress a report on the plans, preparations, and capability of the Federal Government and State and local governments for a national response to medical emergencies arising from the terrorist use of weapons of mass destruction. The report shall be submitted in unclassified form, but may include a classified annex.

(2) The report should be prepared in consultation with the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Veterans Affairs, the Director of the Federal Emergency Management Agency, and the head of any other department or agency of the Federal Government that may be involved in responding to such emergencies. The President shall designate a lead agency for purposes of the preparation of the report.

(b) CONTENTS.—The report shall include the following:

(1) A description of the steps taken by the Federal Government to plan and prepare for a national response to medical emergencies arising from the terrorist use of weapons of mass destruction.

(2) A description of the laws and agreements governing the responsibilities of the various departments and agencies of the Federal Government, and of State and local governments, for the response to such emergencies, and an assessment of the interrelationship of such responsibilities under such laws and agreements.

(3) Recommendations, if any, for the simplification or improvement of such responsibilities.

(4) An assessment of the current level of preparedness for such response of all departments and agencies of the Federal Government and State and local governments that are responsible for such response.

(5) A current inventory of the existing medical assets from all sources which can be made available for such response.

(6) Recommendations, if any, for the improved or enhanced use of the resources of the Federal Government and State and local governments for such response.

(7) The name of the official or office of the Federal Government designated to coordinate the response of the Federal Government to such emergencies.

(8) A description of the lines of authority between the departments and agencies of the

Federal Government to be involved in the response of the Federal Government to such emergencies.

(9) A description of the roles of each department and agency of the Federal Government to be involved in the preparations for, and implementation of, the response of the Federal Government to such emergencies.

(10) The estimated costs of each department and agency of the Federal Government to prepare for and carry out its role as described under paragraph (9).

(11) A description of the steps, if any, being taken to create a funding mechanism for the response of the Federal Government to such emergencies.

TITLE III—MAJOR MEDICAL FACILITY PROJECTS CONSTRUCTION AUTHORIZATION

SEC. 301. AUTHORIZATION OF MAJOR MEDICAL FACILITY PROJECTS.

The Secretary of Veterans Affairs may carry out the following major medical facility projects, with each project to be carried out in the amount specified for that project:

(1) Seismic corrections at the Department of Veterans Affairs medical center in Memphis, Tennessee, in an amount not to exceed \$34,600,000.

(2) Seismic corrections and clinical and other improvements to the McClellan Hospital at Mather Field, Sacramento, California, in an amount not to exceed \$48,000,000, to be derived only from funds appropriated for Construction, Major Projects, for a fiscal year before fiscal year 1998 that remain available for obligation.

(3) Outpatient improvements at Mare Island, Vallejo, California, and Martinez, California, in a total amount not to exceed \$7,000,000, to be derived only from funds appropriated for Construction, Major Projects, for a fiscal year before fiscal year 1998 that remain available for obligation.

SEC. 302. AUTHORIZATION OF MAJOR MEDICAL FACILITY LEASES.

The Secretary of Veterans Affairs may enter into leases for medical facilities as follows:

(1) Lease of an information management field office, Birmingham, Alabama, in an amount not to exceed \$595,000.

(2) Lease of a satellite outpatient clinic, Jacksonville, Florida, in an amount not to exceed \$3,095,000.

(3) Lease of a satellite outpatient clinic, Boston, Massachusetts, in an amount not to exceed \$5,215,000.

(4) Lease of a satellite outpatient clinic, Canton, Ohio, in an amount not to exceed \$2,115,000.

(5) Lease of a satellite outpatient clinic, Portland, Oregon, in an amount not to exceed \$1,919,000.

(6) Lease of a satellite outpatient clinic, Tulsa, Oklahoma, in an amount not to exceed \$2,112,000.

(7) Lease of an information resources management field office, Salt Lake City, in an amount not to exceed \$652,000.

SEC. 303. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There are authorized to be appropriated to the Secretary of Veterans Affairs for fiscal year 1998—

(1) for the Construction, Major Projects, account, \$34,600,000 for the project authorized in section 301(1); and

(2) for the Medical Care account, \$15,703,000 for the leases authorized in section 302.

(b) LIMITATION.—The projects authorized in section 301 may only be carried out using—

(1) funds appropriated for fiscal year 1998 pursuant to the authorization of appropriations in subsection (a);

(2) funds appropriated for Construction, Major Projects for a fiscal year before fiscal year 1998 that remain available for obligation; and

(3) funds appropriated for Construction, Major Projects for fiscal year 1998 for a category of activity not specific to a project.

TITLE IV—TECHNICAL AND CLARIFYING AMENDMENTS

SEC. 401. TECHNICAL AMENDMENTS.

(a) PLOT ALLOWANCE FOR DEATHS IN DEPARTMENT FACILITIES.—Section 2303(a)(2)(A) is amended by striking out “a Department facility (as defined in section 1701(4) of this title)” and inserting in lieu thereof “a facility of the Department (as defined in section 1701(3) of this title)”.

(b) EDUCATIONAL ASSISTANCE ALLOWANCE FOR CERTAIN INDIVIDUALS PURSUING COOPERATIVE PROGRAMS.—Section 3015(e)(1) is amended—

(1) by striking out “(1) Subject to paragraph (2)” and inserting in lieu thereof “(1)(A) Except as provided in subparagraph (B) of this paragraph and subject to paragraph (2)”;

(2) by adding at the end the following: “(B) Notwithstanding subparagraph (A) of this paragraph, in the case of an individual described in that subparagraph who is pursuing a cooperative program on or after October 9, 1996, the rate of the basic educational assistance allowance applicable to such individual under this chapter shall be increased by the amount equal to one-half of the educational assistance allowance that would be applicable to such individual for pursuit of full-time institutional training under chapter 34 (as of the time the assistance under this chapter is provided and based on the rates in effect on December 31, 1989) if such chapter were in effect.”

(c) ELIGIBILITY OF CERTAIN VEAP PARTICIPANTS TO ENROLL IN MONTGOMERY GI BILL.—Section 3018C(a) is amended—

(1) in paragraph (1), by striking out “the date of the enactment of the Veterans' Benefits Improvements Act of 1996” and inserting in lieu thereof “October 9, 1996”;

(2) in paragraph (4), by striking out “during the one-year period specified” and inserting in lieu thereof “after the date on which the individual makes the election described”;

(3) in paragraph (5), by striking out “the date of the enactment of the Veterans' Benefits Improvements Act of 1996” and inserting in lieu thereof “October 9, 1996”.

(d) ENROLLMENT IN OPEN CIRCUIT TELEVISION COURSES.—Section 3680A(a)(4) is amended by inserting “(including open circuit television)” after “independent study program” the second place it appears.

(e) ENROLLMENT IN CERTAIN COURSES.—Section 3680A(g) is amended by striking out “subsections (e) and (f)” and inserting in lieu thereof “subsections (e) and (f)(1)”.

(f) CERTAIN BENEFITS FOR SURVIVING SPOUSES.—Section 5310(b)(2) is amended by striking out “under this paragraph” in the first sentence and inserting in lieu thereof “under paragraph (1)”.

SEC. 402. CLARIFICATION OF CERTAIN HEALTH CARE AUTHORITIES.

(a) ELIGIBILITY FOR HOSPITAL CARE AND MEDICAL SERVICES.—Section 1710(a)(2)(B) is amended by striking out “compensable”.

(b) HOME HEALTH SERVICES.—Section 1717(a) is amended—

(1) in paragraph (1), by striking out “veteran's disability” and inserting in lieu thereof “veteran”;

(2) in paragraph (2)(B), by striking out “section 1710(a)(2)” and inserting in lieu thereof “section 1710(a)”.

(c) AUTHORITY TO TRANSFER VETERANS RECEIVING OUTPATIENT CARE TO NON-DEPARTMENT NURSING HOMES.—Section 1720(a)(1)(A)(i) is amended by striking out “hospital care, nursing home care, or domiciliary care” and inserting in lieu thereof “care”.

(d) ACQUISITION OF COMMERCIAL HEALTH CARE RESOURCES.—Section 8153(a)(3)(A) is amended by inserting “(including any Executive order, circular, or other administrative policy)” after “law or regulation”.

(e) COMPETITION IN PROCUREMENT OF COMMERCIAL HEALTH CARE RESOURCES.—Section 8153(a)(3)(B)(ii) is amended in the second sentence by inserting “, as appropriate,” after “all responsible sources”.

SEC. 403. CORRECTION OF NAME OF MEDICAL CENTER.

The facility of the Department of Veterans Affairs in Columbia, South Carolina, known as the Wm. Jennings Bryan Dorn Veterans' Hospital shall hereafter be known and designated as the “Wm. Jennings Bryan Dorn Department of Veterans Affairs Medical Center”. Any reference to that facility in any law, regulation, document, map, record, or other paper of the United States shall be deemed to be a reference to the Wm. Jennings Bryan Dorn Department of Veterans Affairs Medical Center.

SEC. 404. IMPROVEMENT TO SPINA BIFIDA BENEFITS FOR CHILDREN OF VIETNAM VETERANS.

(a) DEFINITIONS.—The text of section 1801 is amended to read as follows:

“For the purposes of this chapter—

“(1) The term ‘child’, with respect to a Vietnam veteran, means a natural child of a Vietnam veteran, regardless of age or marital status, who was conceived after the date on which the Vietnam veteran first entered the Republic of Vietnam during the period beginning on January 9, 1962, and ending on May 7, 1975.

“(2) The term ‘Vietnam veteran’ means an individual who performed active military, naval, or air service in the Republic of Vietnam during the period beginning on January 9, 1962, and ending on May 7, 1975, without regard to the characterization of the individual’s service.”.

(b) APPLICABILITY OF CERTAIN ADMINISTRATIVE PROVISIONS.—(1) Section 1806 is amended to read as follows:

“§1806. Applicability of certain administrative provisions

“The provisions of sections 5101(c), 5110(a), (b)(2), (g), and (i), 5111, and 5112(a), (b)(1), (b)(6), (b)(9), and (b)(10) of this title shall be deemed to apply to benefits under this chapter in the same manner in which they apply to veterans’ disability compensation.”.

(2) The item relating to section 1806 in the table of sections at the beginning of chapter 18 is amended to read as follows:

“1806. Applicability of certain administrative provisions.”.

(c) AMENDMENTS TO VOCATIONAL REHABILITATION PROVISIONS.—Section 1804 is amended—

(1) in subsection (b), by striking out “shall be designed” and all that follows and inserting in lieu thereof the following: “shall—

“(1) be designed in consultation with the child in order to meet the child’s individual needs;

“(2) be set forth in an individualized written plan of vocational rehabilitation; and

“(3) be designed and developed before the date specified in subsection (d)(3) so as to permit the beginning of the program as of the date specified in that subsection.”;

(2) in subsection (c)(1)(B), by striking out “institution of higher education” and inserting in lieu thereof “institution of higher learning”; and

(3) by adding at the end of subsection (d) the following new paragraph:

“(3) A vocational training program under this section may begin on the child’s 18th birthday, or on the successful completion of the child’s secondary schooling, whichever first occurs, except that, if the child is above

the age of compulsory school attendance under applicable State law and the Secretary determines that the child’s best interests will be served thereby, the vocational training program may begin before the child’s 18th birthday.”.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect as of October 1, 1997.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona [Mr. STUMP] and the gentleman from Illinois [Mr. EVANS] each will control 20 minutes.

The Chair recognizes the gentleman from Arizona [Mr. STUMP].

GENERAL LEAVE

Mr. STUMP. Madam Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on S. 714, the Senate bill presently under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Arizona?

There was no objection.

Mr. STUMP. Madam Speaker, I yield myself such time as I may consume.

Madam Speaker, the House amendments to S. 714 represent a compromise between the House and Senate veterans’ affairs committees on several measures considered by both sides this year. It requires the VA to develop new treatment programs for Persian Gulf war veterans, and clarifies that any Persian war veteran with an illness that could be due to service in the gulf is eligible for VA care.

The bill extends and streamlines laws under which the VA provides cares to homeless veterans and veterans who suffer from chronic mental illness. The bill authorizes funds for major medical facility projects, including funds to carry out seismic corrections projects at two VA medical centers.

The bill also creates a new process for resolving complaints of sexual harassment and employment discrimination at the VA. This process will be independent and free from undue influence from VA managers.

Madam Speaker, I reserve the balance of my time.

Mr. EVANS. Madam Speaker, I yield myself such time as I may consume.

Madam Speaker, I rise in support of S. 714, as amended. Madam Speaker, this agreement includes provisions to clarify, extend, and enhance measures to address homelessness among this Nation’s veterans. The provisions before us today will allow the VA to continue to offer a range of programs to homeless veterans. Together these programs comprise a comprehensive increase that meets veterans’ needs for health care, substance abuse treatment, vocational rehab work, and shelter. In addition, this measure extends the homeless veterans reintegration project administered by the Department of Labor and authorizes \$10 million for this important program for fiscal year 1999.

This measure also permanently authorizes the VA to provide noninstitu-

tional long-term care programs. Many veterans want to live at home as long as possible. Good noninstitutional programs can make this a reality. Under this authority the VA can provide cost-effective programs like home care, home aides, and adult day care to more veterans.

An important change in the eligibility of VA health care for the Persian Gulf veterans is included in this measure. Eligibility will now be based on a veteran’s service, rather than actual exposure to a specific agent or environmental hazard.

Authority is also provided for the VA to create 10 model Persian Gulf veterans’ treatment programs. Seven years has been too long to wait to meet the health care needs of our Persian Gulf veterans. I encourage the VA to develop centers of excellence and innovation for treatment of Persian Gulf symptoms related to their exposure.

The measure also requires the VA to establish a strong and comprehensive policy for mammography screening. The policy will specifically address women veterans over the age of 39 and any other veterans with clinical symptoms or risk factors that will allow physicians and patients to decide how long screening is necessary.

Two clarifying amendments are also included that should be mentioned. The first would clarify that children of Vietnam veterans who are born with spina bifida are eligible for the programs provided by the VA for such children, regardless of the character of the discharge of the child’s Vietnam veteran parent. Additionally, the VA is to develop a child’s vocational training program prior to the child’s eligibility to begin participation in that program.

This measure also extends for 4 years the authority provided in the Native American Veterans Housing Loan Pilot Program. This important program provides direct loans to Native American veterans who reside on trust lands to build or purchase homes on those lands.

I am pleased that the Department of Veterans Affairs Employment Discrimination Prevention Act of 1997 is included in this bill. This is timely, and important legislation to reform the equal employment opportunity process at the VA is long overdue. By removing the EEO process from the facility where the discrimination allegedly occurred, this bill limits the ability of heavy-handed facility directors to unfairly influence the process in a discrimination complaint by requiring that such complaints be handled mostly by full-time, well-trained investigators at the regional EEO field office level. This bill brings greater independence and professionalism to the process.

By removing the final decision-making process from the VA’s Office of General Counsel, this bill eliminates the obvious conflict of interest that exists today, when the General Counsel’s Office is expected to be an advocate for

the Department on one hand, and to decide the merits of a complaint against the Department on another hand.

Madam Speaker, I do want to thank the gentleman from Arizona, the chairman of the committee, for his continuing efforts on behalf of our Nation's veterans. This is the end of our first year of working together with the gentleman from Arizona [Chairman STUMP], and we have had a great experience dealing with him, and but also with his subcommittee chairs, CLIFF STEARNS, JACK QUINN and TERRY EVERETT. I thank them for work on behalf of our Nation's veterans.

I want to thank my equivalent subcommittee ranking members, the gentleman from Illinois, [LUIS GUTIERREZ], the gentleman from California, [BOB FILNER], and the gentleman from South Carolina, [JAMES CLYBURN], for their excellent commitment to our veterans.

Madam Speaker, I rise in support of S. 714, as amended. As amended, S. 714 contains provisions of major importance to our Nation's veterans. It deserves the support of every Member of the House.

A number of the provisions in the measure now before us have already been approved by the House in legislation reported earlier this year by the Committee on Veterans' Affairs. I will not review every provision in this legislation, but will highlight several of the provisions of particular importance.

The Department of Veterans Affairs Employment Discrimination Resolution and Adjudication Act of 1997 is long overdue. The VA's efforts to eradicate harassment in the workplace have met with little, if any, success since I chaired the first oversight hearings on this issue back in 1992. In the 103d Congress, I cosponsored a bill much like the legislation we are considering today which overwhelmingly passed the House, but received no action in the Senate. At that time, the VA believed a proposed Governmentwide reform of the Federal EEO process was in the works, and there was no need to pass legislation to address what most would agree was a very serious problem at the Department.

Nearly 5 years later, the long-promised Governmentwide reform has never come, and the VA's "zero tolerance" policy on sexual harassment has proven ineffective if not abysmal. That's why passage by both bodies of Congress of this timely and important legislation to reform the equal employment opportunity process at the VA is critically important.

By removing the EEO complaint process from the facility where the discrimination allegedly occurred, this bill limits the ability of heavy-handed facility directors to unfairly influence the processing of discrimination complaints; by requiring that such complaints be handled by mostly full-time, well-trained investigators at regional EEO field offices, this bill brings greater independence and professionalism to the process. And by removing the final agency decision-making authority from the VA's Office of General Counsel, this bill eliminates the obvious conflict-of-interest that exists today when the general counsel's office is expected to be an advocate for the Department on the one hand, and to decide the merits of a complaint against the Department on the other.

I want to applaud Chairman EVERETT for his willingness to work with JIM CLYBURN and me to put together a bill that will greatly improve the processing of discrimination complaints at the VA. I also want to thank Senators ARLEN SPECTER, BOB GRAHAM, JAY ROCKEFELLER, LAUCH FAIRCLOTH, and TIM HUTCHINSON for working with us in the House to put together a bill we can all be proud of. I also want to commend the Department of Veterans Affairs for their willingness to work with the committees on language to a bill that I know the VA doesn't love, but that most people—even within the VA—would agree they need.

By enacting this legislation, Congress will help put VA back on the path toward restoring employee trust in the EEO process and eradicating discrimination in the workplace. Our veterans and VA employees deserve no less.

A number of the provisions in the House amendment to S. 714 are derived from H.R. 2206, a bill the House already approved. These provisions include measures to clarify, extend, and enhance measures to address homelessness. On any given night in America one-third of those living on the streets are veterans—many of them are my peers from the Vietnam era. I find this hard to live with—both as a veteran and as an American citizen—and I believe the provisions included in the House amendment provide a greater opportunity to respond to this problem. These provisions will allow VA to continue to offer a range of programs to homeless veterans. Together these programs comprise a comprehensive network that meets veterans' needs for health care, substance abuse treatment, vocational rehabilitation, work, and shelter.

Additionally, the House amendment permanently authorizes VA to provide noninstitutional long-term care programs. Many veterans want to live at home as long as possible—good noninstitutional programs can make this a reality. I encourage VA to take full advantage of this permanent authority to provide cost-effective programs like home care, home aides, and adult day health care to more veterans.

The measure before the House also includes an important change in the eligibility for VA health care for Persian Gulf war veterans. The language makes eligibility for such services contingent upon veterans' service rather than their actual exposure to a specific agent or environmental hazard. The change is significant as it offers veterans, whose illnesses remain undiagnosed, the benefit of the doubt. Until science enables VA to link specific agents with their health consequences, suffering veterans will have the ability to access VA services to treat their special health care needs.

It also offers a provision to create 10 model Persian Gulf veterans' treatment programs in VA. Seven years has been too long to wait to meet the health care needs of these men and women. I am hopeful using this grant approach for funding will allow VA to develop some real centers of excellence and innovation for treatment of veterans' symptoms related to their gulf war deployment.

This measure will also extend authority for VA's Health Professional Scholarship Program for another year, but it will require VA to submit a report on the program's effectiveness in the first 6 months after enactment.

The measure requires VA to establish a strong and comprehensive policy for mammo-

gram screening. The policy will specifically address women veterans over the age of 39 and other veterans with clinical symptoms or risk factors, but will allow physicians and patients to decide how often screening is necessary.

Madam Speaker, I am very pleased that the compromise measure we are now considering includes provision which extends the homeless veterans reintegration project [HVRP] administered by the Department of Labor and authorizes \$10 million for the program. There is virtually no disagreement that one-third of the homeless men in this country are veterans—and that approximately 60 percent of those individuals are veterans of the Vietnam era. This means, Mr. Chairman, that every night, in this great country of ours, more than 280,000 veterans are sleeping on America's streets or in homeless shelters.

Since 1987, HVRP, a modest, cost-effective program designed to help homeless veterans reenter and succeed in the job market, has proven its worth. More than 41,000 homeless veterans have received help and support from the community-based organizations funded under HVRP, and many were placed in jobs at a cost of less than \$1,500 per veteran. Few Government programs can claim to have achieved so much with so little.

Earlier this year, the Veterans' Affairs Committee voted unanimously to fund HVRP. Republicans and Democrats alike came together to show their support for the men and women who have served honorably in our Nation's Armed Forces. Additionally, I was very pleased when the House unanimously approved an amendment I offered for myself and my distinguished colleague from California, Mr. FILNER, to the Labor, Health and Human Services Appropriation to increase HVRP funding, and I look forward to working with my colleagues on the Labor Appropriations Committee next year to ensure that HVRP is fully funded in fiscal year 1999.

Included in the House amendment to S. 714 are two clarifying amendments which deserve mention. First, the compromise would clarify that children of Vietnam veterans who are born with spina bifida are eligible for the programs provided by the VA for such children regardless of the character of discharge of the child's Vietnam veteran parent. Additionally, the agreement would clarify that VA assessment, evaluation, counseling, and the development of a child's vocational training program must begin at a time which will enable the child to begin participation in that program upon successful completion of secondary schooling or on the child's 18th birthday. These provisions are important to fair and effective implementation of the new spina bifida legislation, and I am pleased they are a part of this compromise measure.

Established under section 8 of Public Law 102-547, the Native American Veteran Housing Loan Pilot Program, administered by the Department of Veterans Affairs [VA], provides direct home loans to native American veterans who reside on trust lands to build or purchase homes on those lands. Previously, native American veterans who resided on trust lands were unable to qualify for VA home loan benefits. The authority for this program expired on September 30, 1997, and I strongly support the 4-year extension of the program included in the compromise agreement.

Under the pilot program, VA can make a loan to a native American veteran for a home

on trust lands only if VA had entered into a memorandum of understanding [MOU] with the Tribal entity that had jurisdiction over the trust land. Since the establishment of the program in 1992, VA has entered into 47 such MOU's and 164 loans have been made to native American veterans for the purchase, construction, or improvement of dwellings on trust land. Negotiations continue with hundreds of other tribes to establish memorandums of understanding and more than 90 individual loan applications are pending.

Although the numbers of native Americans who have taken advantage of the loan opportunities available under this program are smaller than expected, new outreach and reporting requirements included in the compromise agreement should result in an increased understanding of the program among Native Americans and thus increased participation.

The legislation we bring to the floor today also includes provisions from H.R. 2571, VA medical care major construction and lease authorizations for fiscal year 1998, another bill the House passed in October. This bill accommodates the administration's construction spending priorities as well as those projects for which appropriations have already been made.

The major construction projects require modest funding, but are critical to providing access to veterans in areas where their needs cannot be met or in maintaining patient safety in existing facilities which are deficient in conforming to seismic code. I am also pleased with the emphasis this bill places on outpatient projects and development of information resources management centers.

Leasing, rather than building, to meet VA's needs is also a move in the right direction. VA has sometimes been criticized for using "bricks and mortar" to meet its space requirements while facilities in the community stand vacant. The leases this bill authorizes are a more flexible means by which VA can provide the capacity it needs today, but may not need tomorrow.

Enhanced-use leases are a relatively new venture for VA, but they have proven to be a cost-effective means of providing programs to VA beneficiaries VA could not otherwise afford. The measure we offer today repeals limitations on the number of projects VA can enter in any given year or under current authority.

Enhanced-use leases allow VA to offer leases land or space to operate programs that ensure discounted benefits for VA, its beneficiaries or its employees over the terms of the lease. Space has been offered for a diverse range of services including child-care that benefits VA employees, co-generation projects, research facilities, and patient services.

I urge my colleagues from both sides of the aisle to join me in support of the provisions to improve health care and benefits for America's veterans that we bring to the floor today. As we approach Veterans Day 1997, this legislation will serve as a part of the appropriate recognition we pay to the men and women who have served our Nation in uniform. This legislation will honor their service and sacrifice and be a tangible expression of our continuing commitment to care for those who have borne the battle, and their survivors and dependents.

Madam Speaker, I reserve the balance of my time.

Mr. STUMP. Madam Speaker, I yield 2 minutes to the gentleman from Alabama [Mr. EVERETT], the chairman of the subcommittee.

(Mr. EVERETT asked and was given permission to revise and extend his remarks.)

Mr. EVERETT. Madam Speaker, I rise in strong support of S. 714, as amended, the Veterans Benefits Act of 1997.

Madam Speaker, I particularly want to address title I of the bill, which is derived from H.R. 1703, the Department of Veterans Affairs Employment Discrimination Resolution and Adjudication Act.

I introduced H.R. 1703 on May 22, 1997, and the House passed it on October 6, 1997. Title I represents a compromise agreement with the Senate on H.R. 1703 and S. 801, the Senate companion bill. I certainly recommend the results to my colleagues. The Senate drew much of the bill from the text of H.R. 1703, and the compromise is entirely consistent with the intent of the House bill.

Legislation to address the VA sexual harassment discrimination problems has been a very long time coming, since 1993, as a matter of fact. I am pleased with title I. I particularly want to thank Chairman STUMP for making it a priority for the Committee on Veterans' Affairs. I also want to thank the gentleman from Illinois [Mr. EVANS] from the committee, the gentleman from South Carolina [Mr. CLYBURN], ranking Democrat on the Subcommittee on Oversight and Investigations, for their original cosponsorship of H.R. 1703 and the leading roles they have played in the development of this important legislation. Also, the gentleman from Florida [Mr. BILIRAKIS] and the gentleman from Indiana [Mr. BUYER] were original cosponsors of H.R. 1703 and have been active in these provisions every step of the way.

Of course, without our Senate colleagues we would have no bill today. I want to commend Chairman SPECTER of the Senate Committee on Veterans' Affairs and Senator ROCKEFELLER, the ranking Democrat, for their hard work and cooperation on making this legislation possible today.

Madam Speaker, title I is for the loyal, dedicated employees of the VA who care for and serve our veterans. Some of them do not have the workplace environment of fairness and respect they deserve. I am optimistic these provisions, along with changes already occurring at the VA, will result in greatly improved employment confidence in the VA's ability to address sexual harassment and other discrimination problems.

This is good and much-needed legislation. I urge my colleagues to act favorably on S. 714, as amended.

Mr. EVANS. Madam Speaker, I yield 3 minutes to the gentleman from California [Mr. FILNER], a member of the committee.

Mr. FILNER. Madam Speaker, I rise in strong support of the Veterans Bene-

fits Act of 1997, S. 714, as amended. Veterans' programs and benefits will be enhanced as a result of enactment of this legislation.

I am particularly pleased that this legislation includes provisions which clarify eligibility for and implementation of the new program that provides benefits for the children of Vietnam veterans who are born with spina bifida. This very important program is in the early days of implementation, and we must ensure that the Veterans Administration is administering the benefits provided in this program in accordance with the intent of Congress.

Madam Speaker, I also want to point out the extension of the Native American Veteran Housing Loan Pilot Program included in section 201 of this bill. Under this program, native Americans who live on trust lands can receive direct loans to build, purchase, or renovate a home.

Prior to the enactment of this program as a pilot 5 years ago, these native American veterans were not eligible for VA home loan assistance. Although this direct loan program has been generally successful, we have been somewhat disappointed in the number of native Americans who have taken advantage of the loans available under this program.

I believe that the outreach and reporting requirements included in S. 714 will significantly increase participation and enable the VA to more effectively administer this program.

Also included in this bill is a requirement that the VA develop a national policy on mammography screening for women veterans. All of us know that the incidence of breast cancer among American women has reached near epidemic levels. Our women veterans are no less at risk than our female civilians.

□ 1600

We also know that critical to the management of this disease is early detection, and mammography is an important weapon in the fight against breast cancer. I want women veterans who have served in the Armed Forces on our behalf to have the same high level of access to mammography screening that I would want for members of my own family. Section 208 of this bill will ensure that access.

Madam Speaker, S. 714 is an excellent bill, and it is fitting that this legislation be approved just before Veterans Day. I urge my colleagues to demonstrate their support for America's veterans by voting for S. 714.

Mr. STUMP. Mr. Speaker, I yield 4 minutes to the gentleman from New York [Mr. QUINN], the chairman of the Subcommittee on Veterans Benefits.

Mr. QUINN. Mr. Speaker, I join my good friend, the gentleman from California [Mr. FILNER], in making note that Veterans Day, of course, is only a few days away, and it is appropriate that we come here together today to make improvements to several veterans' benefits programs.

