

I reserve the remainder of my time.

Mr. REID. Mr. President, will the Senator yield any time he has remaining?

Mr. KENNEDY. Yes. I yield such time as remains to the Senator from Nevada.

Mr. REID. Mr. President, if there is no Republican seeking recognition, 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. REID. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

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

Mr. REID. Mr. President, we will make arrangements with Senator SNOWE, who wishes to speak. She has time. The Republicans want her to use it; and we want her to use it, too. But in the meantime, we have Senator KENNEDY here.

I ask we go to the next matter, which is, by virtue of the unanimous consent agreement, now before us.

#### PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002—CONFERENCE REPORT

The PRESIDING OFFICER. Under the previous order, the clerk will report the conference report.

The assistant legislative clerk read as follows:

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 3448), to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies, having met, have agreed that the House recede from its disagreement to the amendment of the Senate and agree to the same with an amendment, and the Senate agree to the same, signed by all conferees on the part of both Houses.

The Senate proceeded to the consideration of the conference report.

(The conference report is printed in the House proceedings of the RECORD of May 21, 2002, on page H2691.)

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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 President, I ask unanimous consent the order for the quorum call be rescinded.

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

Mr. REID. Mr. President, I ask unanimous consent that the time for the quorum I suggest be charged evenly to both sides.

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

Mr. REID. I suggest the absence of a quorum.

The PRESIDING OFFICER. Without objection, the clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. KENNEDY. Mr. President, as I understand, there is an hour and a half evenly divided; am I correct?

The PRESIDING OFFICER. The Senator is correct.

Mr. KENNEDY. I yield myself such time as I might use.

Mr. President, today, the Senate considers historic legislation to enhance the Nation's preparedness for bioterrorism. This legislation has benefitted from the leadership of many Members of Congress on both sides of the aisle and on both sides of the Capitol. I thank all of our colleagues who have made such important contributions to this legislation. In particular, I commend my fellow conferees for their dedicated and effective leadership on this issue in the conference committee on this legislation. Under the skillful and effective leadership of our conference chairman, Representative BILLY TAUZIN, the conferees and their staffs have worked tirelessly to ensure that this legislation was completed in a timely manner, and I thank them for their efforts.

Our conference has reported legislation that will provide a historic \$4.6 billion investment to prepare the Nation to respond effectively to bioterrorism. This is the single greatest investment our Nation has ever made in public health.

Many members of the public had never heard of the word "bioterrorism" before the anthrax attacks of last fall showed us all how chillingly vulnerable we are to this new form of terrorist attack. But bioterrorism was a challenge that our committee had addressed long before the terrible events of September 11 and the anthrax attacks of October.

In 1998, my colleague, Senator BILL FRIST, and I began to assess the Nation's preparedness for the new challenge of bioterrorism. We learned of the terrible loss of life that could result from a major attack using anthrax, Ebola, smallpox or some other deadly biological weapon. In the Armed Services Committee, my colleagues and I learned that biological weapons engineers in the former Soviet Union had conducted chilling experiments to make these already deadly pathogens yet more lethal through genetic engineering.

Our committee learned that our Nation's preparedness for the threat of bioterrorism was dangerously inadequate. Supplies of vaccine against smallpox were decades old and insufficient to protect the entire US population. We also learned that more and more germs were becoming resistant to the antibiotics doctors rely on to treat dangerous infections. The Nation's public health agencies were underfunded and understaffed. Rapid commu-

nication of information about dangerous disease outbreaks is an essential part of a national bioterrorism response yet many public health agencies lacked equipment as basic as a fax machine or an e-mail account.

To address these grave deficiencies in our Nation's response to bioterrorism and other public health emergencies, Senator FRIST and I—together with many of our colleagues in the Senate—introduced The Public Health Threats and Emergencies Act of 2000. Congress approved this legislation later that year.

The act was the basis for the infusion of needed resources that were provided to help prepare for bioterrorism in the supplemental appropriation at the end of last year. I commend my colleagues on the Appropriations subcommittees, Senator HARKIN, Senator INOUE and Senator SPECTER, and our distinguished chairman and ranking member of the Appropriations Committee, Senator BYRD and Senator STEVENS, for their vision and leadership in recognizing the needs of the Nation for bioterrorism preparedness, and for providing the funds that will help our Nation prepare for this threat. I look forward to working with these distinguished colleagues on our supplemental appropriation and on funding for the initiatives authorized in the conference report for fiscal year 2003.

I wish I could say that all the deficiencies that Senator FRIST and I learned about in 1998 have been put right. Sadly, I cannot. But we have made a good start. Public health and laboratory personnel have received intensive training in identifying biological weapons. The laboratory technicians who identified the cause of the mysterious illnesses in Florida as anthrax had recently received such training. Without that preparation, it is impossible to know how long the anthrax attack would have gone undetected.

Our legislation authorized rebuilding of CDC's dilapidated and obsolete facilities in Atlanta. In 1998, we found that the laboratories and facilities of the CDC were in a shocking state of disrepair. Ceilings leaked onto sensitive equipment. Offices were scattered across Atlanta, requiring scientists to spend time fighting traffic when they should be fighting disease. Our legislation authorizes the funds needed to complete the CDC's building plan.

No Member of this body has been a more forceful and dedicated advocate for the CDC than my good friend, Senator MAX CLELAND. He has spared no effort in his determination to enhance the ability of CDC to improve the health of every American. He was one of the original sponsors of the legislation the Congress enacted 2 years ago to improve the CDC, and his leadership has been indispensable in including provisions to enhance CDC in the conference report. His vision and leadership has enabled CDC to become a magnet for new health care companies in

Atlanta, and he has been a guiding force in the development of a new business park. Through these tireless efforts, CDC has contributed not only to the Nation's health, but to the economy and prosperity of Atlanta and the entire State of Georgia. Senator CLELAND's leadership has been instrumental in adding over \$300 million for CDC facilities to the supplemental appropriation.

Public health agencies have received new funds to invest in better training, improved laboratory equipment and modern communications technology. Medical researchers are using the tools of this new century of the life sciences to discover better ways to prevent or cure deadly infections.

We have come a long way since 1998, but we still have far to go. Too many communities are still underprepared for bioterrorism. Too many hospitals—crippled by savage cutbacks in their funding under Medicare and Medicaid—cannot make the investments needed to prepare for bioterrorism. Too many Americans are still at risk.

The conference report that the Senate is considering today expands and extends the legislation approved 2 years ago so that we can build on the progress we began in 1998.

The keys to responding effectively to a bioterrorist attack lie in three concepts: detection, treatment, and containment.

Detecting an attack is the key to containing it. Initiatives authorized in the conference report will improve the training of doctors to recognize the symptoms of a bioterrorist attack, so that precious hours will not be lost as doctors try to diagnose their patients. The report will accelerate development of new methods for disease surveillance, using modern information technology to provide real-time reporting of disease outbreaks. The report will also provide public health laboratories with the training, the equipment, and the personnel needed to identify biological weapons as quickly as possible.

Once an attack has been identified, we must have adequate medical supplies to contain it and treat its victims. The conference report requires the production of enough doses of smallpox vaccine to meet the needs of every American, so that the Nation will be protected if our enemies ever unleash this ancient plague. The legislation also enhances Federal stockpiles of pharmaceuticals, vaccines and other medical supplies that can be brought to the aid of communities affected by terrorism, as was done by Secretary Thompson so swiftly and effectively in the terrible aftermath of the attacks on New York and the Pentagon.

Bioterrorism is a threat to the entire Nation and it demands a national response. Our legislation authorizes \$1.6 billion in grants to states to enhance bioterrorism preparedness in every state in the nation. The conference report also sets aside \$520 million to enhance hospital preparedness for bioter-

rorism. Since bioterrorism will affect entire communities, our legislation encourages hospital planning to be integrated with community-wide planning by funding partnerships between hospitals and state or local governments. Our legislation also includes a proposal made by my friend, Representative ED MARKEY, to provide needed medications to communities living in the shadow of nuclear power plants.

The report will enhance preparedness for bioterrorism at the national, state and local levels. Because of the initiatives we approve today, American families can go to sleep tonight knowing that their security will be enhanced.

Title II of the conference report provides important, new protections against the misuse of dangerous pathogens like anthrax. These provisions are a decisive step forward for the security of our country. Once implemented, they will assure greater certainty over the possession and use of the substances which cause anthrax, plague and botulism.

Ever since the attacks using anthrax in the fall, our country has been trying to figure out how this could have happened. And we have learned that we don't even know who possesses anthrax in the United States. In response, and through the leadership of Senators FEINSTEIN, HARKIN, and DURBIN, we've added significant new authority for the CDC and the Department of Agriculture to oversee the possession of anthrax and other dangerous biological agents that could be used to harm our citizens or agriculture.

Laboratories will now have to register to possess such materials, and they will have to meet guidelines to ensure the safety and security of these materials. Individuals who work with these materials in labs will now be screened to see whether they are terrorists or might otherwise put the agents to criminal use.

Most importantly, we have enhanced the controls on these materials while preserving the ability to pursue legitimate research—research that will produce the treatments, vaccines, and tests that will protect us from these biological agents, should they ever be used against us.

In light of the anthrax attacks, we have become increasingly concerned that terrorists could use food as a delivery vehicle for one of these agents, or that terrorists could attack with biological agents capable of crippling or destroying our food supply and our agricultural economy. And so, we have given the FDA more funding and substantial new authority to protect the food we eat, and the USDA more funding to enhance the security of the food supply and agribusiness.

I am proud of these accomplishments. In the hands of the FDA, these provisions will be at work every day to better protect the health and safety of Americans. They will prevent deliberate attacks on our country, and they will help reduce our country's epidemic

of foodborne illness. By some estimates, contaminated food in our country causes 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each and every year.

For many years, Senators CLINTON, DURBIN, MIKULSKI and REED have understood this problem and have long championed strong, new food safety authority and resources for the FDA. Senator DURBIN has made this a top priority throughout his congressional career in both the House and Senate. For years, Senator MIKULSKI and I have sought new authorities over imported foods.

Thanks to the provisions in this legislation, the American public will greatly benefit from what has been rightly described by the New York Times as "the most significant expansion of federal authority over the food industry in more than six decades."

FDA will have new authority to prevent unsafe food from entering the country, new authority to inspect food records and require additional records to assist in tracing the origins of foodborne illness, and new authority to register food manufacturers. And we've provided for grants to States for food inspections and for surveillance and detection of outbreaks of foodborne illness.

FDA also has more authority to track imported drugs, and authority to monitor more closely bulk ingredients of drugs, medical devices, and foods that are imported for export to ensure that these products are not diverted into domestic commerce.

Just as we have focused attention on securing our Nation's food supply, Senator JEFFORDS has led our efforts to secure our Nation's water supply. Thanks to Senator JEFFORDS' patient and deliberative efforts, this legislation will better protect the American public. As chairman of the Environment and Public Works Committee, our colleague worked closely with the ranking member, Senator BOB SMITH, on provisions to anticipate and prevent vulnerabilities in our water supply. Their careful work will fund and enable community water systems across the country to assess their vulnerabilities, address immediate and urgent security needs, and carefully plan for potential terrorist attack.

I am also happy to note that the conference report includes S. 1275, "The Community Access to Emergency Defibrillation Act" authored by myself and Senator FRIST. This important legislation has the demonstrated potential to save two of thousands of lives annually and is strongly endorsed by the American Heart Association.

I am very pleased we have reauthorized the Prescription Drug User Fee Act, PDUFA, for the second time. When I authored the Prescription Drug User Fee Act of 1992 with Congressmen DINGELL and WAXMAN and Senator HATCH, I hoped this law would provide urgently needed funds to the Food and Drug Administration to speed the review of new drugs. Before user fees

were enacted, FDA was short staffed and underfunded. Every beneficial drug delayed because FDA had insufficient staff to act promptly represented a therapeutic opportunity denied to patients and consumers.

