had snuck into this country by way of ports in Miami, Fort Lauderdale, Savannah, and elsewhere. These individuals allegedly hid themselves in cargo containers, and then walked away from the ports dressed as stevedores.

This body must provide our customs agents with the tools they need to defend our borders and wage a protracted war on terrorism. We should not, however, give these same agents an incentive to violate our privacy and our civil liberties, particularly when doing so will provide us absolutely no extra security. If we allow our fears to goad us into abandoning the Constitution, then the enemies of freedom and democracy will have won.

Ostensibly, security measures such as the provisions of this bill I have just discussed should be crafted in a manner to protect our democracy. If those security measures actually end up imperiling the democratic rights and freedoms their sponsors claim they protect, then they should be abandoned.

I urge my colleagues to support the rule. I further urge them to please support the Rangel substitute, and oppose the underlying bill if the substitute is not adopted.

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

Mrs. MYRICK. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I thank the gentleman from Florida for bringing up the fact that there were those 25 extremists who came in through the ports in shipping containers. It just drives home again the need for this bill and additional enforcement. I thank him for that.

Mr. Speaker, I have no further requests for time, I yield back the balance of my time, and I move the previous question on the resolution.

The previous question was ordered.

The SPEAKER pro tempore (Mr. FOSSELLA). The question is on the resolution.

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

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

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

The Sergeant at Arms will notify absent Members.

The vote was taken by electronic device, and there were—yeas 386, nays 32, not voting 16, as follows:

[Roll No. 188]

YEAS—386

Abercrombie
Ackerman
Aderholt
Akin
Allen
Andrews
Armey
Baca
Bachus
Baird
Baker
Baldacci
Baldwin
Ballenger
Barcia
Barr
Barrett
Bartlett
Barton
Bass
Bentsen
Bereuter
Berkley
Berry
Biggert
Bishop
Blagojevich
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonior
Bono
Boozman
Borski
Boswell
Boucher
Boyd
Brady (PA)
Brady (TX)
Brown (FL)
Brown (OH)
Brown (SC)
Bryant
Burr
Buyer
Callahan
Calvert
Camp
Cannon
Cantor
Capito
Capps
Cardin
Carson (IN)
Carson (OK)
Castle
Chabot
Chambliss
Clayton
Clement
Clyburn
Coble
Collins
Combest
Condit
Conyers
Cooksey
Costello
Cox
Coyne
Cramer
Crane
Crenshaw
Crowley
Cubin
Culberson
Cummings
Cunningham
Davis (CA)
Davis (FL)
Davis (IL)
Davis, Jo Ann
Davis, Tom
Deal
DeLauro
DeLay
DeMint
Diaz-Balart
Dicks
Dingell
Doggett
Dooley
Doolittle
Doyle
Dreier
Duncan
Dunn
Edwards
Ehlers
Ehrlich
Engel
English
Eshoo
Etheridge
Evans
Everett
Farr
Fattah
Ferguson
Flake
Fletcher
Foley
Forbes
Fossella
Frelinghuysen
Frost
Gallegly
Ganske
Gekas
Gephardt
Gibbons
Gilchrest
Gillmor
Gilman
Gonzalez
Goode
Goodlatte
Gordon
Goss
Graham
Granger
Graves
Green (TX)
Green (WI)
Greenwood
Grucci
Gutierrez
Gutknecht
Hall (TX)
Hansen
Harman
Hart
Hastings (FL)
Hastings (WA)
Hayes
Hayworth
Hefley
Herger
Hill
Hilleary
Hilliard
Hinojosa
Hobson
Hoeffel
Hoekstra
Holden
Holt
Honda
Hooley
Horn
Hostettler
Houghton
Hoyer
Hulshof
Hunter
Hyde
Inslee
Isakson
Israel
Issa
Istook
Jackson (IL)
Jefferson
Jenkins
John
Johnson (CT)
Johnson (IL)
Johnson, E. B.
Johnson, Sam
Jones (NC)
Kanjorski
Kaptur
Keller
Kelly
Kennedy (MN)
Kennedy (RI)
Kerns
Kildee
Kilpatrick
Kind (WI)
King (NY)
Kingston
Kirk
Kleczka
Knollenberg
Kolbe
LaFalce
LaHood
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Leach
Levin
Lewis (CA)
Lewis (KY)
Lipinski
LoBiondo
Lofgren
Lowey
Lucas (KY)
Lucas (OK)
Luther
Lynch
Maloney (CT)
Maloney (NY)
Manzullo
Matheson
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCrery
McGovern
McHugh
McInnis
McIntyre
McKeon
McNulty
Meeks (NY)
Menendez
Mica
Millender-McDonald
Miller, Dan
Miller, Gary
Miller, Jeff
Mink
Mollohan
Moore
Moran (KS)
Moran (VA)
Morella
Murtha
Myrick
Nadler
Napolitano
Nethercutt
Ney
Northup
Norwood
Nussle
Oberstar
Ortiz
Osborne
Ose
Otter
Owens
Oxley
Pallone
Pascrell
Paul
Pelosi
Pence
Peterson (MN)
Petri
Phelps
Pickering
Pitts
Platts
Pombo
Pomeroy
Portman
Price (NC)
Pryce (OH)
Putnam
Quinn
Radanovich
Rahall
Ramstad
Regula
Rehberg
Reyes
Reynolds
Rivers
Rodriguez
Roemer
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Ross
Rothman
Roukema
Roybal-Allard
Royce
Rush
Ryan (WI)
Ryun (KS)
Sanchez
Sanders
Sandlin
Sawyer
Saxton
Schiff
Schrock
Scott
Sensenbrenner
Serrano
Sessions
Shadegg
Shaw
Shays
Sherman
Sherwood
Shimkus
Shows
Shuster
Simmons
Simpson
Skeen
Skelton
Slaughter
Smith (MI)
Smith (NJ)
Smith (TX)
Smith (WA)
Souder
Spratt
Stark
Stearns
Stenholm
Strickland
Stump
Sullivan
Sununu
Sweeney
Tancredo
Tanner
Tauscher
Tauzin
Taylor (MS)
Taylor (NC)
Terry
Thomas
Thompson (CA)
Thompson (MS)
Thornberry
Thune
Thurman
Tiahrt
Tiberi
Toomey
Towns
Turner
Udall (CO)
Udall (NM)
Upton
Velazquez
Visclosky
Vitter
Walden
Walsh
Wamp
Watkins (OK)
Watson (CA)
Waxman
Weiner
Weldon (FL)
Weldon (PA)
Weller
Wexler
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Woolsey
Wu
Wynn
Young (AK)
Young (FL)

NAYS—32

Becerra
Bilirakis
Capuano
Clay
DeFazio
DeGette
Delahunt
Filner
Ford
Frank
Hinchey
Jackson-Lee (TX)
Jones (OH)
Kucinich
Lee
Lewis (GA)
Markey
McDermott
Meehan
Miller, George
Neal
Obey
Olver
Pastor
Payne
Rangel
Sabo
Schakowsky
Stupak
Tierney
Waters
Watt (NC)

NOT VOTING—16

Berman
Burton
Deutsch
Emerson
Hall (OH)
Linder
Mascara
McKinney
Meek (FL)
Peterson (PA)
Riley
Schaffer
Snyder
Solis
Traficant
Watts (OK)

□ 1203

Ms. LEE, and Messrs. FORD, WATT of North Carolina and MEEHAN, Mrs. JONES of Ohio and Ms. JACKSON-LEE of Texas changed their vote from ''yea'' to ''nay.''

Mr. GILLMOR and Mr. TOWNS changed their vote from ''nay'' to ''yea.''

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated against:

Ms. SOLIS. Mr. Speaker, during rollcall vote No. 188 on H. Res. 426, rule providing consideration of H.R. 3129, I was unavoidably detained. Had I been present, I would have voted "no."

CONFERENCE REPORT ON H.R. 3448, PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Mr. TAUZIN. Mr. Speaker, pursuant to House Resolution 427, I call up the conference report on 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.

The Clerk read the title of the bill.

The SPEAKER pro tempore (Mr. FOSSELLA). Pursuant to House Resolution 427, the conference report is considered as having been read.

(For conference report and statement, see proceedings of the House of May 21, 2002 at page H 2691.)

The SPEAKER pro tempore. The gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Michigan (Mr. DINGELL) each will control 30 minutes.

The Chair recognizes the gentleman from Louisiana (Mr. TAUZIN).

GENERAL LEAVE

Mr. TAUZIN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on the legislation.

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

There was no objection.

Mr. TAUZIN. Mr. Speaker, I yield myself 5 minutes.

Mr. Speaker, it is my privilege to bring before the House the conference report to accompany H.R. 3448, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This bill will in short order help ensure America's health security, and I urge my colleagues to join me in sending it to the President's desk.

I want to thank the gentleman from Michigan (Mr. DINGELL), first of all, the ranking minority member of our committee, who, together, with our other members of our committee, put this bill together and secured over 400 votes on this House floor last December for its passage. Now we bring my colleagues back the conference report, bringing together the best of the Senate bill, authored by Senator TED KENNEDY and Senator BILL FRIST, and I want to thank them on the Senate side for their work.

Over 25 Members worked on this conference between the House and Senate, and I want to also thank the Committee on Agriculture and Committee on the Judiciary members, the administration, and the many interested parties who have helped us draft this conference report.

Mr. Speaker, it is crucial that America's public health emergency system be prepared to respond to the new and emerging threats, and we are here to take care of that job today. The conference report makes broad and dramatic investments in our public health infrastructure to help secure our country and provide safety for the American people.

Let me emphasize a few areas. First of all, communications. The conference report will improve communications between all levels of government, public health officials, first responders, health care providers and facilities during emergencies. It authorizes grants in fiscal year 2002 and beyond in grants to State, local governments, public and private health care facilities to improve planning, preparedness, enhance laboratory capacity, educate and train health care personnel.

It will make the Department of Health and Human Services, give it a new focus so they can improve coordination and accountability through a new Assistant Secretary for Emergency Preparedness. We will also ensure that sufficient drugs, vaccines and other supplies are available for our security.

It enhances those controls on deadly biological agents, agents to help prevent bioterrorism to establish a database of dangerous pathogens. It imposes new registration requirements on the most dangerous of those agents and toxins and mandates tough new safety and security requirements to ensure that only legitimate scientists working on appropriate laboratory facilities can gain access to these potential weapons of mass destruction.

The conference report also helps to protect the safety of America's food supply. We are substantially increasing the resources of the FDA so they can hire inspectors at borders and develop new methods to detect contaminated foods. In addition, we are providing the Secretary with the additional regulatory authority he has requested so that FDA can detain foods where there is credible evidence that it is contaminated or poses a threat to human beings.

H.R. 3448 will also ensure that drinking water systems across the country assess their vulnerability to terrorist attacks and develop emergency plans to prepare for and respond to such attacks. Americans deserve to know that we are taking concerted efforts and action today to protect the safe drinking water of our country.

Finally, Mr. Speaker, I am pleased to report that this bill contains a reauthorization of the Prescription Drug User Fee Act, a critical act that provides the money to test prescription drugs before they are authorized by the FDA for use in our society.

Mr. Speaker, I urge my colleagues to support the conference report. This is a critical, must-do piece of legislation to help this country face the new threats we face, and I urge the adoption of this conference report.

On December 20, 2001, Environment and Hazardous Materials Subcommittee Chairman PAUL E. GILLMOR provided a detailed explanation of Title IV for the RECORD as passed by the House. I want to expand upon those remarks and note several aspects of this title as they have been supplemented in conference with the Senate. As evidenced by the conference report to accompany H.R. 3448, the Senate did not have any comparable provisions to Title IV in their bioterrorism legislation. Therefore, the House and Senate conferees utilized Title IV as passed by the House as base text for the final provision.