I would like to take my time this afternoon, Mr. Speaker, to address the sections of S. 714 that fall within the jurisdiction of our Subcommittee on Veterans Benefits. I first would like to acknowledge the subcommittee ranking member, the gentleman from California [Mr. FILNER], and the bipartisan spirit in which he helped craft this bill. Without the strong cooperation of both sides of the aisle, I do not think we would be able to present these improvements to our veterans' benefits.

Section 201 of S. 714 continues VA's authority to provide direct loans to Native Americans through the year 2001. This program offers the opportunity to Native American veterans living on tribal trust land to purchase a home that they might not otherwise be able to acquire. The program requires the VA to conclude a memorandum of understanding with tribal governments that, among other things, gives the VA access to the property in case of foreclosure, thus protecting the interests of the taxpayer.

The bill would add specific outreach requirements such as participation in Native American conferences and outstationing loan guaranty specialists in tribal facilities only on a part-time basis. The bill also adds new reporting requirements so that Congress may gain a better understanding of the outcomes of the program.

Section 203 makes changes to several homeless programs, including an extension of the VA's authority through December 31, 1999, to sell, lease, or donate foreclosed VA property to nonprofit organizations or State and local governments for the purpose of providing housing for our homeless veterans.

It also extends the Department of Labor's authority to operate the Homeless Veterans Reintegration Project through 1999 and continues to authorize \$10 million per year for the same program. This program is a grant program administered by the Veterans Employment and Training Service and is designed to work with community-based organizations who focus on providing employment services to unemployed, homeless veterans.

Since its inception in 1988, through and up till 1995, the program has served almost 42,000 homeless veterans, placing nearly 19,000 in jobs. This is an accomplishment for a program that has traditionally been funded only at about \$2 or \$3 million per year.

Also, section 401 makes several technical and clarifying amendments to burial and educational benefits.

Finally, Mr. Speaker, section 404 of the bill also makes clarifying changes to the spina bifida legislation that was passed during the late hours of our 104th Congress. This new section further defines eligibility by establishing January 9, 1962, as the earliest date on which a veteran's service in Vietnam would qualify a child for these benefits. That date conforms to the date on which United States forces began using defoliants in Vietnam.

The bill also further specifies the age at which the Secretary may provide vo-

catational training as graduation from high school or the child's 18th birthday, whichever occurs first. It also requires that a vocational plan must be developed in time for the child to begin training when authorized.

Mr. Speaker, these provisions add to what is already the most complete program for veterans' benefits in the world. It is the right thing to do. I urge all our colleagues to support S. 714, as amended.

Mr. EVANS. Mr. Speaker, I yield 3 minutes to the gentleman from South Carolina [Mr. CLYBURN], a member of the committee.

Mr. CLYBURN. Mr. Speaker, I thank the gentleman from Illinois [Mr. EVANS], the ranking subcommittee member, for yielding me the time.

Mr. Speaker, I rise today in strong support of the Department of Veterans Affairs Employment Discrimination Prevention Act. This legislation is contained in S. 714, the compromise agreement which is before us today.

This year's Subcommittee on Veterans Oversight hearings have demonstrated the extremely sensitive and serious problem of sexual harassment within the Department of Veterans Affairs. The legislation we are considering today meets these glaring problems head-on.

The gentleman from Illinois [Mr. EVANS] and I were original cosponsors of similar legislation back in 1993. At that time, we were told that changes were in the works regarding the EEO process at VA and throughout the Federal Government and that there was no need for this legislation. This expected Government-wide solution never happened. The Senate never acted on the bill we passed in 1993. And here we are today, almost 5 years later, dealing with the sexual harassment problems that continue to fester at the VA.

It is a tribute to the leadership of the Subcommittee on Oversight chairman, the gentleman from Alabama [Mr. EVERETT], and I thank him for recognizing the continuing need for legislation to improve the EEO process at the VA. Without his commitment to this issue, it is likely that we would not be on the floor today considering final passage of this significant EEO reform legislation.

It is also a tribute to the VA that it has finally recognized its EEO process is seriously flawed and that it has independently proposed administrative changes that draw in large part from the bill we introduced earlier this year.

The VA's proposal did not go far enough, however, and that is why we need to approve this legislation today. By voting in favor of this bill, we in Congress will be doing our part to bring professionalism and independence to the EEO process at the VA and to help restore the faith and trust in the process that has been so lacking over the past few years.

Mr. STUMP. Mr. Speaker, I yield 2 minutes to the gentleman from Louisiana [Mr. COOKSEY], a former flight surgeon and member of the committee.

Mr. COOKSEY. Mr. Speaker, I rise in support of the House amendments to S.

714 and to comment specifically on one provision of this legislation.

Our colleagues in the other body pressed for the inclusion of language which would have established in law specific medical practice criteria for VA clinicians. As a physician and as a legislator, I strongly believe that, as a matter of public policy, we should not attempt to legislate how medicine is practiced. While this bill expresses a sense of the Congress regarding a VA policy, that expression does not bind the VA.

I commend the chairman for following that wise course in this measure, and I urge my colleagues to support it.

Mr. EVANS. Mr. Speaker, I yield 3 minutes to the gentleman from Hawaii [Mr. ABERCROMBIE].

Mr. ABERCROMBIE. Mr. Speaker, I rise today in strong support of the bill to extend the Native American Veterans Housing Loan Program and for other purposes.

In July I introduced H.R. 2317, the House companion bill to S. 714. I am pleased that we are able to take up the Senate's version today. I would like to thank the gentleman from Arizona [Mr. STUMP] and the gentleman from Illinois [Mr. EVANS] and the staff of the Committee on Veterans' Affairs for working hard to strike the compromise which made it possible to take up this bill on the floor today. I would especially like to thank Debra Wada of Senator AKAKA's staff and Jill Cochran of the Committee on Veterans' Affairs for their hard work on improving benefits for native American veterans.

In 1992, the Native American Veterans' Home Loan Equity Act was enacted to establish and implement a pilot program to make direct housing loans to aid native American, Indian, Alaska or Hawaii Native or Pacific islander, veterans in purchasing, constructing, or improving dwellings on trust lands.

The Department of Veterans Affairs has successfully entered into agreements to provide direct loans to members of 46 Indian tribes and Pacific island groups. The VA is in negotiation with hundreds of other tribes to establish memorandums of understanding which would make this program available to those tribes. It is important that we extend this program to allow those native American tribes who are still in negotiations with the VA to have a chance to apply for these loans.

Through June of 1997, 164 loans were made to both Pacific islanders and native American veterans, with 90 applications pending. To date none of those loans issued has been foreclosed. This is an extremely successful program and is the only program available for this group of veterans who live on trust lands to finance homes for their families. The Department of Veterans Affairs supports the extension of this program.

Therefore, Mr. Speaker, the main issue here is equity. Native American

veterans have a right to the same benefits available to other veterans. I urge my colleagues to support this important legislation.

Mr. STUMP. Mr. Speaker, I yield 3 minutes to the gentleman from Florida [Mr. STEARNS], chairman of the Subcommittee on Health.

(Mr. STEARNS asked and was given permission to revise and extend his remarks.)

Mr. STEARNS. Mr. Speaker, I thank the gentleman from Arizona [Mr. STUMP], the distinguished chairman of the Committee on Veterans' Affairs.

Mr. Speaker, as we take up this bill just 2 days before Veterans Day, we are in a very concrete way underscoring our commitment to veterans. Among its key provisions, these amendments to S. 714 provide important direction to the Department of Veterans Affairs to address what we believe is a glaring problem, the need to improve the care VA provides to Persian Gulf veterans.

Our committee has held what the American Legion 2 months ago described as "the most comprehensive and important hearings on Gulf War veterans since the end of the Gulf War." This legislation stems from those hearings and would require VA to take a new approach, beginning with creating and funding demonstration programs. This should lead VA to develop new, improved models for treating veterans with undiagnosed or ill-defined conditions.

The bill would also clarify that Persian Gulf veterans are eligible for care of any condition which may be due to their service in the gulf, whether or not it can be linked to toxic substances or environmental hazards.

These amendments would also extend many expiring programs, including VA's authority to provide noninstitutional services to the elderly and needed assistance for homeless veterans.

Mr. Speaker, the legislation also provides needed authorization for VA medical facility construction and leasing initiatives for fiscal year 1998. For these and many other reasons, I support this bill. This is an excellent bill, and I urge all the Members to support it.

Mr. Speaker, I include the following statement for the RECORD:

Mr. Speaker, as we take up this bill just 2 days before Veterans Day, we are in a very concrete way underscoring our commitment to veterans.

Among its key provisions, these amendments to S. 714 provide important direction to the Department of Veterans Affairs to address what is both one of the most glaring problems in the area of veterans affairs, and the most pressing problem facing many Persian Gulf war veterans—the need for effective health care. In wrestling with this problem, our committee has held what the American Legion 2 months ago described as "the most comprehensive and important hearings on Gulf War veterans since the end of the Gulf War." Our findings and resultant legislation have frankly not commanded the attention associated with still speculative questions regarding

toxic chemical exposures. We have found that VA treatment, particularly of veterans with hard to diagnose problems, has been uneven from facility to facility. Too often, veterans have fallen through the cracks, and complex cases have not received coordinated care. VA's primary care system appears ill-suited to help the many veterans who suffer from ill-defined, multiple-system health problems. Lack of understanding of the illnesses affecting Persian Gulf war veterans has fueled a perception in many veterans that VA clinicians lack empathy for their conditions. This legislation would begin to remedy the kinds of problems Persian Gulf veterans and independent observers have highlighted about the treatment these veterans have, and in some cases have not, received.

This legislation would require VA to take a new approach in caring for these veterans, beginning with creating and funding demonstration programs to test new approaches to treating Persian Gulf veterans with undiagnosed or ill-defined conditions. Among the approaches VA is to develop under the bill are the use of case managers to oversee all facets of the veteran's care, establishment of specialized clinics serving only Persian Gulf veterans, and the use of multidisciplinary treatment aimed at symptom management. The bill would also expand VA law regarding Persian Gulf veterans' eligibility for care to clarify that such veterans are eligible for care of any condition which may be due to their service in the gulf, whether or not such condition may be attributable to toxic substances or environmental hazards.

Our amendments to S. 714 would also extend a number of expiring health care programs on which our veterans depend. I am very pleased that the bill includes provisions I authored which give VA ongoing authority to provide noninstitutional care and services to the elderly, and which extend, streamline, and improve VA programs serving veterans who are chronically mentally ill and the homeless. This legislation gives VA the tools it needs to serve this population, as well as to work in partnership with communities to help eradicate veteran homelessness. I am pleased that, increasingly, VA is expanding its partnership activities in this and other areas. In that regard, this bill would also enable VA to develop more beneficial public/private partnerships. In adopting provisions passed by the House in April, this measure would allow VA to expand an effective program of leasing unused property for development of facilities such as assistive living facilities, day care centers, and other uses that can benefit veterans or the medical centers that serve them.

The legislation also provides needed authorization for a limited number of VA medical facility construction and leasing initiatives for fiscal year 1998.

I am pleased at what we have accomplished for our veterans in this legislation. I would acknowledge that a number of House-passed provisions on which the Senate had held no hearing are not included in this measure. These provisions include sections 7 and 8 of H.R. 2206. Section 7 would have provided a needed exemption of VA research personnel from an existing policy aimed at reducing the number of VA personnel in certain employment grades. While our committee has not objected to efforts to reduce the numbers of middle management positions in the VA, the failure to exempt researchers is particularly short-

sighted and damaging to a program so integral to VA's health care mission. We strongly urge that the Department adopt an exemption, and not wait for us to enact this provision next session. The enactment of section 8 of H.R. 2206 would have ruled out future legislative efforts to open the Federal supply schedule on pharmaceuticals. The committee recognizes, however, that in repealing section 1555 of the Federal Acquisition Streamlining Act of 1994 this year, Congress has, as a matter of law, effectively rejected as ill-advised the concept of opening the Federal supply schedule to cooperative purchasing.

Overall, this is an excellent bill. I urge Members to support it.

Mr. EVANS. Mr. Speaker, I yield myself such time as I may consume.

I want to thank everybody who has worked on making this legislation happen, particularly the committee's staff. On our side, I would like to recognize the contribution of Mike Durishin, Jill Cochran, Mary Ellen McCarthy, Susan Edgerton, Sandra McClellan, Adam Sachs, Debbie Smith, Beth Kilken, and Tom O'Donnell. They have been of great assistance to us, particularly me in my first year in this position as ranking Democratic member, and we appreciate their time and energy.

Mr. Speaker, I reserve the balance of my time.

Mr. STUMP. Mr. Speaker, I yield 2 minutes to the gentleman from New York [Mr. GILMAN], the chairman of the Committee on International Relations.

(Mr. GILMAN asked and was given permission to revise and extend his remarks.)

Mr. GILMAN. Mr. Speaker, I thank the gentleman from Arizona [Mr. STUMP] for yielding me the time.

Mr. Speaker, I rise in strong support of S. 714, the Homeless Veterans Act. I commend the gentleman from Arizona [Mr. STUMP], the distinguished chairman of the Committee on Veterans' Affairs, and the gentleman from New York [Mr. QUINN], the chairman of the Subcommittee on Veterans' Benefits, for bringing this measure to the floor before this session adjourns.

This bill reauthorizes a pilot program which permits the VA to make direct housing loans to native American veterans through December 2003, which extends the authority of the VA to enter into enhanced-use leases through December 31, 1999. Such leases permit the VA to have the ability to use underutilized property through leases with private and public entities.

Moreover, this legislation also extends for 2 years the VA's authority to operate a health professional scholarship program as well as to provide noninstitutional alternatives to veterans' nursing home care and also provides funding for spina bifida cases, which need a great deal of attention.

Accordingly, I urge our colleagues to join in supporting this important legislation which will significantly aid our veterans.

Mr. EVANS. Mr. Speaker, I yield whatever time I have remaining for

purposes of control to the gentleman from Arizona [Mr. STUMP], the chairman of the full committee.

Mr. STUMP. Mr. Speaker, I thank the gentleman from Illinois [Mr. EVANS] for yielding me the time.

I yield 2 minutes to the gentleman from Connecticut [Mr. SHAYS].

□ 1615

Mr. SHAYS. Mr. Speaker, I thank the gentleman for yielding me this time. I rise in support of this legislation and to say that, sadly, when it comes to the diagnosis and treatment and research for gulf war veterans, we find the Federal Government has too often had a tin ear and a cold heart and frankly a very closed mind. I do not view this as a political problem or a challenge that rests with one party, Republican or Democrat. Sadly, the Veterans Administration, the Department of Defense, the Central Intelligence Agency, and even the Food and Drug Administration have not been responsive to our veterans.

As the Chair of a panel that did 11 hearings and made recommendations on this issue, one of the key components is that we ultimately need, in my judgment, to bring research out of the control of the DOD and VA and give it to an agency that will begin to focus more on the chemical components of the myriad of illnesses that affect our veterans.

I urge both the Committee on Veterans' Affairs and the Committee on National Security to put even more focus on this. I know that the President's commission has come out with some recommendations. The Subcommittee on Human Resources of the Committee on Government Reform and Oversight has come out with some recommendations. I think we are at a point where we clearly need to recognize that our troops are not being properly diagnosed, they are not being effectively treated, and they are not being fairly compensated. But I think we are at a point where we are starting to see that change. I know that with the help of the gentleman from Arizona [Mr. STUMP] and the help of the gentleman from Illinois [Mr. EVANS], we are going to see renewed energy in this area. I think this bill is a start in that process and for that, I am grateful. I thank both gentlemen.

Mr. STUMP. Mr. Speaker, I yield 3 minutes to the gentleman from Indiana [Mr. BUYER], a member of the committee, and also the chairman of the Subcommittee on Military Personnel of the Committee on National Security.

Mr. BUYER. Mr. Speaker, I thank the gentleman for yielding me this time. Let me congratulate the gentleman from Arizona [Mr. STUMP] and the gentleman from Illinois [Mr. EVANS] for their work on this bill. I would like to discuss section 103 of this bill. I am disappointed that coming out of the conference with the House and the Senate, the language that the House adopted has in fact been

changed. We were seeking to have an independent commission to review what I find to be the very poor culture that is in the Nation's second largest agency, that of the VA. There is not any Member of this House that has taken on the issue of race and gender that I have over the past year with what occurred at Aberdeen in sexual misconduct in the military. The gentlewoman from California [Ms. HARMAN], the gentlewoman from Florida [Mrs. FOWLER] and I have traveled the world to our military bases and looked at those issues on gender and race relations. We have taken on the systems and subsystems in the military, and we have been very aggressive.

When we turned our eyes upon the VA itself, we began to see a culture problem within the VA, a system whereby the victims were being revictimized through the Office of General Counsel. We saw individuals in their leadership kind of give a wink and a nod to a hostile workplace. Let me congratulate the gentleman from Alabama [Mr. EVERETT] and the gentleman from Arizona [Mr. STUMP] for taking these issues right on and the gentleman from South Carolina [Mr. CLYBURN] on the oversight.

Why I was seeking to have an independent commission is I wanted it stripped completely out of the hands of the VA because of my lack of trust in those who are doing the oversight in the VA itself. I recognize in the language in here, they have been very careful to make sure that there is some insurance here. We are asking the Secretary to have an agreement to make sure that the entity carries out its responsibilities and exercises judgments concerning the assessments in a manner free of any influence. That means I do not want to hear anything over the next year that the VA somehow is scrubbing the contractor or getting some kind of review or pressures. If that is going to happen, I am going to be pretty upset. Because I know what happens when we do independent contracting with the Pentagon. The Pentagon today will ask us an issue and it is politically sensitive and they begin to control and manipulate the contractor. I want to make sure that we have a work environment in the VA that is free of these hostilities. I want to make sure that we have a system there that stops the revictimizing of the victim because it is very difficult for us to actually measure how does that impact upon the care to the veteran itself.

Let me congratulate the gentleman from Arizona [Mr. STUMP], because the gentleman from Arizona [Mr. STUMP], the gentleman from Illinois [Mr. EVANS] and others, want to make sure that we have a good system. I hope and I pray that what has been worked out here is, in fact, going to meet the ends for which the gentleman from Arizona and I both want. My message for coming here to the well today is that I will be watching and I know the gentleman from Arizona will, too, over the con-

tract. I will be watching the VA just like the gentleman from Alabama [Mr. EVERETT] has done on the oversight to make sure that there are no manipulations whatsoever with the contractor and that the assessment that is done is completely independent, because if they do not, we are coming down on them hard.

Mr. STUMP. Mr. Speaker, I yield myself such time as I may consume. I thank the gentleman for his kind remarks.

Mr. Speaker, I would like to thank Senator SPECTER, Senator ROCKEFELLER and the staff of the Senate Veterans' Affairs Committee for their hard work in reaching an agreement on this bill.

I also want to thank the members of the House Committee on Veterans' Affairs who participated in the development of this legislation with the Senate. The gentleman from Illinois [Mr. EVANS], the ranking member, has been very cooperative through this entire process. The gentleman from Alabama [Mr. EVERETT], the gentleman from Florida [Mr. STEARNS], and the gentleman from New York [Mr. QUINN], the subcommittee chairmen; the gentleman from South Carolina [Mr. CLYBURN], the gentleman from Illinois [Mr. GUTIERREZ], and the gentleman from California [Mr. FILNER], the ranking members, also put in a great deal of time to move this committee's agenda.

I especially want to thank the gentleman from Louisiana [Mr. COOKSEY] and the gentleman from Arkansas [Mr. SNYDER]. Both are physicians and both are members of this committee. We have indeed been very fortunate to have them. They were especially helpful in negotiations with the Senate.

I would like to thank the staff of the House Committee on Veterans' Affairs for their diligent work on behalf of America's veterans. Three staff members will be leaving us this year: Ira Greenspan, Allison Clarke, and Sloan Rappoport.

On behalf of all committee members, I want to express our deepest appreciation for all their hard work and efforts and wish them the very best in their future endeavors.

Mr. Speaker, I include for the RECORD a detailed joint explanatory statement of the provisions considered during our deliberations on this measure.

JOINT EXPLANATORY STATEMENT FOR S. 714, THE PROPOSED "VETERANS BENEFITS ACT OF 1997"

S. 714, the proposed "Veterans Benefits Act of 1997" reflects a compromise agreement the Senate and House of Representatives Committees on Veterans' Affairs have reached on a number of bills considered in the Senate and House during the 105th Congress, including H.R. 1092, passed by the House on April 16, 1997, H.R. 1703, passed by the House on October 6, 1997, H.R. 2206, passed by the House on October 6, 1997, H.R. 2571, passed by the House on October 6, 1997, S. 714, passed by the Senate on November 5, 1997, S. 986, ordered reported by the Senate Committee on

October 7, 1997, S. 801, ordered reported by the Senate Committee on October 7, 1997, and S. 999, ordered reported by the Senate Committee on October 7, 1997.

The Committees on Veterans' Affairs have prepared the following explanation of S. 714 (hereinafter referred to as the compromise agreement). Differences between the provisions contained in the compromise agreement and the related provisions in the bills listed above are noted in this document, except for clerical corrections and conforming changes made necessary by the compromise agreement, and minor drafting, technical, and clarifying changes.

VA EMPLOYMENT DISCRIMINATION RESOLUTION
AND ADJUDICATION

Current law

Within the statutory framework of title VII, United States Code, the Equal Employment Opportunity (EEO) complaint process for the Department of Veterans Affairs (VA) is governed by federal regulations and Equal Employment Opportunity Commission (EEOC) directives applicable to all federal agencies. The EEO program at VA is under the direction of the Deputy Assistant Secretary for Equal Opportunity, who reports to the Assistant Secretary for Human Resources and Administration.

The complaint process begins when a VA employee contacts a facility EEO counselor. That counselor is appointed by the facility director who is the EEO Officer for the facility and the custodian of the complaint process. Counseling allows an opportunity for informal resolution of a complaint at the local level. Most EEO counselors perform EEO duties in addition to unrelated VA responsibilities, and all EEO counselors report to the facility director. On receipt of a formal complaint, VA must advise the complainant that it is required to conduct a complete and fair investigation within 180 days. The notice also advises the complainant of the right to appeal the final decision to the EEOC. The facility director (EEO Officer) accepts formal complaints and refers those believed to be procedurally defective (about 25 percent a year) to the Office of General Counsel (OGC) for legal review. If any part of the complaint is accepted, the OGC advises the facility and requests the appointment of an EEO investigator to the case. The investigator provides a Report of Investigation to both the complainant and the EEO Officer.

The agency and complainant may settle the complaint at any point in the EEO process. If a settlement is not reached after the Report of Investigation has been received, the complainant may request either a final agency decision from VA without a hearing, or a hearing by an EEOC Administrative Judge and then a final agency decision. If the complainant is dissatisfied with the agency's final decision, he or she may appeal it to the EEOC Office of Federal Operations. The final step in the complaint process is a title VII civil action in Federal district court. The complainant has the right to file a civil action against the agency any time after 180 days have passed since the filing of a formal complaint with the EEOC Office of Federal Operations. Once in Federal Court, the complainant leaves the EEO administrative complaint system.

House bill

Section 2 of H.R. 1703 would direct the Secretary to establish a new VA employment discrimination complaint resolution system whose employees would be supervised by and report to an Assistant Secretary or Deputy Assistant Secretary for complaint resolution management. A new Office of Resolution Management (ORM) would be supported by district managers, field offices, full time

EEO counselors and investigators, and 40 FTEE collateral duty counselors. In addition, the ORM would be authorized to make certain final agency decisions on procedural issues.

Section 3 of H.R. 1703 would establish a VA Office of Employment Discrimination Complaint Adjudication (OEDCA). The bill would transfer final agency decision authority on substantive issues from the Office of the General Counsel to OEDCA. The OEDCA, located in VA Central Office, would be a quasi-independent complaint adjudication unit. The Director of the OEDCA would report directly to the Secretary or Deputy Secretary. In addition to its complaint adjudication responsibilities, the OEDCA would be responsible for creating an efficient and effective complaint tracking system.

Section 4 of H.R. 1703 would provide an effective date of 90 days after enactment of this Act.

Section 5 of H.R. 1703 would establish an independent panel to review EEO and sexual harassment procedures within VA. The panel would be composed of six members—three appointed jointly by the chairman and ranking member of the House Committee on Veterans' Affairs, and three appointed jointly by the chairman and ranking member of the Senate Committee on Veterans' Affairs.

Senate bill

Section 2 of S. 801 would establish a structural component for the Office of Resource Management (ORM) which is identical to section 2 of H.R. 1703. Additionally, section 2 of S. 801 would require the VA Office of Inspector General to investigate allegations of discrimination against all GS-15s and above, and report to Congress and the Secretary. Section 2 would also require the Secretary to ensure that complainants may elect to consult with full-time EEO employees or part-time EEO employees. Section 2 would contain more specific reporting requirements including information on counseling relating to employment discrimination, the number and type of employment discrimination complaints, the status of such complaints, and the terms of any settlement.

Section 3 of S. 801 is identical to section 3 of H.R. 1703.

Section 4 of S. 801 would require the Secretary to contract with a private entity to assess VA's discrimination complaint resolution system. The assessment would include a study of the effectiveness of the training and maintenance of groups of VA employees assigned to investigate claims and provide counseling; the education and training of VA employees regarding their rights and obligations under EEO laws; the use of alternative dispute resolution procedures and settlements in resolving EEO complaints; and other programs, procedures or activities of VA relating to the EEO laws.

Section 5 of S. 801 is identical to section 4 of H.R. 1703.

Compromise agreement

Section 101 follows section 2 of the House bill except that it requires VA to transmit a quarterly notice to the Committees on Veterans' Affairs of the House and Senate which summarizes each employment discrimination complaint filed in the preceding quarter against certain high ranking VA employees. The notice will not include the name of the individual who filed the complaint or name of the individual against whom the complaint is filed. The notice will summarize the nature of the allegations and identify the VA EEO regional field office at which the complaint was filed. The notice will also include a redacted copy of the complaint of employment discrimination and any attachments. Section 101 also requires the Secretary to ensure that complainants may elect to consult

with fulltime EEO employees or part-time EEO employees. Section 101 contains the expanded reporting requirements included in the Senate bill.

Section 102 follows section 3 of the House bill.

Section 103 follows section 4 of the Senate bill, with an additional requirement that the Secretary ensure the independence of the private entity conducting the assessment of VA's employment discrimination complaint resolution system.

NATIVE AMERICAN HOME LOAN PROGRAM

Current law

Subchapter V of chapter 37, title 38, United States Code, authorizes the Secretary of the Department of Veterans Affairs (VA) to conduct a pilot program making direct loans to Native Americans to purchase, construct, renovate, or refinance homes on trust land. The Secretary is required to enter into a memorandum of understanding (MOU) with the various tribal governments prior to making any such loans. The MOU must give the Secretary access to the property for any purpose such as appraisal or monitoring of construction in connection with the loan. Tribal governments must agree to assist with the implementation in a responsible and prudent manner.

The maximum loan amount is \$80,000 unless the Secretary determines that local housing costs justify a higher amount. The Secretary is required to establish appropriate credit underwriting standards which give consideration to the purpose of the program. The Secretary is also required to conduct an outreach program to educate tribal organizations and Native American veterans about the program. The program expired September 30, 1997.

House bill

The House bill contains no provision changing current law.

Senate bill

Section 1 of S. 714 would extend the authority to carry out this program through December 31, 2003, and add provisions regarding specific outreach requirements. These include consulting about the housing needs of Native Americans with the National Congress of American Indians, the National American Indian Housing Council and the Department of Hawaiian Homelands, as well as distributing information to tribal organizations. The bill also requires an annual report by February 1 of each year detailing the operations of the program, outreach activities and an analysis of the pool of Native American veterans who are eligible for participation in the program.

Compromise agreement

Section 201 includes the Senate provisions with added outreach and reporting requirements and extends VA's program authority to December 31, 2001.

TREATMENT AND REHABILITATION FOR SERIOUSLY MENTALLY ILL AND HOMELESS VETERANS

Current law

Current law includes several provisions which authorize specific VA programs to assist homeless veterans and to contract for residential care for homeless veterans, mentally ill veterans, and veterans suffering from substance abuse or dependence.

Section 1720A of title 38, United States Code, permits the Secretary to contract for care, treatment, and rehabilitative services in various treatment facilities—subject to a review of the quality and effectiveness of its programs—for eligible veterans suffering from alcohol or drug dependence or abuse disabilities.

The Secretary is also given the authority to work in consultation with the Secretary

of Labor and the Director of the Office of Personnel Management to urge federal agencies and appropriate private companies to provide employment opportunities to those veterans who have completed such programs.

Under this section of law, the Secretary is directed to provide referral services to non-eligible veterans who seek alcohol or drug dependence assistance.

The authority to furnish such care expires after December 31, 1997.