The past decade has more than fulfilled my hopes and expectations. The FDA has done a remarkable job of reviewing new drugs in a rapid but deliberative manner. Patients have benefitted from the agency's dramatic success in speeding drug reviews, and this legislation promises to continue this track record of success.

At the same time that speedier approvals have benefitted patients, there have been growing concerns over whether faster speed to market for drugs has come with heightened risks to patients. The fact that more new drugs have reached American consumers first in the world means they are also the first to be exposed to new risks and new safety concerns. A recent Pulitzer Prize-winning investigation by David Willman of the Los Angeles Times documented the urgent need to balance rapid approval of drugs with an equal commitment to assuring safety.

This concern is substantiated by a recent General Accounting Office study which I requested on the user fee program. According to GAO, the proportion of safety-related drug withdrawals has increased for drugs approved under PDUFA II compared to drugs approved under the first PDUFA. While only 1.6 percent of drugs approved from 1993 through 1996 were withdrawn for safety reasons, over 5 percent of drugs approved from 1997 through 2000 were withdrawn due to safety. While the number of drugs involved is still small only seven in the latter period compared to two in the earlier period—this report is still an important caution and a substantial increase in our investment in drug safety is warranted.

These are the issues I have shared and discussed for years with patient advocates, consumer groups and independent scientists. And for many years, I have made clear that we must restore public confidence in the FDA's stewardship of prescription drugs. Our dramatic investments in drug reviews had to be matched by a corresponding renewal of effort in post-marketing surveillance and drug safety. Anything less would only serve to cast doubts on the integrity of FDA's regulation of drug safety.

In the past year, our committee, including Senators REED, CLINTON, BINGAMAN, MIKULSKI, HARKIN, DODD, and EDWARDS, worked closely with the Patient and Consumer Coalition and with independent drug safety experts to develop solutions. We found that our concerns were shared by our colleagues in the House, including Congressmen DINGELL, BROWN, WAXMAN AND STUPAK. Throughout congressional deliberations on the reauthorization of prescription drug user fees, we agreed upon the need for additional resources and stronger authorities for FDA.

While it is important for us to bring drugs to market quickly, we agreed that this redoubles our obligation to assure the safety of those drugs.

Today, I am happy to say that is precisely what we have accomplished in this legislation.

First, the FDA's performance goals relating to the speed of approval have not changed. The many review staff hired by FDA with user fees can continue to scrutinize the safety of drugs seeking approval. The increased fees in the new agreement will be used not to further accelerate the approval of drugs, which is already the fastest in the world, but to assure that the studies underlying drug applications are given the most careful possible scrutiny to assure that the drugs are in fact safe and effective.

The public and my colleagues in the Senate should also understand that the performance goals contained in all of the PDUFA agreements are not goals for the approval of new drugs; rather they are goals for the timely review of new drugs. FDA meets these goals whether or not the agency approves or denies approval of a drug.

Best of all, I want my colleagues to know that this reauthorization is a tremendous accomplishment where drug safety is concerned. We will increase FDA's drug safety spending by over 80 percent over the life of this user fee agreement. With FDA's annual drug safety activities currently funded at \$36 million, this legislation will ensure an increase of \$29 million in the fifth year of this agreement, for a total of \$65 million in annual drug safety funding at FDA.

To achieve this goal, we have made a fundamental change to how user fees are used. The user fee agreement includes a dramatic funding increase of \$76 million over five years for FDA to plan, execute and fund drug safety "risk management" activities for newly marketed drugs. While these activities would be limited in scope and duration, FDA will be able to greatly expand its focused scrutiny of these drugs.

But in order to give FDA greater freedom of action, we have also mandated substantial funding increases for the agency's Office of Drug Safety. In fiscal year 2003, the Office will receive an additional \$5 million, and an additional \$10 million in fiscal year 2004, with increases assured in subsequent years. Since these funds will be drawn from FDA's appropriations, Congressman TAUZIN, my fellow conferees and I are committed to doing all that is necessary to ensure that these are new funds and will not be cannibalized from FDA's other essential programs and activities.

We have made other important steps to advance public health and safety. In response to the explosion of direct-to-consumer drug advertising, we have authorized an additional \$27 million over five years for FDA's scrutiny of drug advertising and promotions. In re-

sponse to delays in generic drug approvals, some of which arise from anti-competitive practices by the brand-name drug industry, we have authorized an additional \$45 million over five years for FDA's Office of Generic Drugs to ensure that generic drugs reach the public more quickly.

We have also squarely addressed a persistent problem with the prescription drug industry. For years, drug companies would promise to complete post-market, or phase IV, clinical trials to answer important questions about their products. These commitments paved the way for reaching the market earlier. In the case of fast track drugs and drugs approved through the accelerated approval, these trials were mandatory. Yet many companies have failed to begin or complete these trials. And to respond, FDA's only—and usually unacceptable—recourse would be to withdraw a drug for market.

The industry's track record has been disappointing. According to the FDA, since 1998, only four of 109 post-market commitments have been fulfilled for fast track drugs. Only a quarter of the industry's commitments for standard drugs since 1991 have been fulfilled. And only a third of its commitments for accelerated approval drugs since 1992 have been fulfilled.

Five years ago, I urged the adoption of new authorities for FDA to enable the agency to bring these companies into compliance with the law and to ensure these essential trials are conducted in a timely way. I am very pleased that this legislation includes new authority for the FDA to publicize the failure of companies to fulfill their legal obligations to complete post-market studies. FDA will publicize such failures through their website, through 'dear prescriber' letters, and public statements on the late, uncompleted studies and the resulting, unanswered questions of clinical benefit and safety. I am hopeful that the FDA will be able to employ these new tools to bring about more responsible conduct by the industry, and consequently resolve unresolved questions of drug safety and efficacy.

I am disappointed that some of my colleagues objected to addressing in this legislation a crucial priority for children's health. The FDA has a Pediatric Rule that requires a company, before approval of a drug, to study in children the use for which approval is sought in adults. It also gives FDA the authority to require, in certain circumstances, that drugs that are already marketed be studied for their approved use in children. The Pediatric Rule has always served as a complement to pediatric exclusivity, which we recently reauthorized in the Best Pharmaceuticals for Children Act.

But today, the Rule is being challenged in court by parties who believe the drug industry should be free to decide when or whether to determine their drugs are safe and effective for

children. The Rule was recently threatened with withdrawal, but the Administration reconsidered this ill-advised step.

That is why a clear signal must be sent. This research is of critical importance to children. Without the Rule, less of this research will be conducted. And some products, such as biologicals, will not be studied at all.

With my colleagues, Senators CLINTON, DODD and DEWINE, I intend to pursue this issue in the coming months. We cannot afford to compromise the health of our children with half measures.

Finally, I am disappointed that we could not reach agreement on legislation enacting medical device user fees. In 1994, I introduced such legislation with Congressmen DINGELL and WAXMAN. But dissension within the device industry prevented us from enacting this important reform. Since then, the FDA Center for Devices and Radiological Health and suffered severe losses in its budget and staffing. Its staff has shrunk by almost eight percent since 1995 and it has effectively lost more than \$34 million in its base funding.

With support of my colleague, Senator GREGG, we urged the FDA and the device industry to seek agreement on performance goals and fees. And to their great credit, the FDA and the industry reached agreement. But some in the device industry insisted on including extraneous proposals that could not be worked out in the limited time available.

Medical device user fees are a win for patients, the industry and the FDA. That is why I am committed to achieving a consensus on this issue. I believe that we can enact such legislation, so long as we can dispense with extraneous controversies and focus on the common goals of restoring the resources of FDA's device center, establishing reasonable performance goals for device reviews, and assuring that safe and effective devices are approved in a more timely manner.

The timely completion of the conference report would not have been possible without the hard work of the many staff members who worked on this important legislation. I particularly want to thank Bill Baird of Senate Legislative Counsel and Pete Goodloe of House Legislative Counsel. Both of these dedicated professionals worked many long, late hours and met many tight deadlines to allow this report to be completed.

I want to also thank Patrick Morrissey, Tom DiLenge, Brent Delmonte, Amit Sachdev, Bob Meyers and Nandan Kenkeremath from Congressman TAUZIN's staff; Katy French, Vince Ventimiglia, and Steve Irizarry from Senator GREGG's staff; Adam Gluck, Eric Juzenas, and Lowell Ungar with Senator HARKIN; Rhonda Richards with Senator MIKULSKI; Alison Taylor, Jo-Ellen Darcy, and Sean Donohue with Senator JEFFORDS; Deb Barrett

and Jim Fenton with Senator DODD; Shana Christrup, Helen Rhee and Dean Rosen from Senator FRIST's staff; John Ford, David Nelson, Edith Holleman, Bridgett Taylor and Dick Frandsen from Congressman DINGELL's staff; Karen Nelson, Ann Witt and Greg Dotson with Congressman WAXMAN.

On my own staff, I want to thank David Bowen for his outstanding work on all aspects of the bioterrorism issue. He has been tireless and insightful and I know everyone involved in this effort appreciates his work.

I also want to thank Paul Kim and David Dorsey for their extraordinary efforts to assure protection of our food and water supply, as well as providing better security for potentially dangerous bio-materials in our nation's laboratories. They also worked very hard to assure that the Prescription Drug User Fee Agreement was a step forward for every patient in this country.

David Nexon, my Health Staff Director, brought his usual energy and commitment to the effort. Michael Myers, the Health, Education, Labor, and Pension Committee Staff Director, kept his hand on the tiller throughout.

The conference report is a landmark in our national response to terrorism and the security threats of this new century. Congress today sends the message in one unified and clear voice that this nation will not remain unprepared for the threat of bioterrorism. The front lines in the new war against bioterrorism will be our health care system. Today we take a historic step forward in preparing America's health care professionals to win the war against bioterrorism.

#### AMENDMENT NO. 3462, AS MODIFIED

Mr. KENNEDY. Mr. President, I ask unanimous consent that the Corzine amendment No. 3462 be modified with the language at the desk; further, that the amendment be agreed to, and the motion to reconsider be laid upon the table.

The PRESIDING OFFICER (Mr. CARPER). Is there objection? Without objection, it is so ordered.

The amendment (No. 3462), as modified, is as follows:

Beginning on page 208, beginning on line 4, strike all through page 211, line 19, and insert the following:

#### SEC. 1143. BORDER SEARCH AUTHORITY FOR CERTAIN CONTRABAND IN OUTBOUND MAIL.

(a) IN GENERAL.—The Tariff Act of 1930 is amended by inserting after section 582 the following:

##### “SEC. 583. EXAMINATION OF OUTBOUND MAIL.

“(a) EXAMINATION.—

“(1) IN GENERAL.—For purposes of ensuring compliance with the Customs laws of the United States and other laws enforced by the Customs Service, including the provisions of law described in paragraph (2), a Customs officer may, subject to the provisions of this section, stop and search at the border, without a search warrant, mail of domestic origin transmitted for export by the United States Postal Service and foreign mail transiting the United States that is being imported or exported by the United States Postal Service.

“(2) PROVISIONS OF LAW DESCRIBED.—The provisions of law described in this paragraph are the following:

“(A) Section 5316 of title 31, United States Code (relating to reports on exporting and importing monetary instruments).

“(B) Sections 1461, 1463, 1465, and 1466, and chapter 110 of title 18, United States Code (relating to obscenity and child pornography).

“(C) Section 1003 of the Controlled Substances Import and Export Act (relating to exportation of controlled substances) (21 U.S.C. 953).

“(D) The Export Administration Act of 1979 (50 U.S.C. App. 2401 et seq.).