In this regard, the first and most significant change agreed to by the conferees was the requirement that community water systems submit a written copy of their completed vulnerability assessment to the Administrator of the EPA. The choice of "written copy" in this context is intentional. Since vulnerability assessments contain highly sensitive information, the conference report avoided any requirement or option for electronic submissions and there is no authority for EPA to put such information into its data systems or to create public access of any kind. In addition, the submission requirement applies only to copies of the assessment itself and does not include any supporting documentation, work papers or other preparatory or analytical material.

Second, I would note that the Federal FOIA exemption covering these submissions and information flowing from these submissions is complete; all information and all information derived from these submissions is exempt from disclosure. Moreover Title IV does not create "FOIA events" at the state and local level since it provides that the requirement to submit a vulnerability assessment to EPA does not create any obligation under State and local law to submit a copy of the assessment to any other governmental authority. And while it permits U.S. officials to "discuss the contents" of the vulnerability assessments with appropriate state and local officials, the substitute does not authorize U.S. officials to provide copies of these assessments to anyone, except as specifically provided in the bill.

Third, EPA is required to handle all submitted information under strict security arrangements and protocols. These protocols are to ensure that no one, other than specifically authorized personnel, have access to any part of the submission or to information derived from the submission. The only allowed exceptions to this restriction are for specified actions under identified sections of the Safe Drinking Water Act. Knowingly or recklessly violating these restrictions is subject to criminal prosecution and fines.

Fourth, it is important to note that the conference agreement on Title IV did not establish any new regulatory role or transfer any new regulatory power to EPA. No new authorities were transferred to the Agency beyond the passive receipt of vulnerability assessments under Section 1433. As noted in the previous statement by Subcommittee Chairman GILLMOR, EPA has no power to promulgate regulations or guidance to define what is an "acceptable" vulnerability assessment; there is only a one-time duty to provide information to community water systems by August 1, 2002. In addition, Section 1433 only defines a vulnerability assessment to the extent that it includes a review of certain specified items, most of which are based on the definition of a public water system under Section 1401 of the SDWA. Thus, no community water system is required to use any particular vulnerability assessment tool, to conduct any specific type of analysis, to determine the consequences of any intentional or terrorist acts, analyze the use of any specific chemicals or characterize the risk of any offsite impacts.

In addition, Section 303 of the conference Substitute authorizes the Secretary to detain a shipment of food where FDA has credible evidence or information indicating that such food "presents a threat of serious adverse health consequences or death to humans or animals." This section does not grant FDA authority to detain whole categories or types of foods, rather it applies to specific shipments or articles of food that the Secretary has credible evidence or information of, based on an investigation, examination or investigation, that they present a threat of serious adverse health consequences or death to humans or animals. The "serious adverse health consequences or death" standard that is used consistently in Title III, Subtitle A was drawn from title 21, Section 7.3 of the Code of Federal Regulations, relating to the situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Furthermore, Section 307 of the Conference Substitute authorizes the Secretary to develop a regulation for prior notice of food imports. In developing such a regulation, the Secretary of

Health and Human Services should coordinate and consult with the Secretary of Treasury regarding the notifications already required by the U.S. Customs Service with the goal of eliminating, reducing or consolidating duplicative or unnecessary notice requirements and minimizing potential trade impacts of the prior notice requirements of this section. Finally, Section 305 of the Conference Substitute does not impose a registration fee.

In addition to my earlier remarks on Title II, I want to clarify two other provisions contained in this important title. First, in both the HHS and USDA regulatory program sections, the conference substitute creates a new notification requirement whenever ''a release, meeting criteria establish by the Secretary, has occurred outside of the biocontainment area'' of a registered person's facility. As is clear from the statutory text—''a release . . . has occurred''—this provision covers actual releases, not threatened or possible releases. Second, the phrase ''meeting criteria established by the Secretary'' is meant to make clear that we are leaving it up to the two Secretaries to determine, independently, the type or nature of releases to be covered by this provision as it applies to each regulatory regime. We expressly do not intend to incorporate the definitions and interpretations of the term ''release'' as it is used in a Comprehensive Environmental Response, Compensation, and Liability Act.

Finally, we create a ''(b)(3)'' statute exempting certain categories of information relating to select agents from the Freedom of Information Act (FOIA). Specifically, we bar disclosure under FOIA of registration and transfer documents, including information derived therefrom that could identify a registered person, or the agents being stored by a registered person; security-related information; and compilations of registration and transfer information. We also protect site-specific information on inspection reports, provided that the agency determines public disclosure would endanger public health and safety. By adding this additional requirement for inspection documents, we are striving to ensure a fair balance between public accountability and security. When a registered person is publicly known to be working with select agents, public disclosure of an inspection report is less likely to endanger public health or safety (provided that security-specific information is redacted), and may improve it by ensuring public accountability. But when the activities of a registered person are not publicly known, revealing the identity and location of a registered person would more likely endanger public health or safety. The agencies will need to consider such matters on a case-by-case basis.

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

Mr. DINGELL. Mr. Speaker, I yield myself 3 minutes.

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

Mr. DINGELL. Mr. Speaker, I want to rise first to commend my good friend and colleague, the gentleman from Louisiana (Mr. TAUZIN), for the distinguished work he has done not only on producing a good bill but on producing a good bipartisan bill.

This is a good piece of legislation. Many have worked on it and I can recommend it to the House without reservation. We bring them an excellent legislation to the floor, a matter of great national importance. This is going to improve our preparedness against terrorism. All of us know why the legislation is needed, and now.

The bill, which was sponsored by the gentleman from Louisiana (Mr. TAUZIN) and I and a number of our colleagues, passed the House originally by 418 to 2. The Senate bill, an excellent piece of legislation, sponsored by Senators KENNEDY and FRIST, passed by unanimous consent. It is, as I mentioned, an excellent bill.

The conference report we have now before us is a superb product, thanks to the leadership of the gentleman from Louisiana (Mr. TAUZIN) and Senators KENNEDY and FRIST, as well as all of the conferees who worked very hard on this legislation, and the staff, which deserves great commendation for their labor.

The Act authorizes funds for planning, preparation, and response and activity across the board to deal with those questions, with special emphasis on the State and local level, an area where there is needed and necessary concern. It is hoped that this bill will then make it possible for those who will be provided in this bill and their funding to move directly to the front lines where they are needed, and that will include assistance in shoring up our frayed public health network and our first responders, who are largely officers of the local and State governments.

The bill has important new protections for the food supply of the Nation, an area of particular and long-standing concern. We provide new inspection resources for imported food, but these will only be a down payment on what is ultimately going to be necessary.

Other new authorities are included in the report, registration and detention provisions of the legislation which will help the Secretary to manage imports more efficiently and effectively in the public interest and in the interest of consumers.

There are many other excellent provisions, including improvement in drinking water supply safety, tighter controls on dangerous biological agents. These are important steps and they must be taken now.

Finally, we reauthorize the Prescription Drug User Fee Act which has led to faster FDA approvals of prescription drug applications, and we increase funding for drug safety efforts.

I repeat, this is a good bill. It is an excellent start as our Nation works to improve its abilities to defend against an assault by enemies using biologic agents and other kinds of agents to create danger, hazard and death for our American people.

Mr. Speaker, I reserve the balance of my time, and I ask unanimous consent to yield the balance of my time to the gentleman from Ohio (Mr. BROWN) for him to control on behalf of the minority.

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

There was no objection.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Georgia (Mr. NORWOOD), a distinguished member of our committee.

Mr. NORWOOD. Mr. Speaker, I just want to point out that this bill represents a mammoth undertaking by the Committee on Energy and Commerce, and I would like to compliment the hard work done by the gentleman from Louisiana (Mr. TAUZIN), the chairman, and the gentleman from Michigan (Mr. DINGELL), the ranking member, in bringing this important legislation to the floor. It is something that we must pass, we must get into law immediately, and I am delighted that we are doing so in a bipartisan way.

There are things I would like to see different in this bill, as I presume most Members would, but we simply do not have that luxury. We have to find a way to protect the American people from bioterrorism today with a bill that can become law immediately.

The gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Michigan (Mr. DINGELL) and too many others to mention have actually found that way in this bill. This bill will provide additional support for the Centers for Disease Control and Prevention, and I want to thank the gentleman from Georgia (Mr. CHAMBLISS), my good, dear friend, for his work in that area, as well as the public and private health care systems throughout America's local communities.

It will improve communication among all levels of government, which is where we clearly have the greatest problem at present. It provides a stockpile of sufficient drugs, vaccines and other supplies that we found we were short of when forced to abandon our offices to anthrax last year. It encourages a development of new drugs and vaccines to combat bioterrorism, and it increases the security at our borders and for our food and drug supplies and waterworks.

I compliment the chairman for getting the Prescription Drug User Fee Act reauthorized through 2007 as an important precursor to solving the long-term challenges of the prescription drug cost.

Mr. Speaker, we can make improvements later. We need action yesterday. I urge the passage of this bill today.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself 4 minutes.

American lives depend on the strength and the reach and the cohesiveness of our public health system. For far too long, we have neglected our public health infrastructure, the men and women on the front lines, and the resources they need to do their job.

This bill makes a new investment in the Nation's public health and vaccines and in food safety. I am particularly gratified by the strong language concerning antibiotic resistance and the

very positive work we have done to improve the safety of imported food.

I want to recognize the hard work of staff who has been laboring over this bill for several months, pulling some all-night sessions, long weekend sessions. On the Committee on Energy and Commerce, Edith Hollaman and John Ford and Bruce Guinn and Jonathan Cordone on the minority; and with the majority, Nandan Kenkeremath, Amit Sachdev, Tom DeLinge and Pat Morrisey; also with the gentleman from California's (Mr. WAXMAN) office, Ann Witt; and especially three people in my office, Ellie Dghongy, Katie Porter and Earl Seeley, for their outstanding work on this very complicated and extraordinarily complex issue.

□ 1215

This legislation authorizes PDUFA, the Prescription Drug User Fee Act. By increasing the resources available to FDA, PDUFA has enabled the agency to reduce the time needed to assess safety and efficacy of new prescription drugs. Expediting access to beneficial new medicines is good for consumers and good for public health. However, more rapid approval times, coupled with increasingly aggressive marketing by drug manufacturers, all too often have safety consequences.

More new drugs in the marketplace, more Americans taking these drugs due to the barrage of direct-to-consumer advertising, if a lethal side effect surfaces once a new drug hits the market, millions of Americans are affected. That is why it is critical to bolster FDA's drug safety capabilities. One of the most important provisions in this bill enables FDA to devote a portion of the user fees it collects from the drug industry to enhance its pre- and post-market drug safety functions.

We took steps to ensure that the focus on rapid approval time does not put pressure on FDA to drain resources from other important functions, like drug safety, like the review of drug advertising, and, importantly, the review of generic drugs. We also laid the groundwork for improving the process by which drug user fees are established.

The public interest is never served when a regulatory body and the industry it regulates get too close. FDA depends on user fees from the industry it regulates, consumers depend on FDA to focus on public health and public safety, not on drug industry profits. FDA has established performance goals to demonstrate that it is applying the user fees in an effective manner. Historically, the drug industry and FDA have jointly established these goals behind closed doors.

We have taken steps to make sure consumers are part of that process. Regardless of where the revenues come from, FDA's responsibility is the consumer, not the drug industry, something they need to always remember. Any and every goal it sets should reflect that fact.

Mr. Speaker, I want to briefly mention one disappointment in this process. Last year, we passed legislation giving the drug industry a patent extension if they conduct tests to make sure their drugs are safe in children. Some of us question why the Federal Government had to bribe drug companies in order to get them to do tests that should be mandatory. We know many new drugs are prescribed for kids now. We know doctors are forced to fly blind, making decisions about the right medicine, the right dose, without the benefit of clinical testing.

