intervening action or debate, and that any statements relating to this measure be printed in the RECORD.

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

The committee amendment in the nature of a substitute was agreed to.

The title amendment was agreed to.

The bill (S. 2936), as amended, was read a third time and passed.

IMPROPER PAYMENTS REDUCTION ACT OF 2002

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of calendar No. 727, H.R. 4878.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 4878) to provide for estimates and reports of improper payments by Federal agencies.

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Governmental Affairs, with an amendment.

[Strike the part shown in black brackets and insert the part shown in italic.]

H.R. 4878

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

[SECTION 1. SHORT TITLE.

[This Act may be cited as the ''Improper Payments Information Act of 2002''.

[SEC. 2. ESTIMATES OF IMPROPER PAYMENTS AND REPORTS ON ACTIONS TO REDUCE THEM.

[(a) IDENTIFICATION OF SUSCEPTIBLE PROGRAMS AND ACTIVITIES.—The head of each agency shall, in accordance with guidance prescribed by the Director of the Office of Management and Budget, annually review all programs and activities that it administers and identify all such programs and activities that may be susceptible to significant improper payments.

[(b) ESTIMATION OF IMPROPER PAYMENT.—With respect to each program and activity identified under subsection (a), the head of the agency concerned shall—

[(1) estimate the annual amount of improper payments; and

[(2) include that estimate in its annual budget submission.

[(c) REPORTS ON ACTIONS TO REDUCE IMPROPER PAYMENTS.—With respect to any program or activity of an agency with estimated improper payments under subsection (b) that exceed one percent of the total program or activity budget or $1,000,000 annually (whichever is less), the head of the agency shall provide with the estimate under subsection (b) a report on what actions the agency is taking to reduce the improper payments, including—

[(1) a statement of whether the agency has the information systems and other infrastructure it needs in order to reduce improper payments to minimal cost-effective levels;

[(2) if the agency does not have such systems and infrastructure, a description of the resources the agency has requested in its budget submission to obtain the necessary information systems and infrastructure; and

[(3) a description of the steps the agency has taken to ensure that agency managers (including the agency head) are held accountable for reducing improper payments.

[(d) DEFINITIONS.—For the purposes of this section:

[(1) AGENCY.—The term ''agency'' means an executive agency, as that term is defined in section 102 of title 31, United States Code.

[(2) IMPROPER PAYMENT.—The term ''improper payment''—

[(A) means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and

[(B) includes any payment to an ineligible recipient, any payment for an ineligible service, any duplicate payment, payments for services not received, and any payment that does not account for credit for applicable discounts.

[(3) PAYMENT.—The term ''payment'' means any payment (including a commitment for future payment, such as a loan guarantee) that is—

[(A) made by a Federal agency, a Federal contractor, or a governmental or other organization administering a Federal program or activity; and

[(B) derived from Federal funds or other Federal resources or that will be reimbursed from Federal funds or other Federal resources.

[(e) APPLICATION.—This section—

[(1) applies with respect to the administration of programs, and improper payments under programs, in fiscal years after fiscal year 2002; and

[(2) requires the inclusion of estimates under subsection (b)(2) only in annual budget submissions for fiscal years after fiscal year 2003.

[(f) GUIDANCE BY THE OFFICE OF MANAGEMENT AND BUDGET.—The Director of the Office of Management and Budget shall prescribe guidance to implement the requirements of this section.]

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improper Payments Information Act of 2002''.

SEC. 2. ESTIMATES OF IMPROPER PAYMENTS AND REPORTS ON ACTIONS TO REDUCE THEM.

(a) IDENTIFICATION OF SUSCEPTIBLE PROGRAMS AND ACTIVITIES.—The head of each agency shall, in accordance with guidance prescribed by the Director of the Office of Management and Budget, annually review all programs and activities that it administers and identify all such programs and activities that may be susceptible to significant improper payments.