“(E) Section 38 of the Arms Export Control Act (22 U.S.C. 2778).

“(F) The International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

“(b) SEARCH OF MAIL NOT SEALED AGAINST INSPECTION AND OTHER MAIL.—Mail not sealed against inspection under the postal laws and regulations of the United States, mail which bears a Customs declaration, and mail with respect to which the sender or addressee has consented in writing to search, may be searched by a Customs officer.

“(c) SEARCH OF MAIL SEALED AGAINST INSPECTION WEIGHING IN EXCESS OF 16 OUNCES.—

“(1) IN GENERAL.—Mail weighing in excess of 16 ounces sealed against inspection under the postal laws and regulations of the United States may be searched by a Customs officer, subject to paragraph (2), if there is reasonable cause to suspect that such mail contains one or more of the following:

“(A) Monetary instruments, as defined in section 1956 of title 18, United States Code.

“(B) A weapon of mass destruction, as defined in section 2332a(b) of title 18, United States Code.

“(C) A drug or other substance listed in schedule I, II, III, or IV in section 202 of the Controlled Substances Act (21 U.S.C. 812).

“(D) National defense and related information transmitted in violation of any of sections 793 through 798 of title 18, United States Code.

“(E) Merchandise mailed in violation of section 1715 or 1716 of title 18, United States Code.

“(F) Merchandise mailed in violation of any provision of chapter 71 (relating to obscenity) or chapter 110 (relating to sexual exploitation and other abuse of children) of title 18, United States Code.

“(G) Merchandise mailed in violation of the Export Administration Act of 1979 (50 U.S.C. App. 2401 et seq.).

“(H) Merchandise mailed in violation of section 38 of the Arms Export Control Act (22 U.S.C. 2778).

“(I) Merchandise mailed in violation of the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

“(J) Merchandise mailed in violation of the Trading with the Enemy Act (50 U.S.C. App. 1 et seq.).

“(K) Merchandise subject to any other law enforced by the Customs Service.

“(2) LIMITATION.—No person acting under the authority of paragraph (1) shall read, or authorize any other person to read, any correspondence contained in mail sealed against inspection unless prior to so reading—

“(A) a search warrant has been issued pursuant to rule 41 of the Federal Rules of Criminal Procedure; or

“(B) the sender or addressee has given written authorization for such reading.

“(d) SEARCH OF MAIL SEALED AGAINST INSPECTION WEIGHING 16 OUNCES OR LESS.—Notwithstanding any other provision of this section, subsection (a)(1) shall not apply to mail weighing 16 ounces or less sealed against inspection under the postal laws and regulations of the United States.”.

(b) CERTIFICATION BY SECRETARY.—Not later than 3 months after the date of enactment of this section, the Secretary of State shall determine whether the application of section 583 of the Tariff Act of 1930 to foreign mail transiting the United States that is imported or exported by the United States Postal Service is being handled in a manner consistent with international law and any international obligation of the United States. Section 583 of such Act shall not apply to such foreign mail unless the Secretary certifies to Congress that the application of such section 583 is consistent with international law and any international obligation of the United States.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), this section and the amendments made by this section shall take effect on the date of enactment of this Act.

(2) CERTIFICATION WITH RESPECT TO FOREIGN MAIL.—The provisions of section 583 of the Tariff Act of 1930 relating to foreign mail transiting the United States that is imported or exported by the United States Postal Service shall not take effect until the Secretary of State certifies to Congress, pursuant to subsection (b), that the application of such section 583 is consistent with international law and any international obligation of the United States.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, I thank the Senator from Massachusetts for his exceptional leadership on this piece of legislation, along with the many members of the committee I have worked with and about whom I will talk later on as I discuss the implications of this piece of legislation. Also, I thank our House colleagues who produced an excellent bill on their own. As a result, we were able to merge the best of the two which, I believe, produce a superb package, although lacking in a couple of items, as alluded to by the chairman of the committee.

It is basically an extremely positive package, and it puts us well down the road to addressing what is clearly one of the most threatening situations we have as a society, and that is the capacity of those who wish us ill—and, regrettably, there are a number of people and organizations in this world who wish us ill and would use weapons of mass destruction against us, which would include biological warfare.

We saw, of course, the devastating impact of a biological event with the anthrax incident, and the President has been speaking about this as he has been moving through Europe on his trip, that some nations in this world are continuing to develop biological weapons and may be making those weapons available to terrorists.

We as a nation, whether we like it or not, have to get ready to confront this threat. This bill will do a great deal to put us in a position to accomplish that.

The bill is structured around a variety of points, and I will go into them in specific detail, but the concept of the bill is basically to significantly improve our Federal capability to deal with a biological event and prepare ourselves with adequate vaccines and adequate research in the area of devel-

oping vaccines to confront bioterrorism and, at the same time, look to the local communities and the States and significantly improve the public health capability of the States and the local communities so that they, as the first responders, will be able to manage an event should the worst occur, and we will be able to deal with it in an effective and prompt way.

The bill makes a significant commitment of resources well beyond what we had anticipated making when we started down this road but which are necessary. In this war on terrorism, we cannot look at pricetags, we must look at results. It is going to cost a great deal to accomplish the results we need.

This bill, although long-awaited, will definitely better prepare this Nation to respond to attacks which use biological, chemical, or other weapons of mass destruction.

The bill provides grants to States and local public health agencies to assist in preparing for a biological terrorist attack. With these resources, unlike prior law, even small States such as New Hampshire are assured the ability to prepare and respond to a bioterrorist attack or other public health emergency.

Because of the importance of State preparedness and the amount of resources that have been provided, I intend to play an active role in making sure these funds are not just received by hospitals and State and local governments but that they are well spent for the benefit of the American citizenry.

An important part of this bill is ensuring that the funds are spent consistent with a State's bioterrorism plans. In addition, we have already begun oversight of the program and look forward to working with the administration and grant recipients as work under the grants begins in earnest.

Further, under section 102, we will help ensure effective communication and cooperation among the State, local, and Federal agencies by creating a new Assistant Secretary for Public Health Emergency Preparedness at HHS.

Also, the volunteer spirit has always been alive and well, especially in New Hampshire, and I am pleased this conference report includes several provisions which are designed to facilitate voluntarism in preparing for public health emergencies and especially bioterrorism emergencies.

Title I also includes a number of provisions intended to further speed lifesaving products to citizens before we are faced with another serious threat of bioterrorism.

Section 121 ensures that stockpiles of products are improved immediately so that there is an adequate supply to protect our citizens from bioterrorism and other threats. This year we provided the funding necessary to fulfill this commitment, and the Secretary is directed to improve not just the stock-

pile contents but the supply chain management of and local access to products.

The bill improves the Secretary's authority to, one, prioritize and do research on new vaccines and therapies; two, rely on all available forms of proof of safety and effectiveness, including animal trials; and three, accelerate approval of these products. This is absolutely critical if we are to be prepared with adequate vaccines to make sure our citizenry is protected.

Title II includes the expanded Gregg-Feinstein provisions initially passed by the Senate late last year as part of the appropriations legislation.

As the recent anthrax attack has suggested, current authorities have been inadequate to ensure the Government can track the use of biological agents and toxins such as anthrax and botulinum toxins, West Nile virus, and the like, and to protect against their misuse.

The bill makes critical improvements in the Secretary's ability to identify who is handling and doing research with these agents and toxins, to ensure they are qualified to handle these agents, and to ensure they are not restricted due to inappropriate background or current intent.

The bill also ensures that universities, laboratories, and agencies working with these agents are registered, appropriately qualified, and have adequate security in place.

Many of these agents are used in important research or for important therapeutic purposes in animals and humans. These uses must remain protected and promoted even as we protect the public from their misuse. The bill ensures important exemptions, for example, for FDA-approved products using or investigating these agents or toxins.

Title III of the bill provides the FDA with additional inspection, record-keeping, and detainment authority to ensure the safety of America's food and drug supply and increases the number of FDA food inspectors. Senator KENNEDY spoke about this at some length.

The bill also improves our capacity to prevent, detect, and respond to an attack on American farmers, livestock, and poultry producers, and certainly Senator ROBERTS deserves great credit for that. I know he is going to be speaking in a few minutes.

Finally, it provides funds to community drinking water systems to allow them to assess any possible vulnerabilities and to institute measures to prevent tampering. Many have been concerned about having these vulnerability studies go to the EPA which does not have a solid track record of maintaining control over sensitive information. We must ensure that the EPA allocates resources and institutes procedures designed to prevent this information from falling into the wrong hands. It would do no good for us to develop these studies and then find that terrorists had been able to use these studies against us.

Conferees also succeeded in reauthorizing PDUFA, which has already been mentioned by the chairman, which has so successfully ensured patients timely access to safe, effective, and lifesaving drugs. By collecting fees from pharmaceutical companies, FDA can hire additional reviewers and support staff and speed the drug review process without compromising safety or review quality.

Under the agreement, the amount of funding FDA receives under the program will increase by over 28 percent, and in today's deficit environment this will be of significant assistance. Voluntary user fees are substantial and essential sources of revenue that the agency cannot afford to lose.

I am concerned, however, that this bill does not include some of the following items that are particularly critical to the ability of this country to rapidly prepare for, detect, or respond to biological threats, including anthrax, smallpox, and botulism.

In the antitrust area, the Senate bill included a bipartisan consensus provision supported by the Judiciary Committee that would extend protection to manufacturers of vaccines and their therapies for bioterrorism agents when the companies were engaged in discussions with the Secretary over how best to meet the unmet needs of the United States.

It is critical these companies be able to discuss frankly with the Secretary their capacities and their strengths so that they can have rapid research and develop new vaccines and drugs that protect us against bioterrorism acts. This provision was, regrettably, dropped in conference over my strong objection. I will continue to press for it in other arenas.

In many critical respects, this Nation remains unprepared for bioterrorism threats simply because the threat of unreasonable and abusive lawsuits has kept good ideas and good products from being available to our citizens. Examples include decontamination services and cleanup services for contaminated worksites, unavailable because of a threat a lawyer might sue the company.

Lifesaving vaccines also remain undeveloped for these same reasons. Respirator manufacturers risk the threat of suit when volunteers misuse a mask in the midst of the chaos during a crisis.

I intend to work for a solution this year with many of my colleagues who have expressed support for reasonable liability protections so we can bring on to the market the necessary devices and vaccines in order to address these needs and make sure our marketplace is able to respond effectively to the threat.

Finally, I note my disappointment that the final package did not include critical new user fee programs for the FDA's device on animal drug centers and accompanying reforms that would dramatically improve regulation of those products. These programs and re-

forms are essential to ensuring that our Nation continues to be the leader in developing lifesaving therapies and technologies.

However, I am heartened by the extraordinary bipartisan, bicameral support demonstrated for those provisions during the conference. I look forward to working with my colleagues, particularly Senator DODD, Senator HUTCHINSON, and Senator KENNEDY, in the development of a strong user fee and reform package. I understand the House intends to move this separately, and certainly I hope we will be able to do the same in the Senate.

There are a lot of people who worked very hard on this bill to make it a success. Certainly Senator KENNEDY was a leader, and he is to be congratulated for his foresight in this matter. Senator FRIST, whose knowledge in this area is unique and brings so much to the table in the Senate, was a major player in designing much of this bill; Senator ENZI and Senator TIM HUTCHINSON for their critical role in ensuring the capacity of all States, but especially rural States, to have capacity to prepare for attacks. Senator SUSAN COLLINS played a critical role in developing the Senate food supply safety provisions, a role reflected in a long history working to pass such legislation. Senator HUTCHINSON also played the single most critical role in the provision protecting America's agricultural livestock and poultry provisions. His animal enterprise provision, which will protect our folks working on the next generation of lifesaving vaccines and medicines, is absolutely essential.

