or such comments as the Senator from Arkansas might have.

Mr. BUMPERS. Mr. President, I just want to close my part of the program by complimenting my very able and long-time assistant, John Ball, who has been with the Small Business Committee as both staff director and director for the ranking member now for many, many years. He has performed yeoman service on this.

I also hasten to say that the work of Keith Cole and Louis Taylor has been truly outstanding. Between these three people, and Senator BOND and myself, but especially the staff members, we think we have crafted a pretty good bill. I want to pay my special thanks publicly to these staffers who have labored very hard to make this possible.

I am prepared to go forward with final passage.

The PRESIDING OFFICER (Mr. FRIST). The question is on agreeing to the substitute amendment, as amended

The amendment (No. 3534), as amended, was agreed to.

Mr. BOND. Mr. President, I move to reconsider the vote.

Mr. BUMPERS. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The question is on agreeing to the committee amendment in the nature of a substitute, as amended.

The committee amendment, as amended, was agreed to.

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

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The yeas and nays were ordered.

Mr. BOND. Mr. President, I ask that this measure be set aside pursuant to the previous agreement.

The PRESIDING OFFICER. The bill is set aside.

Mr. BOND. Mr. President, pursuant to a previous agreement between the leaders, the vote will be set aside until Tuesday.

Mr. President, I ask unanimous consent that Senator MURKOWSKI be added as a cosponsor.

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

Mr. BOND. Mr. President, I join with my ranking member in complimenting the staff. John Ball I have worked with for several years. We are very pleased with the leadership of Louis Taylor on the Small Business Committee and Keith Cole who has had previous experience on the other side in Congress, and we are delighted that he has come to be with us on the Senate side.

These three staffers have had a very interesting several weeks. They have had an opportunity to meet more people in this administration. We have had

the support from the elected officials in the Federal Government for regulatory reform, but we have certainly had a tremendous amount of interest and attention and full-time, around-the-clock work for our staff members dealing with the members of the agencies who will be affected.

I can say to all of our friends in small businesses and small entities around the country that it is quite apparent that this measure will have an impact on the way that agencies deal with small entities and small businesses.

I believe that we have, with the help of many useful comments from the agencies themselves, crafted a workable but significant change in the culture of the Federal agencies in regard to small entities and small businesses.

Mr. BUMPERS. Mr. President, I have nothing further to add. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

BALANCED BUDGET DOWNPAYMENT ACT, II

Mr. HATFIELD. Mr. President, what is the pending business?

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:.

A bill (H.R. 3019) making appropriations for fiscal year 1996 to make a further down-payment toward a balanced budget, and for other purposes.

The Senate resumed consideration of the bill.

Pending:

Hatfield modified amendment No. 3466, in the nature of a substitute.

Lautenberg amendment No. 3482 (to amendment No. 3466), to provide funding for programs necessary to maintain essential environmental protection.

Hatch amendment No. 3499 (to amendment No. 3466), to provide funds to the District of Columbia Metropolitan Police Department.

Boxer/Murray amendment No. 3508 (to amendment No. 3466), to permit the District of Columbia to use local funds for certain activities.

Gorton amendment No. 3496 (to amendment No. 3466), to designate the "Jonathan M. Wainwright Memorial VA Medical Center", located in Walla Walla, Washington.

Simon amendment No. 3510 (to amendment No. 3466), to revise the authority relating to employment requirements for recipients of scholarships or fellowships from the National Security Education Trust Fund.

Simon amendment No. 3511 (to amendment No. 3466), to provide funding to carry out title VI of the National Literary Act of 1991, title VI of the Library Services and Construction Act, and section 109 of the Domestic Volunteer Service Act of 1973.

Coats amendment No. 3513 (to amendment No. 3466), to amend the Public Health Service Act to prohibit governmental discrimination in the training and licensing of health professionals on the basis of the refusal to

undergo or provide training in the performance of induced abortions.

Bond (for Pressler) amendment No. 3514 (to amendment No. 3466), to provide funding for a Radar Satellite project at NASA

a Radar Satellite project at NASA. Bond amendment No. 3515 (to amendment No. 3466), to clarify rent setting requirements of law regarding housing assisted under section 236 of the National Housing Act to limit rents charged moderate income families to that charged for comparable, nonassisted housing, and clarify permissible uses of rental income is such projects, in excess of operating costs and debt service.

Bond amendment No. 3516 (to amendment No. 3466), to increase in amount available under the HUD Drug Elimination Grant Program for drug elimination activities in and around federally-assisted low-income housing developments by \$30 million, to be derived from carry-over HOPE program balances.

Bond amendment No. 3517 (to amendment No. 3466), to establish a special fund dedicated to enable the Department of Housing and Urban Development to meet crucial milestones in restructuring its administrative organization and more effectively address housing and community development needs of States and local units of government and to clarify and reaffirm provisions of current law with respect to the disbursement of HOME and CDBG funds allocated to the State of New York.

Lautenberg amendment No. 3518 (to amendment No. 3466), relating to labor-management relations.

Santorum amendment No. 3484 (to amendment No. 3466), expressing the Sense of the Senate regarding the budget treatment of Federal disaster assistance.

Santorum amendment No. 3485 (to amendment No. 3466), expressing the Sense of the Senate regarding the budget treatment of Federal disaster assistance.

Santorum amendment No. 3486 (to amendment No. 3466), to require that disaster relief provided under this Act be funded through amounts previously made available to the Federal Emergency Management Agency, to be reimbursed through regular annual appropriations Acts.

Santorum amendment No. 3487 (to amendment No. 3466), to reduce all Title I discretionary spending by the appropriate percentage (.367%) to offset Federal disaster assistance.

Santorum amendment No. 3488 (to amendment No. 3466), to reduce all Title I "Salary and Expense" and "Administrative Expense" accounts by the appropriate percentage (3.5%) to offset Federal disaster assistance.

Gramm amendment No. 3519 (to amendment No. 3466), to make the availability of obligations and expenditures contingent upon the enactment of a subsequent act incorporating an agreement between the President and Congress relative to Federal expenditures.

Wellstone amendment No. 3520 (to amendment No. 3466), to urge the President to release already-appropriated fiscal year 1996 emergency funding for home heating and other energy assistance, and to express the sense of the Senate on advance-appropriated funding for FY 1997.

Bond (for McCain) amendment No. 3521 (to amendment No. 3466), to require that disaster funds made available to certain agencies be allocated in accordance with the established prioritization processes of the agencies.

Bond (for McCain) amendment No. 3522 (to amendment No. 3466), to require the Secretary of Veterans Affairs to develop a plan for the allocation of health care resources of the Department of Veterans Affairs.

Warner amendment No. 3523 (to amendment No. 3466), to prohibit the District of Columbia from enforcing any rule or ordinance

that would terminate taxicab service reciprocity agreements with the States of Virginia and Maryland.

Murkowski/Števens amendment No. 3524 (to amendment No. 3466), to reconcile seafood inspection requirements for agricultural commodity programs with those in use for general public consumers.

Murkowski amendment No. 3525 (to amendment No. 3466), to provide for the approval of an exchange of lands within Admiralty Island National Monument.

Warner (for Thurmond) amendment No. 3526 (to amendment No. 3466), to delay the exercise of authority to enter into multiyear procurement contracts for C-17 aircraft.

Burns amendment No. 3528 (to amendment No. 3466), to allow the refurbishment and continued operation of a small hydroelectric facility in central Montana by adjusting the amount of charges to be paid to the United States under the Federal Power Act.

Burns amendment No. 3529 (to amendment No. 3466), to provide for Impact Aid school

construction funding. Burns amendment No. 3530 (to amendment No. 3466), to establish a Commission on restructuring the circuits of the United States Courts of Appeals.

Coats (for Dole/Lieberman) amendment No. 3531 (to amendment No. 3466), to provide for low-income scholarships in the District of Columbia.

Coverdell amendment No. 3532 (to amendment No. 3466), to provide funds for employment-related activities of the 1996 Paralympic Games.

Bond/Mikulski amendment No. 3533 (to amendment No. 3482), to increase appropriations for EPA water infrastructure financing, Superfund toxic waste site cleanups, operating programs, and to increase funding for the Corporation for National and Community Service (AmeriCorps).

Mr. COVERDELL addressed the Chair.

The PRESIDING OFFICER. The Senator from Georgia.

AMENDMENT NO. 3532 TO AMENDMENT NO. 3466 Mr. COVERDELL. Mr. President, I call up my amendment numbered 3532.

The PRESIDING OFFICER. Th amendment is now before the Senate.

Mr. COVERDELL. Mr. President, it is my understanding that this amendment has been cleared on both sides.

Mr. President, I urge its adoption. The PRESIDING OFFICER. Is there further debate on the amendment?

Without objection, the amendment is agreed to.

So the amendment (No. 3532) was agreed to.

Mr. COVERDELL. Mr. President, I thank the chairman of the Appropriations Committee, the senior Senator from Oregon, and the ranking member, the new Senator from Oregon, for their cooperation on this important amendment.