We were told the patent extension incentive was important to get drug companies to conduct tests on drugs already on the market, but that the bill did not supplant FDA's authority to require the testing for new drugs. Well, it appears the drug industry and my Republican colleagues, who on this issue apparently are doing its bidding, have changed their mind. The administration has waffled on whether to maintain the regulations that affirm the testing requirement.

My colleague, the gentleman from California (Mr. WAXMAN) has introduced legislation to codify that requirement, in other words, to ensure that children receive the proper drugs in the proper dosage. If we could depend on the drug industry to make sure their drugs are safe, the drug industry would not be fighting regulations that require them to do so.

Other than those small number of criticisms, Mr. Speaker, this is good legislation.

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

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Florida (Mr. BILIRAKIS), the chairman of the Subcommittee on Health of the Committee on Energy and Commerce.

Mr. BILIRAKIS. Mr. Speaker, I thank the gentleman for yielding me this time, and I rise in support of the conference report.

This important legislation strengthens our ability as a country to detect and respond to bioterrorist threats or attacks. Just this week, the Vice President stated that another terrorist assault is almost certain. Therefore, Mr. Speaker, it is crucial that we quickly pass this legislation and send it to the President for his signature.

The legislation is a strong and comprehensive measure that enhances the security of our Nation. First, we strengthen our public health systems by increasing State and local preparedness to detect and respond to an attack. Secondly, this bill enhances security measures in relation to the handling, transport and storage of dangerous substances. Third, we strengthen our Nation's food security systems. And, fourth, we improve the safety and security of our drinking water systems.

Mr. Speaker, this is a comprehensive approach and a meaningful step to improve our Nation's security systems. The conference report includes provisions to reauthorize the Prescription Drug User Fee Act. This is critically important, because without this program the Food and Drug Administration would have lost millions of dollars and numerous personnel which are used to review and approve lifesaving medicines. I am very pleased we worked in a truly bipartisan, bicameral manner to reauthorize this program.

Unfortunately, we were not able to reach resolution on medical device changes. But I am committed, Mr. Speaker, I like to think we all are, to working to update device laws this year.

I want to take a moment to thank the staff who worked so hard to complete this legislation, particularly to single out Pete Goodloe, the House's Legislative Counsel. We would not have been able to complete this legislation in a timely fashion without his expert services.

Unfortunately, there are so many other staff that have worked so hard, I am unable to name each of them here today. But please know that our country will be better prepared in the future because of your hard work.

Mr. Speaker, this is a strong measure supported by all the conferees, and I urge my colleagues to support this conference report.

Mr. BROWN of Ohio. Mr. Speaker, I yield such time as he may consume to my friend, the gentleman from Texas (Mr. STENHOLM).

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

Mr. STENHOLM. Mr. Speaker, I rise in support of H.R. 3448.

Mr. Speaker, I rise today in support of H.R. 3448, the Bioterrorism Preparedness Act conference report. I appreciate the work that Chairman TAUZIN and Ranking Member DINGELL have put into this bill, and I want to thank them both for the respectful and helpful way they have dealt with concerns raised by the agricultural community.

However, I do need to express my concerns about the thoroughness of the process in regard to many provisions under the jurisdiction of the House Agriculture Committee. I would have been much more comfortable with a more deliberative process, including a hearing record and outside input.

The conference report includes significant changes in the following areas: the regulation of biological research facilities; changes in the way our food is inspected; changes to human and animal disease monitoring efforts, and many more.

Many of the provisions of this conference report appear to be needed, and are very logical in light of our Nation's current security concerns. For example, language in this agreement to coordinate and enhance our control of dangerous biological agents and toxins is certainly timely and important. In addition, this conference agreement contains needed authorizations to upgrade and secure facilities working with biological agents, both for human and animal disease research.

Given the importance of these issues, along with the willingness of the other conference

members to make a few important changes to the bill, I am going to support the conference agreement. Still, I feel I must reiterate that it would have been better if many of the provisions in this agreement, the majority of which are not emergency in nature, had gone through a more thorough and regular legislative process.

Given the reality of the choices before us today, and the importance of some of the provisions in this legislation, I urge Members to support passage of the conference report.

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentlewoman from California (Ms. HARMAN), a member of the committee.

Ms. HARMAN. Mr. Speaker, I thank the gentleman for yielding me this time; and I hope that he will add my staffer, Carolyn Cobberly, to the list of brilliant staffers who have added to this legislation.

Mr. Speaker, serving on the Committee on Energy and Commerce is a high honor. The chance to work on impressive bipartisan legislation like this is why I came to Congress.

The possibility of another bioterrorist attack is real and our Nation must be prepared to respond. Our top priority must be to develop a national strategy to identify the most likely threats and prioritize our response. We already know that al Qaeda and rogue states like Iraq have attempted to acquire biological agents, and we have yet to discover and prosecute the individual or group responsible for the anthrax attacks that killed five people in October and November.

Our government's response to the bioterrorist attacks of October and November was deeply flawed. We have talented people, but we have been lacking the resources and coordination to make our response effective. We must act now to improve our terrorism response before another tragedy occurs.

This legislation moves us in the right direction. It creates lines of communication and organizations to coordinate the roles that our public health agencies, military, and FBI will play in bioterrorism response. It also directs substantial investments to the State and local governments that need it most. All terrorism is local, and our response must be local. This bill provides resources where they are needed most.

I am particularly glad that this bill includes funds to speed up the renovation of CDC's buildings and facilities. I have visited the Centers for Disease Control and Prevention in Atlanta and seen talented people working there in the shabbiest conditions. This legislation authorizes $300 million in each of the next 2 years to improve the security of CDC facilities and construct much-needed research facilities.

I am also glad this bill will increase our investment in improving the IT capabilities of public health agencies across the Nation. One-third of public health agencies are not connected to the Internet. If we are to communicate effectively, we need to develop comprehensive, syndromic surveillance systems to detect the outbreak of diseases, and we need to have all public health agencies on line.

This bill is excellent legislation, and I urge its passage.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 5 minutes to the gentleman from North Carolina (Mr. BURR), the distinguished vice chairman of the full committee.

Mr. BURR of North Carolina. Mr. Speaker, I thank the chairman of the Committee on Energy and Commerce for yielding me this time.

At this time, Mr. Speaker, let me recognize the tremendous work of the chairman, of the ranking member, the gentleman from Michigan (Mr. DINGELL), Senator KENNEDY, Senator FRIST, who headed the Senate side, but more importantly the great work of committee and personal staffs of all the Members who served on that conference. This was not an easy thing to hammer out. It took many late nights on the part of staff. There was a lot of give and take; but it meant that something that was important to this country, something that was timely and urgent, actually got addressed in a sufficient way.

Mr. Speaker, I rise today in support of the conference report. This legislation has been long in the making and is long overdue when we look at what we have gone through. But H.R. 3448 puts in motion the resources, $4.6 billion in 2 years, and authorities needed to close the gaps in our Nation's public health infrastructure.

I would like to speak briefly about a few of the many important provisions included in this bill. I am grateful that the managers agreed to retain the provisions authorizing the National Medical Response System. These provisions are built around legislation introduced earlier and recognize the critical role played by personnel of the National Disaster Medical Response Teams in responding to all disasters, not just bioterrorism. The members of the National Disaster Medical Response Teams are nearly all volunteers who are called away from their real jobs on a moment's notice, and they deserve the liability and job protections we extend to them in this bill.

I am also pleased the managers recognized the need to revitalize and modernize the lab facilities and other buildings at the Centers for Disease Control. This section, which builds on the hard work of the gentleman from Georgia (Mr. CHAMBLISS), the gentlewoman from California (Ms. HARMAN), and the gentleman from Georgia (Mr. LINDER) and their bill H.R. 3219, authorizes a dramatic ramp-up in our facility spending for the CDC.

The legislation also takes into account the central role played by the centers in operating and maintaining a robust public health communications and surveillance system that we were shocked to find out was not electronically connected to every public health entity in this country. But after this bill, it will be connected. The centers are a national asset, and they need our support in order to carry out their very important mission.

The grant program authorized in this legislation, Mr. Speaker, is the real heart of this bill. Building on the work being done on an emergency basis by the administration, these grants will enable our State and local governments as well as hospitals to train personnel, purchase needed equipment, and strengthen the communication and disease surveillance that they have done up to this point. It is our hope spending in these areas will not only help improve our ability to respond to bioterrorist attacks but also strengthen critical elements in our overall public health system.

The bill also tightens control on access to dangerous biological agents and toxins by establishing a reporting and tracking system that was not in place. We do not mean to introduce these provisions to be burdensome on researchers, but as we have learned post-September 11, our ability to know where these agents and toxins are is vitally important.

Title 3 strengthens the safety of the food and drug supply in the United States. I believe that with subsequent regulations from HHS, we found a balance between information requirements and information activities. None of us want to make it a burden to import food and bulk drugs. But after 9–11, we realized we have to have a better handle on the items that cross our borders and where they are.

In this legislation, Mr. Speaker, we also reauthorize the Prescription Drug User Fee Act. The last time we reauthorized this act was when we passed the food, drug modernization act in 1997. This time, PDUFA is reauthorized with increased emphasis on post-market surveillance and generic drug review. The FDA and patients across the United States will benefit greatly from this legislation and that reauthorization.

Finally, let me once again extend my thanks to the many personal and committee staffs on both sides of the Hill who put really invaluable time into working out the differences on this. Like many others, it is not perfect; but it is pretty darn good. It is this legislation will go a long way in restoring the viability of our Nation's public health infrastructure at a time when it is vitally needed.

Mr. Speaker, today I urge my colleagues to support this conference report, support the good work of the House and the Senate, and let us move forward with rebuilding things that we know now we need to rebuild.

Mr. BROWN of Ohio. Mr. Speaker, I yield 1 minute to the gentleman from Massachusetts (Mr. MARKEY).

□ 1230

Mr. MARKEY. Mr. Speaker, the litany of saints has been mentioned of staffers who have worked on this bill. I

would like to add just two more: one is Jeff Duncan, who is my legislative staff director; the other is Kristen Kulinowski, who is in the gallery right now with her mother and father and husband, who worked on the provision that will provide for the Federal Government to give to the States or to local communities who request it the potassium iodide which would serve as the antidote to thyroid cancer which is the very real and greatest danger in the event of a successful attack of a bioterrorist group at a nuclear power plant or an unwanted accident at a power plant.

And so this is a huge step forward, which I believe is going to really increase public health and safety. I want to thank the majority for their great assistance on this and thank all the people in the minority as well for their great help.

Mr. Speaker, I rise to commend the conferees for their hard work on this important bill. H.R. 3448 includes a provision of mine that will take an important step toward protecting public health in the event of an act of terrorism at our Nation's nuclear power plants. I thank Mr. TAUZIN for working with me in the House Energy and Commerce Committee to include a provision on stockpiling potassium iodide to protect public health in the event of a successful terrorist attack against a nuclear power plant. Potassium iodide is a safe and effective drug that protects the thyroid gland by saturating it with a safe form of iodine so that it cannot absorb the radioactive iodine produced during the plant's normal operation.

My provision, which was adopted in committee and passed by the House with broad bipartisan support, will provide greater protection of public health than existing programs. The Nuclear Regulatory Commission has a voluntary program that provides States with free potassium iodide for people within 10 miles. However, a State must submit a formal request to the NRC to get the free pills, and some States have refused to do so. My provision allowed States or local governments to request potassium iodide for people within 20 miles of these plants, thus expanding the radius of protection beyond the 10-mile emergency planning zone, and would have allowed local governments to request this important protection even if the State had refused to accept the NRC's offer.

The bioterrorism bill that was passed by the Senate had no potassium iodide provision, so we worked together in conference committee to produce the amended provision under consideration today in title 1, section 127. This amended provision directs the President to provide potassium iodide to States and local governments, and provides a mechanism for local governments to request the pills where the State has not done so. The local government is eligible to request potassium iodide from the President only if the State government does not have a plan for stockpiling or has a plan that does not go beyond 10 miles. The local government must first petition the State to modify the State's plan to include the population requested by the local government. If the State does not modify its plan, the local government must submit a stockpiling and distribution plan to the State and the State must certify that the local government's plan is not inconsistent with the State's emergency plans.