I am also pleased with the inclusion in this bill of so much of Senator HUTCHINSON's legislation concerning improvement in the ability to bring antibioteerrorism products to the American citizen; Senator SESSIONS for his tremendous effort with regard to the minor use, minor species provisions, which would have provided safe and effective drugs for minor animal species for which therapies are currently unavailable.

Unfortunately, this provision was not included in the final bill, but it is sound policy and I will continue to support his efforts and to pass this legislation; Senator ROBERTS whose attention to the issue of farm policy and the effect of bioterrorism issues relative to our farm community was absolutely critical to the design of this bill.

At a staff level, I have an exceptional staff. They have worked thousands of hours, days and nights, and I thank them very much. Vince Ventimiglia, Steve Irizarry, and Katy French did a superb job. I also thank the majority staff led by David Nixon, and the many people he has working with him. Also, I thank Dean Rosen on Senator FRIST's staff.

I yield 10 minutes to the Senator from Kansas, Mr. ROBERTS.

The PRESIDING OFFICER. The Senator from Kansas is recognized.

Mr. ROBERTS. I thank the Senator for yielding. The completion of the

Bioterrorism Preparedness Act conference report, in my view, represents an absolutely vital and significant step forward for our Nation as we work to protect ourselves from any kind of a terrorist attack involving bioterrorism.

I also had the privilege of being chairman and now ranking member of the Emerging Threats Subcommittee of the Armed Services Committee. We had witness after witness and commission after commission. We asked them: What keeps you up at night? Each and every time when we tried to prioritize the threat that faced this country, bioterrorism was listed as No. 1.

I thank Senator KENNEDY for his leadership with regard to this bill. I echo the comments by Senator GREGG, who has been extremely helpful and led the effort on our side. I especially thank Senator FRIST whose expertise and leadership with the Centers for Disease Control and the Department of Health and Human Services, plus his personal expertise, is second to none. If he is not the godfather of this bill, he is indeed the godprince. So I thank him for those efforts.

This bill also represents a significant advancement in helping to protect agriculture and our Nation's food supply from a possible agroterrorist attack. The legislation contains language based on numerous provisions I introduced in the bill some time ago. It was called the Biosecurity for Agriculture Act. I think that was last fall.

Specifically, the bill provides funding authorization for \$190 million for expanded agroterrorism research in 2002 and such sums as necessary in the future years.

This language will allow us to significantly expand our research capabilities to deal with these threats. It will allow us to expand existing research partnerships between the Department of Agriculture and many of our land grant universities to develop first-responder capability in case we have an agroterrorist attack. It is going to create many additional partnerships. It will increase the coordination between the Department of Agriculture and the intelligence community, and undertake research to develop what we call rapid field test kits that will allow us to make a determination of the possible introduction of any pathogen or disease within minutes or hours instead of days or weeks, as often occurs, as of today.

In addition, the bill also includes language similar to that I introduced to authorize funding for the upgrades of the Department of Agriculture research facilities at Plum Island, NY, Ames, IA, Laramie, WY, and Athens, GA. These facilities really represent the frontline in the Department of Agriculture's research efforts to prevent disease outbreaks in the United States.

Why is the inclusion of this provision in this particular bill so important? I am not aware of any specific threat, but the possibility of agroterrorism or



food security attacks is very real, and it has increased since September 11.

Second, we know the former Soviet Union had developed literally tons of biowarfare agents that were to be aimed at the North American food supply. Many of these agents are still housed in unsecured facilities. I have been there. Senator LUGAR has been there. Many of the scientists are simply unemployed and are willing to work for the highest bidder, and that is a grave concern.

Third, we know several of the September 11 hijackers had significant agricultural training. It would be very easy to introduce a disease such as foot and mouth disease or Kernal Bunt, and the effects would be devastating to our grain supply and our livestock production. Our exports would be lost and consumer confidence would simply plummet. Food shortages would occur in our Nation's cities.

This is particularly frightening when we realize that agriculture is one of the few sectors of the economy with a trade surplus. Using 1999 numbers, agriculture and agribusiness-related industries accounted for approximately 22 million jobs, almost 17 percent of the gross domestic product. The overall contribution to the Nation's GDP in 1999 was \$1.5 trillion. That is at risk. And the cheap U.S. food supply kept the total portion of the individual income spent on food to about a dime or 10 percent—one dime out of the consumer's disposal income dollar for that so-called market basket of food. A terrorist attack would certainly endanger that.

The importance of this sector to our economy, and our national security, cannot be underestimated. We must take the steps to protect our agricultural producers, our farmers, our ranchers, and our food supply. This bill represents a very important step.

I thank my colleagues who have worked with me on this issue. I thank the staff of the HELP Committee in working with my staff and those on the Agriculture Committee. I thank them for their assistance, including these provisions in this legislation.

I yield back the remainder of my allotted time.

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. FRIST. Mr. President, we have learned a lot about terrorism since September of last year. We have learned that terrorists prey on vulnerability. Our vulnerability becomes their target. This bill reduces our vulnerability when it comes to this threat of bioterrorism and thus reduces the likelihood of an attack by reducing our vulnerability and reduces the potential damage an attack may cause by improving and strengthening our response.

We have learned the goal of a bioterror attack is not only to hurt people directly but to paralyze them, to cause panic. This bill will calm the nerves and keep order in the event there is another bioterror attack.

This bill addresses prevention and preparedness, as well as response. Indeed, this bill touches all areas of preparedness: Protecting our food and water, boosting medical stockpiles, and supporting our local communities and public health infrastructure.

This bill emphasizes the local response and local preparedness. It recognizes that it is local people who will respond in the event of a bioterror attack. It is about whom you call when you suspect something, whom you call if you are worried about bioterrorism: The family doctors, the emergency workers, the health care professionals. Today, with this legislation we make the first people on the scene our first priority.

Over 3 months after the tragedies of September 11 and slightly more than 60 days after the anthrax attacks, Congress provided a record \$3 billion in emergency bioterrorism funding. This was in December of last year. This was a historic investment. As we have learned since that time, it must be only a downpayment toward ensuring that America is fully prepared to respond to bioterrorism and other public health risks.

Today, we take another important and very necessary step toward securing our Nation with the Public Health Security and Bioterrorism Preparedness and Response Act. It is a cohesive and comprehensive framework to improve our public health system and thereby reduce our vulnerability.

I, too, thank Senator KENNEDY and Senator GREGG for their leadership and their tremendous contributions to this conference report. I thank our colleagues in the House of Representatives, primarily Chairman TAUZIN and Representative DINGELL, for their huge and important efforts. Yesterday's overwhelming vote in the House in favor of passing this conference agreement demonstrates this legislation is truly broad and bipartisan.

There is no question we live today in a more dangerous world, much more dangerous than we envisioned before September 11, much more dangerous than we had envisioned before the anthrax-laden letters were delivered across the east coast. We are not unprepared for a bioterror attack, but we are clearly underprepared. This bill goes a long way in boosting that preparedness and reducing the vulnerabilities.

We know terrorists around the world, including al-Qaida, are intent on using biological weapons against us. We know more than a dozen nations—including Iraq, North Korea, Libya, Syria—have the capability to produce chemical and biological weapons, and many have stockpiled such biological weapons in the past. We know thousands of Soviet scientists who have the expertise to develop biological weapons are, today, unemployed, and potentially available to the highest bidder.

Yes, the risk is real. We know the risk is increasing. The National Intelligence Council warns:

The biological warfare capabilities of state and non-state actors are growing worldwide. This trend leads us to believe that the risk of an attack against the United States, its interests and allies will increase in the coming years.

This bill is the foundation and framework for our response.

Iraq launched a robust biological program in 1985 and has admitted to producing large quantities of agents and weapons, including 19,000 liters of botulinum—in fact, 10,000 liters loaded into munitions—and 8,500 liters of anthrax—and 6,500 were loaded into munitions. During the gulf war, Iraq weaponized 100 bombs and 15 missile warheads with botulinum, and 50 bombs and 10 missile warheads with anthrax.

Nonstate actors are also a threat. CIA Director George Tenet has been quoted recently in the New York Times as saying: Documents recovered from al-Qaida facilities in Afghanistan show that Osama bin Laden was pursuing a sophisticated biological weapons research program. U.S. forces discovered a facility in southern Afghanistan near Kandahar that was being built to produce biological agents.

Our vulnerabilities remain high. This bill addresses reducing those vulnerabilities. Most public health departments in the United States do not have staff fully trained in bioterrorism. A recent report showed that one-third of public health departments serving 25,000 or fewer people had no Internet access, and one-quarter of public health staff had no electronic or e-mail. Today more than 99 percent of food imported into this country is never inspected.

The American people, with passage of this legislation, should rest easier, knowing that our Government is taking the steps necessary to respond to this threat at the local level, at the State level, and at the national level. This legislation will ensure that we continue to act both rapidly and appropriately to secure the Nation against future attacks on our freedom.

What does the bill do? The conference agreement provides the resources necessary to improve the training of those first responders, to those doctors, to nurses, to public health officials at the local level. They are the first line of defense. The bill authorizes \$300 million both in 2002 and 2003 to strengthen the capabilities of the Centers for Disease Control and Prevention and modernize its facilities. The bill enhances our national research capabilities and helps speed the development of needed drugs, of needed vaccines, diagnostic tests, and other priority countermeasures. And the bill helps ensure that our national strategic pharmaceutical stockpile is adequate to meet the needs of America.

The October anthrax-laden letters underscored the importance of coordination, the importance of communication. The conference agreement puts in place structures to ensure improved

government coordination, as well as improved collaboration between government and the private sector. The legislation helps us develop the state-of-the-art communication infrastructure so we can more readily and more rapidly identify and treat infectious disease outbreaks. It also helps ensure that our children and other vulnerable populations are better prepared.

This conference agreement will significantly improve our ability to protect our water supply, our food supply, our Nation's agriculture, and it will help better track and regulate the use of dangerous pathogens within our borders.

The bill focuses on what happens at the local level, at the community level. If you are suspicious, if an attack occurs, you pick up the telephone, you call somebody, or go to a local facility. This bill underscores the importance of support at the local level.

The legislation will provide significant new resources, \$1.6 billion in the year 2003 alone, to strengthen our State and local public health systems. We have underinvested in our public health infrastructure in the last 30 years in this country.

As the title of the bill makes clear, this legislation will not only improve our ability to respond to bioterrorism but to other public health risks, and emergencies as well, whether they be from other intentional acts of terrorism, nuclear attacks, chemical accidents or attacks, or from naturally occurring infectious disease outbreaks, the so-called dual use of the investment that we put in public health today.

I am proud to be part of this legislation. I believe that years from now America will look back upon this bill as landmark legislation, a landmark achievement, a turning point in our commitment to strengthening our defenses, focusing on biological threats.

As has been mentioned by my colleagues, I am very pleased with the reauthorization of what is called the Prescription Drug User Fee Act. This important law helps make it possible for the Food and Drug Administration to hire additional manpower and expertise to speed the drug approval process so consumers can benefit more quickly in a safe way from life-saving drugs.

I am also pleased this agreement includes the Frist-Kennedy Emergency Access to Defibrillator Act, an act which has passed the Senate earlier this year, a provision which will provide annual grants to deploy lifesaving cardiac heart defibrillators in more public buildings.

My colleague, Senator GREGG, has already recognized so many people who have participated in such an admirable way to this bill. There are items that I, too, would like to have included in this particular bill that are not in the final package, items that I think we must continue to address in the Senate and in committee. I believe we need more certainty if private industry truly is to

become a partner in combating bioterrorism. To harness the genius, to harness the resources of private companies in these efforts, we should continue to find ways to protect companies from frivolous lawsuits and provide pharmaceutical research companies and others the certainty that they will not face antitrust enforcement simply because they are collaborating with the Government and their business partners to more rapidly and more rationally develop vaccines and other countermeasures.