The Secretary was also tasked with conducting ongoing clinical evaluations of drug and alcohol abuse treatment to veterans, and to report to Congress on the findings.

Section 115 of Public Law 100-322 (as extended through subsequent laws) authorizes the VA to conduct a pilot program to provide care, treatment and rehabilitative services in halfway houses, therapeutic communities, psychiatric residential treatment centers, and other community-based treatment facilities to eligible homeless veterans suffering from chronic mental illness disabilities. This program is set to expire on December 31, 1998.

Section 7 of Public Law 102-54 authorizes the Secretary to carry out a compensated work therapy and transitional housing demonstration program, which expires on December 31, 1997.

Section 107 of the Veterans' Medical Programs Amendments of 1992 requires the Secretary to (1) assess all programs developed by VA facilities which have been designed and established to assist homeless veterans; and (2) to the maximum extent practicable, seek to replicate at other VA facilities those programs which have as a goal the rehabilitation of homeless veterans. It also requires directors of VA medical centers and regional benefits offices, in coordination with non-VA organizations with experience working with local homeless persons, to develop lists of all programs assisting homeless persons and encourages the cooperative development of a local plan for coordinating services for homeless veterans. The law also requires VA medical center directors and regional office directors to meet, to the maximum extent feasible through existing programs and available resources, the identified needs of homeless veterans and attempt to inform homeless veterans whose needs cannot be met of services available in the area.

Section 2 of the Homeless Veterans Comprehensive Service Programs Act of 1992 requires the Secretary to establish and operate, through September 30, 1997, a pilot program to expand and improve the provision of benefits and services by the Department of Veterans Affairs to homeless veterans. VA is authorized to operate up to eight demonstration programs, and each site shall include a comprehensive and coordinated array of specialized services.

House bill

Section 2(a) of H.R. 2206 would consolidate, extend and revise, in part, Department of Veterans Affairs programs which serve veterans who are homeless or suffer from chronic mental illness or substance abuse or dependence. It would amend chapter 17 to title 38, United States Code, by adding a new subchapter entitled "Treatment and Rehabilitation for Seriously Mentally Ill and Homeless Veterans."

New section 1771 would authorize the Secretary to provide outreach services; care, treatment, and rehabilitative services; and therapeutic transitional housing assistance to veterans suffering from serious mental illness, including veterans who are homeless.

New section 1772 would authorize the Secretary, in conjunction with operating compensated work therapy programs, to operate residences and facilities as therapeutic hous-

ing. The provision would give the Secretary latitude to purchase, lease, or otherwise acquire residential housing in such a way as to best expedite the opening and operation of transitional housing. Such housing would be subject to requirements specified in the bill, to include a requirement that only eligible veterans and a house manager may live at a residence; veterans residents would be required to make payments that contribute to covering their board and the operating costs of the facility. Furthermore, residents would be prohibited from drinking or taking drugs and would be subject to drug testing. Any resident in violation of this policy could be expelled. All zoning, building permit, and other similar community requirements—as well as State and community fire and safety requirements—would be applicable. The measure would authorize the Secretary to set reasonable payment rates for residents, limit the duration of each veteran's residence, and establish qualifications for the house manager. The Secretary would have broad authority in selecting property to be established as transitional housing. The Secretary could consider any suitable defaulted residential property, any suitable space within a facility already under the Department's jurisdiction but no longer in use, and any other property acquired by the Department. The measure makes specific provision for the transfer of defaulted property from the Veterans Benefits Administration as well as obtaining property from the Department of Housing and Urban Development. The Secretary may dispose of any property acquired for this purpose and funds obtained by such a sale would go to the General Post Fund. Section 1772 would also provide that payments received by the VA under this section be deposited in the General Post Fund. The measure would require the Secretary to manage the program so that expenditures for any fiscal year do not exceed by more than \$500,000 proceeds credited to the General Post Fund under this section. Operating funds and receipts would be accounted for separately and would each be stated in the President's budget for each fiscal year.

New section 1773 would direct the Department, subject to the availability of appropriations, to operate no fewer than eight comprehensive-services centers to assist homeless veterans.

New section 1774 would, subject to available funding, require VA, in assisting homeless veterans, to coordinate, and permit the Department to provide authorize services in conjunction with other agencies of State, local, and Federal government, and non-governmental organizations. It would also require VA facility directors to assess and identify local homeless veterans, needs and the adequacy of existing programs to meet those needs, and take appropriate action, to the extent practicable to meet those needs. Such assessments are to identify homeless veterans' needs in the areas of health care, education and training, employment, shelter, counseling, and outreach services. Each assessment is also to comment on the adequacy of current VA programs with regards to these needs. This section would also require local VA officials to work with other governmental entities and homeless advocacy groups to develop a list of programs designed to assist homeless persons and homeless veterans in the area; provide outreach to the developers of local homeless programs to coordinate the provision of services to homeless veterans; attempt to identify and meet the needs of homeless veterans; and inform the homeless veteran population in the area whose needs cannot be met by the VA director of services available to such veterans in the community.

Senate bill

Section 2(a) of S. 714 would extend the VA's authority under section 1720A of title 38, United States Code, to treat and rehabilitate veterans with alcohol or drug dependence or abuse disabilities through December 31, 1999.

Section 2(c) of S. 714 would extend the VA's authority to provide community-based care to homeless veterans under the Veterans' Benefits and Services Act of 1988 through December 31, 1999.

Section 2(d) of S. 714 would extend the VA's Compensated Work Therapy and Therapeutic Transitional Housing demonstration program under Public Law 102-54 through December 31, 1999.

Section 2(e) of S. 714 would amend the Homeless Veterans Comprehensive Service Programs Act of 1992 to extend through September 30, 1999 (1) VA's authority to operate comprehensive service centers to assist homeless veterans, (2) VA's authority to make grants and to assist homeless veterans, and (3) the authorization of appropriations for that Act.

Compromise agreement

Section 202 generally follows the House bill, except that the program authorities would include a sunset date of December 31, 2001.

SALE OR LEASE OF VA PROPERTIES TO HOMELESS PROVIDERS

Current law

Section 3735 of title 38, United States Code, authorizes the Secretary of the VA to sell, lease or donate foreclosed VA properties to nonprofit organizations or a State or political subdivision of a State for the purpose of assisting homeless veterans and their families in acquiring shelter. Properties eligible for transfer under this program are those not likely to be sold at a price that would reduce the VA's liability on the property. Providers must comply with all zoning codes and agree to use the property to shelter primarily homeless veterans and their families. The Secretary may make loans on such properties at below-market rates and may waive all fees required under section 3729 of title 38, United States Code. The program expires December 31, 1997.

House bill

The House bill contains no provision changing current law.

Senate bill

Section 2 of S. 714 would extend the authority to carry out this program through December 31, 1999.

Compromise agreement

Section 203(a) includes the Senate provision.

EXTENSION OF HOMELESS VETERANS COMPREHENSIVE SERVICE GRANT PROGRAM

Current law

Section 3 of the Homeless Veterans Comprehensive Service Programs Act of 1992 (38 USC section 7721 note) authorizes the Secretary to establish and operate a grant program to assist eligible entities in establishing new programs to furnish outreach, rehabilitative services, vocational counseling and training, and transitional housing assistance to homeless veterans. This program expired on September 30, 1997 and limited the Department to providing grants for no more than 25 service centers and no more than 20 programs which incorporate the procurement of vans for use in outreach to, and transportation for, homeless veterans to carry out the intention of the law.

House bill

Section 3 of H.R. 2206 would extend VA's authority to make such grants to September

30, 1999 and would strike the limitation on the number of grants which may be awarded for specified purposes.

Senate bill

Section 2(e)(2) of S. 714 would extend the grant program until September 30, 1999.

Compromise agreement

Section 203(b) follows the Senate bill.

HOMELESS VETERANS REINTEGRATION PROJECT

Current law

The Stewart B. McKinney Homeless Assistance Act (title 42, section 11448(e)(1)) authorizes the Department of Labor to provide grants to community based organizations focusing on returning homeless veterans to the work force. The program is administered by the Veterans Employment and Training Service. From 1988 through 1996, the program served over 41,000 homeless veterans, placing over 18,000 in jobs. The program expires December 31, 1997.

House bill

The House bill contains no provision changing current law.

Senate bill

Section 4(e) of S. 714 would amend the Stewart B. McKinney Homeless Assistance Act (title 42, section 11448(e)(1)) to extend the expiration date of the Homeless Veterans Reintegration Project to December 31, 1999, and authorize expenditures up to \$10,000,000 per year.

Compromise agreement

Section 203(c) includes the Senate provision.

ANNUAL REPORT ON ASSISTANCE TO HOMELESS VETERANS

Current law

Section 1001 of the Veterans Benefits Improvements Act of 1994 (38 USC section 7721 notes) requires that the Secretary, by April 15 of each year, submit to the Committees a report on the activities of the VA's homeless programs. The annual report is to include the number of homeless veterans provided assistance under VA programs, the cost of providing these programs, and any other information the Secretary deems appropriate.

House bill

Section 4 of H.R. 2206 would expand the scope of this reporting requirement. It would require the VA to report on its evaluation of the effectiveness of its programs relating to residential work therapy, outreach, community-based residential treatment, and case management, as well as contract care programs for alcohol and drug dependence or abuse disabilities. Further, it would require the Secretary to evaluate and report on the effectiveness of programs established through grants awarded under the Homeless Veterans Comprehensive Service Grant Program.

Senate bill

The Senate bill contains no comparable provision.

Compromise agreement

Section 204 follows the House bill.

ENHANCED-USE LEASES OF DEPARTMENT OF VETERANS AFFAIRS REAL PROPERTY

Current law

Under section 8169 of title 38, United States Code, the Secretary's authority to enter into enhanced-use leases of Department of Veterans Affairs real property expires after December 31, 1997.

Section 8168 of title 38, United States Code, limits the number of enhanced-use leases (other than leases for child care centers) which the Secretary may execute to 20, and sets a 10-project cap on such leases during any one fiscal year.

House bill

Section 101 of H.R. 1052 would extend the Secretary's authority to enter into such leases to December 31, 2002 and would repeal the limits on the number of enhanced-use leases which the Secretary may execute.

Senate bill

Section 3 of S. 714 would change the limit from 20 to 40 and extend the program until December 31, 1999.

Compromise agreement

Section 205 generally follows the House bill except that the program would expire on December 31, 2001.

NONINSTITUTIONAL ALTERNATIVES TO NURSING HOME CARE

Current law

Section 1720C of title 38, United States Code, authorizes the Secretary to conduct a pilot program for the furnishing of medical, rehabilitative and health-related services in noninstitutional settings for eligible veterans for nursing home care. This provision authorizes VA services through December 31, 1997.

House bill

Section 5 of H.R. 2206 would provide ongoing authority for this program.

Senate bill

Section 4 of S. 714 would extend the program through December 31, 1999.

Compromise agreement

Section 206 follows the House bill.

HEALTH PROFESSIONAL SCHOLARSHIP PROGRAM

Current law

Section 7611 of title 38, United States Code, authorizes the Department to institute the Department of Veterans Affairs Health Professional Scholarship Program, which gives students the opportunity to receive VA health care scholarships in exchange for a specified period of employment in VA after graduation. In authorizing an extension of that program through December 31, 1997, Congress in section 202 of Public Law 104-110 required the Department to evaluate the efficacy of the program and compare its costs and benefits with alternative approaches to ensure adequate recruitment and retention of health professionals. The Department failed to carry out that report requirement.

House bill

The House bill contains no provision changing current law.

Senate bill

Section 4(b) of H.R. 714 would extend the program through December 31, 1999.

Compromise agreement

Section 207 would extend the program to December 31, 1998 and would also require that the Department report to Congress within six months in accordance with the requirement in Public Law 104-110.

MAMMOGRAPHY STANDARDS

Current law

Section 106(a)(2) of the Veterans Health Care Act of 1992 (38 USC 1710 note) provides that the Department may provide breast examinations and mammography to women veterans.

House bill

The House bill contains no comparable provision.

Senate bill

S. 999 would specify that the Department follow the recommendations of the American Cancer Society regarding the frequency of screening mammograms for women in specific age groups.

Compromise agreement

Section 208 would require the VA's Under Secretary for Health to develop a national

policy for the VHA with respect to mammography standards for veterans. Such a policy would specify standards of mammography screening and include recommendations on screening for women over the age of 39 and veterans with clinical symptoms, risk factors or family history of breast cancer. The section would also provide for clinician discretion on this matter. Additionally, the section includes a section (c) Sense of the Congress, that the policy adopted by VHA in sections (a) and (b) shall be in accordance with the guidelines endorsed by the Secretary of Health and Human Services and the Director of the National Institutes of Health.

PERSIAN GULF WAR VETERANS

Current law

Section 703 of Public Law 102-585, as amended, directs the VA to provide a health examination (including any appropriate diagnostic tests), consultation, and counseling with respect to the results of such an examination to any Persian Gulf War veteran who requests such an examination. Such examination findings are also to be included in a Persian Gulf War Veterans health registry, to be maintained by the VA.

Section 1710(e)(1)(c) of title 38, United States Code, provides eligibility for care, through December 31, 1998, to any veteran of the Persian Gulf War who may have been exposed to a toxic substance or environmental hazard during such service for any condition which may be associated with such exposure.

House bill

Section 6(a) of H.R. 2206 would specify that Persian Gulf veterans shall be verbally counseled on the results of health examinations carried out under section 703 of Public Law 102-582, as amended.

Section 6(b) of H.R. 2206 would clarify that a Persian Gulf veteran is eligible for VA health care for any condition—not just for exposure of a toxic substance or environmental hazard—which may be associated with service in the Gulf.

Section 6(c) of H.R. 2206 would direct the Secretary to carry out a program of demonstration projects designed to test innovative approaches to treating Persian Gulf veterans at up to 10 VA medical centers across the country. Three treatment models—a specialized Persian Gulf clinic, a multidisciplinary treatment program aimed at managing symptoms, and the use of case managers—would be used at at least two demonstration sites. The Secretary is required to provide \$5 million in appropriated funds for use in carrying out these projects. Before a location has been designated as a demonstration site, a peer review panel must determine the efficacy of the selection, using as its criteria the facility's ability to attract outstanding and innovative physicians to the project and to effectively evaluate the activities of the project.

Senate bill

The Senate bill contains no comparable provisions.

Compromise agreement

Section 209 follows the House bill except that it does not include Section 6(a), which contains a provision relating to VA counseling of Persian Gulf veterans.

REPORT ON MEDICAL EMERGENCIES ARISING FROM TERRORISM

House bill

The House bill contains no provision changing current law.

Senate bill

Section 432 of S. 986 requires the President by March 1, 1998, to submit to Congress a report on plans, preparations and the capability of all levels of government to respond nationally to medical emergencies arising from

the terrorist use of weapons of mass destruction. The report is to be prepared in consultation with specified departments and agencies of the Federal government, and the President is to designate a lead agency for purposes of preparing the report. The section specifies matters to be included in such report, including a description of steps taken to prepare to respond to such emergencies; a description of existing obligations, roles, and lines of authority within government for such a situation; an assessment of current level of preparedness and listing of existing medical assets available to respond; and estimated costs of government agencies and departments to prepare for and carry out their respective roles.

Compromise agreement

Section 210 follows the Senate bill.

CONSTRUCTION AUTHORIZATION

AUTHORIZATION OF MAJOR MEDICAL FACILITY PROJECTS

Current law

Section 8104(a)(2) of title 38, United States Code, provides that no funds may be appropriated for any fiscal year, and the Secretary of Veterans Affairs may not obligate or expend funds (other than for advance planning and design), for any major medical facility project unless funds for that project have been specifically authorized by law.

House bill

Section 1(1) of H.R. 2571 would authorize the Secretary to carry out a seismic corrections project at the Memphis VA Medical Center in an amount not to exceed \$34.6 million.

Section 1(2) of H.R. 2571 would authorize the Secretary to make seismic corrections and other improvements at the McClellan Hospital in Sacramento, California using up to \$48 million in previously appropriated funds.

Section 1(3) of H.R. 2571 would authorize the Secretary to carry out outpatient improvement projects with already-appropriated funds at facilities in Mare Island, Vallejo, California and Martinez, California in an amount not to exceed \$7 million.

Senate bill

Section 201 of S. 986 contains provisions substantively similar to section 1(1) of H.R. 2571.

S. 986 contains no comparable provision to sections 1(2) and 1(3) of H.R. 2571.

Compromise agreement

Section 301 follows the House bill.

AUTHORIZATION OF MAJOR MEDICAL FACILITY LEASES

Current law

Section 8104(a)(2) of title 38, United States Code, provides that no funds may be appropriated for any fiscal year, and the Secretary of Veterans Affairs may not obligate or expend funds (other than for advance planning and design), for any major medical facility lease unless funds for that lease have been specifically authorized by law.

House bill

Section 2 of H.R. 2571 would authorize the Secretary to carry out the following leases of satellite outpatient clinics: Jacksonville, FL, \$3.095 million; Boston, MA, \$5.215 million; Canton, OH, \$2.115 million; Portland, OR, \$1.919 million; and Tulsa, OK, \$2.112 million.

Section 2 of H.R. 2571 would authorize the Secretary to carry out the following leases of information resources management field offices: Birmingham, AL, \$595,000; and Salt Lake City, UT, \$652,000.

Senate bill

Section 202 of S. 986 contains provisions identical to section 2 of H.R. 2571, except

that the lease for the satellite outpatient clinic in Canton, OH is authorized for \$735,000.

Compromise agreement

Section 302 follows the House bill.

AUTHORIZATION OF APPROPRIATIONS

Current law

Section 8104(a)(2) of title 38, United States Code, provides that no funds may be appropriated for any fiscal year, and the Secretary of Veterans Affairs may not obligate or expend funds (other than for advance planning and design), for any major medical facility lease unless funds for that project or lease have been specifically authorized by law.

House bill

Section 3(a)(1) of H.R. 2571 would authorize to be appropriated to the Department of Veterans Affairs for fiscal year 1998 \$34.6 million for the Construction, Major Projects account to be used for major medical facility projects.

Section 3(a)(2) of H.R. 2571 would authorize to be appropriated to the Department of Veterans Affairs for fiscal year 1998 \$15.703 million for the Medical Care account to be used for major medical facility leases.

Section 3(b) of H.R. 2571 would limit the authorized projects to be carried out using only (1) specifically authorized major construction funds appropriated for fiscal year 1998; (2) funds appropriated for Construction, Major Projects before fiscal year 1998 that remain available for obligation; and (3) funds appropriated for Construction, Major Projects, for fiscal year 1998 for a category of activity not specific to the project.

Senate bill

Section 203(a) of S. 986 would authorize appropriations for Fiscal Years 1998 and 1999. It would authorize a \$34.6 million appropriation for the Construction, Major Projects account and a \$14.323 million appropriation for the Medical Care account.

Section 203(b) differs from section 3(b) of H.R. 2571 only in that both fiscal years 1998 and 1999 are included.

Compromise agreement

Section 303 follows the House bill.

CLARIFICATION ON ELIGIBILITY FOR HEALTH CARE

Current law

In amendments to section 1710 in Public Law 104-262, Congress provided, in pertinent part, that VA "shall" (subject to available appropriations) furnish hospital care and medical services to a veteran "who has a compensable service-connected disability" (38 U.S.C. section 1710(a)(2)(A)). Section 1710(a)(2)(B) of title 38, United States Code, reflects similar terminology in providing for care of any veteran discharged or released for active service "for a compensable disability".

House bill

The House bill contains no provision changing current law.

Senate bill

Section 412(a) of S. 986 would strike the word compensable from section 1710(a)(2)(B), as amended by P.L. 104-262.

Compromise agreement

Section 402(a) follows the Senate provision.

HOME IMPROVEMENTS

Current Law

A technical amendment in the Veterans' Health Care Eligibility Reform Act of 1996 was construed by the Department as having had the effect of limiting to so-called "category A" veterans' eligibility for VA payments for home improvements and structural alterations. Higher-income ("category

C") veterans, who had been eligible for a one-time \$1200 benefit under prior law, were deemed ineligible under the change

House bill

Section 9(a) of H.R. 2206 would amend section 1717(a)(2)(B) of title 38, United States Code, to clarify that category C veterans under VA treatment are eligible for the one-time \$1200 home improvement/structural alteration benefit.

Senate bill

Section 412(b) of S. 986 contains a similar provision.

Compromise agreement

Section 402(b) follows the Senate bill.

TRANSFERS TO COMMUNITY NURSING HOMES

Current law

Under section 1720 of title 38, United States Code, VA may only transfer to, and provide for care in, a community nursing home, veterans who have received VA inpatient care. Existing law makes no provision for such transfer and placement on the part of a veteran who, in the course of VA provision of ambulatory treatment, is found to need nursing home care.

House bill

The House bill contains no provision changing current law.

Senate bill

Section 412(c) of S. 986 would strike the limitation in section 1720 of title 38, United States Code, which restricts VA transfers and placements into community nursing homes to veterans receiving inpatient care, and would authorize such needed placements for any veteran under care in a VA facility.

Compromise agreement

Section 402(c) follows the Senate provision.

SHARING OF HEALTH-CARE RESOURCES: PURCHASING

Current law

Under section 8153 of title 38, United States Code, VA may enter into agreements with any entity to buy health care resources. Where VA proposes to obtain such resources from an affiliated institution or organization, it may do so, under section 8153(a)(3)(A), "without regard to any law or regulation" requiring competition. VA may also procure such resources from a source other than an affiliated entity under simplified procedures aimed at promoting competition to the maximum extent practicable; such "simplified procedures . . . shall permit all responsible sources to submit a bid. . . ." (38 USC section 8153(a)(3)(B)).

House bill

The House bill contains no provision changing current law.

Senate bill

Section 412(d) of S. 986 would amend section 8153(a)(3)(A) to clarify that purchases of resources from an affiliated entity are exempt from otherwise applicable requirements for competition not only in law or regulation but also in any Executive order, circular, or other administration policy. Section 412(e) of S. 986 would amend section 8153(a)(3)(B) to clarify that VA may reasonably limit the number of sources sought for bids under its authority to employ simplified procedures.

Compromise agreement

Sections 402(d) and 502(e) follow the Senate provision

HOSPITAL REFERENCE

Current law

The VA medical facility in Columbia, South Carolina is named the "Wm. Jennings Bryan Dorn Veterans' Hospital".

House bill

Section 9(b) of H.R. 2206 would redesignate this facility as the "Wm. Jennings Bryan Dorn Department of Veterans Affairs Medical Center".

Senate bill

The Senate bill contains no comparable provision.

Compromise agreement

Section 403 follows the House bill.

Current law

SPINA BIFIDA

Current law

Chapter 18 of title 38, United States Code, authorizes the Secretary to provide medical care, compensation, and vocational training benefits for Vietnam veterans' children who are conceived following service in Vietnam and are born with spina bifida. The veteran must have been discharged under conditions other than dishonorable. Compensation in the amounts of \$200, \$700, and \$1,200 is based on the severity of the disability. Children are eligible for up to 24 months of vocational training generally following completion of high school.

House bill

The House bill contains no provision changing current law.

Senate bill

The Senate bill contains no comparable provision.

Compromise agreement

Section 404 includes technical and clarifying amendments to chapter 18 title 38, United States Code, including a provision to provide benefits regardless of the veteran's type of discharge.

COMPENSATION AND PENSION MEDICAL EXAMINATIONS

Current law

Physicians employed by the Veterans Health Administration may conduct disability examinations of veterans who have applied for VA monetary benefits. Section 504 of Public Law 104-272 authorizes VA to conduct a pilot program involving use of physicians who provide such examinations under contract arrangements. VA is to report on its experience under such program by October 1999.

House bill

The House bill contains no provision changing current law.

Senate bill

Section 411 of S. 986 would add a new section 7704 to title 38, United States Code, which would authorize the Under Secretary for Benefits to reimburse the Under Secretary for Health for costs incurred in providing disability examinations.

Compromise agreement

The compromise bill contains no provision on this subject.

PERSONNEL POLICY

Current law

Section 711 of title 38, United States Code, requires the Secretary to report to Congress and delay for a specified period any systematic reduction in grade of employees engaged in direct patient care or who are professional employees and computer specialists.

House bill

Section 7 of H.R. 2206 would amend section 7425 of title 38, United States Code, to provide that Veterans Health Administration employees in positions involving the provision (or supervision) of patient care or the conduct of research are not subject to any reduction (required by law or Executive

branch policy) in the number of percentage of employees or personnel positions within specified pay grades.

Senate bill

The Senate bill contains no comparable provisions.

Compromise agreement

The compromise bill contains no provision relating to this subject.

PURCHASES OF PHARMACEUTICAL PRODUCTS

Current law

The Federal Government, primarily through the General Services Administration, negotiates and awards contracts for products and services through federal supply schedules. The Government issues solicitations, receives offers from prospective vendors, negotiates with them on product and service prices, and award contracts. Such contracts give vendors the right to sell goods and services to the government during the period that the contract is in effect; federal agencies order products and services directly from a vendor and pay the vendor directly. Congress, by law, has authorized a variety of other entities, including certain Indian tribal governments, to make purchases from the federal supply schedule. The General Services Administration, which has responsibility for managing the federal supply schedules, has delegated responsibility for managing a number of such schedules, including the schedule for pharmaceuticals, to the Department of Veterans Affairs.

House bill

Section 8 of H.R. 2206 would amend section 8125 of title 38, United States Code, to provide that, notwithstanding any other provision of law, any product listed on the pharmaceutical Federal Supply Schedule may only be procured from that schedule by or for the federal government or any other entity specified in federal law or regulation as of July 1, 1997.

Senate bill

The Senate bill contains no similar provisions.

Compromise agreement

The compromise bill contains no provision relating to this subject.

PARKING FEES

Current law

Section 8109(d)(1) requires the collection of parking fees (other than from veterans and volunteers) at VA health care facilities under specified circumstances.

House bill

The House bill contains no provision changing current law.

Senate bill

S. 309 would prohibit the collection of parking fees at VA parking facilities used in connection with a medical facility which is operated jointly under a health care resources sharing agreement with the Department of Defense.

Compromise agreement

The compromise bill contains no provision relating to this subject.

SHARING OF HEALTH-CARE RESOURCES: SELLING

Current law

Under section 8153 of title 38, United States Code, VA may enter into agreements with any entity to sell health care resources. Section 8153(e) requires, as a precondition to VA's furnishing services to nonveterans under section, that VA make certain findings, including a determination "that veterans will receive priority under such an arrangement".

House bill

The House bill contains no provision changing current law.

Senate bill

Section 412(f) of S. 986 would amend section 8153(a)(3)(B) to strike the language regarding veterans receiving a priority under such an arrangement and substitute language to require a determination that "care to veterans will not be diminished as a result of such an arrangement".

Compromise agreement

The compromise bill contains no provision on this subject.

CONSOLIDATION OF HOUSING LOAN REVOLVING FUNDS

Current law

Chapter 37 of title 38, United States Code, establishes the Direct Loan Revolving Fund, the Loan Guaranty Revolving Fund, and the Guaranty and Indemnity Fund at the Department of the Treasury for deposits and disbursements related to veterans' home loan guaranty and direct home loan programs.

House bill

The House bill contains no provision changing current law.

Senate bill

The Senate bill also contains no provision changing current law.

Compromise agreement

The compromise bill contains no provision on this subject.

RECOUPMENT OF SPECIAL SEPARATION INCENTIVES

Current law

Section 1174 of title 10 authorizes the Secretary of Defense to pay a special separation bonus to active duty service members who have served between six and 20 years. Separation pay is based on length of service and base pay at the time of separation. This pay is subject to taxation.

Section 1174(h) of title 10 and section 5304 of title 38 requires the Secretary of Veterans Affairs to offset the amount of compensation paid to a veteran due to service connected disability by an amount equal to special separation incentives. Section 653 of Public Law 104-201 limited VA's recoupment on special separation incentives made on or after September 30, 1996 to the net amount after taxes.

House bill

The House bill contains no provision changing current law.

Senate bill

Section 431 of S. 986 would amend chapter 53 of title 38, to add a new provision limiting recoupment for any compensation paid after December 5, 1991 to 75 percent of the special separation pay.

Compromise agreement

The compromise bill contains no provision on this subject.

ENHANCE STATE CEMETERY GRANT PROGRAM

Current law

Chapter 24 of title 38, United States Code, authorizes the Secretary of Veterans Affairs to provide grants to States to establish new veterans' cemeteries or to expand or improve existing veterans' cemeteries owned by the State. Under this authority, VA may grant up to 50 percent of the cost of the land and improvements to that land. If the State owns the land at the time of the grant, the value of the land may be counted for up to 50 percent of the State's contribution.

House bill

The House bill contains no provision changing current law.