In addition, the conferees agreed to commission a study by the National Academies on the most effective and safe way to distribute and administer potassium iodide on a mass scale. I wish to make clear that this study will not consider the overall safety and efficacy of potassium iodide as a medical preventative to thyroid diseases caused by exposure to radioactive iodine. The Food and Drug Administration, Nuclear Regulatory Agency, and Federal Emergency Management Agency have all concluded that potassium iodide is safe and effective. In fact, the FDA has stated that the risks of radiation-induced thyroid cancer in children so far outweigh the negligible risk of side effects, that it is better for a child to take a full adult dose than to take no potassium iodide at all. Thus, the study will only address how best to incorporate potassium iodide into a comprehensive emergency plan that may include evacuation and sheltering.

One thing I would like the National Academies study to consider is whether a 20-mile radius goes far enough to protect people in the event of a core melt-through plus breach of containment. The Nuclear Regulatory Commission's own documents show a significant risk to the thyroid as far away as 200 miles from the plant in such a scenario, yet the official evacuation zone only extends to 10 miles. The NRC disputes this documentation yet has failed to produce for me any new studies that justify the 10-mile zone. The Chernobyl accident resulted in increased thyroid cancers hundreds of miles from the plant. I would strongly recommend the National Academies study whether 20 miles is sufficient.

While this provision doesn't go as far as I would like, it is an important first step in expanding the radius of protection from nuclear terrorism. I thank all the members of the conference committee who worked on this bill and I urge my colleagues to vote for its passage.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. LAHOOD). The Chair would remind Members not to refer to people in the gallery.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Illinois (Mr. SHIMKUS), a distinguished lieutenant colonel.

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

Mr. SHIMKUS. Mr. Speaker, the committee and our work, especially the Committee on Energy and Commerce, is two-for-two, 2 days in a row, two good bills, bipartisan agreement. I want to applaud both our majority side and our colleagues on the other side for two good pieces of legislation.

Since the attacks of September 11 and the recent anthrax exposures, our Nation has had to reevaluate its ability to respond to a bioterrorism attack. The anthrax attacks, though small in scale compared to the scenarios envisioned by bioterrorism experts, strained the public health system and raised concern that the Nation is insufficiently prepared to respond to bioterrorist attacks. Improving public health preparedness, food safety protection, and response capacity offers protection not only from bioterrorist attacks but also from naturally occurring public health emergencies.

This conference report substantially improves our country's ability to plan and prepare for such an emergency. It increases the ability of the Federal Government and communities to plan for any future biological emergencies. This includes improving communications and the public information flow, updating lab capabilities, authorizing a national stockpile, and assisting our health care providers to be prepared to provide care.

In particular, Mr. Speaker, title II of this legislation creates a list of all biological agents and toxins and regulates which individuals can work with them. As many of the Members are aware, the Justice Department will start giving lie detector tests to hundreds of current and former Federal employees who worked at two Federal facilities where anthrax was kept. One former researcher at one of the labs said that nothing was in place to prevent workers from removing the deadly germs from the labs. This legislation will make sure that the government is well aware where these dangerous toxins and agents are being researched and stored and exactly who will be doing the research. If this provision had been in place prior to last year, the anthrax attacks might have been prevented.

In addition, title I of this bill includes a provision that addresses health personnel shortages that would impact the ability of the Nation to respond during a bioterrorism attack. The bill establishes grants for training and education of these critical health care providers.

I ask for full support of this bill.

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentlewoman from California (Mrs. CAPPS), a registered nurse who is on our committee.

Mrs. CAPPS. I thank my colleague for yielding time.

Mr. Speaker, I rise in support of the conference report on the bioterrorism preparedness bill. This bill is a good example of what we can accomplish when we work together. The bill we produced under the leadership of Chairman TAUZIN and Ranking Member DINGELL will strengthen our public health infrastructure and make a much-needed increase in resources for food and water safety and security.

I am very pleased that one of my bills, the Community AED Act, was included in this legislation. I introduced this bill earlier this year with my colleague, the gentleman from Illinois (Mr. SHIMKUS). It will help local communities place automatic external defibrillators in public places. Quick access to AEDs can mean the difference between life and death for victims of sudden cardiac arrest. Making sure AEDs are readily available will improve our ability to cope with public health emergencies.

I am also pleased that this bill sets aside funds to train health care workers to identify and treat symptoms of bioterrorism. And it provides the Secretary of Health and Human Services

with a small pool of funds to address workforce shortages. But as a part of our goal of preparing for bioterrorism, we still need to do more to address the shortage of nurses. Nurses, for example, will be called upon to deal with patients who may have been infected by a biological agent, and we do not have enough nurses. That is why I have been working with Chairman TAUZIN, Chairman BILIRAKIS, the gentleman from Michigan (Mr. DINGELL), the gentleman from Ohio (Mr. BROWN), and others in the House and Senate to complete the Nurse Reinvestment Act passed here last year. The passage of this nursing legislation as a complement to the bill before us today is essential to making us ready for bioterrorism.

I am pleased that Chairman TAUZIN and Chairman BILIRAKIS have given me their assurances that we will finish this bill by the end of June. These bills together can help our Nation be ready for tragedies we do not even want to imagine.

I urge my colleagues to support this bioterrorism bill and commit to final passage of the Nurse Reinvestment Act.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 1 minute to the gentleman from South Dakota (Mr. THUNE) from the Committee on Agriculture which contributed a great deal to this bill.

Mr. THUNE. Mr. Speaker, I thank the gentleman for yielding time. I want to commend the gentleman from Louisiana (Mr. TAUZIN) for his hard work in bringing together different bills in a bipartisan way that meet the public health threats that we face as a Nation. I particularly want to thank both Chairman TAUZIN and Chairman COMBEST for including language in this bill to authorize an agricultural bioterrorism early-warning surveillance system for animal diagnostic laboratories. This network will provide early detection of bioterrorist events, natural or intentional contamination of our food supply, animal disease outbreaks involving agents which impact human health and early recognition of newly emergent and economically important diseases such as foot and mouth disease. The network will also enhance coordination between State and Federal laboratories as well as public health agencies. In my State, South Dakota State University will benefit greatly from this particular provision.

Mr. Speaker, the infrastructure our Nation needs to protect and prepare itself for bioterror attacks cannot be overlooked. This legislation meets those needs so that people across our Nation can feel safe and secure with the understanding that should the worst happen, we will be ready.

I ask my colleagues to support the conference report.

Since the attacks of September 11th we have all become far more sensitive to the threat of a bioterrorist attack here at home. It is critical that our citizens feel secure at home, that our first responders are properly trained and prepared and that the food that crosses our borders is safe.

I want to thank my colleague Chairman BILLY TAUZIN for his hard work to bring two different bills together in a bipartisan compromise that meets the public health threats we face as a Nation. This bill uses new ideas and new resources to help government officials at every level prepare for bioterrorist threats and public health emergencies.

The bill authorizes more than $1.5 billion in grants to improve bioterror planning and preparedness and to develop new drugs, therapies and vaccines.

The bill authorizes $300 million for the Centers for Disease Control and Prevention to upgrade and improve their facilities and capabilities.

The bill authorizes more than $1.15 billion for the Secretary of Health and Human Services to expand medicine stockpiles and the purchase of additional small pox vaccines.

The bill also grants authority to USDA to impose new registration requirements to regulate those agents that are most devastating to crops and livestock. Additionally, the bill creates tough new criminal penalties to enforce these important new regulations.

Importantly, the bill authorizes $545 million for FDA and USDA to hire hundreds of new inspectors at our borders and to develop new methods to detect contaminated foods. The bill also provides new regulatory powers to FDA to safeguard our food supply. These new resources and authorities will substantially improve the federal government's ability to ensure the safety of America's food supply.

Finally, I would like to thank both Chairman TAUZIN and Chairman COMBEST for including language to authorize an agricultural bioterrorism early warning surveillance system for animal diagnostic laboratories. This network will provide early detection of bioterrorist events, natural or intentional contamination of our food supply, animal disease outbreaks involving agents which impact human health and early recognition of newly emergent and economically important diseases such as Foot and Mouth Disease. The network will also enhance coordination between State and Federal laboratories, as well as public health agencies. In my state, South Dakota State University will benefit greatly from this provision.

Mr. Speaker, the infrastructure our nation needs to protect and prepare itself for bioterror attack cannot be overlooked. This legislation meets those needs so that people across our Nation can feel safe with the understanding that should the worst happen we will be ready.

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentleman from New Jersey (Mr. PALLONE), who is a leading force on the Subcommittee on Health.

Mr. PALLONE. Mr. Speaker, I rise today in support of the conference report. As a conferee on title IV, the drinking water security and safety provisions, I am very pleased with the compromise that was reached. Title IV of this bill includes strong provisions that will, first, require community water systems to conduct detailed assessments of their vulnerability to attack by terrorists and of available remedies; and, second, require EPA experts to review the findings of the vulnerability assessments.

An FBI warning issued in January of this year notified water officials that Osama bin Laden's al Qaeda network had considered and investigated the possibility of attacking water distribution systems. That is why my colleagues and I thought it was absolutely critical that the final bioterrorism legislation address this issue.

The final bill assures that all vulnerabilities to terrorist attacks, including attacks intended to contaminate the water supply and to release chemicals into neighboring communities, are identified and that available safety measures are evaluated. The bill accomplishes this by requiring community water systems serving over 3,300 persons to conduct vulnerability assessments. Each community water system must certify to the administrator of the EPA that they have conducted a vulnerability assessment. The administrator is also required to provide baseline information regarding which kinds of terrorist attacks or other intentional acts are probable threats. Then these vulnerability assessments, once completed, will be sent to the EPA for secure keeping and to help the government understand the threats to our water systems and develop plans to protect our safe drinking water supply. We authorize $160 million through fiscal year 2005 for this goal.

I want to thank the gentleman from California (Mr. WAXMAN). The language in title IV is a tremendous improvement over the House-passed bill. I would also like to thank the conferees and the staff on the Democratic side, Dick Frandsen, also Greg Dotson with the gentleman from California's office, and Heather Zichal with my office.

This is a good bill. I urge its passage.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 1 minute to the gentleman from Indiana (Mr. BUYER), a distinguished and valued member of the Committee on Energy and Commerce.

Mr. BUYER. Mr. Speaker, I would like to thank Chairman TAUZIN and Ranking Member DINGELL for their diligence and hard work on the conference report. Also after September 11 as we were coming together to put together a bioterrorism bill, Chairman TAUZIN gave me an assignment. Given my expertise with regard to the Department of Defense military health delivery system and the VA, it was to actually draft a medical education piece, a component of this bill. The expertise with regard to how to identify and treat chemical and radiological agents and biological toxins and pathogens rests with the Department of Defense. We have taken this knowledge from the DOD and moved it into the VA because of the VA's nexus as teaching hospitals. We are not going to establish new community standards of medical practice, that is what is extremely important here, but we are going to make sure that our first responders, our doctors, are able to identify and treat these new threats in the future. That is what this bill does.

I want to thank the chairman and the gentleman from Michigan for their hard work at the conference, along with the gentleman from Ohio (Mr. BROWN). I appreciate their work.

Mr. BROWN of Ohio. Mr. Speaker, I yield 1 minute to the gentleman from California (Mr. WAXMAN), whose two staff people, Karen Nelson and Tim Westmoreland, did particularly outstanding work. He was on the conference committee with the gentleman from New Jersey (Mr. PALLONE).