Let me say that many people do not realize that immediately following the 1996 Olympics will occur the World Paralympics for which the amendment is addressed.

I deeply appreciate the cooperation and assistance.

Mr. HATFIELD. I thank the Senator. Mr. COVERDELL. Mr. President, I move to reconsider the vote by which the amendment was agreed to.

Mr. HATFIELD. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. HATFIELD. Mr. President, I have a unanimous-consent request that has been agreed to on both sides that I would like to propound at this time.

I ask unanimous consent that it be in order for me to send an amendment to the desk at this time; further, that it not count as one of the managers' amendments under the consent agreement.

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

AMENDMENT NO. 3536 TO AMENDMENT NO. 3466 Mr. HATFIELD. Mr. President, I send the amendment to the desk.

The PRESIDING OFFICER. The clerk will report.

The clerk read as follows:

The Senator from Oregon [Mr. HATFIELD] proposes an amendment numbered 3536 to amendment No. 3466.

Mr. HATFIELD. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

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

The amendment is as follows:

On page 577 of the pending amendment, strike lines 14 through the period on line 23.

Mr. HATFIELD. Mr. President, my amendment strikes a portion of this bill related to Oregon's request for a welfare waiver. I am striking this language because the Secretary of Health and Human Services has now assured me that the administration will complete its commitment to my State.

I should like to read the letter to the Senate that I have just received from Secretary Shalala.

Mr. President, I offer this amendment on behalf of my colleague, Senator WYDEN, as well, because he has been deeply involved and interested and concerned about this issue as well.

The letter is addressed to me as chairman of the Appropriations Committee.

DEAR MR. CHAIRMAN: I am pleased to inform you that an agreement has been reached between the Department of Health and Human Services officials and the State of Oregon on the key issues that would allow the State to implement the Oregon Option welfare reform demonstration for AFDC, JOBS, and related HHS programs, including issues pertaining to federal funding. The uniqueness of Oregon's proposal in the context of the Administration's Memorandum of Understanding with the State warrants a special approach, to be applied only in Oregon, to carrying out this demonstration. You have my commitment that I officially will grant the waiver as soon as HHS staff and State staff can finalize the details of an agreement.

Oregon and HHS staff together have crafted an agreement that demonstrates a solid partnership for testing new approaches to welfare reform. This agreement focuses on achieving important outcome-based benchmarks for helping families move from welfare to work and reducing child poverty.

DONNA SHALALA.

Mr. President, let me just give a brief background to this amendment and the process leading up to it.

I wish to also amend her letter that I have just read on a verbal understanding that we had this morning, and that is relating to the timing of this waiver in the language "as soon as HHS and State staff can finalize the details of an agreement." She committed herself this morning to me that this would not take longer than 2 weeks. And the Governor of our State, in conversation with him this morning as well, indicated that this would be a satisfactory time period.

This action delivers the final and most critical piece of what we call the Oregon Option. Oregon's situation is unique. There is not another State in the Union that has achieved this particular status.

In September 1994, 40 members of Federal agencies, most based in Washington, DC, visited Oregon to talk about doing business differently. In December 1994, nine Cabinet members including the Vice President of the United States signed a memorandum of understanding with Oregon's Governor in a coast-to-coast satellite televised ceremony.

At this point, Mr. President, I ask unanimous consent to insert in the RECORD a copy of the memorandum of understanding reached between my State and the Federal Government.

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

MEMORANDUM OF UNDERSTANDING REGARDING "THE OREGON OPTION"

I. PURPOSE

The purpose of this Memorandum of Understanding is to encourage and facilitate cooperation among Federal, State and local entities to redesign and test an outcomes oriented approach to intergovernmental service delivery. This special partnership and longrange commitment will serve as demonstration of principles and practices which may serve as a model for improvements nationwide.

II. BACKGROUND

In July 1994, Oregon proposed a multi-year demonstration with the Federal Government to redesign intergovernmental service delivery, structured and operated to achieve measurable results that will improve the lives of Oregonians.

Oregon is uniquely suited for an experimental demonstration to develop an outcomes oriented approach to intergovernmental services. The State and many local governments have begun using an outcomes model for establishing long-range vision, setting public priorities, allocating resources, designing services, and measuring results. The Oregon Legislature has endorsed the Oregon "Benchmarks." Further, many nonprofit organizations, businesses, and civic groups in Oregon are aligned to a benchmark process with State, county and local jurisdictions.

III. PRINCIPLES TO GUIDE COOPERATION

The following principles should guide the parties cooperation in this undertaking:
A re-designed system would be:

Structured, managed, and evaluated on the basis of results (i.e., progress in achieving benchmarks).

Oriented to customer needs and satisfaction, especially through integration of services.

Biased toward prevention rather than remediation of problems.

Simplified and integrated as much as possible, delegating responsibilities for service,

design, delivery, and results to front-line, local-level providers, whether they are local agencies or local offices of state agencies.

IV. RESPONSIBILITIES OF THE PARTIES

The parties to this memorandum will work together as partners to (1) identify benchmarks, strategies, and measures that provide a framework for improved intergovernmental service delivery and (2) undertake efforts to identify and eliminate barriers to achieving program results.

V. AUTHORITIES

The principles and responsibilities covered in this memorandum are intended to improve the coordinated delivery of intergovernmental programs. This memorandum does not commit any of the parties to a particular level of resources; nor is it intended to create any right or benefit or diminish any existing right or benefit, substantive or procedural, enforceable at law by a party against the United States, State of Oregon, any state or federal agency, any state or federal official, any party of this agreement, or any person. While significant changes to the intergovernmental service delivery system are anticipated as result of this effort, this is not a legally binding or enforceable agreement. Nothing in this memorandum alters the responsibilities or statutory authorities of the Federal agencies, or State or local governments.

SIGNATURES OF MEMORANDUM OF UNDERSTANDING REGARDING "THE OREGON OPTION"

Vice President Al Gore. Secretary Labor HHS Donna E. Shalala. Secretary of Housing Henry G. Cisneros. Director, Office of National Drug Control Policy Lee P. Brown.

Secretary of Labor Robert B. Reich. Secretary of Education Richard W. Riley. Attorney General Janet Reno. Secretary of Agriculture Mike Espy. Secretary of Commerce Ronald H. Brown. Dir. of the White House Office of Management and Budget Alice M. Rivlin.

Asst. to President for Domestic Policy Carol H. Pasco.

Oregon

Governor, Barbara Roberts.
Senate President, John Kitzhaber.
Mayor PDX, Vera Katz.
Commission, Salem, Randall Franke.
Mayor of Corvallis, Charles Vars.
Mayor, City of Gresham, Gussie McRobert.
Mayor of Ashland, Katherine Golden.
Mayor of Independence, Marion Rossie.
Commissioner LaGrande, John Howard.
Commissioner Lane, Steve Cornacchia.
Multnomah County, Beverly Stein.

Mr. HATFIELD. With the understanding that we had the blessings of all levels of Government, the Oregon Legislature passed a comprehensive welfare reform bill that became the basis for the Oregon option welfare reform waiver request. Oregon's JOBS Plus Program gives parents the opportunity to find substantive work with above-minimum wage pay and includes employer involvement. Employees earn a livable wage while learning valuable work skills.

Oregon's attempt to reform welfare is designed to allow people the opportunity to work, thereby taking them off the welfare rolls. Through innovative program planning, Oregon has seen a decline in its welfare casework the last 2 years while facing increases in population. And I wish to repeat this. Oregon has had a decline with this experimental program in its welfare case-

load the past 2 years while facing increases in population. With this waiver, we will be able to move further into that program of reform.

On July 3, 1995, 9 months ago, Oregon submitted its waiver request to the Department of Health and Human Services and Department of Agriculture. We then fell into the abyss. With Congressional welfare reform appearing possible, including changes that would allow Oregon to implement most of the options without waivers, action slowed down on all sides. I became very concerned that the rhetoric and the reality were incongruent. I inserted language in this omnibus appropriations bill to force the administration to act on our request one way or the other. This is not the way I like to do business, Mr. President, but I had no other recourse. I am very pleased that today the administration has delivered on their promises. The idea behind the Oregon option is that outcomes and results govern the expenditure of funds, not direction from Washington. Today, the administration, and in particular Secretary Shalala, has sent a clear and unequivocal message of a commitment to results.

I thank the administration for allowing us to go forward. Their commitment is well placed. The Vice President referred to the Oregon option in December 1994, as quoted in the Oregonian, "This is all about going from redtape to results." The Vice President's senior policy adviser was quoted in the August 6, 1995 Washington Post as saying,

The Oregon option is probably the largest system of performance-based government in the United States that is actually up and running. We see it as a possible model for the future of Federal-State relations.

While I cannot guarantee that the approach Oregon wants to take on welfare reform will be successful because we do not live in a world of guarantees, we have seen positive strides with our programs thus far. We have a great track record of delivering on our promises. Our Governor, John Kitzhaber, and the head of our welfare department, Steve Minnich, deserve the gratitude of all Oregonians for the effort they have expended to make these programs work.