Senate bill

Section 421 of S. 986 contains provisions to increase the VA share of the project costs for

state veterans' cemeteries funded under the grant program. This provision would authorize the Secretary to grant up to 100 percent of the cost of improvements to the land to be purchased and up to 100 percent of the initial

equipment costs. For existing cemeteries, the Secretary would be authorized to grant up to 100 percent of the cost of the improvements made to any additional land purchased for expansion or 100 percent of the

cost of improvements to existing cemetery land.

Compromise agreement

The compromise bill contains no provision relating this subject.

NOTICE

Incomplete record of House proceedings. Except for concluding business which follows, today's House proceedings will be continued in the next issue of the Record.

CONFERENCE REPORT ON S. 830, FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

Mr. BLILEY submitted the following conference report and statement on the Senate bill (S. 830) 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:

CONFERENCE REPORT (H. REPT. 105-399)

The Committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) 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, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the "Food and Drug Administration Modernization Act of 1997".

(b) **REFERENCES.**—Except as otherwise specified, whenever in this Act an amendment or repeal is expressed in terms of an amendment to or a repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; references; table of contents.
Sec. 2. Definitions.

TITLE I—IMPROVING REGULATION OF DRUGS

Subtitle A—Fees Relating to Drugs

Sec. 101. Findings.
Sec. 102. Definitions.
Sec. 103. Authority to assess and use drug fees.
Sec. 104. Annual reports.
Sec. 105. Savings.
Sec. 106. Effective date.
Sec. 107. Termination of effectiveness.

Subtitle B—Other Improvements

Sec. 111. Pediatric studies of drugs.
Sec. 112. Expediting study and approval of fast track drugs.
Sec. 113. Information program on clinical trials for serious or life-threatening diseases.
Sec. 114. Health care economic information.
Sec. 115. Clinical investigations.
Sec. 116. Manufacturing changes for drugs.
Sec. 117. Streamlining clinical research on drugs.

Sec. 118. Data requirements for drugs and biologics.
Sec. 119. Content and review of applications.
Sec. 120. Scientific advisory panels.
Sec. 121. Positron emission tomography.
Sec. 122. Requirements for radiopharmaceuticals.
Sec. 123. Modernization of regulation.
Sec. 124. Pilot and small scale manufacture.
Sec. 125. Insulin and antibiotics.
Sec. 126. Elimination of certain labeling requirements.
Sec. 127. Application of Federal law to practice of pharmacy compounding.
Sec. 128. Reauthorization of clinical pharmacology program.
Sec. 129. Regulations for sunscreen products.
Sec. 130. Reports of postmarketing approval studies.
Sec. 131. Notification of discontinuance of a life saving product.

TITLE II—IMPROVING REGULATION OF DEVICES

Sec. 201. Investigational device exemptions.
Sec. 202. Special review for certain devices.
Sec. 203. Expanding humanitarian use of devices.
Sec. 204. Device standards.
Sec. 205. Scope of review; collaborative determinations of device data requirements.
Sec. 206. Premarket notification.
Sec. 207. Evaluation of automatic class III designation.
Sec. 208. Classification panels.
Sec. 209. Certainty of review timeframes; collaborative review process.
Sec. 210. Accreditation of persons for review of premarket notification reports.
Sec. 211. Device tracking.
Sec. 212. Postmarket surveillance.
Sec. 213. Reports.
Sec. 214. Practice of medicine.
Sec. 215. Noninvasive blood glucose meter.
Sec. 216. Use of data relating to premarket approval; product development protocol.
Sec. 217. Clarification of the number of required clinical investigations for approval.

TITLE III—IMPROVING REGULATION OF FOOD

Sec. 301. Flexibility for regulations regarding claims.
Sec. 302. Petitions for claims.
Sec. 303. Health claims for food products.
Sec. 304. Nutrient content claims.
Sec. 305. Referral statements.
Sec. 306. Disclosure of irradiation.
Sec. 307. Irradiation petition.
Sec. 308. Glass and ceramic ware.
Sec. 309. Food contact substances.

TITLE IV—GENERAL PROVISIONS

Sec. 401. Dissemination of information on new uses.
Sec. 402. Expanded access to investigational therapies and diagnostics.
Sec. 403. Approval of supplemental applications for approved products.
Sec. 404. Dispute resolution.

Sec. 405. Informal agency statements.
Sec. 406. Food and Drug Administration mission and annual report.
Sec. 407. Information system.
Sec. 408. Education and training.
Sec. 409. Centers for education and research on therapeutics.
Sec. 410. Mutual recognition agreements and global harmonization.
Sec. 411. Environmental impact review.
Sec. 412. National uniformity for nonprescription drugs and cosmetics.
Sec. 413. Food and Drug Administration study of mercury compounds in drugs and food.
Sec. 414. Interagency collaboration.
Sec. 415. Contracts for expert review.
Sec. 416. Product classification.
Sec. 417. Registration of foreign establishments.
Sec. 418. Clarification of seizure authority.
Sec. 419. Interstate commerce.
Sec. 420. Safety report disclaimers.
Sec. 421. Labeling and advertising regarding compliance with statutory requirements.
Sec. 422. Rule of construction.

TITLE V—EFFECTIVE DATE

Sec. 501. Effective date.

SEC. 2. DEFINITIONS.

In this Act, the terms "drug", "device", "food", and "dietary supplement" have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

TITLE I—IMPROVING REGULATION OF DRUGS

Subtitle A—Fees Relating to Drugs

SEC. 101. 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 subtitle will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified, for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the 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, as set forth in the Congressional Record.

SEC. 102. 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 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 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 amending the first sentence of paragraph (5) to read as follows:

"(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form.";

(5) in paragraph (7)(A)—

(A) by striking "employees under contract" and all that follows through "Administration," the second time it occurs 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"; and

(B) in subparagraph (B)—

(i) by striking "section 254(d)" and inserting "section 254(c)";

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

(iii) by striking "102d Congress, 2d Session" and inserting "105th Congress, 1st Session"; 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) one 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. 103. 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 an indication for other than a rare disease or condition. 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), if 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 PEDI-
ATRIC INDICATIONS.—A supplement to a human drug application proposing to include a new indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).

"(G) REFUND OF FEE IF APPLICATION WITH-
DRAWN.—If an application or supplement is withdrawn after the application or supplement was filed, the Secretary may 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 refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a 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.—Except as provided in subparagraph (B), 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 one 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 one 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 the 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 is submitted 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), under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), 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.".

(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) TOTAL 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 one or more fees assessed under subsection (a) where the Secretary finds that—";

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

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

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

"(E) the applicant involved 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.";

(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 are 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 under this section that 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 this section pursuant to appropriation Acts for a subsequent fiscal year.".

(g) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—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 WAIVERS AND REFUNDS.—Any requests for waivers or refunds for fees assessed under section 736 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 379h) 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. Any requests for waivers or refunds pertaining to a fee for a human drug application or supplement accepted for filing prior to October 1, 1997 or to a product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998, shall be evaluated according to the terms of the Prescription Drug User Fee Act of 1992 (as in effect on September 30, 1997) and part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (as in effect on September 30, 1997). The term "person" in such Acts shall continue to include an affiliate thereof.

SEC. 104. ANNUAL REPORTS.

(a) PERFORMANCE 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 letters described in section 101(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) FISCAL 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. 105. SAVINGS.

Notwithstanding section 105 of the Prescription Drug User Fee Act of 1992, the Secretary shall retain the authority to assess and collect any fee required by part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act for a human drug application or supplement accepted for filing prior to October 1, 1997, and to assess and collect any product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998.

SEC. 106. EFFECTIVE DATE.

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

SEC. 107. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 102 and 103 cease to be effective October 1, 2002, and section 104 ceases to be effective 120 days after such date.

Subtitle B—Other Improvements

SEC. 111. PEDIATRIC STUDIES OF DRUGS.

Chapter V (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 new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall 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 accepted in accordance with subsection (d)(3)—

"(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to 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 such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(4)(D) of such section, is deemed to be three years and six months rather than three years; and

"(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven 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 subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) 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 section 505(c)(3) or section 505(j)(4)(B) 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 the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with experts in pediatric research 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 to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b), the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

“(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to 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 such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

“(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(4)(D) of such section, is deemed to be three years and six months rather than three years; and

“(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven 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 section 505(c)(3) or section 505(j)(4)(B) 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 section 505(c)(3) or section 505(j)(4)(B) 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 from the Secretary under subsection (a) or (c), 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 new 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. Such agreement shall be in writing and shall include a timeframe for such studies.

“(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, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

“(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATION.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a new 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 the applicable period under clauses (ii) through (iv) of section 505(c)(3)(D) or clauses (ii) through (iv) of section 505(j)(4)(D), but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j) until the determination under subsection (d) is made, but any such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable six-month period under 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) DEFINITIONS.—As used in this section, the term ‘pediatric studies’ or ‘studies’ means at least one 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.

“(h) LIMITATIONS.—A drug to which the six-month period under subsection (a) or (b) has already been applied—

“(1) may receive an additional six-month period under subsection (c)(1)(A)(ii) for a supplemental application if all other requirements under this section are satisfied, except that such a drug may not receive any additional such period under subsection (c)(2); and

“(2) may not receive any additional such period under subsection (c)(1)(B).

“(i) RELATIONSHIP TO REGULATIONS.—Notwithstanding any other provision of law, if any pediatric study is required pursuant to regulations promulgated by the Secretary and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

“(j) SUNSET.—A drug may not receive any six-month period under subsection (a) or (c) unless the application for the drug under section

505(b)(1) is submitted on or before January 1, 2002. After January 1, 2002, a drug shall receive a six-month period under subsection (c) if—

“(1) the drug was in commercial distribution as of the date of enactment of the Food and Drug Administration Modernization Act of 1997;

“(2) the drug was included by the Secretary on the list under subsection (b) as of January 1, 2002;

“(3) the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population and that the drug may provide health benefits in that population; and

“(4) all requirements of this section are met.

“(k) REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program established under this section. 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 on taxpayers and consumers, including the impact of the lack of lower cost generic drugs on patients, including on lower income patients; and

“(4) any suggestions for modification that the Secretary determines to be appropriate.”

SEC. 112. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 125, is amended by inserting before section 508 the following:

“SEC. 506. FAST TRACK PRODUCTS.

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

“(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition. (In this section, such a drug is referred to as a ‘fast track product’.)

“(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. 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)(3) of the Public Health Service Act.

“(3) DESIGNATION.—Within 60 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 product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

“(b) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—

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

“(2) LIMITATION.—Approval of a fast track product 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 effect on the clinical endpoint; and

“(B) that the sponsor submit copies of all promotional materials related to the fast track product during the preapproval review period and, following approval and for such period

thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

“(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include 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 product fails to verify clinical benefit of the product;

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

“(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

“(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

“(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

“(A) provides a schedule for submission of information necessary to make the application complete; and

“(B) pays 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 disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to fast track products; and

“(2) establish a 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 products (as defined in section 506(a)(1) of the Federal Food, Drug, and Cosmetic Act) that describes the policies and procedures that pertain to section 506 of such Act.

SEC. 113. 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)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the ‘data bank’). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

“(B) The Secretary shall establish the data bank 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.

“(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. 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 section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, 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 shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

“(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 Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

“(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

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 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 shall not be used 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 data bank under section 402(j) of the Public Health Service Act.

(2) REPORT.—Not later than two 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—

(A) of the public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act;

(B) on the adverse impact, if any, on device innovation and research in the United States if

information relating to such device investigations is required to be publicly disclosed; and

(C) on such other issues relating to such section 402(j) as the Secretary determines to be appropriate.

SEC. 114. 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 under this paragraph if the health care economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act 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. 115. CLINICAL INVESTIGATIONS.

(a) CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: “If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.”.

(b) WOMEN AND MINORITIES.—Section 505(b)(1) (21 U.S.C. 355(b)(1)) is amended by adding at the end the following: “The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).”.

SEC. 116. MANUFACTURING CHANGES FOR DRUGS.

(a) IN GENERAL.—Chapter V, as amended by section 112, is amended by inserting after section 506 the following section:

“SEC. 506A. MANUFACTURING CHANGES.

“(a) IN GENERAL.—With respect to a drug for which there is in effect an approved application under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

“(1) the holder of the approved application or license (referred to in this section as a ‘holder’) has validated the effects of the change in accordance with subsection (b); and

“(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

“(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).

“(b) VALIDATION OF EFFECTS OF CHANGES.—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effects 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.

“(c) MAJOR MANUFACTURING CHANGES.—

“(1) REQUIREMENT OF SUPPLEMENTAL APPLICATION.—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

“(2) CHANGES QUALIFYING AS MAJOR CHANGES.—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug. Such a change includes a change that—

“(A) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in subsection (a) for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection);

“(B) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

“(C) is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

“(d) OTHER MANUFACTURING CHANGES.—

“(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

“(A) The Secretary may in accordance with paragraph (2) authorize holders to distribute such drugs without submitting a supplemental application for such changes.

“(B) The Secretary may in accordance with paragraph (3) require that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications for such changes.

“(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

“(2) CHANGES NOT REQUIRING SUPPLEMENTAL APPLICATION.—

“(A) SUBMISSION OF REPORT.—A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information developed under subsection (b) by the holder in validating the effects of the change. The report shall be submitted by such date as the Secretary may specify.

“(B) AUTHORITY REGARDING ANNUAL REPORTS.—In the case of a holder that during a

single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph by submitting a single report for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

“(3) CHANGES REQUIRING SUPPLEMENTAL APPLICATION.—

“(A) SUBMISSION OF SUPPLEMENTAL APPLICATION.—The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) by the holder in validating the effects of the change.

“(B) AUTHORITY FOR DISTRIBUTION.—In the case of a manufacturing change to which paragraph (1)(B) applies:

“(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph, unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced.

“(ii) The Secretary may designate a category of such changes for the purpose of providing that, in the case of a change that is in such category, the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change.

“(iii) If the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change.”

(b) TRANSITION RULE.—The amendment made by subsection (a) takes effect upon the effective date of regulations promulgated by the Secretary of Health and Human Services to implement such amendment, or upon the expiration of the 24-month period beginning on the date of the enactment of this Act, whichever occurs first.

SEC. 117. STREAMLINING CLINICAL RESEARCH ON DRUGS.

Section 505(i) (21 U.S.C. 355(i)) is amended—

(1) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(2) by inserting “(1)” after “(i)”;

(3) by striking the last two sentences; and

(4) by inserting after paragraph (1) (as designated by paragraph (2) of this section) the following new paragraphs:

“(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

“(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

“(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

“(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a ‘clinical hold’) if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

“(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

“(i) the drug involved represents an unreasonable risk to the safety of the persons who are

the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

“(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

“(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

“(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.”

SEC. 118. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary of 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(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) 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. 119. CONTENT AND REVIEW OF APPLICATIONS.

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

“(4)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

“(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

“(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant

shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

“(i) with the written agreement of the sponsor or applicant; or

“(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

“(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

“(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

“(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

“(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).”

(b) SECTION 505(j).—

(1) AMENDMENT.—Section 505(j) (21 U.S.C. 355(j)) is amended—

(A) by redesignating paragraphs (3) through (8) as paragraphs (4) through (9), respectively; and

(B) by adding after paragraph (2) the following:

“(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

“(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

“(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

“(i) with the written agreement of the sponsor or applicant; or

“(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

“(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the direc-

tor and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

“(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

“(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

“(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).”

(2) CONFORMING AMENDMENTS.—Section 505(j) (21 U.S.C. 355(j)), as amended by paragraph (1), is further amended—

(A) in paragraph (2)(A)(i), by striking “(6)” and inserting “(7)”;

(B) in paragraph (4) (as redesignated in paragraph (1)), by striking “(4)” and inserting “(5)”;

(C) in paragraph (4)(I) (as redesignated in paragraph (1)), by striking “(5)” and inserting “(6)”;

(D) in paragraph (7)(C) (as redesignated in paragraph (1)), by striking “(5)” each place it occurs and inserting “(6)”.

SEC. 120. SCIENTIFIC ADVISORY PANELS.

Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

“(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

“(2) The Secretary may delegate the appointment and oversight authority granted under section 904 to a director of a center or successor entity within the Food and Drug Administration.

“(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

“(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

“(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

“(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

“(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

“(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the

panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

“(5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

“(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

“(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

“(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.”

SEC. 121. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

“(ii) The term ‘compounded positron emission tomography drug’—

“(I) 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) (21 U.S.C. 351(a)) 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 Pharmacopoeia 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 on 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 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 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 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 on which the Secretary establishes procedures and requirements under paragraph (1), whichever is longer.

(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 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)).

(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:

(1) A notice entitled "Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop", published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10594.

(2) A notice entitled "Draft Guideline on the Manufacture of Positron Emission Tomography Radiopharmaceutical Drug Products; Availability", published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10593.

(3) A final rule entitled "Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography", published in the Federal Register on April 22, 1997, 62 Fed. Reg. 19493 (codified at part 211 of title 21, Code of Federal Regulations).

(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. 122. 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. 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 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, 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, one 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. 123. MODERNIZATION OF REGULATION.

(a) **LICENSES.**—

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

"(a)(1) 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—

"(i) 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; and

"(ii) 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).

"(3) 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 new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

(g) **APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.**—Section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by subsection (d), is further amended by adding at the end the following:

"(j) The Federal Food, Drug, and Cosmetic Act applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act."

(h) EXAMINATIONS AND PROCEDURES.—Paragraph (3) of section 353(d) of the Public Health Service Act (42 U.S.C. 263a(d)) is amended to read as follows:

“(3) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

“(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

“(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.”.

SEC. 124. PILOT AND SMALL SCALE MANUFACTURE.

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

“(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.”.

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

“(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.”.

SEC. 125. INSULIN AND ANTIBIOTICS.

(a) CERTIFICATION OF DRUGS CONTAINING INSULIN.—

(1) AMENDMENT.—Section 506 (21 U.S.C. 356), as in effect before the date of the enactment of this Act, is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 301(j) (21 U.S.C. 331(j)) is amended by striking “506, 507.”.

(B) Subsection (k) of section 502 (21 U.S.C. 352) is repealed.

(C) Sections 301(i)(1), 510(j)(1)(A), and 510(j)(1)(D) (21 U.S.C. 331(i)(1), 360(j)(1)(A), 360(j)(1)(D)) are each amended by striking “, 506, 507.”.

(D) Section 801(d)(1) (21 U.S.C. 381(d)(1)) is amended by inserting after “503(b)” the following: “or composed wholly or partly of insulin”.

(E) Section 8126(h)(2) of title 38, United States Code, is amended by inserting “or” at the end of subparagraph (B), by striking “; or” at the end of subparagraph (C) and inserting a period, and by striking subparagraph (D).

(b) CERTIFICATION OF ANTIBIOTICS.—

(1) AMENDMENT.—Section 507 (21 U.S.C. 357) is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 201(aa) (21 U.S.C. 321(aa)) is amended by striking out “or 507”, section 201(dd) (21 U.S.C. 321(dd)) is amended by striking “507.”, and section 201(ff)(3)(A) (21 U.S.C. 321(ff)(3)(A)) is amended by striking “, certified as an antibiotic under section 507.”.

(B) Section 301(e) (21 U.S.C. 331(e)) is amended by striking “507(d) or (g).”.

(C) Section 306(d)(4)(B)(ii) (21 U.S.C. 335a(d)(4)(B)(ii)) is amended by striking “or 507”.

(D) Section 502 (21 U.S.C. 352) is amended by striking subsection (l).

(E) Section 520(l) (21 U.S.C. 360j(l)) is amended by striking paragraph (4) and by striking “or Antibiotic Drugs” in the subsection heading.

(F) Section 525(a) (21 U.S.C. 360aa(a)) is amended by inserting “or” at the end of para-

graph (1), by striking paragraph (2), and by redesignating paragraph (3) as paragraph (2).

(G) Section 525(a) (21 U.S.C. 360aa(a)) is amended by striking “, certification of such drug for such disease or condition under section 507.”.

(H) Section 526(a)(1) (21 U.S.C. 360bb) is amended by striking “the submission of an application for certification of the drug under section 507.”, by inserting “or” at the end of subparagraph (A), by striking subparagraph (B), and by redesignating subparagraph (C) as subparagraph (B).

(I) Section 526(b) (21 U.S.C. 360bb(b)) is amended—

(i) in paragraph (1), by striking “, a certificate was issued for the drug under section 507.”; and

(ii) in paragraph (2) by striking “, a certificate has not been issued for the drug under section 507.” and by striking “, approval of an application for certification under section 507.”.

(J) Section 527(a) (21 U.S.C. 360cc(a)) is amended by inserting “or” at the end of paragraph (1), by striking paragraph (2), by redesignating paragraph (3) as paragraph (2), and by striking “, issue another certification under section 507.”.

(K) Section 527(b) (21 U.S.C. 360cc(b)) is amended by striking “, if a certification is issued under section 507 for such a drug.”; “, of the issuance of the certification under section 507.”; “, issue another certification under section 507.”; “, of such certification.”; “, of the certification.”; and “, issuance of other certifications.”.

(L) Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking “, section 507 (d) or (g).”.

(M) Section 735(1) (21 U.S.C. 379g(1)(C)) is amended by inserting “or” at the end of subparagraph (B), by striking subparagraph (C), and by redesignating subparagraph (D) as subparagraph (C).

(N) Subparagraphs (A)(ii) and (B) of sections 5(b)(1) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amended by striking “or 507”.

(O) Section 45C(b)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 is amended by striking “or 507”.

(P) Section 156(f)(4)(B) of title 35, United States Code, is amended by striking “507,” each place it occurs.

(c) EXPORTATION.—Section 802 (21 U.S.C. 382) is amended by adding at the end the following:

“(i) Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 801(e)(1).”.

(d) TRANSITION.—

(1) IN GENERAL.—An application that was approved by the Secretary of Health and Human Services before the date of the enactment of this Act for the marketing of an antibiotic drug under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as in effect on the day before the date of the enactment of this Act, shall, on and after such date of enactment, be considered to be an application that was submitted and filed under section 505(b) of such Act (21 U.S.C. 355(b)) and approved for safety and effectiveness under section 505(c) of such Act (21 U.S.C. 355(c)), except that if such application for marketing was in the form of an abbreviated application, the application shall be considered to have been filed and approved under section 505(j) of such Act (21 U.S.C. 355(j)).

(2) EXCEPTION.—The following subsections of section 505 (21 U.S.C. 355) shall not apply to any application for marketing in which the drug that is the subject of the application contains an antibiotic drug and the antibiotic drug was the subject of any application for marketing received by the Secretary of Health and Human Services under section 507 of such Act (21 U.S.C. 357) before the date of the enactment of this Act:

(A)(i) Subsections (c)(2), (d)(6), (e)(4), (j)(2)(A)(vii), (j)(2)(A)(viii), (j)(2)(B), (j)(4)(B), and (j)(4)(D); and

(ii) The third and fourth sentences of subsection (b)(1) (regarding the filing and publication of patent information); and

(B) Subsections (b)(2)(A), (b)(2)(B), (b)(3), and (c)(3) if the investigations relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(3) PUBLICATION.—For purposes of this section, the Secretary is authorized to make available to the public the established name of each antibiotic drug that was the subject of any application for marketing received by the Secretary for Health and Human Services under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) before the date of enactment of this Act.

(e) DEFINITION.—Section 201 (21 U.S.C. 321), as amended by section 121(a)(1), is further amended by adding at the end the following:

“(j) The term ‘antibiotic drug’ means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.”.

SEC. 126. 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. 127. APPLICATION OF FEDERAL LAW TO PRACTICE OF PHARMACY COMPOUNDING.

(a) AMENDMENT.—Chapter V is amended by inserting after section 503 (21 U.S.C. 353) the following:

“SEC. 503A. PHARMACY COMPOUNDING.

“(a) IN GENERAL.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

“(1) is by—

“(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

“(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

“(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

“(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

“(i) the licensed pharmacist or licensed physician; and

“(ii) (I) such individual patient for whom the prescription order will be provided; or

“(II) the physician or other licensed practitioner who will write such prescription order.

“(b) COMPOUNDED DRUG.—

“(1) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

“(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

“(i) that—

“(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

“(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

“(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);

“(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;

“(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

“(C) 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; and

“(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

“(2) DEFINITION.—For purposes of paragraph (1)(D), the term ‘essentially a copy of a commercially available drug product’ does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

“(3) DRUG PRODUCT.—A drug product may be compounded under subsection (a) only if—

“(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

“(B) such drug product is compounded in a State—

“(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

“(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

“(c) ADVERTISING AND PROMOTION.—A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

“(d) REGULATIONS.—

“(1) IN GENERAL.—The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

“(2) LIMITING COMPOUNDING.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

“(e) APPLICATION.—This section shall not apply to—

“(1) compounded positron emission tomography drugs as defined in section 201(ii); or

“(2) radiopharmaceuticals.

“(f) DEFINITION.—As used in this section, the term ‘compounding’ does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product’s manufacturer and other manufacturer directions consistent with that labeling.”

(b) EFFECTIVE DATE.—Section 503A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act.

SEC. 128. 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. 129. REGULATIONS FOR SUNSCREEN PRODUCTS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and

Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.

SEC. 130. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) IN GENERAL.—Chapter V, as amended by section 116, is further amended by inserting after section 506A the following:

“SEC. 506B. 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 is prescribed by the Secretary in regulations issued by the Secretary.

“(2) AGREEMENTS PRIOR TO EFFECTIVE DATE.—

Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Administration Modernization Act of 1997, 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 subsection (a) 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 information on the 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 506B of the Federal Food, Drug, and Cosmetic Act;

(2) an evaluation of—

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

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

(3) any legislative recommendations respecting the postmarketing studies.

SEC. 131. NOTIFICATION OF DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—Chapter V, as amended by section 130, is further amended by inserting after section 506B the following:

“SEC. 506C. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

“(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug—

“(1) that is—

“(A) life-supporting;

“(B) life-sustaining; or

“(C) intended for use in the prevention of a debilitating disease or condition;

“(2) for which an application has been approved under section 505(b) or 505(j); and

“(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product,

shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

“(b) REDUCTION IN NOTIFICATION PERIOD.—The notification period required under subsection (a) for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation in which—

“(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

“(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

“(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

“(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;

“(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code; or

“(6) the manufacturer can continue the distribution of the drug involved for 6 months.

“(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs described in subsection (a) to appropriate physician and patient organizations.”.

TITLE II—IMPROVING REGULATION OF DEVICES

SEC. 201. INVESTIGATIONAL DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

“(6)(A) Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

“(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

“(ii) changes or modifications to clinical protocols that do not affect—

“(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

“(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

“(III) the rights, safety, or welfare of the human subjects involved in the investigation.

“(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

“(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

“(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

“(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30

days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). 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 (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

“(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except—

“(i) with the written agreement of the sponsor or applicant; or

“(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

“(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.”.

(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 statistically valid and reliable 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.”.

SEC. 202. SPECIAL REVIEW FOR CERTAIN DEVICES.

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

(1) by redesignating paragraph (3) as paragraph (4); and

(2) by adding at the end the following:

“(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

“(A) representing breakthrough technologies,

“(B) for which no approved alternatives exist,

“(C) which offer significant advantages over existing approved alternatives, or

“(D) the availability of which is in the best interest of the patients.”.

SEC. 203. EXPANDING HUMANITARIAN USE OF DEVICES.

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

(1) in paragraph (2), by adding after and below subparagraph (C) the following 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 in an emergency situation that approval from a local institutional review committee can not be obtained in time to prevent serious harm or death to a patient”; and

(B) by adding after and below subparagraph (B) the following:

“In a case described in subparagraph (B) in which a physician 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 local 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.”;

(3) by amending paragraph (5) to read as follows:

“(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.”; and

(4) by amending paragraph (6) to read as follows:

“(6) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.”.

SEC. 204. DEVICE 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 a performance standard under this section, the Secretary shall, by publication in the Federal Register, recognize all or part of an appropriate 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 a premarket submission requirement or other requirement under this Act to which such standard is applicable.

“(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, 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 meet any requirement regarding devices under this Act.

“(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices 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 making 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 two 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 section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.”

(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 standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.”

(d) CONFORMING AMENDMENTS.—Section 514(a) (21 U.S.C. 360d(a)) is amended—

(1) in paragraph (1), in the second sentence, by striking “under this section” and inserting “under subsection (b)”; and

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking “under this section” and inserting “under subsection (b)”; and

(3) in paragraph (3), by striking “under this section” and inserting “under subsection (b)”; and

(4) in paragraph (4), in the matter preceding subparagraph (A), by striking “this section” and inserting “this subsection and subsection (b)”.

SEC. 205. SCOPE OF REVIEW; COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

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

“(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

“(D)(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 for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. 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 one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

“(iii) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determina-

tion by the Secretary could be contrary to the public health.”

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

“(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

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

“(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the “Director”) may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

“(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

“(II) that such use could cause harm.