Mr. WAXMAN. Mr. Speaker, I thank the gentleman for yielding me time. I want to congratulate the leadership of our committee on both the Republican and the Democratic side and all the staffs who worked on this legislation and urge support for the conference report. It includes many valuable provisions that deserve our support. In particular, it provides significant funding to the Centers for Disease Control and Prevention and to State and local public health systems and hospitals to improve their ability to respond to bioterrorist attacks and other public health emergencies.

The report also includes important new food safety authority to the Food and Drug Administration, authority that will be essential in the event of a bioterrorist attack.

I am also pleased that we were able to make significant improvements to title IV of this legislation to help protect the Nation's drinking water from terrorist attack. Under these provisions, community water systems will prepare vulnerability assessments and provide these assessments to EPA. EPA will then be able to use the assessments to address the threat of terrorism and for any other lawful purpose. These provisions are a step forward. I am glad they have been included in this legislation.

This conference report includes many valuable provisions that deserve our support. In particular, it provides significant funding to the Centers for Disease Control and Prevention and to State and local public health systems and hospitals to improve their ability to respond to bioterrorist attacks and other public health emergencies.

The report also includes important new food safety authority to the Food and Drug Administration—authority which will be essential in the event of a bioterrorist attack. The report authorizes the FDA to: Require food companies to register with the FDA their names and locations; detain food if there is information that it may present a serious risk to health, either at the border or in domestic commerce; require importers to give the FDA prior notice that a food will be coming into the US; require food companies to keep records that will assist the FDA to trace contaminated food; and inspect food establishments when there is a reason to believe that they are holding food that presents a serious risk to health.

We were also able to make significant improvements to Title IV of this legislation to help protect the nation's drinking water from terrorist attack. Under these provisions, community water systems will prepare vulnerability assessments, and provide those assessments to EPA.

EPA will then be able to use the assessments for a number of critical purposes: To ensure that vulnerabilities are being adequately assessed; to ensure that federal grants are awarded appropriately; to conduct thorough inspections under the Safe Drinking Water Act; to address significant vulnerabilities under section 1431 of the Safe Drinking Water Act; to share with law enforcement and intelligence agencies; and for any other lawful purpose.

I would also note that the report contains reauthorization of the Prescription Drug User Fee Act. For the first time, we have included provisions that will allow the FDA to use user fee money to watch over the safety of drugs after they are marketed. This is of great importance, particularly at a time when questions have been raised about whether faster drug approvals have undercut drug safety.

These provisions are a step forward, and I am glad they have been included in this legislation.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 1 minute to the gentleman from Ohio (Mr. GILLMOR), the distinguished chairman of the Subcommittee on Environment and Hazardous Materials of the Committee on Energy and Commerce.

Mr. GILLMOR. Mr. Speaker, I want to commend Chairman TAUZIN, Ranking Member DINGELL, and the others who have worked so hard to produce a conference committee report that certainly I am in very strong support of.

In particular, I want to highlight the need to support the drinking water protection provisions contained in title IV. Just yesterday, newspapers were running front page stories about New York City worrying about the vulnerability of their water system. As chairman of the Subcommittee on Environment and Hazardous Materials, I am pleased that our committee is tackling that issue, which is a serious concern not only of some of our biggest systems but some of our medium and small-sized systems as well.

I believe the original House language on title IV was preferable to the provisions in the conference report, but I am glad we were able to retain the core features of the House bill. Specifically, we require drinking water systems to do vulnerability assessments and to compile emergency response plans. In addition, we provide money for mandates and establish emergency funds.

I strongly support the bill.

As chairman of the Environment and Hazardous Materials Subcommittee of the House Energy and Commerce Committee, which has jurisdiction over the Safe Drinking Water Act, I am taking this opportunity to elaborate on and clarify the provisions of the conference report on Title IV of H.R. 3448, the Public Health Security and Bioterrorism Preparedness Response Act of 2002. I want to provide a more detailed explanation of Title IV for the RECORD.

Title IV of the Public Health Security and Bioterrorism Preparedness Response Act of 2001 requires community water systems serving over 3,300 individuals to conduct vulnerability assessments and to prepare or revise emergency response plans which incorporate the results of the vulnerability assessment. The legislation, however, also recognizes that many community water systems have conducted or will be in the process of conducting vulnerability assessments at the time of enactment. Title IV is thus explicitly drafted not to create a regulatory program which could slow down ongoing efforts or to require systems that have completed vulnerability assessments to undertake another such assessment. The title only requires that systems certify that an assessment has been completed by a specific date, not that the assessment was initiated and/or completed before or after the date of enactment. Moreover, the title only requires that systems submit a written copy of the assessment to the Administrator of EPA. Thus, the title does not require that any preparatory or supplementary material or analysis be provided to the Agency.

By only requiring submission of a written copy, Title IV recognizes that vulnerability assessments can contain highly sensitive information which would pose a danger if disclosed. The conference agreement on Title IV did not include any requirement or option for the submission of these assessments in electronic form. This recognizes that the information protocols required under Title IV will tightly control access to the assessments and that these documents will not be available or placed on EPA electronic systems which have been demonstrated to be vulnerable to unauthorized access.

Title IV requires strict security arrangements, procedures, equipment and locations be established at EPA before the Agency shall receive the submitted written copies of vulnerability assessments. These protocols are to ensure that no one, other than specifically authorized individuals, have any access to any part of the submission or to information derived from the submission. Only very specific exceptions to these restrictions are allowed under Title IV and knowingly or recklessly violating these restrictions carries with it criminal sanctions of both imprisonment and fines.

Title IV does not create a regulatory role for the Environmental Protection Agency (EPA) in defining what is or is not an acceptable vulnerability assessment. EPA is provided no regulatory authority in this regard; instead, the Agency is only to provide information once to community water systems (by August 1, 2002) regarding what kinds of terrorist attacks are probable threats. EPA is to coordinate its efforts with other agencies and departments of government who have expertise in this area, to compile information readily available or already developed, and to promptly distribute this information. The statute does not provide a continuing duty for EPA in this area past the date specified in the legislation.

In this regard, vulnerability assessments are defined in statute only to the extent that they include a review of certain specified items. These items are those which make up the physical structure of a public water system (as defined in section 1401 of the Safe Drinking Water Act (SDWA)), electronic, computer or other automated systems, physical barriers, the use, storage, or handling of various chemicals and the operation and maintenance of a drinking water system. Title IV recognizes that there are many different types and sizes of community water systems (CWS) and gives CWS wide discretion to devise and conduct a vulnerability assessment. EPA is not given any

rulemaking or other authority to define further what is or is not a vulnerability assessment meeting the requirements of section 1433. Nor does Title IV require that a community water system utilize any particular vulnerability assessment tool, or conduct any specific type of analysis. Community water systems are not required to determine the consequences of intentional acts or terrorist acts, analyze their use of specific chemicals, including chlorine, as opposed to other chemicals, or to characterize the risk of any offsite impacts. Further, the term ''physical barriers'' does not necessarily include ''buffer zones'' or any other area around physical structures.

Title IV recognizes that vulnerability assessments could contain very sensitive information about a drinking water system which would be of assistance to a terrorist or an individual contemplating an attack. Therefore, Title IV provides a full, complete and airtight exemption from disclosure under the federal FOIA requirement (5 U.S.C. 552) for all information submitted to EPA and any information derived therefrom. Further, the Title addresses the situation where a state or local FOIA requirement could be ''triggered'' by submission of a written copy of a vulnerability assessment to EPA. The Title provides that no community water system will be compelled to submit a copy of the vulnerability assessment to any governmental entity that is occasioned by the requirement that the system submit such assessment to EPA.

Title IV does not contain any requirement that the EPA or any other governmental body receive for review emergency response plans prepared by water systems. Nor does Title IV contain any requirement that community water systems provide such information to EPA or to any other person or governmental entity. Community water systems are to coordinate with local emergency planning committees (LEPCs) in the preparation or revision of emergency response plans for the purpose of avoiding duplication of effort and taking advantage of previous information developed by the LEPCs for first responders and local government response. There is no requirement that community water systems disclose any of the information developed by the vulnerability assessments to the LEPCs.

The legislation authorizes EPA to provide financial assistance to CWS for several specified purposes. EPA may provide assistance for vulnerability assessments, for developing or revising emergency response plans and for expenses and contracts designed to address basic security enhancements of critical importance and significant threats to public health. The Title also authorizes assistance for small water systems and immediate and urgent security needs, subject to limits specified in the Title. Title IV does not define either ''basic security enhancements of critical importance'' or ''significant threats to public health.'' However, existing SDWA programs which provide assistance to water systems have not provided assistance for continuing expenses such as operations and maintenance or personnel expenses. This legislation does not change this long-established public policy and specifically indicates that basic security enhancements do not include expenditures for personnel costs, or monitoring, operation or maintenance of facilities, equipment of systems.

Finally, Title IV clarifies that EPA has discretion to act under Part D, Emergency Powers, of the Safe Drinking Water Act (SDWA) when the Agency has received information about a specific threatened terrorist attack or when the Agency has received information concerning a potential terrorist attack (but not necessarily a specific, identified threat) at a drinking water facility. In exercising this discretion, the EPA should only rely upon substantial, credible information. EPA should not interpret ''potential terrorist attack'' to mean that there is merely some possibility or statistical probability of a terrorist attack. Neither should EPA interpret a general warning, general announcement or general condition to be sufficient information of a threatened or potential terrorist attack. Specific, credible information is required, and all other elements of section 1431 must be met, including the existence of an imminent and substantial endangerment to the health of persons, that appropriate State and local authorities have not acted to protect the health of persons served by the drinking water system, and that the EPA Administrator has consulted with State and local authorities regarding the correctness of the information regarding both the specific threat and the actions which the State or local authorities have taken. The authority granted to EPA in section 1431 is a limited, case-by-case, contingent emergency power.

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentleman from Texas (Mr. BENTSEN).

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

Mr. BENTSEN. Mr. Speaker, let me start out by congratulating the committee for putting together this legislation and putting together the conference report. This is a very good bill. I think it says a lot about the Congress that it has been able to respond as quickly as it has to the events of September 11 and the subsequent events of anthrax that we felt right here on Capitol Hill.

Subsequent to September 11, I had the opportunity to meet with the heads of a number of the institutions in the Texas Medical Center which is in my congressional district and is the largest medical center in the United States. In discussions with those individuals, I learned that while we had the knowledge throughout the United States in our various medical complexes to deal with the threat of bioterrorism, we did not necessarily have the means to deploy that knowledge. We really were not prepared to deal with it. And so a number of the institutions followed the lead of the Committee on Energy and Commerce and others in the Congress to try and address this and say that the Federal Government and the taxpayers would make an investment in making sure that we could deploy those medical assets the next time there is an attack.

As some of the speakers said, this bill may not go far enough, and I would concur with that; but it certainly is a very good start to begin to address this situation, to make sure that not just in the Nation's capital but throughout the United States that our local communities, with their local health care facilities, will begin to put together the plans to be able to deploy these assets to protect the American populace.

□ 1245

That is what we ought to be doing in this body to address that. So I want to commend the Members, the chairman and ranking member of the full committee and subcommittees that worked on this, and I urge my colleagues to pass the legislation.

Mr. Speaker, I rise today in support of the conference report for H.R. 3448, the Public Health Security and Bioterrorism Preparedness and Response Act. In the wake of the September 11 terrorism attacks on the United States, it is clear that we need to invest in our public health infrastructure to ensure that we are prepared for future terrorism attacks. As the representative for the Texas Medical Center, the nation's largest medical center, I have learned that our nation's hospitals are not adequately prepared for bioterrorism attacks and need federal assistance in order to upgrade their facilities.