I should like to say parenthetically that our Governor was the president of the State senate, and he is a medical doctor. During his time as president of the State senate, he was the one who brought the parties together and crafted the Oregon Health Reform Act, and this is the record of a very dedicated public servant and one who has quietly and with great effectiveness brought about that change in our own health programs in Oregon, at least as far as we could go. And now he has undertaken the welfare program for reform. I am honored to be his messenger to the cause that he represents here in Washington.

My home State of Oregon has a pioneering spirit. We face obstacles armed with creative solutions and the perseverance to see them to conclusion. Each day Oregon proves itself willing to take on hard issues such as health and welfare reform, programs which serve as models for the rest of the country. Mr. President, today I am reminded of the words of Herbert Hoover. He said once, "Words without actions are the assassins of idealism." The Secretary's action certainly maintains my idealism that innovative welfare reform is possible.

I am very pleased to again note that my new colleague, recently elected from my State, and a man who has brought great distinction to our State by his service in the House of Representatives and pursuing programs of this type throughout his political career, has now joined me as a full-fledged partner and I thank him for his continued effort and interest in this matter.

Mr. WYDEN addressed the Chair. The PRESIDING OFFICER. The Sen-

ator from Oregon.

Mr. WYDEN. Mr. President, I first want to extend my appreciation to Senator HATFIELD. The chairman of the committee has done yeoman work on this and on so many issues for our State and for our country. He has honored me with the chance to work with him on the Oregon option in both the House and the Senate. I want him to know how much I appreciate his help and his counsel. I think it is clear that the administration looks to him for leadership on these issues and to a great extent it is because of Senator HATFIELD that the administration consistently comes to us for the opportunity to test these issues. I want the Senator to know how grateful I am to be able to work with him and in particular, to support his amendment today

I think Senator HATFIELD has outlined quite well that the welfare system in America today does not work for anyone. It certainly does not work for taxpayers. In so many instances they watch as their tax dollars are frittered away. And I know that it does not work for many of those who are in the system. I have talked to them, and many of them have said they would very much like to break out of the system, but they get caught in a Catch-22. They may have a child at home and would like to work, but if they start working they lose their child care. So, to a great extent, the welfare system in America today does not work for much of anybody.

What I think Senator HATFIELD has outlined is that Oregon, with our unique Oregon option, a plan that is being tried literally nowhere in the country, is offering the Nation the chance to break out of the encrusted shell of the old welfare system. We are saying, in effect, that we would like to bust loose, like we did with the Oregon health plan, and focus most specifically on results.

Senator HATFIELD has made so many of the important points that I would

like to just touch on one or two others that I believe have great implications for the national debate about the delivery of services in our country, and particularly our human services. We know that many of our colleagues are now part of the debate that suggests either you ought to run everything from Washington, DC, that Washington, DC has the answers, or you should just give it back to the States and see what happens.

The Oregon option is a plan developed with the leadership of our Governor, John Kitzhaber, who has done outstanding work in the human services area, and with the help of the administration. The Oregon option offers an alternative approach that falls in between the two extremes of either running it all from Washington, DC, and saying Washington, DC, has the answers, or simply turning it over to the States and seeing what happens.

Oregon, in effect, with the Oregon option, is saying that if we are allowed to be free of some of the Federal shackles and some of the Federal red tape, we will guarantee we will focus on real accountability with respect to services. We will make sure that the focus is getting people off welfare into gainful employment in the private sector, and we will focus on results, we will focus on accountability.

I suggest to the Senate that the Oregon option does show real promise of getting to a creative third path between those who say "run it all from Washington" and those who just say "turn it all over to the States and we will see what happens." Yes, let us give the States more freedom and more authority, but let us also require accountability. That is what the Oregon option is going to do.

I think it is worth focusing for a moment on how this is actually going to produce change in the system. In the future, with the Oregon option, a welfare office is going to be evaluated not by whether all of the boxes in every application get checked, but by how many individuals actually move into good, nonsubsidized jobs and whether we are reducing the number of children who live in poverty.

Right now, probably the best way to describe the system is that if you have somebody who is on welfare and at home, the system just goes forward. You do not have to adjust any benefits. You do not process any paperwork. There is no job training to account for, no assets that might accumulate. The system just goes on and on and on. Under the Oregon plan, those individuals who are running welfare services, are going to know the focus is on making sure there are results, making sure that you actually see people move into the private sector. This is what reform ought to be all about.

There are a number of specific features about the Oregon plan that I think make great sense for welfare reform generally. Under the Oregon option, the State is going to invest in

what is known as transitional child care and preventive child care. As a Member of the other body, I saw repeatedly that there were individuals, particularly women who head households, who would be able to get off welfare. Sometimes they would get off a couple of times. They would be in the private sector, they would be making headway, then their child care would fall apart, and they would slide back onto public assistance.

The Oregon option, with its innovative approach toward child care is going to help prevent that in the future. The Oregon option allows welfare recipients to keep certain assets that can expedite the transition from welfare to work and make sure people do not fall back on welfare.

Finally, the focus with respect to the State's role is on real work situations, not these make-work kind of arrangements, but real employment opportunities where welfare recipients get trained on-site, by business people who have actual needs in the job markets in our State

A lot of us see the welfare system as something that can be a ladder to a fresh start. It is not supposed to be a feather mattress. It is supposed to be a ladder. I am excited about the chance to change lives for the better in our State, excited about the fact that the Oregon option is going to allow taxpayer dollars to be used in a more effective way.

I want to commend both the administration and Secretary Shalala. I have had a chance to work with her on the Oregon option and the Oregon health plan. We think this is our one-two punch in reforming services that affect thousands of families. Secretary Shalala deserves great credit for that.

Finally, our Governor, as Senator HATFIELD has noted, is consistently out in front in trying to look at these issues. I think, when you write the history of health reform, and I know the President is particularly interested in this issue, the country is going to look at what Oregon has done in health care and the way Oregon has made tough choices and the way Oregon has fo-cused on prevention and focused on medical effectiveness and focused on ways to build a new partnership with providers. Because of Dr. Kitzhaber's work, the Oregon health plan is going to make a difference in health reform across this country. It is going to be something that the rest of the Nation is going to look to. Now, with the Oregon option we have a chance, through welfare reform, to complement the work that has been done on the health care side.

So I urge the adoption of the Hatfield amendment. As you can tell, we are passionate, on a bipartisan basis, about this important cause. It is going to change lives across our State. I think it is going to make a difference across our Nation, and I am pleased and honored to be here with Senator HATFIELD to support his amendment.

I yield the floor.

The PRESIDING OFFICER. The Senator from Oregon.

Mr. HATFIELD. Mr. President, I know of no other comments to be made at this time.

Mr. President, what is the parliamentary situation?

THE PRESIDING OFFICER. If there be no further debate, the question is on agreeing to the amendment.

The amendment (No. 3536) was agreed to.

Mr. HATFIELD. Mr. President, I move to reconsider the vote.

Mr. WYDEN. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. HATFIELD. I thank the Chair, and I thank my colleague for his very strong assistance on this.

Mr. GORTON addressed the Chair. The PRESIDING OFFICER. The Senator from Washington.

AMENDMENT NO. 3496

Mr. GORTON. Mr. President, I have an amendment at the desk and I ask for its immediate consideration.

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

The amendment is now before the Senate.

Mr. GORTON. Mr. President, in Walla Walla, WA, there is a general medical and surgical facility for the Veterans' Administration. That facility serves a wide range of veterans over a very considerable area.

The people of Walla Walla are proud of the facility. The various veterans organizations in the area have asked us to rename it in honor of Gen. Jonathan M. Wainwright. As you know, Mr. President, General Wainwright was a distinguished American military leader, having commanded American troops in the Philippines and Corregidor after the departure of General Mac-Arthur. He was imprisoned for 4 years, released, and ultimately observed the surrender of the Japanese on the U.S.S. Missouri on V-J Day. He won the Congressional Medal of Honor. General Wainwright was born in Fort Walla Walla, while his family was there with the First Cavalry.

The people of Walla Walla are going to erect a statue in his honor, and they wish to rename the facility in honor of General Wainwright.

A bill introduced by the Congressman from the district, Mr. NETHERCUTT, passed the House of Representatives last year. It seems to be buried so deeply in the Veterans' Committee that it is not going to get out certainly in time for the Memorial Day ceremony by which time we hope to have caused this renaming to take place.

This is not a cleared amendment but, Mr. President, I think it should be non-controversial. Senator MURRAY and I very much urge our colleagues to agree with us, to adopt it as a rider to this bill since it has already passed the

With those remarks, I think I need no more time of this body speaking about this amendment, about Walla Walla, or about General Wainwright. So I will yield the floor, but I am constrained at this point to ask for the yeas and nays on the amendment with the hope that will bring the whole subject to the attention of those who have objected to it to this point and that it will soon be cleared.