This is a solid bill. It combines sound policy and enhanced resources to better prepare our Nation and to provide security to the American people. Once again, I commend Senator KENNEDY for his dedication and leadership. In many ways, this legislation builds upon a foundation we began about 3 years ago as we began, in a bipartisan way, to develop this issue of bioterrorism. He and I agree that protecting the American people from bioterrorist attacks and other public health threats and emergencies does require a robust, a reinvigorated public health system.

I also thank and commend the ranking member of the Senate HELP Committee, Senator GREGG, as well as the other Senate Republican conferees he has previously mentioned, Senator ENZI and Senator TIM HUTCHINSON, for the tremendous work he is doing in the agricultural and rural elements of the bill. Other Members, Senators ROBERTS, DEWINE, COLLINS, and HATCH, also were instrumental in drafting this important legislation.

Finally, it is difficult to pass legislation of this magnitude without the assistance and diligence of dedicated staff. Most of those staff members have been recognized already. I do want to thank members of my own staff, in particular Dean Rosen, Helen Rhee, Shana Christrup, and Doug Campos-Outcalt, a fellow in my office. I would also like to recognize the contributions of Vince Ventimiglia, Katy French, and Steve Irizzary of Senator GREGG's staff; David Nexon, Paul Kim, David Bowen, and David Dorsey of Senator KENNEDY's staff; Raissa Geary of Senator ENZI's staff; Kate Hull of Senator HUTCHINSON's staff; and Mike Seyfert and Lisa Meyer of Senator ROBERTS' staff.

Finally, with this bill we will take away one of the most formidable weapons in the terrorist arsenal, and that is our own vulnerability.

I yield the floor.

Mr. KENNEDY. Mr. President, I yield 7 minutes to the Senator from New York.

The PRESIDING OFFICER. The Senator from New York is recognized for 7 minutes.

Mrs. CLINTON. I thank the chairman for yielding me that time. I, too, wish to add my words of gratitude for the work that has been done on this bipartisan, comprehensive bioterrorism legislation. Under the leadership of Chairman KENNEDY and Ranking Member

GREGG, and Senator FRIST, as well as a number of others of our colleagues, we are about to pass legislation that I think will make a significant difference in the health, safety, and preparedness of our Nation. Americans know we cannot wait for another bioterrorism incident such as the one we suffered last fall with respect to the anthrax attacks before we take action to protect ourselves.

This bill contains a number of critical provisions that will improve national, State, and local preparedness. The authorization of a national stockpile of vaccines, antibiotics, and other drugs necessary in the case of an outbreak or other incident is absolutely essential.

Furthermore, the emphasis on public health is long overdue, as Senator FRIST so eloquently stated. This bill will invest over \$1 billion in grants to our States to assure the adequate planning that is necessary to improve State and local public health system preparedness.

I know all of us were surprised when we learned that many public health offices were more in the early 20th century with respect to their equipment and communications capability than in the early 21st century. They didn't have fax machines or e-mail capabilities. One of the problems we encountered with respect to our efforts to get ahead of the anthrax outbreaks and attacks was, in fact, the inability to communicate at different levels of government.

The underinvestment in our public health infrastructure has been unacceptable. Now we are about to reverse it. This is long overdue and to be applauded.

I also appreciate the bill authorizing \$520 million to equip hospitals to respond to bioterrorism.

After 9-11, when we had our hospitals on alert to try to take care of what we at the time thought would be thousands of injured people—unfortunately, it turned out to be thousands of deaths and relatively few people who were injured—we found we were not prepared because we could not perform many of the functions that were necessary, not only to respond to the attacks but the aftermath.

For example, many of the first responders went, after their duties at the Ground Zero site, to be decontaminated. There was no decontamination system. Many ended up at our hospitals in New York and were in very cramped and totally insufficient situations to try to decontaminate them before they went back to Ground Zero.

That is just one example of what we determined was absolutely unacceptable, given the threats we currently face. So we will be providing training and other provisions to promote the development and production of treatments and what is necessary for our hospitals to be prepared.

I also applaud the inclusion of strong provisions to safeguard our food supply



and to provide for the protection of our children. We are finally coming into the recognition that we have not protected our food supply, now that we are in a global marketplace, the way we need to. These provisions that are included are ones that I and others have long believed were absolutely essential to establishing a registration system for food manufacturers, to give the FDA records inspection authority to trace back investigations, to provide for prior notice of imported food, to allow the cross-utilization of inspectors—both from USDA and FDA—to provide grants for surveillance and protection, and to improve the surveillance of diseases affecting both animals and humans.

I am very pleased, too, that this bill contains provisions I introduced in legislation, along with Senator DODD and Congresswoman SLAUGHTER from New York, to address the special needs of children.

We know children have special vulnerabilities, and we also know biological and chemical agents can have a particularly bad and different effect on children because children are lower to the ground where we have gases that are dense and inert. We have other challenges in dealing with what happens to our children dealing with a bioterrorism attack. We have therefore established a national advisory commission on children and bioterrorism, and we will do much more to try to provide guidance on how best to protect our children.

I also applaud the provision of \$100 million to keep Plum Island, off the coast of New York, at its current biosecurity level and to modernize and improve the security of the facilities.

Also, I think it is essential we are adding to our security at water systems and expanding the availability of potassium iodide for communities near nuclear powerplants, such as Indian Point near where I live.

While we have taken such strong steps related to bioterrorism and children and food security and water security, I do have to express a disappointment that we were unable to include the codification of the pediatric rule that would require the testing of drugs that might be prescribed for our children. Senators DODD and DEWINE and I have introduced legislation to bring this about. Unfortunately, we were unable to attain support to have it included. But we will be taking steps, through a markup at the committee level and then with legislation, to try to ensure that the drug manufacturers to whom we have given access to an improved streamlined drug approval process—which we all support—also will be assuring us that the drugs needed by our children are safe and properly labeled.

This is a very good bill. There obviously are some features that should be included to make us stronger in the future, but I applaud my colleagues, and particularly those who shepherded it

through the conference, for making us, today, safer than we would have been otherwise.

The PRESIDING OFFICER. Who yields time?

Mr. GREGG. Will the Chair advise us as to the present status?

The PRESIDING OFFICER. The Senator from New Hampshire has almost 11 minutes remaining, and the Senator from Massachusetts has almost 10 minutes remaining.

Mr. GREGG. I yield 5 minutes to the Senator from Texas.

The PRESIDING OFFICER. The Senator from Texas is recognized for 5 minutes.

Mrs. HUTCHISON. I thank Senator GREGG and Senator KENNEDY for pursuing this bill. I certainly support it. As part of the fight against terrorism, we must dedicate the resources to the growing threat of bioterrorism. This legislation enhances the capabilities of Federal, State, and local governments to coordinate emergency preparedness efforts, to stockpile vaccines and medical supplies, to modernize biosecurity facilities, and try to ensure the safety of America's health and food supply.

I worked with my colleague, Senator PAT ROBERTS, to address the concerns about our food supply and vital agricultural economies. The agricultural bioterrorism provisions in this legislation will authorize the Department of Agriculture to strengthen its capacities to identify, prepare for, and respond to the bioterrorist threats to our farms, ranches, and food processing, packaging, and distribution facilities and systems.

We have a clear priority to ensure the safety of our food and to maintain public confidence. To do so we must identify and quickly control the threat to our food supply, currently the world's safest, most abundant, and affordable.

During the cold war, we knew the Soviet Union had bioweapons that included bioagents aimed at agriculture. Following the gulf war, we know our soldiers showed evidence of possible exposure to chemical and biological weapons. From the terrorist attacks on Japan's subway system with sarin gas to the recent anthrax attacks here in the United States, the public is now acutely aware of bioterrorist threats.

This bill is critical, both for the results it will achieve and the reassurance it will provide.

The Department of Agriculture will be expanded to enhance inspection capability, implement new information technology, and develop methods for rapid detection and identification of plants and animal disease.

The U.S. Department of Agriculture's Veterinarian Services will also be authorized to establish cooperative agreements with State animal health commissions and private veterinarian practitioners to enhance their ability to respond to outbreaks of any animal disease.

This bill directs the Department of Agriculture to establish a long-term

program of research to enhance biosecurity of U.S. agriculture.

America's universities that have demonstrated expertise in animal and plant disease research in coordination with State cooperative extension programs will provide the resources and expertise that will prove invaluable in the war on agricultural bioterrorism.

The front lines of this war on terrorism lie on our own shores, farms and fields, and the States where food is produced. However our States are vulnerable, they will meet the challenge, and they will help us in this war on bioterrorism because they will be able to detect the first evidence of an attack to protect our citizens, our economy, and our food supply.

I urge my colleagues to support the bill before us today. I appreciate the hard work that went into making it come to the floor and making it the priority that it should be for our country.

I thank the Chair. I yield the floor.

#### MEDICARE PROVISIONS IN BIOTERRORISM

Mr. BAUCUS. Mr. President, some of the provisions in the bioterrorism bill have not received much attention. These provisions affect Medicare, Medicaid and the Children's Health Insurance Program, or CHIP.

What we have done here is to give the HHS Secretary the ability to waive certain requirements in the face of a bioterror event or other public health emergency.

For example, the bill would give the Centers for Medicare and Medicaid Services the ability to pay providers for services rendered in good faith during an emergency, even if certain paperwork or other regulations are not followed.

In short, the bill gives our federal health programs the flexibility they need to operate in times of emergency, while ensuring accountability if the waiver authority is ever used. The administration asked Congress for these provisions, and Senator GRASSLEY and I both agreed that they are needed.

I also want to add that the Medicare and Medicaid provisions in this legislation were hammered out together in a bipartisan and bicameral fashion. Although Senator GRASSLEY and I were not conferees, our staffs worked extensively with the conference staffs to negotiate these provisions.

In fact, all of the authorizing Committees, both sides of the aisle and both House and Senate, worked together on these provisions.

Mr. GRASSLEY. Mr. President, allowing items within the jurisdiction of the Finance Committee to be added in conference is not something I do lightly. It is critical that we follow regular order, and that committees of jurisdiction hold hearings and examine proposals before the Senate acts. This is, however, an exceptional situation.

In light of the current threats to our nation, we must make these changes to

make our Federal health care programs more flexible, and more responsive to patients, in times of crisis. In my view, this is important enough to make an exception to our general rule of asserting our committee's jurisdiction. Also urgent are two provisions that stabilize Medicare managed care plans, which many seniors have come to rely on.

And as Senator BAUCUS mentioned, our staffs worked closely with the conferees' staffs to make sure that we were comfortable with the provisions that were included.

Mr. BAUCUS. The Senator is right. And briefly, in addition to the waiver provisions that affect Medicare, Medicaid and CHIP, this legislation includes a provision that will suspend the Medicare+Choice "lock-in" requirement for three years.

Current law requires Medicare beneficiaries to remain in their managed care plan for the full year. HMOs and beneficiary advocacy groups have both urged Congress to suspend this requirement as a way to stabilize this program.

While I appreciate the argument that a plan and a beneficiary should be required to make a full one-year commitment, I don't believe that this is the time to implement the lock-in requirement. Plans are pulling out of the Medicare program every year. Thousands of beneficiaries have lost the plans in their area. Because of the current instability in the program, it is my view that Congress should wait until the program is more stable before we implement the lock-in.