“(ii) Such determination shall—

“(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director’s concerns regarding the proposed labeling;

“(II) specify the limitations on the use of the device not included in the proposed labeling; and

“(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

“(iii) The responsibilities of the Director under this subparagraph may not be delegated.

“(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.”

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

(1) in paragraph (1)(A), by adding after and below clause (ii) the following:

“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.”; and

(2) by adding after paragraph (5) (as added by section 202(2)) 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 supplemental application 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. 206. PREMARKET NOTIFICATION.

(a) SECTION 510.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), in the matter preceding paragraph (1), by adding after “report to the Secretary” the following: “or person who is accredited under section 523(a)”; and

(2) by adding at the end the following subsections:

“(l) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

“(m)(1) Not later than 60 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary as not requiring the report shall be exempt from the requirement to provide a report 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 requirement to submit a report under subsection (k), upon the Secretary’s own initiative or a petition of an interested person, if the Secretary determines that such report 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. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted."

(b) SECTION 513(f).—Section 513(f) (21 U.S.C. 360c(f)) is amended by adding at the end the following:

"(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health)."

(c) SECTION 513(i).—Section 513(i)(1) (21 U.S.C. 360c(i)), as amended by section 205(b), is amended—

(1) in subparagraph (A)(ii)—
(A) in subclause (I), by striking "clinical data" and inserting "appropriate clinical or scientific data" and by inserting "or a person accredited under section 523" after "Secretary"; and

(B) in subclause (II), by striking "efficacy" and inserting "effectiveness"; and

(2) by adding at the end the following:

"(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary 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 subsection (f) or section 520(l)."

SEC. 207. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f) (21 U.S.C. 360c(f)), as amended by section 206(b), 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) of 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), the Secretary shall by written order classify the device involved. 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. 208. CLASSIFICATION PANELS.

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

"(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

"(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have—

"(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code) as the Secretary;

"(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

"(iii) the same opportunity as the Secretary to participate in meetings of the panel.

"(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.

"(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

"(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act."

SEC. 209. CERTAINTY OF REVIEW TIMEFRAMES; COLLABORATIVE REVIEW PROCESS.

(a) CERTAINTY OF REVIEW TIMEFRAMES.—Section 510 (21 U.S.C. 360), as amended by section 206(a)(2), is amended by adding at the end the following subsection:

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

(b) COLLABORATIVE REVIEW PROCESS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 202(1), is amended by inserting after paragraph (2) the following:

"(3)(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 that has been filed as complete under subsection (c), to discuss the review status of the application.

"(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been 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 shall notify the applicant promptly of—

"(I) any additional deficiency identified in the application, or

"(II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

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

SEC. 210. ACCREDITATION OF PERSONS FOR REVIEW OF PREMARKET NOTIFICATION REPORTS.

(a) IN GENERAL.—Subchapter A of chapter V is amended by adding at the end the following:

"SEC. 523. ACCREDITED PERSONS.

"(a) IN GENERAL.—

"(1) REVIEW AND CLASSIFICATION OF DEVICES.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing reports submitted under section 510(k) and making recommendations to the Secretary regarding the initial classification of devices under section 513(f)(1).

"(2) REQUIREMENTS REGARDING REVIEW.—

"(A) IN GENERAL.—In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

"(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

"(C) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended under paragraph (1) by an accredited person, and in such case shall provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the change.

"(3) CERTAIN DEVICES.—

"(A) IN GENERAL.—An accredited person may not be used to perform a review of—

"(i) a class III device;

"(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting; or

"(iii) a class II device which requires clinical data in the report submitted under section 510(k) for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.

"(B) ADJUSTMENT.—In determining for a year the ratio described in subparagraph (A)(iii), the Secretary shall not include in the numerator class III devices that the Secretary reclassified into class II, and the Secretary shall include in the denominator class II devices for which reports under section 510(k) were not required to be submitted by reason of the operation of section 510(m).

"(b) ACCREDITATION.—

"(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

"(2) ACCREDITATION.—

"(A) IN GENERAL.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

"(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the

requirements of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

“(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

“(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

“(ii) take such additional measures as the Secretary determines to be appropriate.

“(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

“(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

“(A) Such person may not be an employee of the Federal Government.

“(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

“(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

“(D) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

“(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

“(i) certify that reported information accurately reflects data reviewed;

“(ii) limit work to that for which competence and capacity are available;

“(iii) treat information received, records, reports, and recommendations as proprietary information;

“(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

“(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

“(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least two or more accredited persons from which the regulated person may select one for a specific regulatory function.

“(5) COMPENSATION OF ACCREDITED PERSONS.—Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

“(c) 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 the Secretary has made a determination described in paragraph (2)(B) of subsection (a) for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection, whichever occurs first.”.

(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, 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.”.

(c) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 331), as amended by section 204(b), is amended by adding at the end the following:

“(y) In the case of a drug, device, or food—

“(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

“(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

“(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.”.

(d) REPORTS ON PROGRAM OF ACCREDITATION.—

(1) COMPTROLLER GENERAL.—

(A) IMPLEMENTATION OF PROGRAM.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the extent to which the program of accreditation required by the amendment made by subsection (a) has been implemented.

(B) EVALUATION OF PROGRAM.—Not later than 6 months prior to the date on which, pursuant to subsection (c) of section 523 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the authority provided under subsection (a) of such section will terminate, the Comptroller General shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the use of accredited persons under such section 523, including an evaluation of the extent to which such use assisted the Secretary in carrying out the duties of the Secretary under such Act with respect to devices, and the extent to which such use promoted actions which are contrary to the purposes of such Act.

(2) INCLUSION OF CERTAIN DEVICES WITHIN PROGRAM.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report providing a determination by the Secretary of whether, in the program of accreditation established pursuant to the amendment made by subsection (a), the limitation established in clause (iii) of section 523(a)(3)(A) of the Federal Food, Drug, and Cosmetic Act (relating to class II devices for which clinical data are required in reports under section 510(k)) should be removed.

SEC. 211. DEVICE TRACKING.

Effective 90 days after the date of the enactment of this Act, section 519(e) (21 U.S.C. 360i(e)) is amended to read as follows:

“Device Tracking

“(e)(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

“(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

“(B) which is—

“(i) intended to be implanted in the human body for more than one year; or

“(ii) a life sustaining or life supporting device used outside a device user facility.

“(2) Any patient receiving a device subject to tracking under paragraph (1) 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.”.

SEC. 212. POSTMARKET SURVEILLANCE.

Effective 90 days after the date of the enactment of this Act, section 522 (21 U.S.C. 360l) is amended to read as follows:

“POSTMARKET SURVEILLANCE

“SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

“(1) implanted in the human body for more than one year; or

“(2) a life sustaining or life supporting device used outside a device user facility.

“(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such 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. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562.”.

SEC. 213. REPORTS.

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

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking “manufacturer, importer, or distributor” and inserting “manufacturer or importer”;

(B) in paragraph (4), by striking “manufacturer, importer, or distributor” and inserting “manufacturer or importer”;

(C) in paragraph (7), by adding “and” after the semicolon at the end;

(D) in paragraph (8)—

(i) by striking “manufacturer, importer, or distributor” each place such term appears and inserting “manufacturer or importer”; and

(ii) by striking the semicolon at the end and inserting a period;

(E) by striking paragraph (9); and

(F) by inserting at the end the following sentence: “The Secretary shall by regulation require distributors to keep records and make such records available to the Secretary upon request. Paragraphs (4) and (8) apply to distributors to

the same extent and in the same manner as such paragraphs apply to manufacturers and importers.”;

(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, repack, 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 (other than the manufacturer or the initial importer) 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.”.

(c) DEVICE USER FACILITIES.—

(1) IN GENERAL.—Section 519(b) (21 U.S.C. 360i(b)) is amended—

(A) in paragraph (1)(C)—

(i) in the first sentence, by striking “a semi-annual basis” and inserting “an annual basis”;

(ii) in the second sentence, by striking “and July 1”; and

(iii) by striking the matter after and below clause (iv); and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting “or” after the comma at the end;

(ii) in subparagraph (B), by striking “, or” at the end and inserting a period; and

(iii) by striking subparagraph (C).

(2) SENTINEL SYSTEM.—Section 519(b) (21 U.S.C. 360i(b)) is amended—

(A) by redesignating paragraph (5) as paragraph (6); and

(B) by inserting after paragraph (4) the following paragraph:

“(5) With respect to device user facilities:

“(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

“(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply.

“(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply except to the extent that the Secretary determines otherwise.

“(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to a user facility unless the facility is included in the subset referred to in subparagraph (A).

“(E) Not later than 2 years after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.”.

SEC. 214. PRACTICE OF MEDICINE.

Chapter IX is amended by adding at the end the following:

“SEC. 906. PRACTICE OF MEDICINE.

“Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any con-

dition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.”.

SEC. 215. NONINVASIVE BLOOD GLUCOSE METER.

(a) FINDINGS.—The Congress finds that—

(1) diabetes and its complications are a leading cause of death by disease in America;

(2) diabetes affects approximately 16,000,000 Americans and another 650,000 will be diagnosed in 1997;

(3) the total health care-related costs of diabetes total nearly \$100,000,000,000 per year;

(4) diabetes is a disease that is managed and controlled on a daily basis by the patient;

(5) the failure to properly control and manage diabetes results in costly and often fatal complications including but not limited to blindness, coronary artery disease, and kidney failure;

(6) blood testing devices are a critical tool for the control and management of diabetes, and existing blood testing devices require repeated piercing of the skin;

(7) the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(8) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes by increasing the number of tests conducted by people with diabetes, particularly children; and

(9) the Food and Drug Administration is responsible for reviewing all applications for new medical devices in the United States.

(b) SENSE OF CONGRESS.—It is the sense of the Congress that the availability of a safe, effective, noninvasive blood glucose meter would greatly enhance the health and well-being of all people with diabetes across America and the world.

SEC. 216. USE OF DATA RELATING TO PREMARKET APPROVAL; PRODUCT DEVELOPMENT PROTOCOL.

(a) USE OF DATA RELATING TO PREMARKET APPROVAL.—

(1) 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 and other trade secrets) 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 (l)(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).”.

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

(A) in paragraph (8), by adding “or” at the end;

(B) in paragraph (9), by striking “, or” and inserting a comma; and

(C) by striking paragraph (10).

(b) PRODUCT DEVELOPMENT PROTOCOL.—Section 515(f)(2) (21 U.S.C. 360e(f)(2)) is amended by striking “he shall” and all that follows and inserting the following: “the Secretary—

“(A) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or

“(B) shall so refer such protocol upon the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data which would be reviewed by such panel substantially duplicate a product development protocol and accompanying data which have previously been reviewed by such a panel.”.

SEC. 217. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.

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”.

TITLE III—IMPROVING REGULATION OF FOOD

SEC. 301. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

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

“(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

“(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

“(i) enable consumers to develop and maintain healthy dietary practices;

“(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

“(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

“(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.”.

SEC. 302. PETITIONS FOR CLAIMS.

Section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) is amended—

(1) by adding after the second sentence the following: “If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.”;

(2) in the fourth sentence (as amended by paragraph (1)) by inserting immediately before the comma the following: “or the petition is deemed to be denied”; and

(3) by adding at the end the following: “If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.”.

SEC. 303. HEALTH CLAIMS FOR FOOD PRODUCTS.

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

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

authorized and may be made with respect to a food if—

“(i) a scientific body of the United States 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) or the National Academy of Sciences or any of its subdivisions 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 (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

“(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 clause, a statement shall be regarded as an authoritative statement of 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 a regulation under the standard in clause (B)(i)—

“(I) prohibiting or modifying the claim and the regulation has become effective, or

“(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; 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.”.

SEC. 304. NUTRIENT CONTENT CLAIMS.

Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding at the end the following:

“(G) A claim of the type described in subparagraph (I)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

“(i) a scientific body of the United States 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) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

“(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has

not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

“(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), 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 clause, a statement shall be regarded as an authoritative statement of 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.

“(H) A claim submitted under the requirements of clause (G) may be made until—

“(i) such time as the Secretary issues a regulation—

“(I) prohibiting or modifying the claim and the regulation has become effective, or

“(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

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

SEC. 305. REFERRAL STATEMENTS.

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 (I)(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, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: ‘See nutrition information 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.”.

SEC. 306. DISCLOSURE OF IRRADIATION.

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

“DISCLOSURE

“SEC. 403C. (a) No provision of section 201(n), 403(a), 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 has been intentionally subject to radiation.”.

SEC. 307. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall make a final determination on any petition pending with the Food and Drug Administration that would per-

mit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not make such determination, the Secretary shall, not later than 60 days following the date of the enactment of this Act, provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an explanation of the process followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

SEC. 308. GLASS AND CERAMIC WARE.

(a) IN GENERAL.—The Secretary may not implement any requirement which would ban, as an unapproved food additive, lead and cadmium based enamel in the lip and rim area of glass and ceramic ware before the expiration of one year after the date such requirement is published.

(b) LEAD AND CADMIUM BASED ENAMEL.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim, and

(2) which is not, by design, representation, or custom of usage intended for use by children,

is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware. Any action taken after January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive shall be taken by regulation and such regulation shall provide that such products shall not be removed from the market before 1 year after publication of the final regulation.

SEC. 309. 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 (3)) and inserting the following flush sentence:

“While such a regulation relating to a food additive, or such a notification under subsection (h)(1) 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 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)(i) Except as provided in clause (ii), the notification program established under this subsection shall not operate in any fiscal year unless—

“(I) an appropriation equal to or exceeding the applicable amount under clause (iv) is made for such fiscal year for carrying out such program in such fiscal year; and

“(II) the Secretary certifies that the amount appropriated for such fiscal year for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subclause (I)) equals or exceeds the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

“(ii) The Secretary shall, not later than April 1, 1999, begin accepting and reviewing notifications submitted under the notification program established under this subsection if—

“(I) an appropriation equal to or exceeding the applicable amount under clause (iii) is made for the last six months of fiscal year 1999 for carrying out such program during such period; and

“(II) the Secretary certifies that the amount appropriated for such period for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subclause (I)) equals

or exceeds an amount equivalent to one-half the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

“(iii) For the last six months of fiscal year 1999, the applicable amount under this clause is \$1,500,000, or the amount specified in the budget request of the President for the six-month period involved for carrying out the notification program in fiscal year 1999, whichever is less.

“(iv) For fiscal year 2000 and subsequent fiscal years, the applicable amount under this clause is \$3,000,000, or the amount specified in the budget request of the President for the fiscal year involved for carrying out the notification program under this subsection, whichever is less.

“(B) For purposes of carrying out the notification program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through fiscal year 2003, except that such authorization of appropriations is not effective for a fiscal year for any amount that is less than the applicable amount under clause (iii) or (iv) of subparagraph (A), whichever is applicable.

“(C) Not later than April 1 of fiscal year 1998 and February 1 of each subsequent fiscal year, the Secretary shall submit a report to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate that provides an estimate of the Secretary of the costs of carrying out the notification program established under this subsection for the next fiscal year.

“(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)”.

TITLE IV—GENERAL PROVISIONS

SEC. 401. DISSEMINATION OF INFORMATION ON NEW USES.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after subchapter C the following:

SUBCHAPTER D—DISSEMINATION OF TREATMENT INFORMATION

SEC. 551. REQUIREMENTS FOR DISSEMINATION OF TREATMENT INFORMATION ON DRUGS OR DEVICES.

“(a) IN GENERAL.—Notwithstanding sections 301(d), 502(f), and 505, and section 351 of the Public Health Service Act (42 U.S.C. 262), a manufacturer may disseminate to—

- “(1) a health care practitioner;
- “(2) a pharmacy benefit manager;
- “(3) a health insurance issuer;
- “(4) a group health plan; or
- “(5) a Federal or State governmental agency;

written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device if the manufacturer meets the requirements of subsection (b).

“(b) SPECIFIC REQUIREMENTS.—A manufacturer may disseminate information under subsection (a) on a new use only if—

“(1)(A) in the case of drug, there is in effect for the drug an application filed under subsection (b) or (j) of section 505 or a biologics license issued under section 351 of the Public Health Service Act; or

“(B) in the case of a device, the device is being commercially distributed in accordance

with a regulation under subsection (d) or (e) of section 513, an order under subsection (f) of such section, or the approval of an application under section 515;

“(2) the information meets the requirements of section 552;

“(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

“(4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary—

“(A) a copy of the information to be disseminated; and

“(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

“(5) the manufacturer has complied with the requirements of section 554 (relating to a supplemental application for such use);

“(6) the manufacturer includes along with the information to be disseminated under this subsection—

“(A) a prominently displayed statement that discloses—

“(i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;

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

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

“(iv) the official labeling for the drug or device and all updates with respect to the labeling;

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

“(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated; and

“(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

“(c) ADDITIONAL INFORMATION.—If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and balanced, the Secretary may require the manufacturer to disseminate—

“(1) additional objective and scientifically sound information that pertains to the safety or effectiveness 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; and

“(2) an objective statement of the Secretary, based on data or other scientifically sound information available to the Secretary, that bears on the safety or effectiveness of the new use of the drug or device.

“SEC. 552. INFORMATION AUTHORIZED TO BE DISSEMINATED.

“(a) AUTHORIZED INFORMATION.—A manufacturer may disseminate information under section 551 on a new use only if the information—

“(1) is in the form of an unabridged—

“(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal (as defined in section 556(5)), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or

“(B) reference publication, described in subsection (b), that includes information about a clinical investigation with respect to the drug 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 or device that is the subject of such a clinical investigation; and

“(2) is not false or misleading and would not pose a significant risk to the public health.

“(b) REFERENCE PUBLICATION.—A reference publication referred to in subsection (a)(1)(B) is a publication that—

“(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug or device;

“(2) has not been edited or significantly influenced by a such a manufacturer;

“(3) is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold;

“(4) does not focus on any particular drug or device of a manufacturer that disseminates information under section 551 and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

“(5) presents materials that are not false or misleading.

“SEC. 553. ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.

“(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the manufacturer prepares and submits to the Secretary biannually—

“(1) a list containing the titles of the articles and reference publications relating to the new use of drugs or devices that were disseminated by the manufacturer to a person described in section 551(a) 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 551(a)) that received the articles and reference publications for the 6-month period described in paragraph (1).

“(b) RECORDS.—A manufacturer that disseminates information under section 551 shall keep records that may be used by the manufacturer when, pursuant to section 555, 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 such section. Such records, at the Secretary’s discretion, may identify the recipient of information provided pursuant to section 551 or the categories of such recipients.

“SEC. 554. REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT.

“(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if—

“(1)(A) the manufacturer has submitted to the Secretary a supplemental application for such use; or

“(B) the manufacturer meets the condition described in subsection (b) or (c) (relating to a certification that the manufacturer will submit such an application); or

“(2) there is in effect for the manufacturer an exemption under subsection (d) from the requirement of paragraph (1).

“(b) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF COMPLETED STUDIES.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary an application containing a certification that—

“(1) the studies needed for the submission of a supplemental application for the new use have been completed; and

“(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of information under section 551.

“(c) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF PLANNED STUDIES.—

“(1) IN GENERAL.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if—

“(A) the manufacturer has submitted to the Secretary an application containing—

“(i) a proposed protocol and schedule for conducting the studies needed for the submission of a supplemental application for the new use; and

“(ii) a certification that the supplemental application will be submitted to the Secretary not later than 36 months after the date of the initial dissemination of information under section 551 (or, as applicable, not later than such date as the Secretary may specify pursuant to an extension under paragraph (3)); and

“(B) the Secretary has determined that the proposed protocol is adequate and that the schedule for completing such studies is reasonable.

“(2) PROGRESS REPORTS ON STUDIES.—A manufacturer that submits to the Secretary an application under paragraph (1) shall submit to the Secretary periodic reports describing the status of the studies involved.

“(3) EXTENSION OF TIME REGARDING PLANNED STUDIES.—The period of 36 months authorized in paragraph (1)(A)(ii) for the completion of studies may be extended by the Secretary if—

“(A) the Secretary determines that the studies needed to submit such an application cannot be completed and submitted within 36 months; or

“(B) the manufacturer involved submits to the Secretary a written request for the extension and the Secretary determines that the manufacturer has acted with due diligence to conduct the studies in a timely manner, except that an extension under this subparagraph may not be provided for more than 24 additional months.

“(d) EXEMPTION FROM REQUIREMENT OF SUPPLEMENTAL APPLICATION.—

“(1) IN GENERAL.—For purposes of subsection (a)(2), a manufacturer may disseminate information on a new use if—

“(A) the manufacturer has submitted to the Secretary an application for an exemption from meeting the requirement of subsection (a)(1); and

“(B)(i) the Secretary has approved the application in accordance with paragraph (2); or

“(ii) the application is deemed under paragraph (3)(A) to have been approved (unless such approval is terminated pursuant to paragraph (3)(B)).

“(2) CONDITIONS FOR APPROVAL.—The Secretary may approve an application under paragraph (1) for an exemption if the Secretary makes a determination described in subparagraph (A) or (B), as follows:

“(A) The Secretary makes a determination that, for reasons defined by the Secretary, it would be economically prohibitive with respect to such drug or device for the manufacturer to incur the costs necessary for the submission of a supplemental application. In making such deter-

mination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate)—

“(i) the lack of the availability under law of any period during which the manufacturer would have exclusive marketing rights with respect to the new use involved; and

“(ii) the size of the population expected to benefit from approval of the supplemental application.

“(B) The Secretary makes a determination that, for reasons defined by the Secretary, it would be unethical to conduct the studies necessary for the supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate) whether the new use involved is the standard of medical care for a health condition.

“(3) TIME FOR CONSIDERATION OF APPLICATION; DEEMED APPROVAL.—

“(A) IN GENERAL.—The Secretary shall approve or deny an application under paragraph (1) for an exemption not later than 60 days after the receipt of the application. If the Secretary does not comply with the preceding sentence, the application is deemed to be approved.

“(B) TERMINATION OF DEEMED APPROVAL.—If pursuant to a deemed approval under subparagraph (A) a manufacturer disseminates written information under section 551 on a new use, the Secretary may at any time terminate such approval and under section 555(b)(3) order the manufacturer to cease disseminating the information.

“(e) REQUIREMENTS REGARDING APPLICATIONS.—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

“SEC. 555. CORRECTIVE ACTIONS; CESSATION OF DISSEMINATION.

“(a) POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.—

“(1) CORRECTIVE ACTIONS.—With respect to data received by the Secretary after the dissemination of information under section 551 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the data indicate that the new use involved may not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such action regarding the dissemination of the information as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease the dissemination of the information.

“(2) RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.—After a manufacturer disseminates information under section 551, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

“(b) CESSATION OF DISSEMINATION.—

“(1) FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only after the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and (unless paragraph (2)(B) applies) has provided an opportunity for a meeting with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the

Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

“(2) SUPPLEMENTAL APPLICATIONS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if—

“(A) in the case of a manufacturer that has submitted a supplemental application for a new use pursuant to section 554(a)(1), the Secretary determines that the supplemental application does not contain adequate information for approval of the new use for which the application was submitted;

“(B) in the case of a manufacturer that has submitted a certification under section 554(b), the manufacturer has not, within the 6-month period involved, submitted the supplemental application referred to in the certification; or

“(C) in the case of a manufacturer that has submitted a certification under section 554(c) but has not yet submitted the supplemental application referred to in the certification, the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies involved.

“(3) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—If under section 554(d)(3) the Secretary terminates a deemed approval of an exemption, the Secretary may order the manufacturer involved to cease disseminating the information. A manufacturer shall comply with an order under the preceding sentence not later than 60 days after the receipt of the order.

“(c) CORRECTIVE ACTIONS BY MANUFACTURERS.—

“(1) IN GENERAL.—In any case in which under this section the Secretary orders a manufacturer to cease disseminating information, the Secretary may order the manufacturer to take action to correct the information that has been disseminated, except as provided in paragraph (2).

“(2) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may not order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

“SEC. 556. DEFINITIONS.

“For purposes of this subchapter:

“(1) The term ‘health care practitioner’ means a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs or devices.

“(2) The terms ‘health insurance issuer’ and ‘group health plan’ have the meaning given such terms under section 2791 of the Public Health Service Act.

“(3) The term ‘manufacturer’ means a person who manufactures a drug or device, or who is licensed by such person to distribute or market the drug or device.

“(4) The term ‘new use’—

“(A) with respect to a drug, means a use that is not included in the labeling of the approved drug; and

“(B) with respect to a device, means a use that is not included in the labeling for the approved or cleared device.

“(5) 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 disclo-

sure 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; and

“(E) that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers.

“SEC. 557. RULES OF CONSTRUCTION.

“(a) UNSOLICITED REQUEST.—Nothing in section 551 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

“(b) DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (g) 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 551, 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.

“(c) PATENT PROTECTION.—Nothing in section 551 shall affect patent rights in any manner.

“(d) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 551 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 556(5)) from requiring authorization from the entity to disseminate an article published by such entity or 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 210, is amended by adding at the end the following:

“(z) The dissemination of information in violation of section 551.”

(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) SUNSET.—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.

(f) 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 subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by 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 such subchapter should be extended beyond the termination date specified in subsection (e), 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 such subchapter including issues relating to—

(i) the effectiveness of such subchapter 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 such subchapter;

(iii) the quality and usefulness of the information provided, in accordance with such subchapter, by the Secretary or by the manufacturer at the request of the Secretary; and

(iv) the impact of such subchapter 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 Comptroller General of the United States shall conduct such study.

(B) REPORT.—Not later than September 30, 2005, the Institute of Medicine or the Comptroller General of the United States, 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.

SEC. 402. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES AND DIAGNOSTICS.

Chapter V (21 U.S.C. 351 et seq.), as amended in section 401, is further amended by adding at the end the following:

“SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

“SEC. 561. 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 or investigational devices 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, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device 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 probable risk to the person from the investigational drug or investigational device is not greater than the probable 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 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), including any regulations promulgated under section 505(i) or 520(g), describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

“(c) TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS AND TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS.—Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an ‘expanded access protocol’), the Secretary shall permit such investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

“(1) under the treatment investigational new drug application or treatment 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 investigational drug application in effect under section 505(i) or investigational device exemption in effect under section 520(g); or

“(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) in the case of an investigational drug or investigational device described in paragraph (3)(A), 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 investigational drug or investigational device 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), including 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 the same type of information that is required by section 402(j)(3) of the Public Health Service Act.

“(d) TERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug or

investigational device if the requirements under this section are no longer met.

“(e) DEFINITIONS.—In this section, the terms ‘investigational drug’, ‘investigational device’, ‘treatment investigational new drug application’, and ‘treatment investigational device exemption’ shall have the meanings given the terms in regulations prescribed by the Secretary.”

SEC. 403. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) STANDARDS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this Act, the Secretary 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 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 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. 404. DISPUTE RESOLUTION.

Subchapter E of chapter V, as added by section 402, is amended by adding at the end the following:

“SEC. 562. DISPUTE RESOLUTION.

“If, regarding an obligation concerning drugs or devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate scientific advisory panel described in section 505(n) or an advisory committee described in section 515(g)(2)(B). Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997.”

SEC. 405. INFORMAL AGENCY STATEMENTS.

Section 701 (21 U.S.C. 371) is amended by adding at the end the following:

“(h)(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

“(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

“(C) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.

“(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

“(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

“(3) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

“(4) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.

“(5) Not later than July 1, 2000, 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 consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.”

SEC. 406. FOOD AND DRUG ADMINISTRATION MISSION AND ANNUAL REPORT.

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

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

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

“(b) MISSION.—The Administration shall—
“(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

“(2) with respect to such products, protect the public health by ensuring that—

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

“(B) human and veterinary drugs are safe and effective;

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

“(D) cosmetics are safe and properly labeled; and

“(E) public health and safety are protected from electronic product radiation;

“(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

“(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.”.

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is further amended by adding at the end the following:

“(f) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with appropriate scientific and academic 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. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with such persons.

“(2) OBJECTIVES OF AGENCY PLAN.—The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to—

“(A) maximizing the availability and clarity 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;

“(B) maximizing the availability and clarity of information for consumers and patients concerning new products;

“(C) implementing inspection and postmarket monitoring provisions of this Act;

“(D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);

“(E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this Act for the review of all applications and submissions described in subparagraph (A) and submitted after the date of enactment of the Food and Drug Administration Modernization Act of 1997; and

“(F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

“(g) ANNUAL REPORT.—The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that—

“(1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f);

“(2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and

“(3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.”.

SEC. 407. INFORMATION SYSTEM.

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

“SUBCHAPTER D—INFORMATION AND EDUCATION

“SEC. 741. INFORMATION SYSTEM.

“The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar

form of request) submitted to the Food and Drug Administration requesting agency action.”.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives on the status of the system to be established under the amendment made by subsection (a), including the projected costs of the system and concerns about confidentiality.

SEC. 408. EDUCATION AND TRAINING.