I am pleased that this conference report authorizes federal funding of $1.6 billion in Fiscal Year 2003 for grants to states, local governments, and public and private health care facilities to improve planning and preparedness activities. Of this total, $520 million in state grants will be made for the preparedness of hospitals, including children's hospitals to enhance their capacity to deal with emergencies such as bioterrorism attacks. I believe that all hospitals should be eligible to receive this funding in order transform their emergency department. This legislation also authorizes $300 million to upgrade and expand the Centers for Disease Control and Prevention (CDC) facilities. During the recent anthrax attacks, we learned that the CDC does not have adequate staff and laboratories to conduct testings for individual anthrax tests. This legislation will correct this insufficiency and invest in our public health response. This measure also authorizes funding of $1.1 billion to expand the supply of vaccines, medicines, and supplies available to treat biological weapons such as anthrax. This funding will also ensure that we have adequate supply of smallpox vaccines and other antidotes for biological agents.

In order to protect public health, this legislation would also give the Food and Drug Administration additional authority to detain and bar food products. While we know that certain imported foods can kill children, yet the FDA does not currently have the ability to bar those who have knowingly imported these foods which have been adulterated or misbranded. This conference report also authorizes the FDA to require food importers to notify the FDA in advance of their arrival. This will help the FDA to carefully monitor which foods are being imported into the United States in order to protect public health. Finally, this bill would require all facilities that manufacture, process, pack, or hold food for consumption to register with the FDA. With registration, the FDA will be able to quickly track food products and appropriately act when any food products result in sickness or illness for our Nation's population. This measure would also provide new resources to protect our water supply. This conference report authorizes $160 million in Fiscal Year 2002 and such sums as necessary for future years. Under this bill, the 353

largest water systems which serve a total of 116 million people will be required to conduct annual vulnerability assessments. The legislation also requires those water systems which serve more than 3,300 persons to prepare an emergency response plan. Both of these requirements will encourage our water systems to carefully analyze their vulnerability to biological attacks and to prepare when their water supply may have been contaminated.

Finally, this legislation includes provisions to reauthorize the Food and Drug Administration's prescription drug user fee program through Fiscal Year 2007. This measure would authorize the collection of $1.2 billion in fees over five years in order to ensure that the FDA has sufficient resources to review prescription drug applications. These additional fees help the FDA to hire additional personnel who can review prescription drugs and medical devices.

I urge my colleagues to support H.R. 3348, legislation that will ensure that our Nation is better prepared when the next terrorism attack comes. With recently warnings of potential terrorism attacks, I believe that our public health infrastructure is well prepared.

Mr. TAUZIN. Mr. Speaker, I yield myself 1 minute to introduce the next speaker.

Mr. Speaker, the gentleman I am about to introduce was not only one of the conferees on this important legislation, but he and the gentleman from Georgia (Mr. LINDER) and I believe the gentlewoman from California (Ms. HARMAN) were extraordinarily diligent in offering this House a special bill to upgrade and enable the Centers for Disease Control, which was woefully inadequate prior to the passage of this bill today.

CDC is an incredibly valued institution in America. Not only does it track and help respond to the spread of infectious diseases, but it is going to be critical in the efforts to defend this country from biological or other forms of attack.

The gentleman from Georgia (Mr. CHAMBLISS), the gentleman from Georgia (Mr. LINDER) and the gentlewoman from California (Ms. HARMAN) are to be congratulated for not only leading this effort, but ensuring that this bill contains those important provisions to enable and improve and to strengthen the quality of the work done by the CDC.

Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Georgia (Mr. CHAMBLISS).

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

Mr. CHAMBLISS. Mr. Speaker, as someone who spent several years working on issues of terrorism and advocating better preparedness and readiness to meet the unique challenges we face from terrorists who want to harm Americans, I am very pleased with the final agreement on this bill. It is clear that we continue to face very real threats from sophisticated terrorists who would use dangerous biological agents in their savage and relentless efforts to carry out acts of violence against Americans.

We must do all we can to keep dangerous biological agents out of the wrong hands. However, whether in response to a terrorist attack, accident or natural outbreak of infectious disease, our public health and disease surveillance system is not as robust and capable as it needs to be to meet the demands which will be placed on it in a severe public health emergency. We recognize that local officials and our doctors, police, firefighters and local emergency responders will be on the front lines of an attack, and we must make sure that they are trained and ready to respond.

This bill will address many of these concerns. A critically important provision taken from the bill authored by the gentleman from Georgia (Mr. LINDER), the gentlewoman from California (Ms. HARMAN) and myself will provide $300 million per year and multi-year contracting authority to the Centers for Disease Control to upgrade and modernize their old and decaying facilities which are in desperate need of repair.

I am particularly pleased that we are taking concrete and far-reaching steps to address the particular issue of agroterrorism. I have felt for a long time that our agriculture infrastructure is very vulnerable to the threat of intentional damage and disease. As part of this bill, we bolster the Department of Agriculture's ability to detect animal and plant diseases and respond as needed to protect our food supply and American agriculture. We expand inspection activities and provide much-needed increases in agriculture biosecurity at colleges, universities and laboratories, including funding for a biocontainment laboratory at the University of Georgia.

Thanks to the strong leadership of the gentleman from Louisiana (Chairman TAUZIN), the gentleman from Michigan (Mr. DINGELL), Senator FRIST and Senator KENNEDY and their staffs, we worked in a bipartisan way to craft a bill that will go a long way toward making our country much better prepared to respond to biological attacks.

Mr. Speaker, I urge the passage of this bill.

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentlewoman from Texas (Ms. JACKSON-LEE).

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

Ms. JACKSON-LEE of Texas. Mr. Speaker, I thank the gentleman for yielding me time, and I would like to thank the chairman of the Committee on Energy and Commerce and the ranking member of the Committee on Energy and Commerce along with the conferees for a report that has taken us a very long way since September 11.

I served on the Homeland Security Task Force chaired by the gentleman from New Jersey (Mr. MENENDEZ), and we worked some hours after September 11 and our focus was in many areas. But I want to raise 2 points that were extremely important to the work that I did on local law enforcement.

We know the first responders were always very important to our communities, but we saw them at work after September 11 in a light that we had never seen before. I want to applaud the State and local preparedness allocation of $1.6 billion in particular, but I do want to emphasize the $520 million for State grants to enhance the preparedness of hospitals, including children's hospitals, clinics, health centers and primary care facilities for bioterrorism.

It was my emphasis in that committee to give the resources to our local clinics, our public health systems, such as the Harris County Health District in my community, which really would face the threat of terrorism in our local communities.

Some days after September 11, I met with over 40 members of our HAZMAT teams and those dealing with these issues around our Metroplex area, and they are the ones that need the support. As we speak, the City of Houston has a prepared plan to submit for 1 of these grants, and I will be encouraging them and working with them for that submission and for receiving such.

Finally, let me say as the ranking member on the INS Subcommittee on Immigration and Claims of the Committee on Judiciary, issues dealing with food entry on our borders is very important, and the provisions dealing with detaining food, providing the FDA with the authority to order detaining of food that may be suspicious, I applaud them for that. The increased inspections, where the FDA can require food importers to notify the FDA 30 days in advance of their arrival at the port of entry, is very important.

Lastly, I would say the prohibition on port shopping is crucial. We know that the Canadian border is one that we need to be concerned about. I would only encourage in my conclusion, Mr. Speaker, that we look to more technology at the border so we can do food x-ray inspection or inspection of the food as it comes across, because that certainly poses a very severe threat.

I ask my colleagues to support the conference report.

Mr. TAUZIN. Mr. Speaker, in addition to the great work done by the Committee on Agriculture, the Committee on the Judiciary was a big contributor to this bill.

I am pleased to yield 2 minutes to the gentleman from Texas (Mr. SMITH), the chairman of the Subcommittee on Crime, Terrorism and Homeland Security of the Committee on the Judiciary.

Mr. SMITH of Texas. Mr. Speaker, first of all, I would like to thank the chairman of the Committee on Energy and Commerce for yielding me time and for his great work on this legislation.

Mr. Speaker, in the wake of the terrorist attacks of September 11 and the subsequent anthrax-laced mail, bioterrorism has become a very real threat

to the American people. The Bioterrorism Preparedness Act of 2002 addresses such threats by improving the ability of the United States to respond to and prevent biological attacks.

This conference report requires coordination among agencies that regulate biological agents and toxins that pose a threat to human health. The Department of Health and Human Services, which has primary responsibility for public health issues, and the Department of Agriculture, which has primary responsibility for animal and plant health, are required to develop a coordinated strategy.

An important provision of this conference bill focuses on enhancing controls of dangerous biological agents and toxins by requiring registration of all persons who possess, use or transfer them. The legislation directs the Secretary of Health and Human Services and the Secretary of Agriculture to develop specific security measures for personnel and facilities that handle these dangerous substances. In addition, the conference report provides criminal penalties for possession of these agents without registration and for their transfer to unregistered persons or facilities.

Mr. Speaker, these are very important additions to the laws already put in place by the USA PATRIOT Act.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself 1½ minutes.

Mr. Speaker, I want to comment briefly on the Medicare provisions in the bill. One or more of my colleagues has expressed concern about the inclusion of some provisions in this legislation that are important. I want to make sure my colleagues understand these measures do not in any way adversely affect Medicare beneficiaries.

Several of us, the gentleman from Michigan (Mr. DINGELL), the gentleman from California (Mr. WAXMAN), the gentleman from New Jersey (Mr. PALLONE), none of us would have signed off on legislation that would have done anything but that.

One of these provisions is critically important for Medicare beneficiaries. Under current law, beneficiaries who choose to enroll in a managed care plan become locked into that plan. They must wait until the annual open enrollment program to switch plans or go into Medicare fee for service.

This bill removes that restriction, delays it for 3 years. We want to continue to delay it. The best we could do in the compromise was a 3-year delay rather than a permanent removal, so that Medicare beneficiaries can leave managed care, are not locked into that plan, can leave any time during the year and not just in the annual open enrollment period.

We also include in the language in the conference report provisions to protect in terms of time, when the Medicare period was moved from July to September. CMS has agreed we have language in the conference report to make sure that is enough time for people to be able to change.

So those provisions on Medicare are solid, they are bipartisanly agreed to. Beneficiaries will benefit, not at all be hurt, but in fact benefit by that language.

Mr. TAUZIN. Mr. Speaker, I yield myself 30 seconds simply to commend the gentleman for his statement.

Mr. Speaker, those provisions were agreed upon in a bipartisan fashion in the regulatory relief bill, which earlier passed this House, and I believe are in the interests of the beneficiaries of the Medicare system. I thank the gentleman for his similar conclusion. They were signed off on by all the committees of jurisdiction as well.

Mr. Speaker, I am pleased to yield 1½ minutes to the gentleman from Pennsylvania (Mr. PITTS) for a colloquy.

Mr. PITTS. Mr. Speaker, I rise also in support of the bioterrorism conference report, and since PDUFA is included in this bill, I would like to enter into a colloquy with the chairman.

Mr. Chairman, as you know, I am very interested in ensuring timely access to plasma therapies for the thousands of people who rely on these lifesaving medicines. The plasma industry pays the fees authorized under PDUFA, yet there are no performance goals associated with plasma lot release, which must occur prior to these products being released by the FDA. Longer lot release times mean that the therapies do not get to patients in a timely manner.

I strongly believe that the FDA should work with the plasma industry to assure greater predictability in lot release and to lessen the amount of time required for lot release.

Mr. Speaker, I would like to ask the chairman to respond.

Mr. TAUZIN. Mr. Speaker, will the gentleman yield?

Mr. PITTS. I yield to the gentleman from Louisiana.

Mr. TAUZIN. Mr. Speaker, first, let me acknowledge the hard work the gentleman has already put forth on this issue. I agree with the gentleman, frankly, and applaud his efforts.

Plasma lot release times have varied greatly over the last few years. Predictability is important. I think the industry and FDA should sit down and begin a dialogue which will lead to greater cooperation and predictability in lot release, and I intend to help the gentleman make sure that dialogue occurs.

Mr. PITTS. Mr. Speaker, reclaiming my time, I thank the gentleman very much.