So, Mr. President, I ask for the yeas and nays on the amendment.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The yeas and navs were ordered.

Mr. GORTON. Thank you, Mr. President. I yield the floor.

Mr. HATFIELD. Mr. President, I do have a group of amendments that have been cleared on both sides. I will make a unanimous-consent request.

AMENDMENT NOS. 3537, 3538, 3539, 3540, 3541, 3542, 3543, 3544, 3545, AND 3546 TO AMENDMENT NO. 3466

Mr. HATFIELD. Mr. President, I now send to the desk a number of amendments that have been cleared on both sides of the aisle. I ask unanimous consent that they be considered en bloc, agreed to en bloc, and that the motions to reconsider be laid upon the table. I withhold.

Mr. President, my unanimous consent request has been formally modified, but that has already been taken care of. I renew my unanimous-consent request.

The PRESIDING OFFICER (Mr. NICKLES). Without objection, the question is on agreeing to the amendments en bloc. The amendments (Nos. 3537, 3538, 3539, 3540, 3541, 3542, 3543, 3544, 3545, and 3546) were agreed to, as follows:

AMENDMENT NO. 3537

Insert the following at the appropriate place under Title III of the Committee amendment:

"SEC. Any funds heretofore appropriated and made available in Public Law 102–104 and Public Law 102–377 to carry out the provisions for the project for navigation, St. Louis Harbor, Missouri and Illinois; may be utilized by the Secretary of the Army in carrying out the Upper Mississippi and Illinois Waterway System Navigation Study, Iowa, Illinois, Missouri, Wisconsin, Minnesota, in Fiscal Year 1996 or until expended.

Mr. BOND. Mr. President, I offer this amendment on behalf of myself, and Senators Harkin, Simon, Grassley, and Moseley-Braun.

The purpose of the amendment is to allow surplus funds previously earmarked to be reprogrammed to the Upper Mississippi/Illinois Waterway Navigation Feasibility Study.

The navigation study in fiscal year 1996 is underfunded and, consequently, will be unable to meet the 6-year study deadline unless more funding is provided. This shortfall has been recognized by Secretary Lancaster who has persisted in reprogramming discretionary money to help make up the shortfall. This amendment provides the Secretary the authority to reprogram an additional sum of money currently

earmarked for the St. Louis harbor study that the corps will not be able to spend this year.

Even with this potential transfer, we understand they remain \$1.8 million underfunded which we will have to make up in fiscal year 1997.

The amendment does not increase the overall cost of the 6-year \$43 million study to update the 50-year-old locks and dams on the Illinois Waterway and Upper Mississippi River.

Mr. President, this study is a priority item. Conference report language in the energy and water appropriations bill for fiscal year 1996 was included directing the corps to:

Expedite work on the study and ensure that the Division Engineer's public notice on the feasibility report is issued no later than December of 1999 . . . because of the need for a timely review of future navigation needs on the upper Mississippi River and Illinois Waterway.

According to the corps in 1992, tows at Upper Mississippi locals 22–25 were delayed a total of 87,000 hours. As river traffic grows over 4 percent per year, the corps estimates that delays at locals 22–25 would be in excess of a day early in the 21st century.

The president of Farmland Industries told us recently that they have 18 trains running round the clock to try to meet foreign demand. Even today, there is 12 million tons of grain on the ground in Iowa that cannot find a ride to markets abroad—what will it be like when freedom-to-farm takes effect and export demand continues to grow? The longer it takes to upgrade the 50-year-old system, the harder it will be for U.S. grain to continue to find a home in the world market at competitive prices.

The bottom line is that this is a trade, competitiveness, and jobs issue. Our farmers need this. This is one of our principal competitive advantages and the action taken now will be the basis of our competitive position 5, 10, and 20 years from now. If we have grain piling up now, what will it be like in 10 years? Who believes that we can remain a reliable exporter of grain if we let our system deteriorate at the same time the Department of Agriculture is projecting record \$60 billion in agricultural exports and a record \$30 billion trade surplus?

Mr. President, Senators who are concerned about competitiveness, promoting trade opportunities, protecting jobs, and growing the economy should be on board this effort. We know the corps is on board and we need to get the Office of Management and Budget on board. This is not a priority at OMB and it should be. Trying to capture the growing Asian market is not pork—it's the economy, stupid.

It is critical that the administration follow the Secretary for Civil Work's lead in pursuing this study. It is a project of national significance that deserves priority attention. It is necessary that the administration make a request for fiscal year 1997 appropria-

tions which accurately reflects the funding necessary to keep this study on schedule. If this study can wait, we are telling farmers that exports can wait. They can't.

Other nations are aggressively emulating our inland waterway system—Brazil, China, and Germany, to name a few. The question is whether we will forsake that advantage to the detriment of our young farmers and nation balance of trade. This is our chief artery to the world market. Some foreign competitors can beat us on price until our grain hits our inland waterway system—which is the cheapest way to ship a ton of grain in the world.

I want to thank the chairman and ranking member of the subcommittee and full committee for accommodating us on this issue. In the coming months and years, the urgency for action will increase to address the lack of capacity on this critical corridor. This will be a priority issue, not just for carriers but for shippers who are farmers. Senators will hear from farmers and farm groups on this issue. This amendment is to promote and permit exports and job growth and I appreciate the support of the Senate.

AMENDMENT NO. 3538

(Purpose: This Amendment adds \$1,000,000 to the Adolescent Family Life program for total funding of \$7,698,000)

On page 546, line 21 of the pending amendment, increase the rescission amount by \$1,000,000.

On page 572, line 16 of the pending amendment, strike "\$129,499,000" and insert in lieu thereof "\$130,499,000".

Mr. SPECTER. Mr. President, as we try to steer toward a growing economy and a balanced budget, there has been a growing consensus that all our goals must rest on a restored ethic of personal responsibility. There is an alarming teenage birth rate in the United States. The teen birthrate in the United States is double the rate in other industrialized societies such as Australia and the United Kingdom. Over 72 percent of teenage births in 1993 were to unwed mothers: 12.000 children were born to mothers under the age of 15. It is worth pausing to reflect on the enormous significance of these statistics regarding out-of-wedlock births. Adolescent pregnancy threatens the health of both the young mother and child. Teenage mothers are more likely to lack adequate prenatal care and to give birth to a low-birthweight baby.

We can reduce unintended teenage pregnancies by encouraging abstinence and personal responsibility. If you want to reduce the number of abortions performed in the United States, teaching children to say "no" to peer pressure is a good starting place. The Adolescent Family Life Program, known as the title XX program, is a worthwhile program which focuses on the issues of abstinence, adolescent sexuality, adoption alternatives, pregnancy, and parenting. The Adolescent Family Life Program has broad bipartisan support when it was originally enacted in 1981

and when it was reauthorized in 1984. Congress appropriated \$6,698,000 for this program in fiscal year 1995; my amendment would increase its funding to \$7,698,000 in fiscal year 1996.

AMENDMENT NO. 3539

On Page 590, after the word "for" on line 19, strike all up to the word "payment" on line 23

On Page 590, after the word "education" on line 25, strike all up to the period on page 591, line 3.

AMENDMENT NO. 3540

(Purpose: To provide for a waiver of the enrollment composition rule under Medicaid for Chartered Health Plan of the District of Columbia)

At the end of title III, on page 771 after line 17, add the following new section:

SEC. . The Secretary of Health and Human Services shall grant a waiver of the requirements set forth in section 1903(m)(2)(A)(ii) of the Social Security Act to D.C. Chartered Health Plan, Inc. of the District of Columbia: *Provided*, That such waiver shall be deemed to have been in place for all contract periods from October 1, 1991 through the current contract period or October 1, 1999, whichever shall be later.

AMENDMENT NO. 3541

At the appropriate place insert the follow-

ing:
SEC. . Of the funds appropriated by Public Law 104-37 or otherwise made available to the Food Safety and Inspection Service for Fiscal Year 1996, not less than \$363,000,000 shall be available for salaries and benefits of in-plant personnel: Provided, That this limitation shall not apply if the Secretary of Agriculture certifies to the House and Senate Committees on Appropriations that a lesser amount will be adequate to fully meet inplant inspection requirements for the fiscal

Mr. COCHRAN. Mr. President, the amendment I offer with my colleague from Arkansas will ensure that funds appropriated to the Food Safety and Inspection Service for fiscal year 1996 are used to cover in-plant inspector salaries and benefits requirements before being obligated for other purposes. The reason for this amendment is simple. The Food Safety and Inspection Service has chosen to purchase computers over paying the salaries of inspectors who ensure the safety of our Nation's meat and poultry supply.