(a) FOOD AND DRUG ADMINISTRATION.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following section:

“SEC. 742. EDUCATION.

“(a) IN GENERAL.—The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for—

“(1) scientific training;

“(2) training to improve the skill of officers and employees authorized to conduct inspections under section 704;

“(3) training to achieve product specialization in such inspections; and

“(4) training in administrative process and procedure and integrity issues.

“(b) INTRAMURAL FELLOWSHIPS AND OTHER TRAINING PROGRAMS.—The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians.”.

(b) CENTERS FOR DISEASE CONTROL AND PREVENTION.—

(1) IN GENERAL.—Part B of title III of the Public Health Service Act is amended by inserting after section 317F (42 U.S.C. 247b-7) the following:

“SEC. 317G. FELLOWSHIP AND TRAINING PROGRAMS.

“The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or non-appointment procedures.”.

(2) EFFECTIVE DATE.—The amendment made by this subsection is deemed to have taken effect July 1, 1995.

SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section:

“SEC. 905. DEMONSTRATION PROGRAM REGARDING CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.

“(a) IN GENERAL.—The Secretary, acting through the Administrator and in consultation with the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).

“(b) REQUIRED ACTIVITIES.—The activities referred to in subsection (a) are the following:

“(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:

“(A) To increase awareness of—

“(i) new uses of drugs, biological products, and devices;

“(ii) ways to improve the effective use of drugs, biological products, and devices; and

“(iii) risks of new uses and risks of combinations of drugs and biological products.

“(B) To provide objective clinical information to the following individuals and entities:

“(i) Health care practitioners or other providers of health care goods or services.

“(ii) Pharmacy benefit managers.

“(iii) Health maintenance organizations or other managed health care organizations.

“(iv) Health care insurers or governmental agencies.

“(v) Consumers.

“(C) To improve the quality of health care while reducing the cost of health care through—

“(i) the appropriate use of drugs, biological products, or devices; and

“(ii) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

“(2) The conduct of research on the comparative effectiveness and safety of drugs, biological products, and devices.

“(3) Such other activities as the Secretary determines to be appropriate, except that the grant may not be expended to assist the Secretary in the review of new drugs.

“(c) APPLICATION FOR GRANT.—A grant under subsection (a) may be made only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

“(d) PEER REVIEW.—A grant under subsection (a) may be made only if the application for the grant has undergone appropriate technical and scientific peer review.

“(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$2,000,000 for fiscal year 1998, and \$3,000,000 for each of fiscal years 1999 through 2002.”.

SEC. 410. MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION.

(a) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—Section 520(f)(1)(B) (21 U.S.C. 360j(f)(1)(B)) is amended—

(1) in clause (i), by striking “, and” at the end and inserting a semicolon;

(2) in clause (ii), by striking the period and inserting “; and”;

(3) by inserting after clause (ii) the following:

“(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.”.

(b) HARMONIZATION EFFORTS.—Section 803 (21 U.S.C. 383) is amended by adding at the end the following:

“(c)(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act.

“(2) The Secretary shall 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.

“(3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on

methods and approaches to harmonize regulatory requirements.

“(4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

“(5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 201(ff).”

SEC. 411. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

“SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

“SEC. 746. ENVIRONMENTAL IMPACT.

“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. 412. NATIONAL UNIFORMITY FOR NON-PRESCRIPTION DRUGS AND COSMETICS.

(a) **NONPRESCRIPTION DRUGS.**—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 411, 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. 751. NATIONAL UNIFORMITY FOR NON-PRESCRIPTION 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 section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997) 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 the Food and Drug Administration Modernization Act of 1997.

“(2) **STATE INITIATIVES.**—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

“(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.**—Subparagraph (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 determined to be 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 determined to be 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, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, 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 determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause

with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause 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, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause 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. 752. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

“(a) **IN GENERAL.**—Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish 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 or 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 requirement 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. 413. FOOD AND DRUG ADMINISTRATION STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD.

(a) **LIST AND ANALYSIS.**—The Secretary of Health and Human Services shall, acting through the Food and Drug Administration—

(1) compile a list of drugs and foods that contain intentionally introduced mercury compounds, and

(2) provide a quantitative and qualitative analysis of the mercury compounds in the list under paragraph (1).

The Secretary shall compile the list required by paragraph (1) within 2 years after the date of enactment of the Food and Drug Administration Modernization Act of 1997 and shall provide the analysis required by paragraph (2) within 2 years after such date of enactment.

(b) **STUDY.**—The Secretary of Health and Human Services, acting through the Food and

Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made of such use.

(c) STUDY OF MERCURY SALES.—

(1) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration and subject to appropriations, shall conduct, or shall contract with the Institute of Medicine of the National Academy of Sciences to conduct, a study of the effect on humans of the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate—

(A) the scope of mercury use as a drug or dietary supplement; and

(B) the adverse effects on health of children and other sensitive populations resulting from exposure to, or ingestion or inhalation of, mercury when so used.

In conducting such study, the Secretary shall consult with the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, and the Administrator of the Agency for Toxic Substances and Disease Registry, and, to the extent the Secretary believes necessary or appropriate, with any other Federal or private entity.

(2) REGULATIONS.—If, in the opinion of the Secretary, the use of elemental, organic, or inorganic mercury offered for sale as a drug or dietary supplement poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from exposure to, or ingestion or inhalation of, mercury. Such regulations, to the extent feasible, should not unnecessarily interfere with the availability of mercury for use in religious ceremonies.

SEC. 414. INTERAGENCY COLLABORATION.

Section 903 (21 U.S.C. 393), as amended by section 406, is further amended by inserting after subsection (b) the following:

“(c) 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. 415. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 214, is further amended by adding at the end the following:

“SEC. 907. 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 relevant expertise, to review and evaluate, for the purpose of making 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 may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness 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. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality 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 in a timely manner.

“(2) LIMITATION.—A final decision by the Secretary on any such application or submission 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.).”

SEC. 416. PRODUCT CLASSIFICATION.

Subchapter E of chapter V, as amended by section 404, is further amended by adding at the end the following:

“SEC. 563. 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 for a product, may submit a request to the Secretary respecting the classification of the product 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 product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, 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 product under subsection (a), or the component of the Food and Drug Administration that will regulate the product, and shall provide to the person a written statement that identifies such classification or such component, 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 based on scientific evidence.

“(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 such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.”

SEC. 417. 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 officials of for-

eign 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. 418. 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)”;

(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. 419. INTERSTATE COMMERCE.

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

SEC. 420. SAFETY REPORT DISCLAIMERS.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 412, is further amended by adding at the end the following:

“SUBCHAPTER G—SAFETY REPORTS

“SEC. 756. 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 that is a food, 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 reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. 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 malfunctioned, caused or contributed to an adverse experience, or caused or contributed to a death, serious injury, or serious illness.”

SEC. 421. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.

Section 301 (21 U.S.C. 331) is amended by striking paragraph (l).

SEC. 422. RULE OF CONSTRUCTION.

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act.

TITLE V—EFFECTIVE DATE

SEC. 501. EFFECTIVE DATE.

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of and the amendments made by sections 111, 121, 125, and 307, shall take effect 90 days after the date of enactment of this Act.

And the House agree to the same.

That the House recede from its amendment to the title of the bill.

TOM BLILEY,
MICHAEL BILIRAKIS,
JOE BARTON,

JAMES GREENWOOD,
RICHARD BURR,
ED WHITFIELD,
JOHN D. DINGELL,
SHERRON BROWN,
HENRY A. WAXMAN,
RON KLINK,

Managers of the Part of the House.

JIM JEFFORDS,
DAN COATS,
JUDD GREGG,
BILL FRIST,
MIKE DEWINE,
EDWARD M. KENNEDY,
CHRISTOPHER DODD,
TOM HARKIN,
BARBARA A. MIKULSKI,

Managers on the Part of the Senate.

JOINT EXPLANATORY STATEMENT OF
THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) 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, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment to the text of the bill struck all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment that is substitute for the Senate bill and the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clerical changes.

The conference agreement on S. 830, the Food and Drug Administration Modernization Act of 1997, provides for (1) the reauthorization of the Prescription Drug User Fee Act of 1992; (2) the improvement of regulation of drugs through such reforms as those pertaining to pediatric studies of drugs, procedures relating to fast track drugs, health care economic information, national uniformity for over-the-counter drugs and cosmetics, and data requirements for drugs and biological products; (3) the improvement of regulation of medical devices through such reforms as those pertaining to device standards and data requirements, procedures relating to humanitarian and breakthrough devices, tracking and postmarket surveillance, and accredited party review; (4) the improvement of regulation of food through such reforms as those pertaining to the timetable and regulatory authority of the Secretary in processing health and nutrient content claims, food contact substance notifications, and information relating to irradiation treatment; and (5) general provisions pertaining to the dissemination of information, expanded access to investigational therapies, and consumer access to information about clinical trials of investigational therapies.

Certain matters agreed to in conference are noted below:

TITLE I—IMPROVING REGULATION OF DRUGS
Prescription Drug User Fee Act (Subtitle A)

The conferees believe it is important to place the PDUFA reauthorization provisions of the Act in the overall context of the budgetary agreements which have been put into place by the 1997 Balanced Budget Agree-

ments (BBA). This Act preserves the original PDUFA adjustment factor and therefore the basic understanding behind the 1992 enactment of this provision: that is, the industry willingness to pay user fees for enhanced performance in the drug approval process. Nevertheless the conferees acknowledge that the 1997 BBA places tight constraints on the appropriations process, particularly in the out years. The conferees expect the appropriators will make every effort to meet the trigger so that FDA is allowed to collect and expend user fees. However, it must be acknowledged that particularly in the fifth year of BBA, budgetary pressures on all discretionary spending will be great.

Breakdowns of the actual spending levels at FDA have not traditionally been provided to the appropriators, making it difficult to conduct oversight. Beginning in Fiscal Year 1998, appropriators will require FDA to submit a directed operating budget as part of the annual budget request. This will serve as a functional breakdown of how appropriated dollars are spent, similar to the report FDA submits annually to show how the agency spent collected PDUFA user fees.

The conferees expect the President's budgetary request for FDA for salaries and expenses to meet the PDUFA levels specified for each of these years and not be based on any assumption of the enactment of new substitutive user fees on other FDA regulated industries.

Pediatric studies of drugs (Sec. 111)

The conference agreement provides that if the Secretary determines that information about a drug may produce health benefits in a pediatric population and makes a written request for pediatric studies (including a time frame for completing the studies), and the studies are completed and are accepted by the Secretary, then the sponsor or manufacturer will qualify for 6 months of extra market exclusivity. The agreement authorizes the Secretary to determine the time frame for completing the studies, but the conferees emphasize that such studies should be sought, conducted, and completed at the earliest possible opportunity. The conferees do not intend that such studies be artificially timed for market advantage.

The agreement provides that no new market exclusivity may be applied to any new drug for which a new drug application is submitted after January 1, 2002. However, the agreement provides a continuation of the program for certain drugs already on the market on the date of enactment. The purpose of this limited extension is to ensure that, with respect to such already marketed drugs, exclusivity remains available if the Secretary determines there is a continuing need for additional information relating to the use of such drugs that may promote health benefits in the pediatric population. This is applicable only to drugs already included on the list under subsection (b) as of January 1, 2002. The Secretary will not list any additional drugs under Section 505A(b) after January 1, 2002. These drugs will be eligible for the applicable 6-month time extension if the requested studies satisfy all requirements of the section.

The conferees expect the Secretary to consult with experts in pediatric research to develop the list of drugs under subsection (b), and to set priorities for studies on these drugs. Such experts should include representatives from the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit (PPRU) Network, and the U.S. Pharmacopeia. The conferees note particularly the excellent efforts of NIH, especially through the PPRU Network, which will contribute significantly to this effort.

The conference agreement also requires that a study be conducted on the program,

by January 1, 2001, that reviews all aspects of the program, including its impact on the price and availability of drugs and the availability of generic drugs.

With respect to any requested studies under this provision, the conferees intend that data collected prior to a request or requirement by the Secretary may be used, in addition to data collected after such request or requirement in satisfying the provisions of this section.

Clinical investigations (Sec. 115)

The conferees note that the requirement for the Secretary to review existing guidance and develop additional guidance, as appropriate, on the inclusion of women and minorities in clinical trials does not require participation of women and minorities in any particular trial. Furthermore, FDA is required to consult with the National Institutes of Health, which has developed inclusion guidelines for subjects in federally funded clinical research, and with representatives of the drug manufacturing industry, to ensure that ethical, scientific, and legal issues specific to privately funded clinical research are considered. The conferees expect FDA to set forth its general policy regarding: the inclusion of women and minorities in drug development research; population-specific analyses of clinical data and assessment of potential pharmacokinetic differences; and the conduct of specific additional studies in women or minorities, where appropriate.

Content and review of applications (Sec. 119)

The Secretary is required to meet with an applicant if the applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of studies, if the sponsor provides the information necessary to discuss and reach agreement on the design and size of such studies. The Secretary may refuse to meet if the sponsor does not provide such information or if the Secretary determines that such meeting is premature or would not be useful.

Positron emission tomography (Sec. 121)

The conference agreement provides for regulation of positron emission tomography (PET) drugs and replaces earlier industry guidance and regulatory standards for PET products promulgated by the FDA. The agreement provides that, until the Secretary establishes procedures under subsection (c)(1) described below, neither a New Drug Application (NDA) nor an Abbreviated New Drug Application (ANDA) is required by a licensed practitioner to produce a compounded PET product in accordance with United States Pharmacopeia (USP) standards.

The agreement requires the Secretary, in two years to establish procedures for approving PET products, including compounded PET products, and good manufacturing practices for such products, taking account of relevant differences between commercial manufacturers and non-profit organizations and in consultation with patient groups, physicians, and others. The Secretary may not require NDAs or ANDAs for these products for four years (or two years after the procedures mentioned above are established).

A compounded PET drug, by definition, must be compounded pursuant to a valid prescription order and in accordance with state law, among other requirements. A PET drug that fails to meet these requirements is not a "compounded PET drug" and therefore is not exempt from section 501(a)(2)(B) (21 USC 351(a)(2)(B)) or from subsections (b) and (j) of section 505 (21 USC 355). PET drugs that fail to meet the definition of a "compounded PET drug" shall be subject to the procedures and requirements established by the Secretary under subsection (c)(1).

Application of Federal law to practice of pharmacy compounding (Sec. 127)

The conference report includes provisions on pharmacy compounding that reflect the conferees' extensive work with the Food and Drug Administration and other interested parties to reach consensus. It is the intent of the conferees to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters under which compounding is appropriate and lawful. The conditions set forth in Section 503A should be used by the state boards of pharmacy and medicine for proper regulation of pharmacy compounding in addition to existing state-specific regulations.

The conferees intend that, as defined in subparagraph (b)(2), copies of commercially available drug products do not include drug products in which the change from the commercially available drug product produces a "significant difference" for the particular patient. For example, the removal of a dye from a commercially available drug product for a particular patient who is allergic to such dye shall be presumed to be a "significant difference." The conferees expect that FDA and the courts will accord great deference to the licensed prescriber's judgement in determining whether the change produces a "significant difference." However, where it is readily apparent, based on the circumstances, the "significant difference" is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09% are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other financial incentives to write prescription for compounded products.

The conferees also expect that the Secretary will develop the list of bulk drug substances described in subsection (b)(1)(A)(i)(III) within one year from the date of enactment. It is the intent of the conferees that the criteria used to develop the list of bulk drug substances and the list itself are to be developed in consultation with the United States Pharmacopoeia. The conferees further intend that where evidence relating to an approval under Section 505 does not exist, the Secretary shall consider other criteria. Finally, the conferees intend that after this list is published, organizations may petition the FDA for inclusion of additional substances on the aforementioned list.

The memorandum of understanding described in Paragraph (b)(3)(B)(i) shall provide guidance on the meaning of inordinate amounts, including any circumstances under which the compounding of drug products for interstate shipment in excess of 5 percent of total prescription order would be included in a "safe harbor" of interstate shipments of compounded products that shall not be deemed inordinate.

As stated in paragraph (e), nothing in Section 503A is intended to change or otherwise affect current law with respect to radiopharmaceuticals, including PET drugs. Further, as stated in paragraph (f), the term compounding does not include mixing reconstituting or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufac-

turer directions consistent with that labeling. Nothing in this provision is intended to change or otherwise affect the Act with respect to reconstitution or other similar processing that is done pursuant to a manufacturer's approved labeling, and other directions from such manufacturer that are consistent with that labeling. In general, such practices, as performed by a licensed practitioner for an identified individual patient, are appropriately regulated by state boards of pharmacy. The conferees intend that facilities required to register with the FDA, including those which are engaged in non-patient specific compounding and reconstitution activities, are appropriately regulated under the Federal Food, Drug and Cosmetic Act.

Finally, with regard to the effective date described in paragraph (b), the conferees expect the FDA to work diligently to consult with necessary parties to promulgate the required regulations and lists. Nothing in paragraph (b) is intended to abrogate the Secretary's responsibility to promulgate such regulations through the notice and comment rulemaking process.

Reauthorization of the Clinical Pharmacology Program (Sec. 128)

The conference agreement extends through fiscal year 2002 the authorization of appropriations of the Clinical Pharmacology Training Program, a program originally authorized under section 2(b) of P.L. 102-222. Nothing in this section of the agreement prohibits the Secretary from continuing the awarding of grants to the original and current grantees. The conferees strongly recommend that the Secretary continue the development of the clinical pharmacology programs at the colleges and universities originally selected to participate in the program.

Regulations for sunscreen products (Sec. 129)

The conference agreement includes a provision requiring FDA to continue diligently with its work to complete its rulemaking process on sunscreen products and to issue regulations within 18 months. The conferees recognize that various technical and scientific issues may take longer to resolve than other aspects of the rulemaking. The conferees do not intend that all regulation in this area be complete or comprehensive by a specified date.

TITLE II—IMPROVING REGULATION OF DEVICES

Scope of review (Sec. 205)

The conference agreement addresses the issue of regulatory burden by ensuring that the impact of the Secretary's necessary review, approval, and oversight functions is not inappropriate. This assurance is achieved by requiring the Secretary to consider, in consultation with an applicant for device approval, the method for evaluating the device's effectiveness that would be appropriate, least burdensome, and reasonably likely to result in the device's approval. The conferees believe that this language is necessary to and consistent with improving communications between the FDA and regulated persons, increasing regulatory efficiency, and decreasing the length of product review and approval.

Premature notification (Sec. 206)

The conference agreement exempts class I devices from premarket notification under section 510(k), except those types that present a potential unreasonable risk of illness or injury, or that are of substantial importance in preventing impairment of human health. The agreement also requires the Secretary to publish a notice listing the types of class II devices that are exempt from premarket notification. The Secretary must publish this initial list within 60 days.

Thereafter, class II devices may be exempted by the Secretary on the Secretary's own initiative or through a petition process. The agreement provides that the Secretary must respond to any such petition within 180 days or the petition will be deemed granted.

The conferees do not intend by this provision that the Secretary should up-classify low-risk class I device in order to avoid exempting them. The conferees believe the appropriate exemption of class I and certain class II devices will allow the Secretary to expend limited premarket review resources on potentially risky and technologically advanced devices. Focusing resources in this manner will ensure the public continues to be adequately protected and will still benefit from the earlier availability of new products.

Accredited party review (Sec. 210)

The conference agreement makes modifications to the House and Senate provisions establishing the process by which the Secretary will accredit person to review and initially classify 510(k) devices. The agreement's provisions relating to the scope and the duration of the pilot program specify that an accredited person may not review a class III device, a class II device that is permanently implantable, life-sustaining or life-supporting, or a class II device for which clinical data are required. The latter category is limited in size to not more than six percent of all 510(k) submissions. In addition, the agreement provides for the termination of the pilot program after the Secretary has met specified targets for inclusion of eligible devices.

Reports (Sec. 213)

The conference agreement amends Section 519 of the Federal Food, Drug and Cosmetic Act to reduce the reporting requirements for device distributors. Manufacturers and importers, however, are required to comply with the existing requirements for medical device reporting. The amendment to section 519(a)(9) requires distributors to keep records and make them available to the Secretary on request. Because distributors will no longer be submitting reports to the Secretary, copies of reports would also not be sent to the manufacturers. This is not intended to provide the FDA with any new statutory authority to require distributors to keep additional records; it merely clarifies that existing record keeping requirements of section 519(a) continue to apply. This provision also removes the registration, listing, and reporting requirements for distributors under section 510. Since user facilities and manufacturers submit medical device reports to the FDA, there is no need for additional reporting by distributors. The FDA is urged to allow all record keeping, including distributor record keeping, to be accomplished through either electronic means or written documentation. The FDA is also urged to revise its current regulations on distributor record keeping (21 C.F.R. §804.35(b)) to provide that distributors need only keep records of complaints for six years from the date a complaint is received by the distributor, consistent with the longest statutes of limitations under State tort laws. Currently, FDA regulations require distributors to keep records for two years from the date of the record of complaint or the expected life of the device, whichever is greater. It is the intent of the conferees to simplify these requirements, since distributors, unlike manufacturers, are not able to determine the expected life of a device. Since these records will be kept by manufacturers as well, it is unnecessarily burdensome for distributors to keep these records for other than a fixed period of time.

The conferees expect the FDA to modify its regulations under Sec. 519(f) to ensure

that the reports under this section are not required from any manufacturer, importer, or distributor who also is regulated and required to make such reports under the Radiation Control for Health and Safety Act of 1968 (21 U.S.C. 36011).

Practice of medicine (Sec. 214)

The conference agreement includes a provision intended by the conferees to emphasize that the FDA should not interfere in the practice of medicine. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA. It is the intent of the conferees that this provision not be construed to affect medical professional liability.

TITLE III—IMPROVING REGULATION OF FOOD
Flexibility for regulations regarding claims (Sec. 301)

The conference agreement clarifies the parameters within which the Secretary may use the interim final rulemaking authority established under this section. This authority enables the Secretary to make proposed regulations on claims effective upon publication, pending consideration of public comment and publication of a final regulation. The conferees' clarifying language emphasizes that this authority may be used when the Secretary determines that it is necessary to enable the Secretary to improve consumer access to important dietary information and to ban or modify a claim in a prompt fashion. The conferees' intent in creating this expedited rulemaking authority for health and nutrient content claims is that it be used primarily to expedite the review of petitions for health and nutrient content claims based on authoritative statements.

Health and nutrient content claims (Secs. 303, 304)

The conference agreement makes streamlined procedures available for the Secretary to permit more scientifically sound nutrition information to be provided to consumers through health and nutrient content claims. This process is triggered by authoritative statements of entities such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and the National Academy of Sciences (NAS). Although the provision specifically permits claims to be made on the basis of a statement produced by subsidiaries of NAS, the conferees intend that the lack of similar language with respect to entities such as NIH and CDC be interpreted as a reflection of the desire of the conferees that statements issued by entities such as NIH and CDC reflect consensus within those institutions. The agreement makes minor modifications to the House provisions on health and nutrient content claims to expedite the process by which such claims are processed. As part of the submissions to the Secretary for health claims based on authoritative statements, a balanced representation of the scientific literature may include a bibliography of such literature.

Disclosure of irradiation (Sec. 306)

The conference agreement ensures that no existing provision of the Federal Food Drug and Cosmetic Act will be considered to require a separate radiation disclosure statement that is more prominent than the declaration of ingredients on the food label. To ensure the intended effect of this provision, the conferees direct the Secretary promptly to publish for public comment proposed amendments to current regulations relating to the labeling of foods treated with ionizing radiation. The conferees expect final regula-

tions to be issued not more than 12 months after the date of enactment of this measure. The public comment process should be utilized by the Secretary to provide an opportunity to comment on whether the regulations should be amended to revise the prescribed nomenclature for the labeling of irradiated foods and on whether such labeling requirements should expire at a specified date in the future. The conferees intend for any required disclosure to be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety.

Food contact substances (Sec. 309)

The conference agreement establishes a notification process for the regulation of components of food packaging, known as food contact substances, which is intended to expedite authorization of the marketing of a food contact substance except where the Secretary determines that submission and review of a food additive petition is necessary to provide adequate determination of safety. The agreement also authorizes appropriations to finance the costs of the new notification process. To protect the Agency from having to reallocate resources within CFSAN to meet the costs of implementation, the agreement provides that implementation is to be triggered only when the FDA receives an appropriation sufficient to fund the program. The conferees strongly encourage the House and Senate to appropriate the funds authorized. The conferees also urge the Committees of jurisdiction, when reauthorizing the notification program, to reevaluate fully its operational effectiveness, the appropriateness of its timeframes, the adequacy of funding, and its protection of the public health.

On the subject of food contact substances, the conferees wish to commend the FDA and the Environmental Protection Agency (EPA) for developing an Administration policy on the question of returning from EPA to FDA regulatory authority over antimicrobials used as food contact substances. This policy addresses the uncertainty unintentionally created by the Food Quality Protection Act of 1996 (FQPA) over the authority for regulating antimicrobials used as food contact substances. Although the legislative language effecting this policy was considered by the conferees to be outside the scope of this conference, the conferees acknowledge the significant need for this change and urge FDA and EPA to continue to work with the Congress to identify and develop an appropriate and expeditious vehicle for action on this matter. In the interim, the conferees urge the agencies not to delay active review of pending petitions and the pursuit of the most immediate means to achieve resolution of this jurisdictional issue.

TITLE IV—GENERAL PROVISIONS

Dissemination of treatment information (Sec. 401)

The conference agreement's inclusion of this section is intended to provide that health care practitioners can obtain important scientific information about uses that are not included in the approved labeling of drugs, biological products, and devices. The conferees also wish to encourage that these new uses be included on the product label. Therefore, the agreement includes strong incentives to conduct the research needed and file a supplemental application for such uses. A manufacturer who seeks to disseminate information about a new use must either certify that it will file a supplemental application or must submit a proposed protocol and schedule for conducting the necessary studies and a certification that a supplemental application will be filed.

Although the conferees intend to ensure that the research is undertaken to get new uses on product labels, the conferees also recognize that there may be limited circumstances when it is appropriate to exempt a manufacturer from the requirement to file a supplemental application. In making the determination of whether to grant an exemption pursuant to subsection (d)(2), the Secretary may consider, among other factors, whether: the new use meets the requirements of section 186(t)(2)(B) of the Social Security Act; 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; the new use is described in a recommendation or medical practice guideline of a Federal health agency, including the National Institutes of Health, the Agency for Health Care Policy Research and the Centers for Disease Control and Prevention of the Department of Health and Human Services; the new use is described in one of three compendia: The U.S. Pharmacopeia-Drug Information, the American Medical Association Drug Evaluation, or the American Hospital Association Formulary Service Drug Information; 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; or the patent status of the product.

The conferees recognize that there may be cases where the size of the patient population may be cause for the Secretary to determine that a supplemental application should not be filed. However, this is intended to be the exception, rather than the rule, in the case of populations suffering from orphan or rare disorders. For many years, this Congress has sought to encourage research into orphan diseases and the approval of innovative drugs for their treatment. The Secretary should examine very carefully whether an exemption from filing a supplemental application might hinder such research and recognize the vital importance of encouraging application for new drugs and new drug uses intended to treat rare disorders.

Expanded access to investigational therapies and diagnostics (Sec. 402)

The conference report provides statutory direction to expand access programs and emphasizes that opportunities to participate in expanded access programs are available to every individual with a life-threatening or seriously debilitating illness for which there is not an effective, approved therapy. The conferees note that they purposely used broad language in this section relating to "serious" conditions, without attempting to define them, in order to permit wide flexibility in implementation. Illnesses that do not cause death, or imminent death, can nonetheless destroy the lives of both patients and their families. The conferees therefore intend that the seriousness of an illness be given broad consideration, to take into account all of the circumstances involved.

Currently, Federal law allows drug companies to make experimental drugs available, under specific circumstances, to seriously and terminally ill patients. However, companies are often reluctant to do so because they fear that inclusion of data on such very ill patients will jeopardize the approval of their product because these patients' medical progress on any therapy may conflict with or be inconsistent with data from patients in the clinical studies. The conferees request that the FDA evaluate ways to address this problem, particularly for terminal

patients who have failed existing approved therapies.

Information system (Sec. 407)

The conferees intend that the information system shall provide access to the information by the applicant under conditions set by the Secretary, except that access shall not be provided under any particular form of information system to any applicant until appropriate safeguards are in place to ensure that integrity and confidentiality of the information for which access is provided.