(b) ESTIMATION OF IMPROPER PAYMENT.—With respect to each program and activity identified under subsection (a), the head of the agency concerned shall—

(1) estimate the annual amount of improper payments; and

(2) submit those estimates to Congress before March 31 of the following applicable year, with all agencies using the same method of reporting, as determined by the Director of the Office of Management and Budget.

(c) REPORTS ON ACTIONS TO REDUCE IMPROPER PAYMENTS.—With respect to any program or activity of an agency with estimated improper payments under subsection (b) that exceed $10,000,000, the head of the agency shall provide with the estimate under subsection (b) a report on what actions the agency is taking to reduce the improper payments, including—

(1) a discussion of the causes of the improper payments identified, actions taken to correct those causes, and results of the actions taken to address those causes;

(2) a statement of whether the agency has the information systems and other infrastructure it needs in order to reduce improper payments to minimal cost-effective levels;

(3) if the agency does not have such systems and infrastructure, a description of the resources the agency has requested in its budget submission to obtain the necessary information systems and infrastructure; and

(4) a description of the steps the agency has taken to ensure that agency managers (including the agency head) are held accountable for reducing improper payments.

(d) DEFINITIONS.—For the purposes of this section:

(1) AGENCY.—The term ''agency'' means an executive agency, as that term is defined in section 102 of title 31, United States Code.

(2) IMPROPER PAYMENT.—The term ''improper payment''—

(A) means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and

(B) includes any payment to an ineligible recipient, any payment for an ineligible service, any duplicate payment, payments for services not received, and any payment that does not account for credit for applicable discounts.

(3) PAYMENT.—The term ''payment'' means any payment (including a commitment for future payment, such as a loan guarantee) that is—

(A) made by a Federal agency, a Federal contractor, or a governmental or other organization administering a Federal program or activity; and

(B) derived from Federal funds or other Federal resources or that will be reimbursed from Federal funds or other Federal resources.

(e) APPLICATION.—This section—

(1) applies with respect to the administration of programs, and improper payments under programs, in fiscal years after fiscal year 2002; and

(2) requires the inclusion of estimates under subsection (b)(2) only in annual budget submissions for fiscal years after fiscal year 2003.

(f) GUIDANCE BY THE OFFICE OF MANAGEMENT AND BUDGET.—Not later than 6 months after the date of enactment of this Act, the Director of the Office of Management and Budget shall prescribe guidance to implement the requirements of this section.

Mr. REID. Mr. President, I ask unanimous consent that the committee substitute be agreed to, the bill, as amended, be read a third time and passed, the motion to reconsider be laid upon the table, with no intervening action or debate, and that any statements relating to the measure be printed in the RECORD.

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

The committee amendment in the nature of a substitute was agreed to.

The bill (H.R. 4878), as amended, was read a third time and passed.

THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

Mr. REID. Mr. President, I ask unanimous consent the Senate proceed to the consideration of H.R. 5651.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 5651) to amend the Federal Food, Drug and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Mr. KENNEDY. Mr. President, I am pleased to support passage of H.R. 5651, ''The Medical Device User Fee and

Modernization Act of 2002.'' Just as passage of a user-fee program was a breakthrough in the regulation of critical prescription drugs, this legislation is a breakthrough in regulation of lifesaving medical devices, devices that can open blocked arteries, keep hearts beating, save the lives of stroke patients, and diagnose deadly cancers in time for effective treatment.

Currently, because FDA lacks adequate resources, too many critical devices are unnecessarily slowed in their progress to patients' bedsides by the regulatory process. At the same time, careful FDA oversight is essential to assure that patients not suffer serious injury or even lose their lives because of devices which are unsafe or ineffective.

By assessing a modest fee on device manufacturers, raising the level of appropriated funds, and setting ambitious performance targets for the FDA, this bill is just what the doctor ordered to speed life-saving devices to the market while protecting the public health.

The goal of establishing a user-fee program for medical devices is one that I have pursued for more than a decade. I am gratified that this legislation finally brings that goal to fruition. It will mean life and hope for thousands of patients each year.