Mr. President, this agency requested \$594 million for fiscal year 1996, a 13-percent increase over the fiscal year 1995 appropriation. With a total allocation for discretionary spending below a freeze at fiscal year 1995 enacted levels, this subcommittee could not grant the requested increase. We appropriated \$544 million to the agency. The President signed the fiscal year 1996 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act on October 21, 1995. Apparently, the Food Safety and Inspection Service did not alter its spending plans for the year to live within the amount appropriated to it. Now, here we are, about half way through the fiscal year, with a request for a supplemental appropriation of \$9.5 million for the Food Safety and Inspec-

tion Service, which includes \$3.2 million for inspector positions, \$3.5 million for training for the new hazard analysis and critical control point [or HACCP], inspection program, and \$2.8 million for the animal production food safety initiative. This supplemental request from the President is offset in budget authority by a proposed rescission in funds appropriated to the Cooperative State Research, Education, and Extension Service buildings and facilities account, but not in outlays, as required by congressional budget rules. In investigating why the Agency faces a shortfall, we are told that the Agency decided to commit the \$8.4 million it had requested for the Field Automation and Information Management initiative, of which between \$4 and \$5 million remain. FSIS chose computers over inspectors. When asked if inspector positions would be protected if the Agency ran short of funds at the end of the fiscal year, the answer was "no." Rather than commit this money to an identified shortfall in inspector funding, it has come to us for more money.

Mr. President, this amendment will ensure that above all, there are adequate numbers of inspectors in the plants for the remainder of the fiscal year to ensure that the meat people put on their tables is safe and wholesome. At the same time, it will ensure that processing plants do not shut down, thereby increasing the cost of meat in the groceries, and reducing prices that farmers receive for their animals because they can't get them to market

We agree with the Department that the modernization of the current inspection program is essential, and endorsed it in the Senate report accompanying the fiscal year 1996 Agriculture Appropriations Act. Where we disagree is that the current inspection system should suffer at the expense of expediting implementation of the new system or other Agency initiatives. It is essential that we maintain the existing system while efforts are underway to implement the new system. In fact, I believe that the No. 2 priority of the Food Safety and Inspection Service should be training to implement the new HACCP rule. Once the new inspection system is in place, then is the time to dismantle the current system.

I hope that my colleagues will join me in supporting this amendment to ensure that adequate funds are available to keep meat and poultry inspectors on the job.

AMENDMENT NO. 3542

On page 769, line 24, delete the word "Of" and insert "Notwithstanding any other provisions of law, of.

On page 770, line 4, after the word "available", insert the words "for operating expenses".

AMENDMENT NO. 3543

(Purpose: To amend the Federal Food, Drug, and Cosmetic Act to authorize the export of new drugs)

(The text of the amendment is printed in today's RECORD under "Amendments Submitted.")

Mr. HATCH. Mr. President, yesterday morning I had the honor of addressing the National Medical Device Coalition, an association of far-thinking medical device manufacturing executives who have come to Washington to press for meaningful Food and Drug Administration reform.

In their visits with Senators and Representatives this week, NMDC members will be offering the most compelling case I know for FDA reform, and, specifically, reform of medical device regulation.

Indeed, they urge that reform of the medical device regulatory process should be a top priority of this Congress, and I couldn't agree more.

As the NMDC points out, there are severe problems facing the medical device industry in our country—problems which impede the ability of manufacturers to maintain our world class competitive edge and continue to produce products which have so many public health benefits.

I think that Wayne K. Barlow, president of the NMDC summed it up the best in his March 11 address to the American Institute for Medical and Biological Engineering. Mr. Barlow, who happens to also be president of Wescor, Inc., a small medical device manufacturer in Logan, UT, said:

The U.S. Medical Device industry is severely challenged. Its survival beyond the 20th century has been case in doubt. The innovative fervor that once characterized our industry is evaporating. We are seeing an alarming exodus of companies, technologies, and jobs to other countries. Do not doubt that we are in a life-or-death struggle nor that its outcome will determine whether our industry has a future in this country.

Mr. Barlow went on to say:

Powerful forces are reshaping health care delivery and the associated markets for health care products in America. The three major components are (1) dynamic restructuring of global markets, (2) Federal regulatory policies, and (3) the U.S. product liability climate. These forces in combination have debilitated the industry. In consequence, America is being pulled down toward second-rate status in medical technology.

I think that the NMDC has done us a valuable service in their concerted emphasis this week to educate the Congress on issues associated with medical devices.

As they point out, this diverse industry is comprised largely of small businesses, which manufacture a wide range of products all of which contribute positively to our U.S. trade balance.

A regulatory climate which threatens the health of these small businesses, threatens the health of our economy as well.

But it also threatens public health, because declining incentives for innovation force production overseas. And when that innovative edge moves offshore, Americans will be deprived of the latest medical products, products which could improve or even save lives.

One of the top priorities of the NMDC, eliminating FDA's involvement

in granting permission to export medical products, is also a top priority of mine, and is the subject of the amendment Senators GREGG, KASSEBAUM, KENNEDY, and I are offering here today.

Let me turn to a specific discussion of the amendment, which is a substitute for the FDA Export Reform and Enhancement Act (S. 593) approved unanimously by the Labor Committee last July.

I want to commend all of my colleagues who have worked on the FDA

export issue in this Congress.

In the House, Congressman FRED UPTON has exhibited a great deal of leadership on this issue. The chairman of the Commerce Committee, Representative THOMAS BLILEY, and the ranking member, Representative JOHN DINGELL, must be credited for working closely together to fashion the House language on export contained in the continuing resolution under discussion today.

In this Chamber, I must recognize all of the original cosponsors of the Senate bill, S. 593: Senators GREGG, KASSEBAUM, ABRAHAM, FRIST, and COATS.

My good friend, Senator KENNEDY, was instrumental in fashioning the compromise language that was unanimously adopted by the Labor Committee in July and in the amendment we now consider.

In the interest of moving forward our important goal of increasing the export of medical products, I ask all of my colleagues to support this amendment.

I think that the amendment we offer today is a vast improvement over current law. It undoubtedly will allow a more free export of American medical products abroad.

However, I must also recognize that our original bill, and the bill approved by the House of Representatives, provides even greater opportunities for such exports, without the intrusive hand of the FDA in first approving those exports. I am hopeful we can work during the conference to get a compromise which will move toward that free-trade concept while still ensuring protection of the public health.

I was chairman of the Labor Committee in 1986 and worked very hard to get the provision in current law which relaxed our restrictive trade policies regarding pharmaceutical products not approved by the FDA.

At that time, the law did not go as far as I would have liked, but we did make some important strides such as permitting the export of drugs not approved by the FDA to 21 specified countries.

Section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act already contains extremely important principles, and sufficient safeguards, in the area of exports:

A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

(A) accords to the specifications of the for-

eign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

A very good argument can be made that this provision alone should constitute our national policy.

It is important to understand that this is essentially the policy of every country in the world, except for the United States.

While I think that it should be the primary responsibility of the government of each nation to protect its own citizens, I am also a realist and know that many believe that additional requirements must be imposed on our domestic manufacturers to ensure public health abroad.

 $\,$ I do not question that well-intentioned motivation. At the same time, I would point out that no other country in the world imposes such requirements.

As I have suggested previously, we should all take note of the perspective of Dr. John Petricciani, an official of the Massachusetts biotechnology firm, Genetics Institute. Inc.

Prior to joining the private sector, Dr. Petricciani spent over 20 years in the Public Health Service, including serving as Director of the FDA Center for Biologics, head of the World Health Organization's biologicals unit and Deputy Director of the Public Health Service National AIDS Program Office. As Dr. Petricciani has stated:

The real issue here is one of benefit and risk. Do the benefits to foreign countries in the current law outweigh the risks imposed on the U.S. in terms of draining jobs and capital investment in research, development, and manufacturing? As has been pointed out by others, one of the results of that drain is the earlier availability of products in Europe and elsewhere than in the U.S. If we were discussing electronics or automobiles, I would not be as concerned because the American people are not being placed at a meaningful disadvantage by such delays.

However, the issue here is medical products that can make a very big difference in the health of the American people. The current law is resulting in new products being introduced first in foreign countries where U.S. firms are forced to manufacture them. I believe that we are paying far too high a price in terms of delayed availability of new products in the U.S. for the theoretical benefit being provided to developing countries.

fit being provided to developing countries. I would also like to point out that if a U.S. company really wanted to export a product that would be acceptable in the U.S., all they would have to do is manufacture it outside the U.S. and export it to a developing country.

Now is the time to revise and reform the current export restrictions—both for public health and international trade considerations.

The question is not whether we should change current law, but how we should change the current law.

As I said earlier, I prefer the House language. But I am also a realist and recognize that to include a provision under unanimous consent today there will be some matters that will not be resolved to my satisfaction.

I would like to review briefly the history of the development of this legislation in the 104th Congress.

First, the companion bills, S.593/H.R. 1300 were introduced last March.

The theory behind this legislation was simple and direct.

Essentially, S. 593 and H.R. 1300 would harmonize the U.S. policy with the policy adopted by every major

trading nation in the world.

This would allow U.S. producers to sell their products freely to World Trade Organization-member countries so long as such products were not violative of the laws of the importing country. This is a good law and good policy and is the rule by which the rest

of the world lives by.

