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

staff, Shana Christrup, Craig Burton and Dean Rosen, on this important bill.

Mr. REED. Mr. President, I rise to express my reservations with the Medical Device User Fee and Modernization Act of 2002. While the legislation offers some improvements to the current medical device approval and regulation process, I have serious concerns about some aspects of the bill and about the process leading to its impending passage in the Senate.

User fees will allow the Food and Drug Administration, FDA, to expedite the review and approval of medical devices, resulting in faster patient access to new and potentially lifesaving technologies. Third party inspections similarly have the potential to enhance the agency's ability to ensure that manufacturing sites are meeting FDA quality standards for device production. And regulating the reprocessing of single use devices should be a positive step for the safe use of these devices. All of these elements of the legislation, however, carry significant potential risk. In our attempts to enhance the efficiency of an agency to which we are not able to give adequate appropriations, we run the risk of undermining FDA's scientific and policy authority and its vital public health mission.

It will be up to the Senate Health, Education, Labor and Pensions Committee, of which I am a member, to pay close attention to the health and safety implications of these provisions as they are implemented. As part of that ongoing oversight, the committee should review and evaluate the manner in which the bill was written and passed. While I understand the importance of this legislation, I am deeply troubled by the lack of a formal process in its development and consideration. I assure you and my colleagues that I will be paying close attention as these new provisions are implemented in the coming months, and I urge my colleagues to do likewise to protect the public health and maintain the vital mission of the FDA.

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

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

The bill (H.R. 5651) was read a third time and passed.

HEALTH CARE SAFETY NET AMENDMENTS OF 2002

Mr. REID. Mr. President, I ask the Chair lay before the Senate a message from the House of Representatives on the bill, S. 1553, to amend the Public Health Service Act to reauthorize and strengthen the health centers program and the National Health Service Corps, and to establish the Healthy Communities Access Program, which will help coordinate services for the uninsured and underinsured, and for other purposes.

The PRESIDING OFFICER laid before the Senate the following message from the House of Representatives:

Amendment:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Health Care Safety Net Amendments of 2002''.

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

TITLE I—CONSOLIDATED HEALTH CENTER PROGRAM AMENDMENTS

SEC. 101. HEALTH CENTERS.

Section 330 of the Public Health Service Act (42 U.S.C. 254b) is amended—

(1) in subsection (b)(1)(A)—

(A) in clause (i)(III)(bb), by striking ''screening for breast and cervical cancer'' and inserting ''appropriate cancer screening'';

(B) in clause (ii), by inserting ''(including specialty referral when medically indicated)'' after ''medical services''; and

(C) in clause (iii), by inserting ''housing,'' after ''social,'';

(2) in subsection (b)(2)—

(A) in subparagraph (A)(i), by striking ''associated with water supply;'' and inserting the following: ''associated with—

''(I) water supply;

''(II) chemical and pesticide exposures;

''(III) air quality; or

''(IV) exposure to lead;'';

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

(C) by inserting before subparagraph (C) (as so redesignated by subparagraph (B)) the following:

''(A) behavioral and mental health and substance abuse services;

''(B) recuperative care services;'';

(D) in subparagraph (B)—

(3) in subsection (c)(1)—

(A) in subparagraph (B)—

(i) in the heading, by striking ''COMPREHENSIVE SERVICE DELIVERY'' and inserting ''MANAGED CARE'';

(ii) in the matter preceding clause (i), by striking ''network or plan'' and all that follows to the period and inserting ''managed care network or plan.''; and

(iii) in the matter following clause (ii), by striking ''Any such grant may include'' and all that follows through the period; and

(B) by adding at the end the following:

''(C) PRACTICE MANAGEMENT NETWORKS.—The Secretary may make grants to health centers that receive assistance under this section to enable the centers to plan and develop practice management networks that will enable the centers to—

''(i) reduce costs associated with the provision of health care services;

''(ii) improve access to, and availability of, health care services provided to individuals served by the centers;

''(iii) enhance the quality and coordination of health care services; or

''(iv) improve the health status of communities.

''(D) USE OF FUNDS.—The activities for which a grant may be made under subparagraph (B) or (C) may include the purchase or lease of equipment, which may include data and information systems (including paying for the costs of amortizing the principal of, and paying the interest on, loans for equipment), the provision of training and technical assistance related to the provision of health care services on a prepaid basis or under another managed care arrangement, and other activities that promote the development of practice management or managed care networks and plans.'';

(4) in subsection (d)—

(A) by striking the subsection heading and inserting ''LOAN GUARANTEE PROGRAM.—'';

(B) in paragraph (1)—

(i) in subparagraph (A), by striking ''the principal and interest on loans'' and all that follows through the period and inserting ''up to 90 percent of the principal and interest on loans made by non-Federal lenders to health centers, funded under this section, for the costs of developing and operating managed care networks or plans described in subsection (c)(1)(B), or practice management networks described in subsection (c)(1)(C).'';

(ii) in subparagraph (B)—

(I) in clause (i), by striking ''or'';

(II) in clause (ii), by striking the period and inserting ''; or''; and

(III) by adding at the end the following:

''(iii) to refinance an existing loan (as of the date of refinancing) to the center or centers, if the Secretary determines—