The legislation also improves regulation of potentially faulty and harmful reprocessed devices. Patients deserve to know that the devices that are used in their medical treatment are safe and effective, whether they are being used for the first time or whether they are being reused.

The legislation provides for a new regime of third party inspections for device manufacturers who manufacture products for both the United States and export. This regime will reduce duplicative inspections, while assuring that FDA remains the final arbiter and safety check on the quality of the manufacturing process for medical devices.

For many years, the FDA's Center for devices and Radiological Health, CDRH, has needed additional funding and staff to better assure the safety and effectiveness of new and innovative medical technologies. As the coauthor of the Medical device User Fee Act of 1994, I have long advocated medical device user fees and I am proud that we have finally secured such funding through a fair and efficient system of user fees.

This legislation will provide great benefits to patient health and safety. I am confident that these fees will assure greater certainty for consumers and manufacturers that the FDA can meet its statutory responsibilities for the timely and thorough review of medical devices.

Under Federal law, medical devices must be reviewed by the FDA prior to marketing. These reviews must be completed in accordance with ambitious statutory timeframes. While the FDA has done an excellent job of reviewing lower risk devices in a timely manner, it has frequently lacked the resources and staff to achieve similar success with the most sophisticated devices, which require premarket approval.

Under this legislation, device companies will pay the FDA fees for the application they submit for review. These fees will raise nearly $150 million over the next 5 years. The legislation also calls for tens of millions of dollars in newly appropriated funding for the FDA's device center.

These funds will be devoted to reviewing device applications and to assuring the post-market safety of devices. I am pleased that the legislation authorizes an additional $3 million in fiscal year 2003 and $6 million in fiscal year 2004 for the post-market surveillance of medical devices.

I want to acknowledge the contributions of Senator HATCH in ensuring that the user fees are fair and equitable to small businesses and startup companies.

The user-fee program will sunset after 5 years, allowing Congress to review whether it has expedited the review of devices and whether improvements are needed to better assure public health and safety.

In addition to medical device user fees, the legislation strengthens the FDA's regulation of reprocessed devices. I believe that the American people will greatly benefit from the new requirements for substantial equivalence determinations and premarket approvals of such devices. I am particularly pleased that there are robust requirements for the assurance of safety and effectiveness of any reprocessed class III devices, such as angioplasty balloons or heart valves.

Finally, the legislation authorizes a 10-year program for third-party inspections of device manufacturing plants. This will enable FDA to better target its enforcement resources—resources that we also increase in the legislation. To ensure that third parties operate appropriately, the bill places important controls over conflicts of interest and places third parties at risk of significant civil monetary, criminal, and debarment penalties, if they act in a manner inconsistent with public health and safety.

Moreover, the bill limits inspections to plants which manufacture devices for export, and ensures that FDA conduct every third inspection before additional third-party inspections take place.

Let me acknowledge the important work of Congressmen TAUZIN, DINGELL, GREENWOOD, Congresswoman ESHOO, and Senator GREGG, the ranking member of the Committee on Health, Education, Labor, and Pensions, in drafting this legislation. I also want to acknowledge the leadership role played by Senator WELLSTONE in moving this legislation through the Senate, and by Senator DURBIN in enduring strong protections over reprocessed devices.

I would like to thank FDA Deputy Commissioner Lester Crawford, Associate Commissioner Peggy Dotzell, Associate Commissioner Amit Sachdev, Center for Devices Director David Feigel, Linda Kahan, and Frank Claunts.

I want to recognize the hard work and dedication of Michael Myers, David Nexon, David Dorsey, and Paul Kim on my staff, as well as Vince Ventimiglia with Senator GREGG, Pat Morrisey, and Brent Delmonte with Congressman TAUZIN, and John Ford and David Nelson with Congressman DINGELL.