Mr. GRASSLEY. I agree, and believe that we have got to take other steps to ensure that seniors understand the choices they have even before the lock-in is in place. I have always believed that informed health care choice is the key to a successful Medicare+Choice system. That is why I fought hard in the 1997 Balanced Budget Act for the National Medicare Education Project, which required CMS—then called HCFA—to start a 1-800 number and to send out detailed plan comparison materials to every senior every year. I think this program has been a success, and I intend to push for additional funding for it this year. But Medicare education needs even more improvement, especially before seniors get locked-in to a specific plan for a whole year. So I think it is important that this bill delays the lock-in requirement. I would also like to point out that our doing so today is in sync with recent recommendations from the Advisory Panel on Medicare Education.

Finally, the bill gives health plans an additional three months to assess their costs before making a decision to participate in the Medicare program. Because of exceptional circumstances with respect to timing, we needed to make this change to the so-called "ACR filing date" now—prior to the time the Finance Committee acts on Medicare legislation. As I have mentioned, I am not normally willing to

make exceptions to Finance Committee jurisdiction, but the circumstances here justify such an exception in this case.

Mr. BAUCUS. Let me summarize by saying that I agree with my good friend Senator GRASSLEY, that every so often there are circumstances that warrant an exception to our jurisdictional concerns, and this is one of them.

Mr. GRASSLEY. I believe that bodes well for our future work together on Medicare legislation in the Finance Committee.

Mr. BAUCUS. Yes, indeed. I look forward to working together in a bipartisan and bicameral fashion on all the other Medicare, Medicaid, and health issues that the Congress will be working on this summer and fall.

Mr. AKAKA. Mr. President, I rise today to give strong support to H.R. 3448, the Public Health Security and Bioterrorism Preparedness and Response Act. The Nation is looking to Congress to provide the building blocks to prepare for and respond to bioterrorism. H.R. 3448 takes several good steps to coordinate and strengthen Federal programs and help states and communities prepare for bioterrorism and other public health crises. As an original cosponsor of the Senate companion bill, I am proud to support the final product. The work that the bill managers and their staff have done in preparing this important legislation is to be commended.

H.R. 3448 provides \$1.1 billion in funding for grants to state and local governments to prepare response plans, buy equipment, and train health care workers for bioterrorism and other public health emergencies, and an additional \$520 million for community hospitals. The Act authorizes funding and establishes safety procedures for scientists to use pathogens for vaccine and disease research. H.R. 3448 builds up many of the Nation's resources that have been weakened from years of neglect and also addresses several new concerns.

Early detection of a biological threat is critical in minimizing the number of people exposed to an agent and the extent that the agent or disease will spread. New tools capable of detecting small quantities of infectious agents in food, water, air and other vectors are needed. For this reason, I introduced S. 1560, the Biological Agent-Environmental Detection Act of 2001. I am pleased to see provisions of my bill included in H.R. 3448, especially the authorization of funding to improve testing, verification, and calibrating of new detection and surveillance techniques and tools. Scientists and engineers in our universities and national labs are conducting exciting research on air and water monitoring and developing satellite-based remote sensing technologies to identify weather patterns that contribute to the spread of infectious disease and biological or chemical attacks. I am convinced that

these men and women can develop robust, effective, and accurate detection methods.

Creating a critical line of defense against bioterrorism must involve health care professionals. Through hearings and discussions with health care providers and bioterrorism experts, it is clear that our doctors and nurses are not trained to recognize or respond to bioterrorism. For this reason, Senator ROCKEFELLER and I introduced S. 1561, Strengthening Bioterrorism Preparedness Through Expanded National Disaster Medical System Training Programs. I am pleased that H.R. 3448 includes our proposal to use the existing emergency communication infrastructure, disaster training program, and community partnerships within the nation's 163 Veterans Affairs hospitals to train VA and Department of Defense staff and local health care providers in recognizing and treating victims of biological weapons.

This is but one way in which the Department of Veterans Affairs serves the nation in bioterrorism preparedness and public health. The \$133 million dedicated to VA will expand these efforts and is well deserved.

Congress has not forgotten the role our local and community hospitals will play in such a crisis. We also are working to give our medical professionals, public health officials, and emergency managers the earliest possible warning of pending outbreaks. The problems we face with bioterrorism are not new, nor are they related solely to bioterrorism. Our hospitals lack the capacity to handle even a handful of extra patients during flu season, let alone hundreds of people seeking critical care during an intentional epidemic. Passing the Public Health Security and Bioterrorism Preparedness and Response Act is only the first step in making America safer. Now we can provide the hard working men and women in public service, academia, and private industry with the resources needed to continue protecting this country from bioterrorism.

Mr. WELLSTONE. Mr. President, I rise today to support the Public Health Security and Bioterrorism Response Act. This act represents a critically important turning point in the readiness of our public health system to respond to the challenge of bioterrorism. In many places in our Nation the public health infrastructure has been underfunded and understaffed. The anthrax attack has demonstrated that our system can be overwhelmed by a bioterrorist attack. This bill provides essential assistance to our network of local and state health departments, public health laboratories, hospitals and health care facilities so that they can protect all of us in the event of further bioterrorist attack, or of other infectious disease outbreaks.

We in Minnesota have long been aware of the dangers of bioterrorism thanks to the efforts of Mike Osterholm, head of the Center for Infectious Disease Research and Policy

at the University of Minnesota. I am very glad that this bill is providing for the kind of bioterrorism preparedness our nation needs.

This bill provides block grants to states to improve public health departments and to get the equipment they need, and to help local governments safeguard their communities from these threats. The bill also provides grants to hospitals and other health care facilities to improve their abilities to respond quickly and effectively to a bioterrorist attack. I am pleased that the authorization for our hospitals has been increased from \$370 to \$520 million. I am also glad this bill emphasizes getting funds to the local level. That is very important. In fact, I would have even gone further in setting aside funds specifically for localities. I am also glad that the antitrust exemption in the Senate bill has been dropped from the conference report.

As Chair of the Subcommittee on Employment, Safety and Training, I am particularly glad that this bill recognizes the threat of bioterrorism in the workplace. Virtually all of the anthrax attacks involved places where people work, including media offices, the U.S. Postal Service and here in the Congress. I am especially happy that this bill includes language which I had suggested to direct the National Institute of Occupational Safety and Health to expand research on the health and safety of workers who are at risk for biological threats or attacks in the work place.

Finally, I am particularly pleased that my provisions regarding mental health were included in this important bill. We know from the outstanding hearings on mental health and terrorism, chaired by Senator KENNEDY in the HELP Committee, that the preparedness and response activities for the mental health consequences of bioterrorism are as important as all other public health initiatives this Congress can support. Recent press reports citing research on the psychological consequences of exposure to terrorist attacks, as well as the necessity of dealing with ongoing threats, have demonstrated clearly that mental health is an integral part of our ability to respond appropriately to bioterrorism attacks.

I am particularly pleased that Public Health Security and Bioterrorism Response Act established mental health response preparedness as one of the primary goals in our national initiative. The mental health provisions in the bill will support federal, state, and local efforts to enhance the preparedness of public health institutions to coordinate mental health services. The bill also establishes as one of the primary responsibilities of the federal Working Group on Bioterrorism and Other Public Health Emergencies to make recommendations regarding the preparedness of public health institutions and emergency service personnel to detect, diagnose, and respond appro-

priately with regard to mental health needs in the aftermath of a biological threat or attack.

A special focus on children's mental health was established through a required National Advisory Committee on Children and Terrorism, whose responsibilities include making recommendations regarding the preparedness of the mental health care system to respond to bioterrorism as it relates to children. Similarly, a required Emergency Public Information and Communications Advisory Committee will include experts on behavioral psychology among its members and will make recommendations on appropriate ways to communicate public health information regarding bioterrorism. The bill also includes mental health training as one of the designated funding activities, specifically to enhance the training of health care professionals to recognize and treat the mental health consequences of bioterrorism or other public health emergencies. And finally, the bill authorizes funding for mental health counseling programs to be coordinated by the Department of Veterans Affairs to develop and maintain various strategies for providing mental health counseling and assistance to local and community emergency response providers, veterans, active duty personnel, and individuals seeking care at Department VA medical centers following a bioterrorist attack or other public health emergency. The VA program also includes funding for training and certification programs.

We know one for thing for sure. It is a mistake to believe that bioterrorism events cannot have lasting impact on the mental health of the individuals who experience them. Let us not repeat the mistakes that were made in the aftermath of the Vietnam war, when the trauma experienced by veterans and their families was ignored or trivialized until well after the optimal time for treatment was past. We have learned from the outstanding research funded by the National Institute of Mental Health and the Department of Veterans Affairs regarding the severity of the trauma-related disorders and the effective ways in which it can be treated. We must ensure that all federal, state, and local public health efforts to respond to and prepare for bioterrorist attacks take advantage of this knowledge.

I do not believe that mental health problems are a widespread or inevitable consequence of bioterrorist attacks. But as we heard from the experts at the HELP Committee hearing, we should not underestimate the severe impact that these events have on people's sense of identity and safety, and how the multiple losses and horrific experiences they go through has the potential to affect them for a long while. There have been many reports in the media of the heightened sense of anxiety and vulnerability throughout our country. These feelings are normal and I have confidence that most Americans

will be able to deal with these crises. But I also firmly believe that the Federal, State, and local governments can play a major role in helping people to understand what has happened to them, and establish programs for mental health services for those who will need it. We in Congress are doing our part by the inclusion of these mental health initiatives within this bill.

In closing, this bill represents an essential step forward in safeguarding both the physical and mental health of our nation in the event of further bioterrorist attack.

Mr. HARKIN. Mr. President, last year, the weakness of our Nation's ability to respond to a bioterrorist attack was exposed. To properly prepare for the future, we must begin to think of our Nation's public health system as the front lines in our battle against terrorism. Unfortunately, our troops were inexperienced, our radar was out of date, and we were short on ammunition. Right now we don't have enough vaccines to protect every American. Public health officials were without the tools and training they need to detect an outbreak and rapidly respond.

Prudence demanded action. That is why Senator SPECTER, Senator BYRD and I crafted and passed a \$3.6 billion bioterrorism initiative to reverse this alarming trend. As a result of this effort, our Nation's defenses against bioterrorism has improved since September 11 and the anthrax attacks of last October, but much more still needs to be done.

As chairman of the Labor-Health and Human Services Appropriations Subcommittee, I held several hearings with a broad variety of people, ranging from leaders of the Federal Government to first responders to our local public health workers.

As a conferee for the bioterrorism bill, I'm proud of the bipartisan work we have been able to achieve on this plan to boost our Nation's bioterrorism prevention and preparedness. The initiatives included in this conference report will build on the Harkin-Specter bioterrorism plan that President Bush signed into law in January, and will aggressively ramp-up efforts to keep America the safest country in the world.

I am especially supportive of the provisions in this conference report that I proposed in a seven-point plan I released following the anthrax attack last fall.

Specifically, the measure will:

Increase training for public health and medical officials: State and local officials, as well as doctors, nurses and other health professionals will be trained in diagnosis and treatment of bioterrorism exposure, as well as rapid communication to colleagues on case exposure and the identification of trends.

Bolster vaccine stockpiles: Currently our stockpile of small pox vaccines could only vaccinate about 25 percent of Americans, and our anthrax vaccine

stockpiles are also vastly inadequate. This legislation will increase funding to increase supplies and improve systems of transport to make sure that the appropriate pharmaceuticals can quickly get where they are needed.

Ensure that there are round-the-clock disease investigators in every state: A number of states have no full-time experts charged with identifying and dealing with infectious diseases. Federal support can be used to ensure that every single state has at least one professional in charge of detecting disease and notifying proper authorities.

Increase hospital surge capacity: The conference report will increase funding for planning and staffing to meet possible high-volume cases of infectious disease exposure. Funds would be administered through an innovative grant program that provides support for wide-ranging initiatives that will improve state and local hospital preparedness for response to bioterrorism and other public health threats.