Because of concerns that such unfettered free trade might possibly subject citizens in Third-World countries to dangerous U.S. exports, a compromise was reached in the Labor Committee last July. The compromise would allow shipment of drugs to any country in the world if they were already approved by one of a list of some 20-odd countries deemed to have sophisticated drug approval and regulatory systems.

The purpose of this so-called bank shot was to decrease the possibility that some small Third World country might somehow unwisely allow, or be somehow coerced to allow, dangerous

products into its borders.

In parallel with this bank shot, the Labor Committee compromise contemplated the creation of a so-called tier II list of countries with regulatory systems found adequate to protect the health and safety of their citizens. Drugs and devices could be shipped directly to those countries even in the absence of an approval of a Tier I country with a sophisticated drug approval system.

Subsequent to the markup, the GAO was requested to provide technical assistance to help the Senate formulate tier II country criteria as well as technical assistance in helping the Senate to select an initial list of tier II countries

Understandably, and perhaps, unavoidably, the creation of these criteria and the initial list has presented contentious issues. Neither the GAO nor FDA are anxious to get involved in the middle of such an inherently complex issue.

I believe there is agreement among sponsors of our amendment today that we will examine this issue in more detail in conference. I feel very strongly that we must allow opportunities for export beyond the tier I realm. That is the future of exports for our country.

Where the GAO and FDA fear to tread, the Congress must, and should, march in.

In the end, I think it is the responsibility of each government to design laws to protect its own citizens so I have philosophical concerns about a system that would preclude a U.S. company to ship a product to another country—even a third world country—when that country has decided to allow the use of that product.

I know that some, including our colleague, Senator SIMON, have, for good

and legitimate reasons, raised concerns about the ability of small developing nations like Botswana to make these crucial regulatory decisions. I just question whether our Food and Drug Administration is as well-positioned as the public health authorities of another country, Botswana included, as to what products are suitable for its citizens.

I am even more skeptical of the wisdom of not providing a tier II mechanism to provide, in the absence of a tier I country approval, direct shipment to countries like Russia, China, India, Brazil, and Argentina.

Why should this Congress presume to forbid American manufacturers the opportunity to sell products in these countries after these governments have independently found that such products are legal to make and use? Can we not rely upon the Chinese and Russian governments to act in the best interests of its own citizens?

I don't think that FDA approval, or the approval of a select list of tier I countries, should be a necessary condition for other countries to decide to approve, or for that matter disapprove, the use of a certain medical product. Accordingly, I believe that, American manufacturers should be given the same opportunity to compete with manufacturers of products approved for use in tier II, but not tier I, countries. Deciding which medical products to allow into the stream of commerce is an important power for each sovereign nation to exercise.

In closing, I want to commend our colleagues in the House for developing a proposal which represents an improvement over the original version of S. 593/H.R. 1300. Frankly, I believe that the imminent hazard provisions of the House-passed bill grants sufficient authority to the Secretary of Health and Human Services to halt shipments of dangerous projects. As a practical matter, I don't think that the imminent hazard provisions of this new Senate amendment act much differently.

We have an opportunity in the 104th Congress to enact FDA export legislation. This legislation can advance the public health of the United States and internationally. This legislation can benefit employees and potential employees of American medical products manufacturers.

It is estimated by experts that each \$1 billion in exports results in the creation of 20,000 new jobs for Americans. We in Congress have a unique opportunity and special responsibility to expand our trading markets for biomedical products.

This legislation is consistent with advancing the public health and with our international trade policy. I commend Senators GREGG, KASSEBAUM, and KENNEDY in moving this amendment and I look forward to working with my colleagues to see if we can resolve this issue in the conference committee.

Mr. KENNEDY. Mr. President, this amendment represents a great deal of

effective work by Senator GREGG, Senator KASSEBAUM, and Senator HATCH, and I commend them for their efforts. The provisions are similar to those in the bill unanimously approved by the Senate Labor Committee last year.

This amendment will reform the export policy of the FDA and enhance the competitive position of U.S. manufacturers of drugs and medical devices in the international market. At the same time, it will protect consumers in the Third World from unapproved, unsafe and ineffective products that might be exported from the United States but that their governments lack the expertise to evaluate.

This amendment represents an appropriate balance between the needs of U.S.-based industries and the need to provide adequate safeguards for the distribution of U.S. medical products in other countries. Multinational pharmaceutical manufactures also recognize that this amendment will ease the major regulatory problems that have been a barrier to locating production facilities in the United States.

For many years, the United States was one of the few countries in the world with a well-developed procedure for approving drugs and medical devices. The FDA is still the gold standard throughout the world, but a number of other industrialized countries have now adopted sophisticated systems for safeguarding their citizens.

In recent decades, foreign markets have become increasingly important to U.S. manufacturers, and foreign competition has become increasingly strong. The United States still leads the world in biotechnology, in medical device development, and in drug development—but we cannot be complacent about maintaining our leadership.

The increasing internationalization of the production and distribution of medical products has been accompanied by a welcome improvement in international efforts to coordinate standards of ethical conduct and to monitor the use of these products in countries around the world. Nonetheless, serious abuses have occurred, and continue to occur.

This legislation recognizes these trends and responds to changing conditions in several ways. First, it recognizes countries whose approval methods have reached international standards of excellence. Exports of products that have not been approved in the United States to countries with such programs have been permitted since 1986. This bill streamlines that process.

In addition, the bill allows manufacturers to export products to any other country in the world, provided that the recipient country wants the product, and provided that the product has been approved by any of the countries specified in the legislation as having excellent drug approval processes. For established, responsible pharmaceutical companies, this requirement is not a burden. They routinely seek approval of a new drug in one of the countries

named in the bill, before any broader exports are contemplated. But this requirement will assure that irresponsible companies do not try to use the label "Made in the U.S.A" to peddle unsafe drugs or medical devices to other nations.

Many of the worst abuses by drug companies have come in deceptive promotions in which approved drugs are promoted for inappropriate uses and without necessary safety warnings. To protect consumers in other countries, the legislation also requires that U.S. drugs marketed in these countries must be labeled in accordance with the requirements of the country that approved the safety of the products. Promotional activities must be consistent with indications and contra-indications on the label.

The bill also authorizes the Secretary of HHS to immediately suspend the export of any American-made drug that poses an imminent hazard to public health in an importing country.

American manufacturers must be free to compete effectively in world markets. But America also has a responsibility to assure that the label "Made in America" will not be used to promote unsafe or ineffective products. This bill strikes an appropriate balance between these two important goals.

Unfortunately, the companion provision in the House bill includes none of these safeguards to protect foreign consumers. Instead, it allows U.S. manufacturers to export any product, no matter how unsafe or ineffective, anywhere in the world. This kind of carte blanch is clearly unacceptable. It does not serve the commercial interests of responsible manufacturers. It makes a mockery of the quality standard that his always been associated with products labeled "Made in the U.S.A." it will endanger innocent foreign consumers, including Americans traveling or living abroad, who rely on that label.

I urge the Senate to adopt this amendment, and to insist on those safeguards in whatever bill is finally sent to the President.

Mr. GREGG. Mr. President, I would like to thank Senators HATCH, KASSE-BAUM, and KENNEDY for their great assistance in the development of this amendment which will reform the laws governing the export of pharmaceutical products and medical devices. It is imperative that this Congress take action immediately to change the inappropriately restrictive laws that grossly limit the export of medical products that can be legally marketed in other countries but are not yet approved by the U.S. Federal Food and Drug Administration [FDA]. On August 2, 1995 the Senate Labor and Human Resources Committee unanimously reported S. 593, the FDA Export Reform and Enhancement Act of 1995. This bill made improvements in the area of free trade while retaining some important public health protections.

Prior to 1986, medical products, including drugs, biologicals, animal

drugs, and medical devices generally could not be exported unless they were approved by the FDA. With the passage of the export legislation authored by Senator HATCH in 1986, this inappropriate and paternalistic policy was somewhat corrected. The 1986 amendments allowed drug manufacturers to ship their products to a codified list of 21 specific countries. It is my understanding that there was no prohibition included in the law that would prevent the expansion of that list, yet in the 10 years this law has been in effect, no attempt has ever been made to modernize this limited list.

On July 13, 1995, I held a hearing before the Aging Subcommittee of the Labor and Human Resources Committee on the issue of whether additional changes in the export laws are needed. There we determined that it is critical that we eliminate unnecessary restrictions which serve to encourage American pharmaceutical and medical devices companies to maintain research, production and investment to conduct clinical research in foreign countries; build factories overseas; and send high paying high-tech jobs to foreign competitive markets. Our current FDA export regimen is causing us to relinquish our intellectual leadership in the health care field. Improvement to the export policy in this country will also free up limited resources at the FDA, better enabling the agency to focus on the mission of timely, efficient approval of new products that meet the needs of American patients in conjunction with comprehensive FDA reform.