Let me also recognize the contributions of Patti Unruh and Richard McKeon with Senator WELLSTONE, Lisa German and Daborah Wolf with Senator JACK REED, Adam Gluck with Senator HARKIN, Deborah Barrett and Stephanie Sikora with Senator DODD, Christina Ho with Senator CLINTON, Rhonda Richards with Senator MIKULSKI, Anne Grady with Senator MURRAY, Dean Rosen with Senator FRIST, Anne Marie Murphy with Senator DURBIN, Bruce Artim and Trisha Knight with Senator HATCH, Karen Nelson and Ann Witt with Congressman WAXMAN, and Steve Tilton with Congressman BILIRAKIS.

I ask my colleagues to join me in supporting passage of H.R. 5651, ''The Medical Device User Fee and Modernization Act of 2002.''

Mr. GREGG. Mr. President, I would like to make a few comments concerning the Medical Device User Fee and Modernization Act of 2002, which was passed by both the House and Senate earlier this morning.

This legislation was the product of a tremendous amount of hard work—from folks in both Chambers and on both sides of the aisle—and includes the most significant improvements in the way medical devices are reviewed and regulated, arguably since 1976.

More importantly, these changes will have a very positive and lasting impact on both patients and consumers.

The legislation accomplishes this in several ways:

User Fees: First, it ensures adequate resources for the Food and Drug Administration (FDA), by creating a new user-fee program, modeled after the one used to review drugs and biologics—which has been incredibly successful.

FDA resources at the device center have dramatically declined in the last 10 years, resulting in significant staff turn-over (as high as 10%) and increased review times (more than 400 days per submission when the statute requires reviews of 180 days).

By charging manufacturers a reasonable fee for reviewing their products, FDA can hire more staff, meet review deadlines, and ensure that patients have timely access to the newest, most innovative medical technologies. I particularly want to thank my friend from Utah, Senator HATCH, for his work on this issue.

Moreover, in order to protect some of the smaller companies—including a substantial number in New Hampshire—the bill in many cases exempt or significantly reduce these fees.

Re-Use: Second, the legislation provides greater protection to patients from reused and reprocessed medical devices. The bill ensures that medical devices—especially some of the more delicate, high risk products, such as angioplasty balloons—are not used over and over again on different patients without first demonstrating that this can be done safely and reliably.

On that note, I would especially like to thank Senator DURBIN for his invaluable assistance in working with us to craft this very important provision. I believe that it will save a great many lives. The legislation that he and I worked on this summer and have introduced separately today represents the foundation for the final product included in this bill.

Third-Party Inspections: Third, it increases the frequency and quality of inspections of medical device manufacturing facilities—both here and abroad—by allowing inspections from FDA-accredited third-parties.

On average, the FDA is currently able to inspect a U.S. facility only once every 7 years, and foreign facilities once every 11 years. This is unacceptable and in direct contravention to the current statutory requirement for inspections every 2 years.

By augmenting FDA's inspection capabilities, we will help ensure that these medical devices are being manufactured in accordance with established manufacturing practices.

Modernizing FDA: Finally, the bill brings FDA regulation into the 21st century, by instituting electronic labeling, electronic registration, and modular reviews of applications. It also establishes a more effective review process for the fastest wave of innovative combination biotechnologies, including drug and biologics coated stents, drug pumps, and engineered tissues.

Working together, these changes will give FDA the tools it needs to work more effectively, and to get the next generation of life-saving medical devices into the hands of doctors and patients more quickly than ever before.

I am also pleased to report that this legislation is widely supported by the administration, FDA, patient/consumer groups, industry, and provider/hospital groups.

I am proud of what we have been able to accomplish here today and believe that this legislation will have a tremendous positive impact on people's lives as they enjoy the benefits of today and tomorrow's medical technology.

Mr. DODD. Mr. President, I would like to applaud my colleagues in both the House and the Senate, particularly Congressman BILLY TAUZIN, Congressman JOHN DINGELL, Senator JUDD GREGG, and Senator TED KENNEDY, for reaching a compromise on this important legislation. I know that there were several difficult issues to be negotiated, and I am pleased that we were able to reach a bipartisan agreement before the end of this Congress.