Improve surveillance and information sharing capacity at all levels of government: The legislation will ensure that all local health departments have access to the Health Alert Network. Currently, health departments in some states don't have fax machines and Internet access. Funding will expand the Health Alert Network so that health professionals are able to quickly key in on outbreaks and share their information around the country and the world.

Expand food safety inspections: Through this bill, every domestic and importer of processed foods must register with the Food and Drug Administration, FDA, farms, restaurants and nonprofit food establishments like soup kitchens are exempted. Also the FDA's authority is expanded to allow them to stop any food or product that may present a public health risk and allows the agency to ban importers who repeatedly violate food safety regulations. Lastly, the FDA is given authority to inspect food processing establishment's records related to food safety. Currently the FDA can only get such records through court action.

Create and maintain a comprehensive database of the locations of biohazardous pathogens: Finally, this legislation will for the first time require that the U.S. Department of Health and Human Services and Agriculture closely regulate and register the possession, use and transfer of the most dangerous pathogens like anthrax and small pox. Security standards for these facilities will be established, and all people with access to the agents will be screened. Facilities with these pathogens will be inspected, and violation of these rules will be punishable by strict criminal and civil penalties.

Again I am very pleased to support this conference report and I look forward to continuing to work in a strong bipartisan process with the President, Secretary Thompson and the rest of the administration to make sure ade-

quate funding is provided for these critically important initiatives.

Mr. HUTCHINSON. Mr. President, the Senate is going to pass landmark legislation today bolstering our Nation's efforts to prepare against future bioterrorist threats and attacks. As a member of the joint House-Senate bioterrorism conference committee, I am pleased to support this conference report.

Eight months ago, five U.S. citizens died due to anthrax, buildings were shut down, and thousands of Americans were tested for possible exposure. Our country learned first hand about the need for improved knowledge about biological weapons and agents—how to detect them, what to do in the case of exposure, and the need for accelerated research and development of countermeasures to defend against such agents.

The Public Health Security and Bioterrorism Preparedness and Response Act provides for the development of vaccines and drugs to defend against biological agents or toxins, improvement of public health emergency response efforts, tightening of requirements for individuals who use and possess biological agents or toxins, enhancement of protections for our food supply and agricultural research facilities, and the development of emergency response plans and security upgrades for our Nation's water systems.

I would like to particularly highlight provisions in the conference report to speed approval of vaccines and drugs developed as countermeasures against biological weapons, improve security at facilities where such countermeasures are researched and developed, and strengthen federal penalties for acts of sabotage against such facilities.

These provisions I introduced as part of freestanding legislation last November, S. 1635, along with Senators GREGG and FRIST. I believe that these provisions are at the heart of our preparedness for future bioterrorist threats and attacks.

I am thankful to my fellow Senate and House conferees for working with me to include a proposal I offered to provide grants for proficiency testing of laboratory personnel in identifying biological agents and toxins. Laboratory personnel will be on the front lines of our detection efforts, and we must make sure they can identify biological toxins and agents.

All States, including Arkansas, will benefit from grants to improve planning and State preparedness efforts, enhance laboratory capacity and educate and train health care personnel. I am also pleased with the inclusion of \$5 million in grants for small community water systems in order to conduct vulnerability assessments, prepare emergency response plans, and make security upgrades.

In summary, this is comprehensive legislation and it is needed legislation. The Public Health Security and Bioterrorism Preparedness and Response Act

lays the foundation for significant changes in America's infrastructure, training, and response programs to protect our Nation's citizens against deadly weapons, particularly biological and chemical agents.

Mr. JEFFORDS. Mr. President, today we will have the opportunity to act positively on one of the most important pieces of legislation that we will consider in this Congress—the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. I am pleased that we are able to vote today on this most vital piece of legislation. Many of our colleagues have worked very hard on this legislation but would like to take this opportunity at the outset of these comments to acknowledge the work of Senator KENNEDY, and Senator FRIST for originally introducing this bill in the Senate, as well as Congressman TAUZIN and Congressman DINGELL for their work in the House.

From the events on September 11, and the anthrax incidents here in our Capitol and around the country, we know first hand that terrorist attacks on America continue to pose a real threat. We are not immune to the cowardly attempts by well-armed and well-financed groups who intend harm upon us, and we must continue to stand strong against those that resent our nation's unyielding commitment to preserve freedom throughout the world.

Today, Congress is taking a step in the right direction. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 solidifies the emergency measures taken last fall by Congress to safeguard the health of all Americans. The Act greatly enhances our ability to prevent and detect bioterrorist threats, and it gives us the resources we need in order to effectively care for our citizens in the event that another biological attack takes place on American soil.

The act is a comprehensive, inter-departmental effort to ensure the safety of American families. This legislation will ensure proper communication across Federal agencies so that all of our available resources are put to their best use. As the cornerstone of our emergency response to public health threats, hospitals will be provided ample resources in order to ensure their preparedness in the event of a biological attack. In addition, we have greatly enhanced our ability to track labs and individuals who possess materials that could be used in bioweapons aimed at people or the food we consume, and there are strong measures taken to further protect the food supply throughout America.

A primary focus of our efforts is to ensure a National Pharmaceutical Stockpile, and to increase production of vaccines for some of the most deadly diseases, including smallpox. There are also provisions for more timely FDA review of generic drugs, and it reauthorizes the Prescription Drug User

Fee Act, PDUFA, an important measure to ensure that newly developed drugs are made available to those who need them most in a safe and timely fashion.

I am also pleased that this bill includes language requiring drinking water systems across the country to assess their vulnerability to terrorist attack and to develop emergency response plans to prepare for and respond to such attacks. We all hope there is no need for implementation of these plans, but information leads to preparation, and I am pleased to have a bill today that recognizes the crucial importance of assessing and addressing potential vulnerabilities.

As chairman of the Committee on Environment and Public Works, I have worried about the lack of information within the Federal agencies about the security of our Nation's critical infrastructure and facilities. For instance, I am aware of one provision in the Clean Air Act which requires the Department of Justice to assess the vulnerabilities of chemical plants. This provision was enacted years before the tragic events of September 11th, but the assessment is not yet complete. And recently, in the wake of criticism that our government should have been more prepared for terrorist attacks, I read a chilling statement from a government official: "People are saying we didn't connect the dots. It's awfully hard to connect the dots if people don't give you the dots."

I do not doubt that industry, communities, local and State governments and emergency responders are taking security measures seriously. But important provisions in this bill will enable our government to "connect the dots," that is, to understand the safety of our Nation's water supply. The substantial funding in this bill will provide enhanced resources for completion of vulnerability assessments quickly, and in a thorough manner. And by requiring that these assessments be provided to the Environmental Protection Agency, we will have the ability to evaluate the security needs of our drinking water systems and to measure our national preparedness for potential threats against our water supply.

In addition, we have addressed the concern that some information in these assessments may be sensitive in nature. Although we recognize that it is most often community knowledge and involvement that is most effective in addressing a community's needs, we also recognize that information in the wrong hands can endanger a community. This bill balances these competing concerns by exempting the content of the assessments from the Freedom of Information Act, by requiring implementation of protocols to secure and limit access to the documents at the EPA, and by imposition of criminal penalties upon persons designated by the EPA Administrator to have access to the documents in EPA's possession who knowingly or recklessly disclose

those documents. It is important to note, however, that there is not a restriction on EPA's discussing the content of the assessments with persons who may benefit from information about the security of our nation's water supply, such as state and local officials, nor is there restriction intended by this bill upon a water system's voluntarily sharing information with other systems, emergency responders or communities. Our attempt to provide a safeguard against broad disclosure of sensitive information does not lead us to conclude that our citizens should not have the information they need to protect and inform themselves.

Finally, I had hoped that this bill would encompass wastewater systems in addition to drinking water systems. I intend to pursue comparable legislation for wastewater systems in this legislative session.

This legislation reflects a remarkable effort that drew from the jurisdictions of several Senate and House Committees including the Health, Education, Labor and Pensions, the Energy and Commerce, Finance, Ways and Means, Agriculture, Judiciary and my own Environment and Public Works. The many Members from these Committees and the conferees are to be commended for their contributions.

Once again I want to acknowledge the yeoman's work done by our staff. In particular I want to recognize HELP Committee staff including, David Nexon, Paul Kim, David Bowen and David Dorsey from Chairman KENNEDY's office; Vince Ventimiglia, Steve Irizarry and Katy French of Ranking Member, Senator GREGG's office; and the staff of Senator FRIST, including Dean Rosen, Helen Rhee and Shanna Christrup, and Doug Campos-Outcalt. Credit also goes to Debra Barrett, Raissa Geary, Adam Gluck, Kate Hull and Rhonda Richards. Finally, I want to acknowledge my own staff, Sean Donohue, Eric Silva, Allison Taylor and Jo-Ellen Darcy who worked diligently to ensure that appropriate public health safeguards were part of this measure, including environmental provisions that will help provide for the safety of our public water systems.

Mrs. FEINSTEIN. Mr. President. I rise in strong support of passage of the conference report for H.R. 3448, the Public Health and Bioterrorism Response Act.

This legislation will make our Nation better prepared for bioterrorist threats and other public health emergencies.

That is why I am pleased that this bill includes funding to bolster the National Pharmaceutical Stockpile, including enough smallpox vaccine to protect every American.

We must ensure that there are sufficient vaccines, drugs, and medical supplies available to protect Americans against any potential biological attack. I believe this bill moves us one step closer to protecting every American from this threat.

It is also crucial that we assist our States and local hospitals and health departments in beefing up their systems, including training personnel and first-responders on how to respond to a bioterrorism attacks.

This legislation includes \$1.6 billion for fiscal year 2003 to address these needs.

I am particularly pleased that the conference report includes a provision which I sponsored along with Senator JUDD GREGG, R-NH, establishing strict new controls for laboratories that handle anthrax, smallpox, and more than 30 other deadly pathogens.

These provisions are the product of extensive negotiations with a number of other Senators including, Senator FRIST, KENNEDY, HARKIN, and DURBIN, as well as House Conferees, and the administration.

The threat of biological attacks became front page news last fall, when deadly anthrax attacks killed five people, infected 23 people, 11 with inhalation anthrax and 12 with cutaneous anthrax, and shut down a Senate office building for 3 months.

The FBI has poured extraordinary resources into apprehending the perpetrator. Over the past 5 months, FBI agents have interviewed more than 5,000 people and offered a \$2.5 million reward. Unfortunately, it has been unable to locate a single witness, fingerprint or a match to the handwriting found on the envelopes.

We still do not know when or if the perpetrator will be found.

It became clear during the investigation of the anthrax attacks that the regulations governing these dangerous substances were too lax.

Our government did not keep track of who possesses these materials.

No special registration was required to possess these agents.

Nor were background checks conducted on the laboratory personnel who handled or had access to these agents.

Under these security conditions, a rogue employee or outside terrorist group could easily gain access to some of the most dangerous pathogens on Earth.

To close these loopholes, I introduced the Deadly Biological Agent Control Act last fall with Senator JON KYL, R-AZ, and a similar provision was approved as part of the fiscal year 2002 Department of Defense Appropriations bill.

I am pleased that key portions of this legislation were included in the final comprehensive bioterrorism package.

The conference report has the following key provisions: All labs that possess these dangerous agents would have to get registered with the Department of Health and Human Services or the Department of Agriculture, for animal pathogens.

The registration process would include rigorous background screening by the Department of Justice of any laboratory employees intending to handle the agents.

Anyone who possesses these agents without obtaining a registration will be subject to 5 years in Federal prison.

The legislation also creates, for the first time, a national database of dangerous pathogens, so that the characterization, location and use of these agents can be tracked.

Tighter controls of these agents are critical because they can be converted into weapons of mass destruction.