In this hearing, we listened to both drug and medical device manufacturers testify as to how the U.S. laws—unparalleled anywhere in the world-are negatively impacting their business, investments, and the patient population they serve in the United States. For example, Steve Ferguson, chief operating officer of the Cook Group, Inc., testified that our consideration of the FDA as the "gold standard" is "generally a joke that you hear throughout the world, the standard is that, FDA approved just means that it is outdated. You are already on to the second or third generations over there, unless you are in the business, it is hard to understand that.

We also heard from Mr. Michael Collins, chief operating officer of Medtronic, who stated—

Every week that the current policy continues to be implemented, more American jobs are lost through the relocation of manufacturing overseas and the loss of market share to foreign competitors.

Mr. Mark Knudson, a managing partner of Medical Innovation Partners, a venture capital firm, testified that: "5 or 10 years ago the pace of innovation and the intensity of regulation were not as mismatched as they are today * * *. We can no longer consider a medical investment opportunity which does not have a European strategy * * * the capital required to reach market is so much greater in the United States today."

I am concerned that if we don't change these laws soon that we will have sent so many of these high-technology businesses overseas, the trend will be irreversible. The domestic drug and device industries are two of the too few sectors of the economy in which the United States is the acknowledged world leader and the U.S. producers have a favorable balance of trade, but the negative turn in these statistics is frightening. The Labor Committee reported out a bill 16 to 0 that began to address this problem. That substitute version of S. 593, worked out between Senators Kassebaum, Hatch, Kennedy, and myself, was clearly a positive expansion of current law.

The bill we are including as a manager's amendment today represents a further iteration of that legislation in an attempt to address issues that remained in the committee-passed bill. This bill allows export of human drugs, animal drugs, biologics or medical devices not approved by the FDA. U.S. products, under this bill, could be exported to any country in the world if a product was approved by at least one country from a list of countries we were able to agree have appropriately sophisticated regulatory systems. These countries consist of the 21 that have this status under current law: Australia, Austria, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom, with the additions of Israel, South Africa, the body of the European Union, and member countries in the European Economic Area-countries in the European Union and the European Free Trade Association.

As under current law, the exported products must be permitted in the importing country and must comply with all of the relevant laws imposed by that country. Moreover, the following safeguards must be satisfied and a FDA-unapproved product may be exported only if the product is made in conformity of good manufacturing practices; the product is not adulterated; the product is labeled and advertised in accordance with the requirements of the approving country; the product is in accordance with the specifications of the foreign purchaser; and, the product is labeled for export and not sold or reimported into the United

Along with free export to the above countries with sophisticated regulatory systems, we have included a provision which ensures this list will not be static, a major problem now. The Secretary, manufacturers, countries, and individuals will have the opportunity to expand the list of countries with sign-off authority on products produced in the United States that have market potential outside of this country. It is our strong intent that this provision will be used to keep the list dynamic.

In addition, we have expanded the provisions in current law for tropical diseases to include other diseases that are not prevalent in the United States. We have done this as a compromise. I personally believe all countries should have complete autonomy over their trade and what products they allow to be marketed to their citizens. However, some of my colleagues disagree, feeling we should play watch-dog over the rest of the world's markets. So, as a middle ground, we have agreed that American companies should have the freedom to explore the development of therapies and cures which address diseases that may be common among the populations of other countries, even though the disease is not often seen in the U.S. There is no good reason why paternalistic United States regulatory policies should relegate citizens of other countries to poor health, particularly when our regulatory regime is so behind-thetimes that the need to pass this bill is universally acknowledged. Any countries not designated by either provision can receive exports of products not approved by FDA if the product is approved by at least one country with regulatory sophistication.

During the course of our hearing, a concern was raised by Senator SIMON that altering the export laws under the original terms of S. 593 might result in the dumping of unsafe products into Third World countries. Dr. John Petricciani, vice president for regulatory affairs with Genetics Institute, a Boston biotechnology firm, and former Director of the FDA's Center for Biologics, and head of the World Health Organization's Biologicals Unit, with 20 years in the Commissioned Corps of the U.S. Public Health Service as Deputy Director of the National AIDS Program Office, responded to Senator SIMON in a letter that is included in the hearing record. I would like to include a portion of his letter for the RECORD here as well:

The real issue here is one of benefit and risk. Do the benefits to foreign countries in the current law outweigh the risks imposed on the U.S. in terms of draining jobs and capital investment in research and development and manufacturing? As has been pointed out by others, one of the results of that drain is the earlier availability of products in Europe and elsewhere than in the U.S. If we were discussing electronics or automobiles, I would not be as concerned because the American people are not being placed at a meaningful disadvantage by such delays.

However, the issue here is medical products that can make a very big difference in the health of the American people. The current law is resulting in new products being introduced first in foreign countries, where U.S. firms are forced to manufacture them. I believe that we are paying far too high a price in terms of delayed availability of new products in the U.S. for the theoretical benefit being provided to developing countries.

I would also like to point out that if a U.S. company really wanted to export a product that would be unacceptable in the U.S., all they would have to do is manufacture it outside the U.S. and export it to a developing country.

American jobs are being sent abroad because of current laws which restrict

the export of drug and medical technology not approved in the United States. These laws not only waste scarce Food and Drug Administration resources—they ignore the sovereignty of our trading partners around the world. Today's world marketplace demands that these barriers to U.S. global competitiveness be reformed.

A 1995 survey of U.S. medical device inventors and manufacturers by the Wilkerson Group showed that more than 90 percent of the firms surveyed planned to market new products overseas first. Ninety-eight percent of medical device companies in the U.S. are small businesses—employing fewer than 500 employees. These companies need to generate sales quickly in order to make appropriate returns to their startup investors, finance their manufacturing operations, and be able to afford the approval process in the United States which costs them a great deal in both time and money.

Although the 1986 Drug Export Act represented a good step forward, it has led to the development of a patchwork quilt of bureaucracy that has forced U.S. manufacturers to establish and maintain facilities outside the United States. At the same time, the law imposes time-consuming requirements on FDA, whose resources should be reprioritized to the review of new, lifesaving medicines and technologies for American patients. Offshore movement often begins with the relocation of clinical trials, closely followed by R&D, which is most efficient when done in conjunction with the medical professionals involved in the trials.

Within the device industry, 50 percent of established companies and 87 percent of startup ventures are moving their clinical trials to foreign countries. This means American patients not only are not receiving access to the most cutting-edge innovative medical products, but also are several generations behind in what products have been approved and are in common use. Clinical trials are also critical to the success of products developed by pharmaceutical companies, who generally expend millions of dollars on this phase of drug development.

In a time of unprecedented harmony in worldwide trade, as reflected by recent passage of GATT, our laws relating to the export of foods, drugs, medical devices, and cosmetics should reflect that comity as well. The rate of growth in the favorable balance of trade that the medical device industry in this country has historically seen is slowing dramatically. The average annual rate of growth in this industry was 26 percent in 1988-1992; it dropped to 11 percent in 1992-1994.

In addition, the increased competition from foreign competitors—as well as American firms who have moved part or all of their operations overseas, and are now foreign competitors as well—is being evidenced in patent activity. The United States has consistently held close to three-quarters of

the medical device patents granted in the United States, but foreign growth in this industry means that foreignowned companies now hold thousands of U.S. patents, not just hundreds.

The paternalistic approach evidenced in our current law is no longer compatible with today's world marketplace. In my view the original version of S. 593, which was introduced by Senator HATCH and co-sponsored by Senators KASSEBAUM, ABRAHAM, FRIST and COATS as well as myself, was a good approach. This would have allowed free export to any World Trade Organization [WTO] member nation, and export to non-WTO members with 30 days notice to the Secretary of HHS, who had the authority to stop exports destined to be imminent hazards to the public health of citizens overseas. Similar efforts were led by Representative FRED UPTON in the House; he introduced the companion bill H.R. 1300 with 24 cosponsors last summer.

However, in the spirit of bipartisanship, Senators HATCH, KASSEBAUM, and I. undertook an effort to try to work with Senator KENNEDY to create a revised bill. The version of this bill being considered here today embodies the resultant compromise. While I believe this legislation is still more restrictive than it should be, there is a real value to moving a good bill rather than gaining nothing. This export bill is good trade policy and is consistent with advancing the public health.

AMENDMENT NO. 3544

(Purpose: To provide for welfare reform in the State of Texas)

On page 577 line 14 of the committee substitute, insert:

'SEC. 213 If the Secretary fails to approve the application for waivers related to the Achieving Change for Texans, a comprehensive reform of the Texas Aid To Families With Dependent Children program designed to encourage work instead of welfare, a request under section 1115(a) of the social Security Act submitted by the Texas department of Human Services on September 30, 1995, by the date of enactment of this Act, notwithstanding the Secretary's authority to approve the applications under such section, the application shall be deemed approved.