Mr. BROWN of Ohio. Mr. Speaker, I reserve my time.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 1 minute to the gentleman from Oklahoma (Mr. LUCAS), a member of the Committee on Agriculture.

Mr. LUCAS of Oklahoma. Mr. Speaker, 8 months ago our perspective on the potential threats to our borders changed forever as we saw the true capacity of evil on our defenseless citizens. Three days ago we were reminded that that threat was still very real when the Vice President, Mr. CHENEY, said the question of another terrorist attack was not if, but when.

Today we in the House take an important step in preventing important attacks by passing this conference committee report. In November of last year I introduced legislation that addressed many of the issues that had been included in title III of the conference report before us today.

Included in both my bill and today's conference report are an increased presence of animal, plant and food and safety inspectors at the ports of entry. The APHIS and FSIS will develop strategies to prevent future incidents where animal and plant diseases are used by terrorists to attack U.S. citizens.

Mr. Speaker, I urge my colleagues to support this conference report. I thank the chairman and ranking member for their diligent efforts.

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentleman from California (Mr. SCHIFF).

Mr. SCHIFF. Mr. Speaker, I thank the gentleman for yielding me time.

Mr. Speaker, I rise in support of the Public Health Security and Bioterrorism Preparedness and Response Act conference report. It has been nearly 8 months since the deadly anthrax attacks, and authorities still have not determined who is responsible. However, it appears very likely that the highly concentrated form of anthrax did not originate from overseas, but rather may have come from an American laboratory.

In addition to unsecured anthrax, we have other challenges involving national, State and local health care workers and first responders, to make sure they are equipped with the tools they need to fight bioterrorism threats, and we also have food security issues to consider, as well as a potentially vulnerable water supply.

Today we are taking a major step forward in addressing some of these issues. In particular I am pleased that the bill contains provisions similar to those included in legislation that I introduced last fall with Senator FEINSTEIN.

Our bill, the Deadly Biological Control Act, will require that the Department of Health and Human Services maintain and regularly update a list of deadly biological agents, viruses and bacteria that poses severe threat to public health and safety. It requires every laboratory that possesses any of these select agents to be government-certified after proving that they will be used strictly for legitimate research purposes and that sufficient measures are in place to safely handle and dispose of those agents while ensuring protection against unlawful access.

□ 1300

Finally, lab employees would have to register with the Department of Health

and Human Services and pass through a criminal background check. These provisions are critical because under current law, laboratories that acquired anthrax and other deadly agents prior to 1997 were not required to register with the government unless they were shipping the agent to another lab, as a result of the thousands of laboratories nationwide which stock deadly biological agents, viruses, and bacteria without uniform security standards or proper Federal oversight. Under these lax security conditions, a rogue employee or outside terrorist group could easily gain access to some of the most dangerous pathogens on Earth.

I applaud the leadership of the gentleman from Michigan (Mr. DINGELL) and the gentleman from Louisiana (Mr. TAUZIN) as they work with the Senate conferees to bring this bill to the floor, and I urge my colleagues to support this important conference report.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the distinguished gentlewoman from Maryland (Mrs. MORELLA).

Mrs. MORELLA. Mr. Speaker, I rise in strong support of the conference report and for the Public Health Security and Bioterrorism Preparedness and Response Act. I indeed thank the gentleman from Louisiana (Mr. TAUZIN), the chairman of the committee, and the gentleman from Michigan (Mr. DINGELL) for their fine work and for the members and the staff of both committees. This is a terrific conference report, it is strong, and it is bipartisan, and it is critically important to our Nation as we continue to boost security in our preparedness against terrorism.

The conference report will improve the public health infrastructure at the national, State, and local levels to address growing threats of bioterrorism. The legislation provides additional resources to prepare us for bioterrorist threats or other public health emergencies.

I am particularly pleased that this legislation will boost programs and provide critical resources for many local communities who were on the front lines in the hours and the days following September 11, and the subsequent anthrax attacks. These brave men and women deserve our fullest commitment.

I look to my own district in Montgomery County, Maryland. Our first responders were there at the Pentagon on that terrible morning of September 11, and the Federal scientists at the National Institutes of Health and the Food and Drug Administration are working harder than ever to produce new treatments and vaccines for anthrax, among other bioterror agents.

The conference report we are considering today ensures emergency readiness and demonstrates a significant Federal commitment to local jurisdictions who ensure the safety and health of the American people.

In addition, the conference report improves protection of our water supply and increases the protection of our Nation's food supply. The Food and Drug Administration, headquartered in my district, will have an increased number of food inspectors to ensure our food is safe from bioterrorists.

Mr. Speaker, the conference report we are considering deserves our fullest support.

Mr. BROWN of Ohio. Mr. Speaker, I yield 2 minutes to the gentleman from Maryland (Mr. WYNN), a member of the Committee on Energy and Commerce.

Mr. WYNN. Mr. Speaker, I rise in strong support of the conference report to H.R. 3448, the Bioterrorism Preparedness Act.

Let me take a moment and congratulate and thank our committee chairman, the gentleman from Louisiana (Mr. TAUZIN), for his outstanding work; as well as our own ranking member, the gentleman from Michigan (Mr. DINGELL), for his work; the subcommittee chairman, the gentleman from Florida (Mr. BILIRAKIS); and my good friend and subcommittee ranking member, the gentleman from Ohio (Mr. BROWN). They have done good work in bringing this bill to the floor in the true spirit of bipartisanship.

I am particularly pleased because this bill provides $1.6 billion for grants to States and local governments, the first responders of our frontline of defense, for public and private health care facilities to improve planning and preparedness activities. It will enhance laboratory capacity, educating and training for health care personnel, and develop new drugs, therapies and vaccines, all a very important task for our homeland security.

This funding is particularly critical to upgrade our local health infrastructure to respond to a bioterrorism attack. I represent suburban communities just outside of Washington, D.C. After September 11, we realized how much we were on the front line. For instance, in my district in Montgomery County, Maryland, we require much-needed assistance to improve disease surveillance and also to train our local personnel, as well as to restore and improve our hospital preparedness, so this is very important to us.

The measure also provides $1.5 billion of funding to expand the current stockpiles of medicines and vaccines such as smallpox. That is what people are concerned about in the area of bioterrorism, and the bill responds.

Finally, the bill provides $300 million in critically important funding to upgrade and expand the Centers for Disease Control and Prevention facilities. It will allow, again, the training of personnel, particularly critical as we enter this new age; facilities improvement for combating bioterrorism in terms of upgrading the security of our labs and also, again, expanding disease surveillance.

Mr. Speaker, this is an excellent bill. Again I commend our leadership on both sides of the aisle for putting it together, and I urge my colleagues to support the conference report.

Mr. TAUZIN. Mr. Speaker, I reserve the balance of my time for closing.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself the remainder of the time.

Mr. Speaker, I thank the gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Florida (Mr. BILIRAKIS) and the gentleman from Michigan (Mr. DINGELL) and the staffs of all of the Members that were involved for their excellent work on this very complicated bill.

All of us are clearly happy with the legislation and disappointed with the legislation. I would like to highlight again as we close in the last couple of minutes a couple of highlights of that. I am particularly happy with the antibiotic resistance language in this bill. It is really the first time Congress, and I give credit to the gentleman from Louisiana (Mr. TAUZIN) and really everybody involved, it is the first time Congress has addressed this issue as seriously as we have on this. It is a serious problem, with drugs as common as penicillin, a drug that we all know, now is not as effective an antibiotic as it was 20 years ago. We are seeing a whole host of antibiotics not as effective as they were. This bill is the first step.

What we have left undone is legislation that we will continue to come to this committee on and hope to work with the gentleman from Louisiana on where half the antibiotics in this country are used for nonmedicinal, nontherapeutic purposes in animals, not to cure sick animals, but to help animals grow faster and to help animals actually not get disease because of the way we pack these animals together in pens that are too small. We are going to need to make some changes there, and I hope this Congress will seriously take that issue up.

I think on food safety, while we have done a reasonably good job on this bill, I hope that we can look more seriously at country-of-origin labeling and some other issues.

I am pleased with post-market surveillance of prescription drugs, as we have pushed through, with PDUFA in speeding up, accelerating the process of approval of prescription drugs, a very good thing to get them on the market more quickly so that consumers can benefit from them, patients can benefit from them. We also have done something in this bill we had not done before, and that is fund post-market surveillance so that when those drugs get on the market more quickly than they have in the past, if there are problems, the FDA is looking much more closely as these drugs are used in a huge part of the population rather than just clinical trials so that we, in fact, can detect much more quickly than before if there is damage done to people with the vast increase in the use of these drugs, with direct consumer advertising and all that.

This legislation also has good provisions with something called DDMAC, which is Division of Drug Market Advertising and Communications at FDA.

It is a review of marketing materials. As the drug companies, more and more, are spending huge numbers of dollars marketing their drugs, I think that will be a particularly positive direction.

I am disappointed, and I hope that we can move in a positive way on the pediatric rule so that as we passed legislation last year on the pediatric exclusivity, to give the drug companies 6 months more patent time, if you will, an extension of their patent so that they would test their drugs on children, test these prescription drugs on children that, in fact, we will codify the pediatric rule at some point so that drug testing will be done immediately on children as it is being done on adults during the clinical trials.

So those are some things I hope we can look for. We have done a good job on this bill with PDUFA; we have done a good job on this bill overall with bioterrorism; we have done a good job with food safety and antibiotic resistance. There is a lot more to do on antibiotic resistance; there is a lot more to do with food safety; there is a lot more to do with preserving safety and efficacy of prescription drugs on the market as we get them on the market more quickly.

So I would close by expressing my gratitude to the conference committee and by imploring the chairman of the Committee on Energy and Commerce, the distinguished gentleman from Louisiana (Mr. TAUZIN), so that we can move forward on some of these other issues during the next few months.

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

Mr. TAUZIN. Mr. Speaker, I yield myself the remaining time.

Let me first thank the gentleman from Ohio (Mr. BROWN) for his kind comments and for the extraordinary work that he and other colleagues on the other side of the aisle have provided us in producing, I think, an excellent bill from conference.

Let me first clarify something. In debate earlier, I think I heard the suggestion that the EPA would be required in the bill to review the vulnerability assessments submitted to it under title IV. I want to be very clear about this. Nothing in this conference report contains that requirement. The report simply makes that discretionary with the EPA. The reports are submitted to EPA, and they are not required to review them. It is a discretionary matter with EPA.

Mr. Speaker, let me first make a point that I think is important. This bill comes up at an extraordinary time in our Nation's history. It comes up in a week when partisanship reared its ugly head as we discussed issues involving 9–11 over the last several weeks. But I want to make something very clear. This bill represents the best of bipartisanship. This bill, shepherded through by the staff, by Reid Stuntz on the Democratic side and Mr. Dave Marventano on our side and the incredible work of the staffs on all three committees, the Committee on Agriculture and the Committee on the Judiciary, has produced a huge bipartisan response to the enemies of our country who think they can threaten us with biological agents or threaten us with attacks upon our food or water supplies and make this country more and more vulnerable.

There was a time before 9–11 when we did not think these thoughts, when we did not have to do what this bill requires. But 9–11 taught, I think, all of us some lessons; and I think it also demonstrated something to the world and to our enemies around the world, that this country is full of heroes. There are heroes who work in our own forces who are in Special Forces right now in Afghanistan and parts of the world we may not even read about who are defending us right now against al Qaeda and the folks around the world who would indeed threaten our security here at home. There are heroes who work in much more quiet and obscure places, in little hospitals, in the CDC, and they work at a border station where they inspect food and drugs coming into this country. They may be members of an ambulance team. They may be members of a first response team. But those heroes in America who demonstrated on 9–11 just how this country can respond when we need to are going to be better armed today with $4.6 billion of new tools.

This is an incredibly important bill. It is a statement, bipartisan statement here in America that we are ready to defend this country, and we are ready to make sure our heroes, both abroad and at home, are equipped with all of the tools they need to make us safer and more secure.