I support this legislation because, first and foremost, it could increase the quality of patient care. At the same time, it will also prove beneficial to the manufacturers who make these devices, and the hospitals and health care providers that use them. By creating a system of user fees for FDA approval of medical devices, we are ensuring that life-improving and life-saving technologies will be available on the market in a more efficient and timely manner. Put more simply, this bill could save lives. In creating a user fee structure, we are expanding a model that has already proven dramatically successful in the prescription drug market.

This bill will also have a positive impact on patient safety by expanding FDA regulation of the medical device reprocessing industry. Device reprocessing can certainly be beneficial when used appropriately. There are environmental benefits, as well as cost savings for hospitals. However, we must ensure that patient safety is not sacrificed. This legislation will do that by providing us with a better understanding of the impact that reprocessing has on the safety and efficacy of devices, and allowing the FDA to prevent the reprocessing of devices when safety is in question.

Again, I thank my colleagues for working so diligently to come to this agreement, and I proudly support this legislation.

HEALTH CARE SAFETY NET AMENDMENTS ACT

Mr. FRIST. Mr. President, I am pleased to speak today on behalf of the Health Care Safety Net Amendments Act, which passed the House of Representatives by a wide margin earlier this week. I urge my colleagues to support this critical bill. This legislation represents an important next step towards improving the quality and availability of health care services for our nation's uninsured and medically underserved.

This critical legislation strengthens our Nation's health care safety net and is vital to helping millions of uninsured Americans get the health care they need. Far too many Americans lack health insurance today. We must tackle this problem head on to reduce the number of people who are not receiving care. This bill takes important steps to expand access to care and responds to the challenges providers, particularly our community health centers, face.

The Health Care Safety Net Amendments Act reauthorizes the Consolidated Health Center program, the National Health Service Corps and the rural health outreach and telehealth grant programs, and establishes the Healthy Communities Access Program. Together, these programs represent our first line of defense in providing health care to the nation's uninsured and underserved. The bill increases funding for these programs, expands access to health centers, improves existing health infrastructures and takes steps to improve the recruitment and retention of health professionals in underserved areas.

A key component of the bill is an increase in funding for the Consolidated Health Centers program, providing more than $1.3 billion for this program. This increase further demonstrates the commitment to this program, which today serves more than 9 million people each year. This is critical to achieving President Bush's goal of doubling the number of community health centers across America.

In 1996, the Health Centers Consolidation Act reauthorized the community health centers, the migrant health centers, health centers for the homeless, and health centers for residents of public housing until 2001. Today, our nation's health centers face difficult environmental and operational challenges. Not only do they serve a significant number of uninsured and increasing numbers of immigrants, but health centers are also affected by aging facilities and difficulties in recruitment, retention, and retraining of health center leadership. Today's legislation responds to those difficulties in order to reinforce the important work being done by our Nation's health centers.

The bill also expands and strengthens the National Health Service Corps, a program that has placed over 20,000 health care providers in health professional shortage areas in the last 30 years. Presently, over 4 million people currently receive care from National Health Service Corps clinicians. However, to help communities meet their basic health care needs, more clinicians are needed in these areas. The legislation improves recruitment and retention of health care professionals through expanded use of scholarship and loan repayment programs and added flexibility for local communities.

Finally, data indicates that uninsured individuals receive most of their care from private health care providers and that private hospitals bear over 60 percent of the costs of uncompensated care; and private, office-based physicians provide more than 75 percent of the ambulatory care for uninsured patients with Medicaid coverage. Given this, today's bill takes into account safety net providers other than those supported by Consolidated Health Centers and the National Health Service Corp, such as local hospitals and emergency room departments, public health departments, home health agencies, and many other health care organizations, through the establishment of the Healthy Communities Access Program that seeks to integrate all of the safety net providers within a community.

I appreciate the hard work and dedication to this issue among my colleagues, including Senators KENNEDY, GREGG and BOND and Representatives TAUZIN, DINGELL, BILIRAKIS and BROWN. I also appreciate the hard work of my