Education and training (Sec. 408)

The conference agreement authorizes the Centers of the FDA that conduct intramural research to provide fellowships and training to appropriate undergraduate, pre-doctoral, and/or post-doctoral candidates. In the past, FDA's Centers provided for a limited number of scientific training positions through Full Time Equivalent programs or interagency agreements with other federal agencies which have the statutory authority to hire trainees through third parties. However, many of the benefits of the training program have been reduced because FDA has not had specific direct authority to conduct and support them. In light of the additional overhead costs, reduced training flexibility, increased paperwork, and hiring delays that have resulted, it is increasingly difficult and impractical for FDA to hire trainees as FTE Service Fellows. As a result, the Intramural Research and Training Authority authorized here is intended to provide the FDA the authority to conduct and support directly the selection and training of fellows, along more efficient use of appropriated funds by reducing overhead and other costs, and permit the training of such candidates as non-FTE positions. The conference agreement also provides similar authority for the Centers for Disease Control and Prevention.

Centers for education and research on therapeutics (Sec. 409)

The conference agreement establishes a demonstration program to conduct research and increase awareness of new products and ways to improve their effective use, and to increase awareness of risks of both new uses and combinations of therapies. In carrying out this demonstration program, the Secretary is directed to act through the Agency for Health Care Policy and Research (AHCPR) in consultation with the FDA Commissioner. The conferees designated AHCPR as the lead agency because of its expertise in the evaluation of the effectiveness of clinical care, its non-regulatory role, and its close working relationship with the health care community in the improvement of the quality of care. Accordingly, this section establishes a new Section 928 in Title IX of the Public Health Service Act, the authorizing statute for AHCPR.

To ensure appropriate coordination and to avoid unnecessary duplication, AHCPR is required to consult closely with the FDA in the development and operation of this demonstration program. The conferees expanded the focus of this demonstration to include ways to improve the effective use of drugs, biological products, and devices as well as risks of new combinations of such products and directed that the clinical information gained in the project would be provided to consumers as well as health care practitioners and insurers. Finally, the conferees direct AHCPR also to consider the appropriate use of products in meeting the purposes of this section.

Environmental impact review (Sec. 411)

The conferees believe that FDA's new procedures implementing the National Environmental Policy Act (NEPA) appropriately eliminate unnecessary paperwork and delays

associated with prior agency practices. Section 411 makes clear that an environmental impact statement (EIS) prepared in accordance with those regulations will meet the requirements of NEPA. The conferees do not intend this section to preclude judicial review of EISs. The conferees understand that the FDA may modify its regulations periodically, in consultation with the Council on Environmental Quality and the FDA's authorizing committees, as new circumstances or information warrants.

Because the Clean Air Act authorizes production of limited quantities of Class I and Class II substances for use in medical devices, there will be a continuing, but limited, supply of these substances. The EPA shall not dictate, promote or otherwise encourage a policy preference for disposal by incineration of the contents of metered-dose inhalers, but instead allow such contents to be recaptured, recycled or reused consistent with section 608(a)(3) of the Clean Air Act until such time that Congress conducts oversight hearings into the issue.

National uniformity for nonprescription drugs and cosmetics (Sec. 412)

Confidentiality of OTC company self-audits

Public policy should encourage drug manufacturers to conduct audits of their activities to candidly alert management to potential problems so that they can be addressed quickly and effectively. If FDA were to assert routine access to these audits, it would create serious disincentives to conducting appropriate audits and preparing thorough reports of the results. FDA already has a policy of not ordinarily requesting audit reports, which is set forth in compliance policy guide (#7151.02, Sec. 130.300) that applies to prescription drug firms. It is expected that OTC drug firms would be subject to the same compliance policy guide. Thus, during routine inspections of OTC drug establishments, FDA would not be expected to request or to review or copy reports and records that result from the firm's own audits and inspections of its operations to assure compliance with applicable FDA requirements such as good manufacturing practice (GMP) regulations. FDA would reserve the right to review such audits in certain limited circumstances as outlined in the compliance guide.

OTC and cosmetics inspection

The conferees intend that FDA exercise its new records inspection authority fairly and carefully, especially with regard to inspections at facilities that manufacture products that are both cosmetics and over-the-counter drugs. Cosmetic products that are also OTC drugs will, under the provisions of this bill, benefit from full national uniformity relating to all regulatory requirements, including those associated with ingredients, labeling, and packaging. Therefore, under these provisions, manufacturers of such OTC products will be subject to records inspection by FDA. The conferees want to make clear that any records inspection applies only to those products for which there is full national uniformity. This new records inspection authority applies only to products determined to be over-the-counter drugs. It does not apply to products that are solely cosmetics.

In the case of an inspection at a facility which deals both with cosmetic products that are OTC drugs and those that are not, FDA inspectors do not have access to any records relating to the cosmetic products. Further, the conferees want to make clear that there is no records inspection authority under these provisions for facilities dealing exclusively with cosmetics.

Finally, the conferees expect that FDA will provide sufficient time and guidance to the over-the-counter drug industry prior to

initiating any program of records inspection and in the early stages of implementing this new requirement.

Effect of national uniformity on state enforcement "little FTC" laws

All states have laws prohibiting false and misleading advertising, modeled on the Federal Trade Commission Act. These laws have been applied to prohibit unsubstantiated claims for nonprescription drugs and cosmetics, and to require corrective advertising. This provision is not intended to preempt the application of these laws under such circumstances.

The Conference Committee intends to make clear that "Little FTC" laws, as they have historically been written and applied, are not preempted. The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging or, if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption.

Effect of national uniformity on state food labeling laws

This provision is not intended to preempt or prohibit States from regulating the labeling of food which derives from animals treated with non-prescription drugs. Nor are these provisions intended to void State regulations on the use of these drugs.

Product classification (Sec. 416)

Subsections (b) and (c) have been amended to make clear that FDA may only modify product classifications for public health reasons based on scientific information.

TOM BLILEY,
MICHAEL BILIRAKIS,
JOE BARTON,
JAMES GREENWOOD,
RICHARD BURR,
ED WHITFIELD,
JOHN D. DINGELL,
SHERROD BROWN,
HENRY A. WAXMAN,
RON KLINK,

Managers on the Part of the House.

JIM JEFFORDS,
DAN COATS,
JUDD GREGG,
BILL FRIST,
MIKE DEWINE,
EDWARD M. KENNEDY,
CHRISTOPHER DODD,
TOM HARKIN,
BARBARA A. MIKULSKI,

Managers on the Part of the Senate.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. UNDERWOOD (at the request of Mr. GEPHARDT) for today and the balance of the week, on account of official business.

Mr. YATES (at the request of Mr. GEPHARDT) for November 8 after 12 noon and November 9, on account of personal reasons.

SENATE BILLS AND CONCURRENT RESOLUTION REFERRED

Bills and a concurrent resolution of the Senate of the following titles were taken from the Speaker's table and, under the rule, referred as follows:

S. 508. An act to provide for the relief of Mai Hoa "Jasmin" Salehi; to the Committee on the Judiciary.

S. 759. An act to amend the State Department Basic Authorities Act of 1956 to require the Secretary of State to submit an annual report to Congress concerning diplomatic immunity; to the Committee on International Relations.

S. 857. An act for the relief of Roma Salobrit; to the Committee on the Judiciary.

S. 1189. An act to increase the criminal penalties for assaulting or threatening Federal judges, their family members, and other public servants, and for other purposes; to the Committee on the Judiciary.

S. 1304. An act for the relief of Belinda McGregor; to the Committee on the Judiciary.

S. 1487. An act to establish a National Voluntary Mutual Reunion Registry; to the Committee on Ways and Means.

S. 1507. An act to amend the National Defense Authorization Act for Fiscal Year 1998 to make certain technical corrections; to the Committee on National Security.

S. Con. Res. 58. Concurrent resolution expressing the concern of Congress over Russia's newly passed religion law; to the Committee on International Relations.

BILL AND JOINT RESOLUTION PRESENTED TO THE PRESIDENT

Mr. THOMAS, from the Committee on House Oversight reported that that committee did on the following dates present to the President, for his approval, a bill and a joint resolution of the House of the following titles:

On November 8, 1997:

H.R. 2264. An act 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.

On November 9, 1997:

H.J. Res. 104. Joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes.

ENROLLED BILLS AND JOINT RESOLUTION SIGNED

Mr. THOMAS, from the Committee on House Oversight, reported that that committee had examined and found truly enrolled bills and a joint resolution of the House of the following titles, which were thereupon signed by the Speaker:

H.R. 1747. An act to amend the John F. Kennedy Center Act to authorize the design and construction of additions to the parking garage and certain site improvements, and for other purposes.

H.R. 1787. An act to assist in the conservation of Asian elephants by supporting and providing financial resources for the conservation programs of nations within the range of Asian elephants and projects with demonstrated expertise in the conservation of Asian elephants.

H.R. 2731. An act for the relief of Roy Desmond Moser.

H.R. 2732. An act for the relief of John Andre Chalot.

H.J. Res. 104. Joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes.

SENATE ENROLLED BILLS SIGNED

The SPEAKER announced his signature to enrolled bills of the Senate of the following titles:

S. 813. An act to amend chapter 91 of title 18, United States Code, to provide criminal penalties for theft and willful vandalism at national cemeteries.

S. 1377. An act to amend the act incorporating the American Legion to make a technical correction.

ADJOURNMENT

Mr. SOLOMON. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 2 o'clock and 2 minutes a.m.), under its previous order, the House adjourned until Wednesday, November 12, 1997, at 12 noon.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XXIV, executive communications were taken from the Speaker's table and referred as follows:

5818. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Corn Gluten; Exemption from the Requirement of a Tolerance [OPP-300505A; FRL-5750-3] (RIN: 2070-AB78) received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Agriculture.

5819. A letter from the Assistant Secretary (Installations and Environment), Department of the Navy, transmitting notification of intent to study a commercial or industrial type function performed by 45 or more civilian employees for possible outsourcing, pursuant to 10 U.S.C. 2304 nt.; to the Committee on National Security.

5820. A letter from the Assistant Secretary (Reserve Affairs), Department of Defense, transmitting a report on the progress of the study on the means of ensuring uniformity in provision of medical and dental care for members of reserve components, pursuant to Public Law 104—201, section 746(b) (110 Stat. 2602); to the Committee on National Security.

5821. A letter from the Assistant to the Board, Board of Governors of the Federal Reserve System, transmitting the Board's final rule—Reserve Requirements of Depository Institutions [Regulation D; Docket No. R-0980] received October 31, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Banking and Financial Services.

5822. A letter from the Director, Office of Rulemaking Coordination, Department of Energy, transmitting the Department's "Major" final rule—Energy Conservation Program for Consumer Products: Final Rule Regarding Energy Conservation Standards for Room Air Conditioners [Docket Nos. EE-RM-90-201 and EE-RM-93-801-RAC] (RIN: 1904-AA38) received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5823. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of State Plans for Designated Facilities and Pollutants: Florida [FL-70-1-9738a; FRL-5920-3] received November 7, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5824. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of Implementation Plans; California State Implementation Plan Revi-

sion, South Coast Air Quality Management District [CA 034-0048; FRL-5917-5] received November 7, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5825. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Diego County Air Pollution Control District, Ventura County Air Pollution Control District [CA 083-0053a; FRL-5911-4] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5826. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Michigan: Final Authorization of Revisions to State Hazardous Waste Management Program [FRL-5918-8] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5827. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Ambient Air Quality Surveillance for Lead [AD-FRL-5903-5] (RIN: 2060-AF71) received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5828. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Removal of Requirement in Gasoline Deposit Control Additives Rule Regarding the Identification of the Oxygenate Content of Transferred Gasoline [FRL-5917-9] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5829. A letter from the AMD—Performance Evaluation and RECORDS Management, Federal Communications Commission, transmitting the Commission's final rule—Amendment of the Commission's Rules to Establish a Radio Astronomy Coordination Zone in Puerto Rico [ET Docket No. 96-2, RM-8165] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5830. A letter from the AMD—Performance Evaluation and RECORDS Management, Federal Communications Commission, transmitting the Commission's final rule—Amendment of Part 15 of the Commission's Rules to permit operation of biomedical telemetry devices on VHF TV channels 7-13 and on UHF TV channels 14-46 [ET Docket No. 95-177] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5831. A letter from the Director, Regulations Policy and Management Staff, Office of Policy, Food and Drug Administration, transmitting the Administration's final rule—Secondary Direct Food Additives Permitted in Food for Human Consumption; Milk-Clotting Enzymes [Docket No. 93F-0461] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5832. A letter from the Chairman, Nuclear Regulatory Commission, transmitting a report on the nondisclosure of safeguards information for the quarter ending September 30, 1997, pursuant to 42 U.S.C. 2167(e); to the Committee on Commerce.

5833. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Egypt for defense articles and services (Transmittal No. 98-21), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5834. A letter from the Director, Defense Security Assistance Agency, transmitting

notification concerning the Department of the Navy's Proposed Letter(s) of Offer and Acceptance (LOA) to Korea for defense articles and services (Transmittal No. 98-20), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5835. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Taipei Economic and Cultural Representative Office (TECRO) in the United States for defense articles and services (Transmittal No. 98-18), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5836. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Taipei Economic and Cultural Representative Office in the United States for defense articles and services (Transmittal No. 98-16), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5837. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Portugal for defense articles and services (Transmittal No. 98-13), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5838. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Portugal for defense articles and services (Transmittal No. 98-11), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5839. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Turkey for defense articles and services (Transmittal No. 98-09), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5840. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Greece for defense articles and services (Transmittal No. 98-12), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5841. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Greece for defense articles and services (Transmittal No. 98-08), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5842. A letter from the Director, Defense Security Assistance Agency, transmitting a report of enhancement or upgrade of sensitivity of technology or capability for Saudi Arabia (Transmittal No. A-98), pursuant to 22 U.S.C. 2776(b)(5)(A); to the Committee on International Relations.

5843. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting notification of a proposed manufacturing license agreement for production of major military equipment with Canada (Transmittal No. DTC-69-97), pursuant to 22 U.S.C. 2776(d); to the Committee on International Relations.

5844. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting notification of a proposed manufacturing license agreement for production of major military equipment with Germany (Transmittal No. DTC-133-97), pursuant to 22 U.S.C. 2776(d); to the Committee on International Relations.

5845. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting notification of a proposed manufacturing license agreement for production of major military equipment with the United Kingdom (Transmittal No. DTC-132-97), pursuant to 22 U.S.C. 2776(d); to the Committee on International Relations.

5846. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Germany and Sweden (Transmittal No. DTC-112-97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5847. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Singapore (Transmittal No. DTC-113-97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5848. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Israel (Transmittal No. DTC-97-97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5849. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Japan (Transmittal No. DTC-98-97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5850. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Kuwait (Transmittal No. DTC-114-97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5851. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to the United Kingdom (Transmittal No. DTC-117-97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5852. A communication from the President of the United States, transmitting the bi-monthly report on progress toward a negotiated settlement of the Cyprus question, including any relevant reports from the Secretary General of the United Nations, pursuant to 22 U.S.C. 2373(c); to the Committee on International Relations.

5853. A letter from the Executive Director, Committee for Purchase from People Who Are Blind or Severely Disabled, transmitting the Committee's final rule—Additions to the Procurement List [97-019] received November 9, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Government Reform and Oversight.

5854. A letter from the Chairman, Defense Nuclear Facilities Safety Board, transmitting the FY 1997 report pursuant to the Federal Managers' Financial Integrity Act, pursuant to 31 U.S.C. 3512(c)(3); to the Committee on Government Reform and Oversight.

5855. A letter from the Chairman, District of Columbia Financial Responsibility and Management Assistance Authority, transmitting the annual report for fiscal year 1997, pursuant to Public Law 104-8; to the Committee on Government Reform and Oversight.

5856. A letter from the Chairman and Chief Executive Officer, Farm Credit Administration, transmitting the semiannual report on

the activities of the Office of Inspector General for the period April 1, 1997, through September 30, 1997; and the semiannual management report for the same period, pursuant to 5 U.S.C. app. (Insp. Gen. Act) section 5(b); to the Committee on Government Reform and Oversight.

5857. A letter from the Director, Federal Mediation and Conciliation Service, transmitting the 1997 annual report in compliance with the Inspector General Act Amendments of 1988, pursuant to Public Law 100-504, section 104(a) (102 Stat. 2525); to the Committee on Government Reform and Oversight.

5858. A letter from the Executive Director, Federal Retirement Thrift Investment Board, transmitting the 1997 annual report in compliance with the Inspector General Act Amendments of 1988, pursuant to Public Law 100-504, section 104(a) (102 Stat. 2525); to the Committee on Government Reform and Oversight.

5859. A letter from the President, Institute of American Indian Arts, transmitting the FY 1997 report pursuant to the Federal Managers' Financial Integrity Act, pursuant to 31 U.S.C. 3512(c)(3); to the Committee on Government Reform and Oversight.

5860. A letter from the Director, National Gallery of Art, transmitting a consolidated report on audit and investigative coverage required by the Inspector General Act of 1978, as amended, and the Federal Managers' Financial Integrity Act, pursuant to 5 U.S.C. app. (Insp. Gen. Act) section 5(b); to the Committee on Government Reform and Oversight.

5861. A letter from the Director, Office of Government Ethics, transmitting the 1997 annual consolidated report in compliance with the Inspector General Act Amendments of 1988 and the Federal Managers' Financial Integrity Act, pursuant to Public Law 100-504, section 104(a) (102 Stat. 2525); to the Committee on Government Reform and Oversight.

5862. A letter from the Independent Counsel, Office of Independent Counsel, transmitting the 1997 annual report in compliance with the Inspector General Act Amendments of 1988, pursuant to Public Law 100-504, section 104(a) (102 Stat. 2525); to the Committee on Government Reform and Oversight.

5863. A letter from the Director, The Morris K. Udall Foundation, transmitting the annual report pursuant to the Federal Managers' Financial Integrity Act and the Inspector General Act for the year ending September 30, 1997, pursuant to 31 U.S.C. 3512(c)(3); to the Committee on Government Reform and Oversight.

5864. A letter from the Acting Director, The Woodrow Wilson Center, transmitting a consolidated report on audit and investigative coverage required by the Inspector General Act of 1978, as amended, and the Federal Managers' Financial Integrity Act, pursuant to 5 U.S.C. app. (Insp. Gen. Act) section 5(b); to the Committee on Government Reform and Oversight.

5865. A letter from the President and Chief Executive Officer, United States Enrichment Corporation, transmitting a consolidated report on audit and investigative coverage required by the Inspector General Act of 1978, as amended, and the Federal Managers' Financial Integrity Act covering the year ended September 30, 1997, pursuant to 31 U.S.C. 3512(c)(3); to the Committee on Government Reform and Oversight.

5866. A letter from the President, United States Institute of Peace, transmitting the strategic plan for the period FY 1997 through 2002, pursuant to Public Law 103-62; to the Committee on Government Reform and Oversight.

5867. A letter from the Assistant Secretary, Land and Minerals Management, Department of the Interior, transmitting the Department's final rule—Patent Preparation

and Issuance [WO-350-1220-00-24 1A] (RIN: 1004-AC-88) received November 4, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Resources.

5868. A letter from the Deputy Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration, transmitting the Administration's final rule—Fisheries of the Exclusive Economic Zone Off Alaska; Insurance Coverage Provisions for Observer Contractors under the North Pacific Interim Groundfish Observer Program [Docket No. 960717195-7255-03; I.D. 100897E] (RIN: 0648-A195) received November 9, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Resources.

5869. A letter from the Assistant Secretary for Employment Standards, Department of Labor, transmitting the Department's final rule—Longshore Act Civil Money Penalties Adjustment (RIN: 1215-AB17) received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on the Judiciary.

5870. A letter from the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, transmitting the Administration's final rule—Temporary Exemption from Chemical Registration for Distributors of Pseudoephedrine and Phenylpropanolamine Products [DEA Number 1681] (RIN: 1117-AA46) received November 4, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on the Judiciary.

5871. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval of Modifications to Michigan's Assumed Program to Administer the Section 404 Permitting Program Resulting from the Reorganization of the Michigan Environmental Agencies [FRL-5918-7] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

5872. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval of Modifications to Michigan's Approved Program to Administer the National Pollutant Discharge Elimination System Permitting Program Resulting from the Reorganization of the Michigan Environmental Agencies [FRL-5918-6] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

5873. A letter from the Director, Office of Regulations Management, Department of Veterans Affairs, transmitting the Department's final rule—Grants to States for Construction or Acquisition of State Home Facilities (RIN: 2900-A184) received November 9, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Veterans' Affairs.

5874. A letter from the Regulatory Policy Officer, Bureau of Alcohol, Tobacco and Firearms, transmitting the Bureau's final rule—Mendocino Ridge Viticultural Area (RIN: 1512-AA07) received October 30, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

5875. A letter from the Assistant Secretary for Employment and Training, Department of Labor, transmitting the Department's final rule—Unemployment Insurance Program Letter [Nos. 41-97 and 44-97] received November 4, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

5876. A letter from the Chief, Regulations Unit, Internal Revenue Service, transmitting the Service's final rule—Material Limitation on Surviving Spouse's Right to Income [Notice 97-63] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

5877. A letter from the Chief, Regulations Unit, Internal Revenue Service, transmitting the Service's final rule—Test of Bankruptcy Appeals Process [Announcement 97-111] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

Mr. BLILEY: Committee of Conference. Conference report on S. 830. An act 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 (Rept. 105-399). Ordered to be printed.

Mr. DIAZ-BALART: Committee on Rules. House Resolution 319. Resolution providing for consideration of the bill (S. 738) to reform the statutes relating to Amtrak, and for other purposes (Rept. 105-400). Referred to the House Calendar.

MEMORIALS

Under clause 4 of rule XXII, memorials were presented and referred as follows:

225. The SPEAKER presented a memorial of the House of Representatives of the Commonwealth of Pennsylvania, relative to House Resolution No. 295 memorializing the Citizens' Committee of the United States Postal Service to consider and recommend to the United States Postal Service Board of Governors the issuance of a commemorative stamp honoring Richard Humphreys, Quaker, goldsmith and philanthropist, on the 160th Anniversary of the founding of Cheyney University of Pennsylvania; to the Committee on Government Reform and Oversight.

226. Also, a memorial of the Legislature of the State of California, relative to Assembly Joint Resolution 38 expressing support for a full, fair, and complete investigation of legal and ethical violations during the 1996 campaigns, and memorializing the President and the Congress to condemn all prejudice against Asian and Pacific Islander Americans, and to publicly support political and civic participation by these persons throughout the United States; to the Committee on the Judiciary.

227. Also, a memorial of the Legislature of the State of California, relative to Assembly Joint Resolution 32 memorializing the President and Congress of the United States to recognize the sacrifices and services rendered to our country by the Hmong-Lao veterans who served in the special guerrilla units that were allied with, and operating in support of, the military forces of the United States during the Vietnam War by granting those veterans and their families full United States citizenship; to the Committee on the Judiciary.

PUBLIC BILLS AND RESOLUTIONS

Under clause 5 of Rule X and clause 4 of Rule XXII, public bills and resolutions were introduced and severally referred, as follows:

By Mr. HORN (for himself, Mrs. MALONEY of New York, Mr. BURTON of Indiana, and Mr. WAXMAN):

H.R. 2977. A bill to amend the Federal Advisory Committee Act to clarify public dis-

closure requirements that are applicable to the National Academy of Sciences and the National Academy of Public Administration; to the Committee on Government Reform and Oversight.

By Ms. VELAZQUEZ (for herself, Mr. GUTIERREZ, and Mr. SERRANO):

H.R. 2978. A bill to require the Secretary of the Treasury to mint coins in commemoration of all the brave and gallant Puerto Ricans in the 65th Infantry Regiment of the United States Army who fought in the Korean conflict; to the Committee on Banking and Financial Services.

By Mr. THOMAS:

H.R. 2979. A bill to authorize acquisition of certain real property for the Library of Congress, and for other purposes; to the Committee on House Oversight.

By Mr. ALLEN:

H.R. 2980. A bill to amend the Solid Waste Disposal Act to require a refund value for certain beverage containers, to provide resources for State pollution prevention and recycling programs, and for other purposes; to the Committee on Commerce.

By Mr. ALLEN (for himself and Mr. BALDACCIO):

H.R. 2981. A bill to amend the Higher Education Act of 1965 relating to financial responsibility for refunds and during provisional certification and change of ownership; to the Committee on Education and the Workforce.

By Mr. GILMAN:

H.R. 2982. A bill to improve the quality of child care provided through Federal facilities and programs, and for other purposes; to the Committee on Government Reform and Oversight, and in addition to the Committees on House Oversight, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. SHERMAN (for himself, Mr. FOX of Pennsylvania, Mr. PALLONE,

Mr. VISCLOSKEY, Mr. BONIOR, Ms. ESHOO, Mr. KENNEDY of Rhode Island, Mr. ROTHMAN, Mr. ROGAN, Mr. WEYGAND, Mr. RADANOVICH, Mr. MORAN of Virginia, Mr. KENNEDY of Massachusetts, and Mr. MARKEY):

H.R. 2983. A bill to promote long term stability in the Caucasus, deter renewed aggression, and facilitate the peaceful resolution of the Nagorno-Karabagh conflict; to the Committee on International Relations, and in addition to the Committee on Banking and Financial Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. BARR of Georgia:

H.R. 2984. A bill to provide an exemption from the Gun-Free School Zones Act of 1990 for conduct that does not violate State or local law; to the Committee on the Judiciary.

By Mr. CARDIN (for himself, Mr. BUNNING of Kentucky, Mr. ENGLISH of Pennsylvania, Mr. ENSIGN, Mr. STARK, and Mr. WELLER):

H.R. 2985. A bill to amend the Immigration and Nationality Act to make certain aliens determined to be delinquent in the payment of child support inadmissible, deportable, and ineligible for naturalization, to authorize immigration officers to serve process in child support cases on aliens entering the United States, and for other purposes; to the Committee on the Judiciary, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. COLLINS:

H.R. 2986. A bill for the relief of the survivors of the 14 members of the Armed Forces and the one United States civilian who were killed on April 14, 1994, when United States fighter aircraft mistakenly shot down 2 helicopters in Iraq; to the Committee on the Judiciary.

By Mr. DAVIS of Virginia (for himself and Mr. KUCINICH):

H.R. 2987. A bill to amend title 5, United States Code, to provide for appropriate overtime pay for National Weather Service forecasters performing essential services during severe weather events, and for other purposes; to the Committee on Government Reform and Oversight.

By Mr. DOOLITTLE:

H.R. 2988. A bill to facilitate the operation, maintenance, and upgrade of certain federally owned hydroelectric power generating facilities, to ensure the recovery of costs, and to improve the ability of the Federal Government to coordinate its generating and marketing of electricity with the non-Federalelectric utility industry; to the Committee on Resources, and in addition to the Committees on Commerce, and Transportation and Infrastructure, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. ENSIGN:

H.R. 2989. A bill to direct the Secretary of the Interior to convey to the St. Jude's Ranch for Children, Nevada, approximately 40 acres of land in Las Vegas, Nevada, to be used for the development of facilities for the residential care and treatment of adjudicated girls; to the Committee on Resources.

By Mr. ENSIGN (for himself, Mr. RANGEL, Mr. LAZIO of New York, Mr. CHRISTENSEN, Mr. GIBBONS, Ms. LOFGREN, Mr. ENGLISH of Pennsylvania, Mr. BACHUS, Mr. RILEY, Mr. CALAHAN, Mr. KENNEDY of Massachusetts, Mr. MICA, Mr. EVERETT, Mr. THOMPSON, Mr. HOUGHTON, Mr. WEYGAND, Mr. ADERHOLT, Mr. CARDIN, Mr. HILLIARD, Mr. CRAMER, Ms. DANNER, Ms. PELOSI, Mr. SKELTON, Mr. DIAZ-BALART, Mr. FILNER, Mr. FROST, Mr. CRAPO, Mr. ADAM SMITH of Washington, Mr. REYES, Mr. NEAL of Massachusetts, Ms. WOOLSEY, and Mr. KUCINICH):

H.R. 2990. A bill to amend the Internal Revenue Code of 1986 to increase the amount of low-income housing credits which may be allocated in each State, and to index such amount for inflation; to the Committee on Ways and Means.

By Ms. ESHOO (for herself and Mr. TAUZIN):

H.R. 2991. A bill to enhance electronic commerce by requiring agencies to use digital signatures, which are compatible with standards for such technology used in commerce and industry, to enable persons to submit Federal forms electronically, and for other purposes; to the Committee on Government Reform and Oversight, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. GRAHAM (for himself, Mr. SAM JOHNSON, Mr. HILLEARY, Mr. INGLIS of South Carolina, Mr. WAMP, Mr. NORWOOD, Mr. BARTLETT of Maryland, Mr. TAYLOR of North Carolina, Mr. STUMP, Mr. HERGER, Mr. MILLER of Florida, Mr. WATTS of Oklahoma, Mr. ISTOOK, Mrs. LINDA SMITH of Washington, Mr. TALENT, Mr.