AMENDMENT NO 3545

(Purpose: To remove regulatory impediments to community development) Section 223B of the amendment is amended

to read as follows:

SEC. 223B. Section 415 of the Department of Housing and Urban Development-Independent Agencies Appropriations Act, 1988 (Public Law 100-202; 101 Stat. 1329-213) is repealed effective the date of enactment of Public Law 104-19. The Secretary is authorized to demolish the structures identified in such section. The Secretary is also authorized to compensate those local governments which, due to this provision, expended local revenues demolishing the developments identified in such provision."

AMENDMENT NO. 3546

To the amendment numbered 3466: On page 406, line 8, strike "\$567,152,000" and insert in lieu thereof "\$567,753,000".

Mr. HATFIELD. Mr. President, I further ask unanimous consent that any statements relating to the amendments be placed in the RECORD at the appropriate place.

The PRESIDING OFFICER. Without

objection, it is so ordered.

Mr. HATFIELD. Mr. President, I ask for action on the adoption of the amendments en bloc.

The PRESIDING OFFICER. They have already been agreed to.

Mr. HATFIELD. I thank the Chair. Mr. DORGAN addressed the Chair. The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. Mr. President, I ask unanimous consent to speak for 15 minutes as in morning business. In making the request, I have spoken with the chairman of the Appropriations Committee. If someone comes to the floor with business on this piece of legislation, if they will simply signal me, I will relinquish the floor, because I think that should take precedence. If no one is on the floor to do business on the appropriations bill, I seek unanimous consent to speak for 15 minutes as in morning business.

The PRESIDING OFFICER. Without

objection, it is so ordered.

Mr. DORGAN. Mr. President, I wanted to come to the floor and speak about two pieces of legislation, one which I introduced last week and one which I will introduce next week, simply to alert my colleagues about what I intend to do with them.

Before I do, let me suggest that I think it is time for us to ask the President and the majority leaders and minority leaders of the House and the Senate to restart the budget negotiations and work to try to reach another

budget agreement.

As I was coming over here this morning, I was thinking about a young man from Jamestown, ND. I was thinking of this issue of the budget, and of trying and failing. We went through all of this last year. In fact, I was one of the two Senate Democratic negotiators, along with Senator Exon. We spent day after day in S-207, at the White House, in the Oval Office, in the Cabinet room. Those of us involved in the negotiations know we did not reach a conclusion. We did not settle on a plan to balance the budget in 7 years, but we should, we can, and we ought to.

I was thinking about the young man from Jamestown, ND, in this context as I came over this morning. He is a young man who attended a wonderful little grade school in Jamestown, and he dreamed of being an astronaut. He grew up to be a strapping, happy young

man named Rick Hieb.

He joined the program to become an astronaut, went to NASA, became an astronaut, and flew up in the space shuttle. I recall seeing Rick in Jamestown not only before he went up in the space shuttle, but also on television, as I sat on my living room couch, watching him and two of his fellow astronauts, who had flown in this mission with him

The mission was that they were to grab, I believe it was, an Intel satellite,

a 10,000-pound satellite that had malfunctioned. They were to grab this satellite in outer space and hold it with an arm they had constructed. They were going to repair this satellite—it had never been done before—traveling 16,000 miles an hour in weightlessness while trying to grab a 10,000-pound satellite.

Rick and his two colleagues went out. Something stuck on the apparatus, and they failed to grab the satellite. Do you know what the headlines were that night? The headlines were that "NASA Failed." "The Astronauts Failed." "The Mission Failed."

The next day, still orbiting in space, they tried again. They spent a couple of hours walking in space, trying to manipulate and maneuver to grab that satellite, and they failed again. And the second day the newspapers said, "NASA Mission Fails." "Astronauts Fail."

Then they spent some time trying to figure out how they could fix this problem, and they spent a day doing that. The next day, they went back out for a third time, and that is when many of us watched them on live television, I think, for about 4 hours, as they orbited around the Earth working this mechanism to grab the Intel satellite and fix the satellite. And they did it.

What they did was something that they had never before rehearsed, they had never planned and they had never done before. But they went out a third time and risked failure because they wanted to succeed.

Rick came to my office some time later. I asked how tough it was to try to do something in space that they had never even practiced. He said, "The shame would have been not to try." There is no shame in trying and failing. The shame is in failing to try, and they went out and failed twice and the world heard that they had failed. The third time they went out and did something no one expected they could do, and they succeeded.

It is not just astronauts in space with the courage and bravery of Rick Hieb and his colleagues who ought to understand the message that the shame is if you fail to try.

Last year, we did not get a budget agreement. The fact is, we ought not quit, we ought to try again. Now is the time for us to try to reach a budget agreement.

We have a circumstance in which the majority leader is running for President. The President is running for relection. We have a very unique political circumstance in this country. It will probably make it a little difficult to deal with the budget issue. But that does not mean we should not continue to try. It is time to restart the budget negotiations, and it is time for us to succeed in developing a plan for a balanced budget in the interest of this country.

Mr. President, let me ask unanimous consent to proceed for as much time as I consume in morning business.

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

Mr. DORGAN. Mr. President, I was speaking about the negotiations to try to reach some kind of a balanced budget plan. I know there has been a lot of windmilling of the arms and gnashing of the teeth and wringing of the hands. There has been a lot of huffing and puffing on both sides of the aisle about the budget deficit and about who is at fault for not reaching a plan of some type to deal with the budget deficit. But the plain fact is, both sides, it seems to me, have something to contribute.

I have said on the floor that the Republicans, I think, need to be commended. The Republicans have said to us, this is something we must do. They have continued to apply pressure that we reach some kind of a solution. That, I think, serves this country's interests. The Democrats also serve this country's interests by saying, yes, let us do that, but let us do it the right way. Just doing it, if you do it the wrong way, can be terribly destructive to this country.

The choices on spending, which is what we are really talking about when we balance the budget, are critically important. Some came to the floor of the Senate and said, "We have a deal for you. Let us cut Star Schools by 40 percent and let us increase spending on star wars by 100 percent."

I do not know what air they breathe. but that does not seem like very clear thinking to me. So the method by which we balance the budget is critically important. How many people do vou want to kick out of the Head Start Program? That is a program that really works and helps children. How many kids do you want to tell, "You no longer have an entitlement to have a hot lunch at school. You come from a poor family, but we decide you have no longer an entitlement to have a hot lunch at school in the middle of the day." How many people want to tell poor children that in this country? Some do, because that has been the proposal.

My point is, we should balance the budget, but we should do it with the right priorities. But, most of all, I think it is time for the President and the Members of the Congress to understand now is the time to try again. If we simply take the lower of the figures on spending cuts offered during this negotiations, the lower of the figures from either party, it adds up to over \$700 billion in spending cuts and adds up to the kind of spending cuts that will reach a balanced budget in the year 2002.

So, it is not a case of not having the will to get there. It is a case of not agreeing to the menu of the spending cuts. It is time to try again. It is time for the President and Members of Congress to sit down, restart the negotiations, and solve this problem.

As I said, before I relinquish the floor, we have a very unique cir-

cumstance facing us. We have a majority leader here in the Senate running for President. We have a President down at the other end of Pennsylvania Avenue who wants to keep his job. A lot of what is going to go on this year, I assume, will have a substantial amount of political overtones.

But there ought not be, it seems to me, a political judgment in this country that says balancing the budget is not important. It is important. It is the right thing to do, and it ought to be done the right way. I think the President and leaders of Congress have an obligation to restart these negotiations, restart them now, and continue budget negotiations until we finalize a plan and agree to a plan to reach a balanced budget. The American people deserve that and this country deserves that

THE TRADE DEFICIT AND JOBS IN OUR COUNTRY

Mr. DORGAN. Mr. President, I want to just speak briefly about two issues. One is a jobs issue and the other is a crime issue. Both, I think, are important to this country. I introduced a bill on one subject last week, and I am going to introduce a bill on the other next week. I just talked about the budget deficit. That has been coming down some in recent years. It is still too high, but it has been coming down.

Nobody talks about the trade deficit. The trade deficit has been going up. Last year was a record. The fact is the trade deficit goes up because we are exporting manufacturing jobs out of this country. It means fewer jobs and fewer opportunities and less income for too many of the American people who need a good job with good income.

How do we deal with the jobs issue? I do not have all the answers. I know we have to deal with the trade deficit. Nobody here talks about it. The trade deficit is going to be repaid ultimately with a lower standard of living in this country. So we have to deal with that.

One thing we ought to do, just for starters, relates to a bill I introduced in the Senate last week. It is very simple. The bill simply says, let us stop providing tax loopholes or tax incentives for those people who move their plants and their jobs overseas. I bet there are not many people here who know that is what goes on in this country.

We have in our Tax Code in this country a provision that says, if you have a manufacturing plant in America, and you have 100 jobs or 1,000 jobs or 10,000 jobs in America, we will give you a deal, you close up that plant, fire those workers, move them overseas, and you get a tax break. You get a tax break

You get two plants sitting side by side across the street from each other, and they make the same product, hire the same number of workers, and one of them closes up and moves overseas and the other one stays here. Guess