In addition, to make sure that this list of dangerous agents is kept up-to-date, it must be reviewed a minimum of every two years.

We need these strong measures because in the wrong hands, these biological agents can be converted into weapons of mass destruction.

According to the calculation of some experts, biological weapons are pound for pound potentially more lethal even than thermonuclear weapons.

For example, the World Health Organization estimates that 50 kilograms of the virus that causes the plague, aerosolized over an urban city of 500,000, would incapacitate one fifth of the population and kill 55,000.

A 1993 report by the U.S. Congressional Office of Technology Assessment estimated that between 130,000 and 3 million deaths could follow the aerosolized release of 100 kilograms of anthrax spores upwind of the Washington D.C. area, lethally matching or exceeding that of a hydrogen bomb.

In sum, I believe it is critical that these laboratory security provisions were incorporated into this bioterrorism bill.

Any comprehensive bioterrorism preparedness package would be incomplete without addressing laboratory security here in the United States.

These controls are reasonable and necessary, given the extraordinary threat posed by biological and chemical weapons.

Ms. LANDRIEU. Mr. President, I would like to take this opportunity to thank the members of the bioterrorism conference committee who have worked tirelessly over the last few months to craft this comprehensive response to our Nation's needs in bioterrorism. I rise today to make one point for the record in regards to this legislation. Following the September 11th attacks, Secretary Thompson, under the authority granted to him by Section 319 of the Public Health Services Act, provided resources to rebuild and replenish our Nation's emergency health care providers who were directly affected by this terrible disaster. In sum, the Secretary awarded over \$35 million in grants to hospitals, ambulance companies, and other first responders who responded or stood ready to respond to the health needs of those injured in the attacks on the World Trade Center and the Pentagon. These awards were made in recognition of the contributions that these providers made, regardless of their ownership. I commend the Secretary for this action.

Disaster strikes without respect to hospital ownership. By exercising his

discretion to award grants to all hospitals who responded, both private and public, Secretary Thompson recognized this important point and more importantly, fulfilled the statutory purpose of Section 319, providing continued access to necessary acute care. Nationally, there are 5,194 hospitals, and of those approximately 1,200 are for-profits. That is one out of every four hospitals. In many markets, for-profit hospitals—not the tax-exempts—serve as the safety net or sole-community providers and that makes them 100 percent of the market in their communities. In my home State, approximately 1/3 of the hospitals are for-profit. If a bioterrorist attack were to ever happen in Louisiana, I can guarantee you that our investor-owned hospitals will play a critical role in the response. Those who are affected by a bioterrorist attack will go to their local hospital for help; they will not check first to see how the hospital is being run.

I am pleased that the conferees added language in this bill to strengthen the Secretary's authority to act as he did in this regard following September 11th. I hope that this administration and the administrations that follow will continue to recognize the important role that all of our hospitals play in the delivery of emergency health care.

Mr. CRAIG. Mr. President, I understand we have one more speaker on our side who is on the way to the floor. I guess there are about 5 minutes remaining.

Mr. KENNEDY. Mr. President, I yield myself 5 minutes.

I wish to comment on the efforts of our friend and colleague from New York, Senator CLINTON, on the pediatric drug labeling rule.

As Senator CLINTON pointed out, this issue is of great importance to herself, Senator DODD, and Senator DEWINE. Senator DODD, who is chairman of the Children's Caucus, Senator DEWINE, and Senator CLINTON have worked very effectively on the question of pediatric drugs, particularly on the recent reauthorization of pediatric drug exclusivity.

I had hoped we would be able to secure the Pediatric Rule in this conference, but we were unable to do so. The research which would flow from this important rule is critical to children. That is why the FDA and the Administration took another look at their proposal to suspend the Rule. It was very wise of them to review that decision and to keep the Rule in place. But with the litigation ongoing, it is still being challenged. This is something we in the Senate will give focus and attention to in the very near future.

I have spoken with Senator DODD, Senator DEWINE, and Senator CLINTON. They know that we will address the Pediatric Rule in our committee in the near future. We will talk to our colleagues about the timing. But we will try to address it in the near future. We

thank them for their continued interest.

So my colleagues understand what is at stake, let me repeat: without the Rule, there will be less research conducted on the impact of many drugs on children, and some products will not be studied at all.

Again, I give my colleagues the assurance that we will pursue this issue in the coming months. We can't afford to compromise children's health.

Mr. President, during consideration of the bioterrorism legislation, there were a number of items which our colleagues raised which were included, a great majority of which were strengthened and which we were able to include in the conference report.

I talked with Senator CARNAHAN about the importance of developing a Web site on bioterrorism so that accurate and good information would be available and accessible to people across the country. This has been included. It will provide important, accurate information to the public as a result of Senator CARNAHAN's legislation. We are certain this will be helpful to families, not only in her State but across the country.

Senator TIM JOHNSON had some important proposals on agricultural bioterrorism. Those provisions were added to strengthen the food safety aspects of our legislation. We have included those, not least of which calls for the President's Council on Food Safety to develop in a timely but collaborative manner a national strategy for food security.

Senator WELLSTONE had major proposals on enhancing the FDA's ability to protect the public health. We included many of those, particularly those strengthening oversight of drug safety and drug promotions.

Senator DASCHLE was enormously interested in how we were going to protect America's farm families. We have many additional protections included in the legislation dealing with agroterrorism, such as mad cow disease, which are very important. His work with Senator ROBERTS led to a broad increase in resources and requirements for USDA.

How much time remains on our side?

The PRESIDING OFFICER (Mr. WYDEN). The Senator from Massachusetts has 6 minutes 10 seconds. The Senator from New Hampshire has 6 minutes 50 seconds.

Mr. CRAIG. Mr. President, I suggest the absence of a quorum, and I ask unanimous consent that the time be equally charged.

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

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

Mr. KENNEDY. Mr. President, for the information of the membership, we



understand Senator COLLINS will be coming in a few moments. After she speaks, we intend to yield back the remaining time and move to a vote. I anticipate we will have a vote on the conference report in probably about 10 minutes. We will ask for the yeas and nays. So Members should be alerted that we will proceed in that manner.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, in a moment, I will yield to Senator COLLINS. But let me, again, thank the chairman for the expert and professional way in which he handled this bill and moved it through the process. It is not the beginning; it is not the end; it is the middle of the process. But as a result of this bill, we will have put in place the mechanisms to produce the vaccines we need as a nation in order to protect ourselves from some of the most virulent biological agents with which we might be attacked—a very important step.

As a result of this bill, we will begin the process of significantly upgrading all the public health capabilities across this Nation, whether it is in large States, small States, large cities, small cities. That is very critical because, as we learned so well in the instance of 9-11, the public health capability of dealing with a crisis is one of the core elements of the first responder, the first line of defense when it comes to a situation resulting from someone attacking our Nation, especially with a biological or chemical agent.

So these two basic streams of effort, which are the core of this bill—the bill has a lot more in it, but that is the core of this bill—are going to make, I believe, a dramatic and significant difference in our capabilities as a nation to handle the threat which we, regrettably, confront now of someone using a biological or chemical agent against us as a nation.

Mr. President, I yield up to 5 minutes, if she wishes it, if I have it, to the Senator from Maine.

The PRESIDING OFFICER. The Senator from Maine is recognized for 4 minutes.

Ms. COLLINS. Mr. President, first, I begin by thanking Senator KENNEDY, Senator JUDD GREGG, Senator BILL FRIST, and all of those who have worked so hard to bring this important legislation to the floor.

I am convinced that the bioterrorism bill to which we are about to give final approval will make a real difference in our Nation's ability to detect and, in the unfortunate event, respond to a bioterrorism attack.

I am particularly pleased that the legislation includes food safety provisions which I have advocated for some time.

In 1998, in my capacity as chairman of the Senate Permanent Subcommittee on Investigations, I conducted a 16-month investigation into the safety of imported food. What we found was truly frightening. We discov-

ered that the FDA inspects fewer than 1 percent of all shipments of imported fruits and vegetables. And we discovered that the safety net for ensuring that imported food was, indeed, wholesome and safe was deeply flawed.

We found that an unscrupulous shipper could very easily ship tainted food from one port to another without detection. If the system was that vulnerable to an unethical shipper, think what a determined terrorist could do.

So I am convinced the provisions included in this bill will make a real difference in helping to ensure the safety of our food supply.

I note that the Secretary of Health and Human Services, Tommy Thompson, recently testified before the HELP Committee that one of his greatest concerns was the vulnerability of our food supply.

I believe the provisions that are included in this bill will help to ensure that our food supply is safe from a terrorist attack.

We have a long way to go in the war against terrorism, but this major bioterrorism legislation is an important step in securing the United States of America.

Again, I commend the two leaders of our committee and all of those who have worked so hard to bring us to agreement on this important legislation.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, finally, again, I thank my colleague, Senator GREGG, and Senator FRIST, Senator COLLINS, and all of our Members for their cooperation and their help.

I urge our colleagues to vote in favor of the conference report.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, have the yeas and nays been ordered?

The PRESIDING OFFICER. They have not.

Mr. KENNEDY. I yield the remainder of our time.

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be.

All time is yielded back.

The question is on agreeing to the conference report. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. REID. I announce that the Senator from Hawaii (Mr. INOUE) is necessarily absent.

Mr. NICKLES. I announce that the Senator from North Carolina (Mr. HELMS) is necessarily absent.

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 98, nays 0, as follows:

[Rollcall Vote No. 124 Leg.]

YEAS—98

Akaka	Dorgan	McCain
Allard	Durbin	McConnell
Allen	Edwards	Mikulski
Baucus	Ensign	Miller
Bayh	Enzi	Murkowski
Bennett	Feingold	Murray
Biden	Feinstein	Nelson (FL)
Bingaman	Fitzgerald	Nelson (NE)
Bond	Frist	Nickles
Boxer	Graham	Reed
Breaux	Gramm	Reid
Brownback	Grassley	Roberts
Bunning	Gregg	Rockefeller
Burns	Hagel	Santorum
Byrd	Harkin	Sarbanes
Campbell	Hatch	Schumer
Cantwell	Hollings	Sessions
Carnahan	Hutchinson	Shelby
Carper	Hutchison	Smith (NH)
Chafee	Inhofe	Smith (OR)
Cleland	Jeffords	Snowe
Clinton	Johnson	Specter
Cochran	Kennedy	Stabenow
Collins	Kerry	Stevens
Conrad	Kohl	Thomas
Corzine	Kyl	Thompson
Craig	Landrieu	Thurmond
Crapo	Leahy	Torricelli
Daschle	Levin	Voinovich
Dayton	Lieberman	Warner
DeWine	Lincoln	Wellstone
Dodd	Lott	Wyden
Domenici	Lugar	

NOT VOTING—2

Helms Inouye

The conference report was agreed to. Mr. REID. I move to reconsider the vote.

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

The motion to lay on the table was agreed to.

Mr. REID. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

# ORDER OF BUSINESS

Mr. REID. Mr. President, we have a number of Senators who indicated they wish to speak. We thought we would be able to start the vote earlier, but we cannot. Each time we get real close, someone else raises an objection. The Republican side does not want us to start on this now for obvious reasons. I can appreciate that.

We have a number of Senators desiring to speak. I assume we should arrange some time. Senator BINGAMAN desires 10 minutes.

Mr. BINGAMAN. Ten minutes would be fine.

Mr. NICKLES. I believe we have a couple of people. I suggest we try and accommodate speakers until 5:40, and then Senator BYRD wants to speak, and then there will be a motion to table and we will start a series of rollcall votes.

Mr. REID. Senator BYRD will speak before 5:40.

Mr. NICKLES. Yes.

Mr. REID. Senator BINGAMAN will speak for 10 minutes, then Senator