THORNBERRY, Mr. CHABOT, Mr. SPENCE, Mr. SANFORD, Mr. TIHART, Mr. KNOLLENBERG, Mrs. MYRICK, Mr. HEFLEY, Mr. SOLOMON, Mr. BARTON of Texas, Mr. PITTS, Ms. DUNN of Washington, Mr. SALMON, Mr. SHADEGG, Mr. LARGENT, Mr. BACHUS, Mr. BALLENGER, Mr. DICKEY, Mr. BLUNT, Mrs. EMERSON, Mr. LAHOOD, Mr. MCKEON, Mr. RADANOVICH, Mr. ROHRBACHER, Mr. COX of California, Mr. SENSENBRENNER, Mr. HUTCHINSON, Mr. HOSTETTLER, Mr. BOB SCHAFFER, Mr. PETERSON of Pennsylvania, Mr. SOUDER, Mr. MCINTOSH, Mr. SESSIONS, Mr. ROYCE, Mr. WELDON of Florida, and Mr. NETHERCUTT):

H.R. 2992. A bill to repeal the Goals 2000: Educate America Act and the National Skill Standards Act of 1994 to allow local areas to develop elementary and secondary education programs that meet their needs; to the Committee on Education and the Workforce.

By Mr. HEFLEY:

H.R. 2993. A bill to provide for the collection of fees for the making of motion pictures, television productions, and sound tracks in National Park System and National Wildlife Refuge System units, and for other purposes; to the Committee on Resources.

By Ms. HOOLEY of Oregon (for herself and Mr. DAVIS of Virginia):

H.R. 2994. A bill to provide for various capital investments in technology education in the United States; to the Committee on Education and the Workforce, and in addition to the Committees on Science, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mrs. JOHNSON of Connecticut (for herself and Mrs. LOWEY):

H.R. 2995. A bill to amend the Internal Revenue Code of 1986 to allow tax-exempt organizations (other than governmental units) a credit against employment taxes in an amount equivalent to the work opportunity credit allowable to taxable employers, and for other purposes; to the Committee on Ways and Means.

By Mr. KENNEDY of Massachusetts:

H.R. 2996. A bill to amend the Securities Exchange Act of 1934 to revise the definition of limited partnership rollup transaction; to the Committee on Commerce.

By Mr. KENNEDY of Massachusetts (for himself, Mr. DELLUMS, Mr. KLECZKA, Mr. LAFALCE, Mr. FILNER, Mr. MCDERMOTT, Mr. BONIOR, Mr. TOWNS, Ms. SLAUGHTER, Mr. LEWIS of Georgia, Mr. JACKSON, Ms. VELAZQUEZ, Mr. MCGOVERN, Mr. BERMAN, Ms. PELOSI, Mr. OLVER, Mr. MARKEY, Mr. WAXMAN, Ms. NORTON, Ms. KILPATRICK, Mr. MEEHAN, Ms. ROYBAL-ALLARD, Mr. MILLER of California, Mrs. MALONEY of New York, Mr. GUTIERREZ, Mr. DELAHUNT, Ms. CARSON, Mr. MARTINEZ, Mrs. MEEK of Florida, Mr. HINCHEY, Mr. OWENS, Mr. TIERNEY, Mr. FATTAH, Mr. PAYNE, Mr. NEAL of Massachusetts, Mr. ACKERMAN, Ms. WATERS, Ms. BROWN of Florida, Mr. POMEROY, and Ms. HOOLEY of Oregon):

H.R. 2997. A bill to establish a commission on fairness in the workplace; to the Committee on Education and the Workforce.

By Mr. LEVIN (for himself and Mr. KILDEE):

H.R. 2998. A bill to amend the Internal Revenue Code of 1986 to exclude from gross income certain amounts received as scholarships by an individual under the National Health Service Corps Scholarship Program; to the Committee on Ways and Means.

By Mr. LEVIN:

H.R. 2999. A bill to amend title XVIII and XIX of the Social Security Act to expand and clarify the requirements regarding advance directives in order to ensure that an individual's health care decisions are complied with, and for other purposes; to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. OXLEY (for himself, Mr. CONDIT, Mr. JOHN, Mr. BLILEY, Mr. FORD, Mr. UPTON, Mr. GREENWOOD, Mr. KLUG, Mr. MARTINEZ, Mr. GOODLING, Mr. TRAFICANT, Mr. TAUZIN, Mr. PETERSON of Minnesota, Mr. STENHOLM, Mr. GILLMOR, Mr. BISHOP, Mr. PAXON, Mr. SISISKY, Mr. LARGENT, Mr. BAESLER, Mr. BUYER, Mr. GOODE, Mr. FRELINGHUYSEN, Mr. BOYD, Mrs. EMERSON, Mr. CRAMER, Mr. BARRETT of Nebraska, Mr. HOLDEN, Mr. BURR of North Carolina, Mr. PICKETT, Mr. HEFLEY, Mr. MCINTYRE, Mr. DUNCAN, Mr. SANDLIN, Mr. PETERSON of Pennsylvania, and Mr. RUSH):

H.R. 3000. A bill to amend the Comprehensive Environmental, Response, Compensation, and Liability Act of 1980; to the Committee on Commerce, and in addition to the Committees on Transportation and Infrastructure, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mrs. LOWEY (for herself, Mrs. JOHNSON of Connecticut, Mr. HOYER, Mrs. MORELLA, Mr. NADLER, Mr. STEARNS, Ms. DELAURO, Mr. LEACH, Mr. LEWIS of Georgia, Mr. WICKER, and Mr. CARDIN):

H.R. 3001. A bill to amend the Public Health Service Act to provide additional support for and to expand clinical research programs, and for other purposes; to the Committee on Commerce.

By Mrs. LOWEY:

H.R. 3002. A bill to expand the educational and work opportunities of welfare recipients under the program of block grants to States for temporary assistance for needy families; to the Committee on Ways and Means.

By Mr. MCCOLLUM (for himself, Mr. LEACH, Mr. LAFALCE, Mrs. ROUKEMA, Mr. BEREUTER, Mr. BAKER, Mr. BACHUS, Mr. KING of New York, Mr. ROYCE, Mr. EHRlich, Mr. BARR of Georgia, Mr. COOK, Mr. SESSIONS, Mr. HILL, and Mr. BONO):

H.R. 3003. A bill to amend the Federal Deposit Insurance Act and the Federal Credit Union Act to safeguard confidential banking and credit union information, and for other purposes; to the Committee on Banking and Financial Services.

By Mrs. MALONEY of New York (for herself, Mrs. MORELLA, and Mr. COBURN):

H.R. 3004. A bill to amend part E of title IV of the Social Security Act to require States to administer qualifying examinations to all State employees with new authority to make decisions regarding child welfare services, to expedite the permanent placement of foster children, to facilitate the placement of foster children in permanent kinship care arrangements, and to require State agencies, in considering applications to adopt certain foster children, to give preference to applications of a foster parent or caretaker relative of the child; to the Committee on Ways and Means.

By Mrs. MALONEY of New York (for herself, Mr. DELLUMS, Mr. MANTON, and Mr. PETERSON of Minnesota):

H.R. 3005. A bill to amend part E of title IV of the Social Security Act to require States to have laws that would permit a parent who is chronically ill or near death to name a standby guardian for a minor child without surrendering parental rights; to the Committee on Ways and Means.

By Ms. MILLENDER-MCDONALD:

H.R. 3006. A bill to direct the Attorney General to provide a written opinion regarding the constitutionality of proposed state ballot initiatives, and for other purposes; to the Committee on the Judiciary.

By Mrs. MORELLA:

H.R. 3007. A bill to establish the Commission on the Advancement of Women in Science, Engineering, and Technology Development; to the Committee on Education and the Workforce, and in addition to the Committee on Science, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. NEUMANN:

H.R. 3008. A bill to amend title II of the Social Security Act to allow workers who attain age 65 after 1981 and before 1992 to choose either lump sum payments over four years totalling \$5,000 or an improved benefit computation formula under a new 10-year rule governing the transition to the changes in benefit computation rules enacted in the Social Security Amendments of 1977, and for other purposes; to the Committee on Ways and Means, and in addition to the Committee on the Budget, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. PALLONE (for himself, Mr. GILMAN, Mr. BROWN of Ohio, Mr. FOX of Pennsylvania, Ms. SANCHEZ, Mr. HORN, Ms. ESHOO, Mr. GREEN, Mr. FROST, Mr. ANDREWS, Mr. FILNER, Mr. ACKERMAN, Mr. WEXLER, Mr. BROWN of California, Mrs. MALONEY of New York, Mr. HASTINGS of Florida, Mr. PASCRELL, Mr. MASCARA, Mr. DAVIS of Illinois, Ms. MILLENDER-MCDONALD, Ms. CARSON, Mrs. CLAYTON, Mr. LAMPSON, Mr. NADLER, Ms. JACKSON-LEE, Mr. ROTHMAN, Mr. ENGEL, Mr. PAYNE, Mr. MCCOLLUM, Mr. SHERMAN, Mr. CRAMER, and Mrs. MORELLA):

H.R. 3009. A bill to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to establish standards for managed care plans; to the Committee on Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. PALLONE (for himself, Mr. SHERMAN, Mr. FOX of Pennsylvania, Mr. VISLOSKEY, Mr. BONIOR, Ms. ESHOO, Mr. KENNEDY of Rhode Island, Mr. ROTHMAN, Mr. ROGAN, Mr. WEYGAND, Mr. RADANOVICH, Mr. MARKEY, Mr. MORAN of Virginia, and Mr. KENNEDY of Massachusetts):

H.R. 3010. A bill to amend the Foreign Assistance Act of 1961 to target assistance to support the economic and political independence of the countries of the South Caucasus; to the Committee on International Relations, and in addition to the Committees on Ways and Means, and Banking and Financial Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. PASCRELL:

H.R. 3011. A bill to amend the Internal Revenue Code of 1986 to exclude certain severance payment amounts from income; to the Committee on Ways and Means.

By Mr. POMEROY:

H.R. 3012. A bill to amend Public Law 89-108 to increase authorization levels for State and Indian tribal, municipal, rural, and industrial water supplies, to meet current and future water quantity and quality needs of the Red River Valley, to deauthorize certain project features and irrigation service areas, to enhance natural resources and fish and wildlife habitat, and for other purposes; to the Committee on Resources.

By Ms. PRYCE of Ohio (for herself, Mr. EWING, and Mr. GREENWOOD):

H.R. 3013. A bill to reduce the incidence of child abuse and neglect, and for other purposes; to the Committee on the Judiciary.

By Mr. RADANOVICH (for himself, Mr. BILBRAY, Ms. ESHOO, Mr. MILLER of California, Mr. ROGAN, Mr. LEWIS of California, Ms. PELOSI, Mr. POMBO, and Mr. FARR of California):

H.R. 3014. A bill to amend the Consolidated Omnibus Budget Reconciliation Act of 1985 to expand the number of county operated health insuring organizations authorized to enroll Medicaid beneficiaries; to the Committee on Commerce.

By Mr. SANDERS:

H.R. 3015. A bill to provide additional appropriations for certain nutrition programs; to the Committee on Appropriations.

By Mr. SANDERS (for himself, Mr. SHAYS, and Mr. DEFazio):

H.R. 3016. A bill to amend section 332 of the Communications Act of 1934 to preserve State and local authority to regulate the placement, construction, and modification of certain telecommunications facilities, and for other purposes; to the Committee on Commerce.

By Mr. SANDERS:

H.R. 3017. A bill calling for ratification of the United Nations Convention on the Rights of the Child; to the Committee on International Relations, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. SCARBOROUGH (for himself and Mrs. THURMAN):

H.R. 3018. A bill to release the reversionary interests retained by the United States in four deeds that conveyed certain lands to the State of Florida so as to permit the State to sell, exchange, or otherwise dispose of the lands, and to provide for the conveyance of certain mineral interests of the United States in the lands to the State of Florida; to the Committee on Agriculture, and in addition to the Committee on Resources, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mrs. LINDA SMITH of Washington:

H.R. 3019. A bill to amend the Federal Election Campaign Act of 1971 to prohibit the use of soft money by political parties, to permit individuals to elect to not have payroll deductions used for political activities, and for other purposes; to the Committee on House Oversight, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. STOKES:

H.R. 3020. A bill to establish a program, primarily through the States and municipalities, and their agents, to facilitate the

environmental assessment, cleanup, and reuse of abandoned or underutilized, potentially contaminated properties not on, or proposed for inclusion on, the National Priorities List; to the Committee on Commerce, and in addition to the Committees on Transportation and Infrastructure, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. STUPAK:

H.R. 3021. A bill to amend the Omnibus Crime Control and Safe Streets Act of 1968 to reduce certain funds if eligible States do not enact certain laws; to the Committee on the Judiciary.

By Mr. WATT of North Carolina (for himself, Mr. CONYERS, and Mr. COLLINS):

H.R. 3022. A bill to amend title 10, United States Code, to authorize the settlement and payment of claims against the United States for injury and death of members of the Armed Forces and Department of Defense civilian employees arising from incidents in which claims are settled for death or injury of foreign nationals; to the Committee on the Judiciary.

By Mr. WELDON of Pennsylvania (for himself and Mr. MARKEY):

H.R. 3023. A bill to end American subsidization of entities contributing to weapons proliferation; to the Committee on Intelligence (Permanent Select), and in addition to the Committees on Banking and Financial Services, and International Relations, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. LIVINGSTON:

H.J. Res. 104. A joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes; to the Committee on Appropriations, considered and passed.

By Mr. LIVINGSTON:

H.J. Res. 105. A joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes; considered and passed.

By Ms. VELAZQUEZ (for herself, Mr. GUTIERREZ, and Mr. SERRANO):

H. Con. Res. 192. Concurrent resolution expressing the sense of the Congress that the heroism of the brave and gallant Puerto Ricans in the 65th Infantry Regiment of the United States Army who fought in the Korean conflict should be commemorated; to the Committee on Veterans' Affairs, and in addition to the Committee on National Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. MICA (for himself, Mr. CONDIT, Mr. UPTON, Mr. WELDON of Florida, Mr. NORWOOD, Mr. PAPPAS, Mrs. FOWLER, Mr. SCARBOROUGH, Mr. SALMON, Mr. PITTS, Mr. HILLEARY, Mr. ROHRBACHER, Mr. CUNNINGHAM, Mr. DOOLITTLE, Mr. MILLER of Florida, Mr. HERGER, Mr. STEARNS, Mr. POMBO, Mr. LUCAS of Oklahoma, Mr. KINGSTON, Mr. SANFORD, Mr. JONES, Mr. BRADY, Mr. BACHUS, Mr. ROGAN, Mr. PICKERING, Mr. LAZIO of New York, Mr. INGLIS of South Carolina, Mr. PORTMAN, Mr. BLUNT, Mr. SHIMKUS, Mr. HEFLEY, Mr. HOSTETTLER, Mr. BURTON of Indiana, Mr. CHAMBLISS, Mr. LATOURETTE, Mr. WELLER, Mr. YOUNG of Florida, Mr. MCDADE, Mr. CALLAHAN, Mr. FOLEY, Mr. DIAZ-BALART, Mr. DICKEY, Mr. WAMP, Mr. COX of California, Mr. MANZULLO, Mr. GILCHREST, Mr. BARTLETT of Maryland, Mr. RIGGS, Mr.

SAXTON, Mr. SHAYS, Mr. THOMAS, Mr. PAUL, Mr. HAYWORTH, Mr. BUYER, Mr. WICKER, Mrs. KELLY, Mr. COLLINS, Mr. EVERETT, Mr. LOBIONDO, Mr. HORN, Mr. KNOLLENBERG, Mr. RAMSTAD, Mr. MORAN of Virginia, Mr. ENSIGN, Mr. NETHERCUTT, Mrs. LINDA SMITH of Washington, Mr. RYUN, Mr. FRANKS of New Jersey, Mrs. CHENOWETH, Mr. SOUDER, Mr. TIAHRT, Mr. GUTKNECHT, Mr. KLUG, Mr. MCCOLLUM, Mr. MCKEON, Mr. DUNCAN, Mr. ENGLISH of Pennsylvania, Mr. THUNE, Mr. SMITH of New Jersey, Ms. GRANGER, Mr. SMITH of Michigan, Mr. WATKINS, Mr. BURR of North Carolina, Mr. WATTS of Oklahoma, Mr. STENHOLM, Mr. PETERSON of Minnesota, Mr. BOYD, Mr. OBERSTAR, Mr. CRANE, and Mr. EHLERS):

H. Con. Res. 193. Concurrent resolution expressing the sense of the Congress that the Attorney General should remove Hani El-Sayegh from the United States to the Kingdom of Saudi Arabia; to the Committee on the Judiciary.

By Mr. SOLOMON:

H. Con. Res. 194. Concurrent resolution providing for a joint session of Congress to receive a message from the President; adopted pursuant to H. Res. 311.

By Ms. HARMAN (for herself, Mr. SAWYER, Mr. REGULA, Mr. SPRATT, Mr. DAVIS of Virginia, Mr. PORTMAN, Mr. BECERRA, Mr. HASTINGS of Florida, Mr. BARRETT of Wisconsin, Mr. WATT of North Carolina, Ms. ROS-LEHTINEN, Mr. HOUGHTON, Mr. DICKEY, Mr. LEWIS of Georgia, Mr. MATSUL, and Ms. MILLENDER-MCDONALD):

H. Con. Res. 195. Concurrent resolution expressing the sense of Congress in support of National Days of Dialogue associated with the national celebration of the birth of Dr. Martin Luther King, Jr. to improve understanding and cooperation across race, ethnicity, culture, gender, religion and creed; to the Committee on the Judiciary.

By Mr. DAN SCHAEFER of Colorado:

H. Res. 317. A resolution providing for the agreement of the House to the Senate amendment to the bill, H.R. 2472, with an amendment; considered and agreed to.

By Mr. GEPHARDT:

H. Res. 318. Resolution relating to a question of the privileges of the House; considered and laid on the table.

By Mr. SOLOMON:

H. Res. 320. Resolution providing for a committee to notify the President of completion of business; adopted pursuant to H. Res. 311.

By Mr. KENNEDY of Massachusetts:

H. Res. 321. A resolution expressing the sense of the House of Representatives that college and university administrators should adopt a code of principles to change the culture of alcohol consumption on college campuses; to the Committee on Education and the Workforce.

ADDITIONAL SPONSORS

Under clause 4 of rule XXII, sponsors were added to public bills and resolutions as follows:

H.R. 27: Mr. RIGGS.
H.R. 34: Mr. SUNUNU.
H.R. 225: Mr. ABERCROMBIE.
H.R. 251: Mr. PETERSON of Pennsylvania.
H.R. 352: Mr. SALMON.
H.R. 409: Mr. PAPPAS.
H.R. 530: Mr. BEREUTER and Mr. CALVERT.

H.R. 543: Mr. SOLOMON, Mr. NETHERCUTT, Mr. DIXON, and Mr. HYDE.

H.R. 586: Mr. JOHNSON of Wisconsin.

H.R. 738: Ms. SLAUGHTER.

H.R. 820: Ms. FURSE.

H.R. 979: Mr. JOHNSON of Wisconsin and Ms. WATERS.

H.R. 992: Mr. DEAL of Georgia and Mr. HUTCHINSON.

H.R. 1151: Mr. ABERCROMBIE and Mr. SESSIONS.

H.R. 1289: Mr. YATES.

H.R. 1334: Mr. RIGGS and Ms. PELOSI.

H.R. 1415: Mr. GOODLING.

H.R. 1519: Mr. STOKES.

H.R. 1525: Mr. McNULTY.

H.R. 1591: Mr. BARR of Georgia, Mr. SNOWBARGER, and Mr. SCARBOROUGH.

H.R. 1628: Mr. KIM.

H.R. 1635: Mr. BAESLER, Mr. SAXTON, Mr. LEACH, Mr. COSTELLO, Mrs. LOWEY, Mr. HINCHEY, Mr. ROMERO-BARCELÓ, Mr. HORN, Mr. WAXMAN, and Mr. SKAGGS.

H.R. 1822: Mr. JOHNSON of Wisconsin.

H.R. 1872: Mr. GREENWOOD, Mr. STRICKLAND, Mr. DAVIS of Virginia, Mr. PALLONE, Mr. LINDER, Mr. DICKS, Mr. GREEN, and Mr. RUSH.

H.R. 1891: Mr. BOEHNER.

H.R. 2053: Mr. LOFGREN.

H.R. 2131: Mr. JOHNSON of Wisconsin.

H.R. 2174: Mr. MALONEY of Connecticut.

H.R. 2229: Mr. WATTS of Oklahoma.

H.R. 2273: Mr. STUPAK, Mr. BAESLER, Mr. MALONEY of Connecticut, and Mr. HUTCHINSON.

H.R. 2319: Mr. LUTHER.

H.R. 2321: Mr. RIGGS.

H.R. 2335: Mr. CONDIT.

H.R. 2363: Mr. CABOT, Mr. DREIER, Mr. KOLBE, Mr. LIVINGSTON, Mr. RYUN, Mr. SAXTON, Mr. SMITH of Oregon, Mr. SOLOMON, Mr. SPENCE, and Mr. WICKER.

H.R. 2369: Mr. CAMPBELL.

H.R. 2391: Mr. KUCINICH, and Mr. MCGOVERN.

H.R. 2397: Ms. SLAUGHTER.

H.R. 2436: Mr. LAFALCE.

H.R. 2483: Mr. FRANKS of New Jersey.

H.R. 2500: Mr. ARMEY, Mr. BAESLER, Mr. BAKER, Mr. BALLENGER, Mr. BARCIA of Michigan, Mr. BARR of Georgia, Mr. BARRETT of Nebraska, Mr. BARTLETT of Maryland, Mr. BARTON of Texas, Mr. BEREUTER, Mr. BLAGOJEVICH, Mr. BLILEY, Mr. BOEHLERT, Mr. BOEHNER, Mr. BONILLA, Mr. BONO, Mr. BOYD, Mr. BRYANT, Mr. BUNNING of Kentucky, Mr. BURR of North Carolina, Mr. CALVERT, Mr. CANADY of Florida, Mr. CHABOT, Mr. CHAMBLISS, Mr. CHRISTENSEN, Mr. CLEMENT, Mr. COBLE, Mr. CONDIT, Mr. COOK, Mr. COOKSEY, Mr. COX of California, Mr. CRANE, Mr. DEAL of Georgia, Mr. DEUTSCH, Mr. DOOLEY of California, Mr. DREIER, Ms. DUNN of Washington, Mr. EHRLICH, Mr. FATTAH, Mr. FOLEY, Mrs. FOWLER, Mr. FOX of Pennsylvania, Mr. FROST, Ms. FURSE, Mr. GILMAN, Mr. GOODE, Mr. GOODLATTE, Mr. GOODLING, Mr. GORDON, Mr. GOSS, Mr. HALL of Texas, Mr. HANSEN, Mr. HASTERT, Mr. HEFLEY, Mr. HILL, Mr. HOLDEN, Mr. HUNTER, Mr. HUTCHINSON, Mr. INGLIS of South Carolina, Mr. JENKINS, Mr. JONES, Mr. SAM JOHNSON, Mr. KASICH, Mrs. KELLY, Mr. KENNEDY of Rhode Island, Mr. KING of New York, Mr. LATOURETTE, Mr. LEWIS of California, Mr. LINDER, Ms. MCCARTHY of Missouri, Mr. MEEHAN, Mr. METCALF, Mr. MORAN of Virginia, Mrs. MYRICK, Mr. NEY, Mrs. NORTHUP, Mr. OXLEY, Mr. PARKER, Mr. PAXON, Mr. PETERSON of Minnesota, Mr. PICKETT, Mr. REDMOND, Mr. RIGGS, Mr. ROEMER, Mr. ROGAN, Mr. ROYCE, Mr. SAXTON, Mr. SCARBOROUGH, Mr. SENSENBRENNER, Mr. SES-

SIONS, Mr. SHIMKUS, Mr. SISISKY, Mr. SKELTON, Mr. ADAM SMITH of Washington, Mr. SMITH of Texas, Mr. SOLOMON, Mr. SPENCE, Mr. STENHOLM, Mr. TANNER, Mrs. TAUSCHER, Mr. TAUZIN, Mr. WATTS of Oklahoma, Mr. WELDON of Florida, Mr. WELLER, Mr. BURTON of Indiana, Mr. DICKEY, Mr. ARCHER, Mr. QUINN, Mr. LAHOOD, Mr. TIAHRT, Mr. DAVIS of Virginia, Mr. THOMAS, Mr. CUNNINGHAM, Mr. ENSIGN, Mr. GIBBONS, Mr. STUMP, Mr. COMBEST, Mr. HAYWORTH, Mr. ROHRBACHER, Mr. CALLAHAN, Mr. EVERETT, Mr. STEARNS, Mr. DELAY, Mr. GINGRICH, and Mr. LIVINGSTON.

H.R. 2509: Mr. LEWIS of Georgia.

H.R. 2524: Mr. ABERCROMBIE.

H.R. 2593: Mrs. LOWEY, Mr. WAMP, Mr. GRAHAM, Mr. NETHERCUTT, Mr. BRADY, Mr. KNOLLENBERG, Mr. SENSENBRENNER, Mr. MCINTOSH, Mr. HOBSON, Mr. TAYLOR of North Carolina, Mr. WELDON of Pennsylvania, Mr. MICA, Mr. DICKEY, Mr. THOMAS, Mr. CANNON, Mr. SAXTON, Mr. SOLOMON, Mrs. KELLY, Mr. MANZULLO, Mr. WELDON of Florida, Mr. PAXON, Mr. SNOWBARGER, Mr. HORN, Mr. SALMON, Mr. DAN SCHAEFER of Colorado, Mr. NEY, Mr. STUMP, and Mr. RAMSTAD.

H.R. 2611: Mr. BLUNT, Mr. DUNCAN, Mr. TAUZIN, Mr. BARR of Georgia, Mr. BILBRAY, Mr. CANNON, Mr. CHRISTENSEN, Mr. HEFLEY, Mr. MCKEON, Mr. MICA, Mrs. LINDA SMITH of Washington, Mr. SMITH of Oregon, Mr. SOUDER, Mr. SPENCE, Mr. EHRLICH, Mr. RIGGS, and Mr. CRANE.

H.R. 2695: Mr. BONIOR, Mr. DELLUMS, Mr. KUCINICH, Mr. MCGOVERN, Ms. LOFGREN, Mrs. THURMAN, and Ms. MILLENDER-MCDONALD.

H.R. 2750: Mrs. THURMAN.

H.R. 2755: Mr. WAXMAN, Mrs. MINK of Hawaii, Mr. FRANK of MASSACHUSETTS, Mr. FROST, Mr. WALSH, Ms. LOFGREN, Ms. CARSON, Ms. KILPATRICK, Mr. BONIOR, and Mr. EVANS.

H.R. 2760: Mr. CALVERT, Mr. BACHUS, and Mr. RADANOVICH.

H.R. 2780: Mr. CAMPBELL, Mr. LARGENT, Mr. MCINTOSH, Mr. BRYANT, Mr. WHITE, Mr. LATOURETTE, and Mr. SALMON.

H.R. 2819: Mr. HERGER and Ms. HARMAN.

H.R. 2820: Mr. CALVERT.

H.R. 2821: Mr. NEAL of Massachusetts.

H.R. 2826: Ms. SLAUGHTER and Ms. NORTON.

H.R. 2829: Mr. ACKERMAN, Mr. DAVIS of Illinois, Mr. FARR of California, Mr. KUCINICH, Mr. PARKER, Mr. POMEROY, Mr. SCHUMER, and Ms. STABENOW.

H.R. 2846: Mr. WATTS of Oklahoma and Mr. EHRLICH.

H.R. 2850: Ms. LOFGREN and Mr. STOKES.

H.R. 2858: Mr. GONZALEZ.

H.R. 2870: Mr. EWING.

H.R. 2921: Mr. WHITFIELD, Mr. SHIMKUS, Mr. NORWOOD, Mr. HALL of Texas, Mr. GREENWOOD, Mr. STEARNS, Mr. HILL, Mr. MCHUGH, Mr. PACKARD, and Mr. BONILLA.

H.R. 2922: Mr. HUTCHINSON.

H.R. 2929: Mr. BACHUS.

H.R. 2938: Mr. MILLER of Florida and Mr. STEARNS.

H.R. 2940: Mr. BAKER.

H.J. Res. 99: Ms. SLAUGHTER.

H. Con. Res. 41: Mr. LOBIONDO.

H. Con. Res. 141: Mr. DAVIS of Illinois and Mr. ADAM SMITH of Washington.

H. Con. Res. 156: Mr. CLEMENT and Mr. CALVERT.

H. Con. Res. 181: Mr. MCGOVERN, Mrs. MORELLA, Mr. GEKAS, Mr. FORBES, and Mr. LAZIO of New York.

H. Res. 119: Mr. ALLEN.

H. Res. 251: Mr. MANTON, Mr. WAXMAN, Mr. ALLEN, and Ms. STABENOW.

H. Res. 279: Ms. SLAUGHTER.