Mr. TAUZIN. Mr. Speaker, when the Joint Statement of Managers was filed last night, it inadvertently omitted some important language concerning a Performance Goals Letter for the authorization of the Prescription Drug User Fee Act (PDUFA).

Chairman TAUZIN and Ranking Minority Member DINGELL hereby submit the following additional statement which they view as authoritative legislative history on the provision in question.

PERFORMANCE GOALS LETTER

Authorization of PDUFA is accompanied by a letter entitled ''PDUFA Reauthorization Performance Goals and Procedures.'' The goals letter is unique to PDUFA. It does not have force of law, but nonetheless the Agency views it as a statement of their obligations, and they issue a yearly report on their performance in meeting the goals specified in the letter.

Title IX of the goals letter is entitled ''Independent Consultants for Biotechnology Clinical Trial Protocols.'' Contained in this title, as negotiated by the agency, is a paragraph ''D. Denial of Requests.'' As forwarded to the Congress, this paragraph previously read: ''except in the most unusual circumstances (for example, it is clearly premature) FDA will honor the request and engage the services of an indep4endent consultant, of FDA's choosing, as soon as practicable. If the Agency denies the request, it will provide a written rationale to the requester within 14 days of receipt.'' Upon agreement of the Conferees, this paragraph shall now read ''D. Denial of Requests: FDA will grant the request unless the Agency determines that engagement of an expert consultant would not serve a useful purpose (for example, it is clearly premature). FDA will engage the services of an independent consultant, of FDA's choosing, as soon as practicable. If the Agency denies the request, it will provide a written rationale to the requester within 14 days of receipt.''

The requirement of the Agency to provide a written rationale for the refusal to engage an independent consultant is not intended to burden the Agency but rather to assist the applicant in understanding the reason for Agency action.

The goals letter also, for the first time, includes a title on ''pre- and Peri-NDA/BLA Risk Management Plan Activities'' (Title VIII). The Managers view this title as a strong addition to the PDUFA regimen. Under this title, user fee monies will be available for postmarket surveillance for up to three years for drug and biological products. The Managers strongly support this Title, and upon agreement of the Managers, the title will now include the following additional language at the end Section D of Title VIII: ''FDA will allocate $76,319,879 in user fees over 5 years to the activities covered in this section. FDA will track the specific amounts of user fees spent on these activities and will include in its annual report to Congress an accounting of this spending.''

W.J. ''BILLY'' TAUZIN,
Chairman.

Mr. BALDACCI. Mr. Speaker, I am pleased that we will be passing legislation today to authorize vital funding for our state and local public health systems. Recognizing the difficulties facing our state and local governments and health facilities following the unprecedented attacks on our country, it's clear that we must greatly expand the resources of our health systems.

Mr. Speaker, immediately following the first Anthrax attacks, I met with public health officials from my State, and with representatives of community health provider systems. What I learned from this discussion is that our local and state health infrastructure and information systems is woefully unprepared to deal with the level of biomedical, chemical and radiological threats for which we clearly now must be prepared.

I am very concerned about the speed of which funds have been distributed to our state and local governments in order to update their health systems to deal with future attacks.

Today with passage of the Bioterrorism bill we will be making a commitment to our states, local governments and health facilities. We will provide significant assistance to their efforts to protect the health of our citizens. Funds will be translated into improvements in preparedness planning, surveillance, lab and hospital capacity and information and communication technology specific to meet the needs of our state and local health systems.

States will receive for bioterror-related activities $1.6 billion in grants in fiscal year 2003, and local hospitals will receive $520 to prepare for medical emergencies, with additional funds authorized at such sums as necessary for fiscal year 2004 through fiscal year 2006. These funds are on top of those already appropriated and distributed for the current fiscal year of over $1 billion.

I would add that as much as I appreciate these specific funds for bioterror threats, I believe other important issues facing our state

and local governments should be addressed. In particular, I support forward funding of fiscal year 2003 monies the President has identified for First Responders in our districts and states. Many of those charged in our state and local governments for maintaining public safety are frustrated with the lack of funding for first responder needs. To date, no funds for local first responders has been sent to our states. I hope that significant funds for First Responders become available for distribution as soon as possible. While the Supplemental legislation which we will consider later today does provide $175 million for first responders, much more is needed to cover costs our local and state governments have incurred and will soon incur to put necessary safety and preparedness plans in place.

Mr. Speaker, I am pleased to support today's bioterrorism conference report and urge my colleagues to support this measure to set aside vital funds to our state and local governments and hospitals.

Mr. GREEN of Texas. Mr. Speaker, I rise today in support of this Bioterrorism Conference Report.

I commend our chairman and ranking member, Mr. TAUZIN and Mr. DINGELL, for their hard work in developing this consensus legislation. This bill represents the kind of common-sense, worthwhile policy that can be produced when the two parties work together.

This bill includes a number of important provisions that will go a long way to improve our nation's ability to prevent and respond to a bioterrorist attack. With the formula grants in this bill, states will be able to better develop their public health infrastructure, so that they can recognize and contain bioterrist outbreaks.

The legislation creates a stockpile of drugs and vaccines, so we are able to quickly treat individuals who are affected. And it improves food safety inspection at our nation's borders to protect our food supply and makes sure that our water supply is not vulnerable to terrorist attack.

This legislation also reauthorizes and improves upon the Prescription Drug User Fee Act, which ensures that life-saving medications make it through the FDA approval process as quickly as possible.

Once again, I thank my colleagues for their hard work on this legislation.

Mr. SHAYS. Mr. Speaker, last Thursday, three men were arrested in Easton, Connecticut after being seen videotaping a water reservoir and filtration plant. The good news: A vigilant employee alerted local police. City and state emergency response teams were mobilized, the FBI was brought in, and the water was tested and found to be safe. The bad news: Before being seen, those three men got past security fences and ''No Trespassing'' signs, and could have destroyed or contaminated facilities supplying drinking water to 238,000 people in southeastern Connecticut.

It appears to have been an innocent mistake, a misguided desire to capture Connecticut's beautiful scenery from the wrong vantage point. But the incident demonstrates the vulnerability of critical water systems to biological terrorism.

This conference report begins to address protection of water supplies by directing updated threat assessments, vulnerability assessments and incorporation of both into current emergency response plans.

The current frustratingly vague string of alerts about potential terrorist acts cannot obscure one hard truth evident even before September 11: It is not a question of whether but only when, where and at what magnitude the United States will be attacked using biological, chemical, radiological or even nuclear weapons. To meet that threat, pharmaceutical stockpiles need to be augmented, disease surveillance should be strengthened, and public health capacities far better integrated into emergency response plans.

This bill is costly. More will be needed in the years to come. But the costs of an uncoordinated, ineffective response to bioterrorism will be paid in human lives, civil disorder, loss of civil liberties and economic disruption that could undermine both national security and national sovereignty.

If there is a ray of hope in the threat of bioterrorism it lies in this irony: improving the public health infrastructure against a man-made biological assault today better prepares us to face natural disease outbreaks every day. Just as biotechnologies can be used to produce both life-saving therapies and deadly pathogens, publics health capabilities are likewise ''dual use,'' enhancing our protection against smallpox attack by a terrorist and an influenza pandemic produced by Mother Nature.

Mr. SHIMKUS. Mr. Speaker, I submit for the RECORD the following on Public Health Security and Bioterrorism Response Act conference.

FOOD AUTHORITIES OF BIOTERRORISM BILL

Title III of the bioterrorism bill responds to legislative proposals presented to Congress by the Department of Health and Human Services. We worked closely with Secretary Thompson and personnel of the Food and Drug Administration to craft the most extensive expansion of the food related enforcement authorities in the history of the Federal Food, Drug, and Cosmetic Act (FFDCA). New authorities provide for expanded records access and maintenance, administrative detention of foods, registration of food facilities and several other provisions that are especially focused on assuring effective oversight of food imports. These new authorities strike a balance by adding significantly to the already strong enforcement authorities of the FDA, while assuring that the authorities will be used only for their intended purposes. I believe that my colleagues will be pleased with how this balance was struck to protect the American consumer and permit a robust competitive food system to provide consumers a wide variety of affordable foods.

ADMINISTRATIVE DETENTION: SECTION 303 OF THE TITLE

Amendment to Section 304 of the FFDCA provides the Secretary with limited authority to detain administratively an article of food where the FDA has ''credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death.'' ''Credible evidence or information'' requires that the FDA have specific evidence or information that it believes to be reliable and probative. The ''serious adverse health consequences'' standard, which is used consistently in Title III of this Act, relates to the situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. This standard corresponds to existing FDA guidance under section 7.3 of Title 21 of the Code of Federal Regulations.

A detention order must be approved by a senior FDA official (district director for the district in which the food to be detained is located or a more senior official). In general, the Secretary should expedite the processing of seizure or injunction actions with regard to food that has been detained. The Secretary is required to provide by regulation for the expedition of such actions in the case of perishable food, such as fresh produce and seafood.

Once a detention order is issued, the Secretary must insure that the detained article of food is kept in a secure facility under conditions commercially appropriate for the food to ensure that the safety and quality of the food is maintained during the detention.

Any person who would be entitled to claim the article of food if the food were seized may appeal a detention order to the Secretary. If an appeal is filed, the Secretary must provide an opportunity for an informal hearing which would be conducted in accordance with the procedures set forth in Part 16 of Title 21 of the Code of Federal Regulations. The Secretary has five days to confirm, modify or terminate the detention order; failure of the Secretary to provide for an informal hearing or to act on the appeal within five days of an appeal automatically terminates the detention order. The Secretary may not thereafter re-institute the terminated detention order.

This section also permits the Secretary to request that the Secretary of Treasury hold food offered for import at a port of entry for a period not to exceed 24 hours if the FDA is unable to inspect, examine, or investigate the food when it is offered for import and the Secretary has ''credible evidence or information'' indicating that the article of food ''presents a threat of serious adverse health consequences or death to humans or animals.'' The purpose of the temporary hold is to permit the FDA to inspect, examine or investigate the article of food. Amendments to Section 801 of the FFDCA provide for prior notice of shipments of imported food; consequently, the temporary hold authority should not be used routinely.

DEBARMENT: SECTION 304 OF THE TITLE

Amendment to Section 306 of the FFDCA would provide broad authority for debarment of persons from food importation so that FDA may protect against persons who might willfully sell harmful foods. Debarment may be based on a felony conviction relating to the importation of food into the United States or upon a person engaging in a pattern of importing adulterated food that presents a threat of serious adverse health consequences. The conferees intend for this authority to be exercised reservedly to assure that only ''bad actors'' are the subject of debarment actions. The courts have defined a pattern of proscribed conduct as three or more separate instances of a similar character. Thus, three violative lots of a common shipment would be of a similar character, but not constitute a pattern because they were effectively shipped at the same time and afforded no notice to the importer. The events that make up the pattern must be of a sufficiently similar nature and time sequence to provide the innocent importer effective notice and opportunity to undertake precautionary procedures to guard against reoccurrence. The managers intend for this debarment authority ordinarily to be exercised based on felony convictions. In the absence of a felony conviction, permissive debarment authority should be exercised only pending felony prosecution.

REGISTRATION: SECTION 305 OF THE TITLE

A new Section 415 of the FFDCA would provide require that the Secretary implement an expansive program of registration of facilities engaged in manufacture, processing,

packing or holding food for human consumption to assist the Secretary in promptly contacting management of concerned food facilities in the event of a threat to food safety. The registration is to include information regarding the name and address of the facility, as well as all trade names under which the facility conducts business. Also, if the effectiveness of the registration system would be significantly enhanced without undue burden, the Secretary may require by guidance that the general food category of products of the facility be specified. Within 18 months of enactment the Secretary is required to promulgate implementing regulations, which shall specify compliance timeframes and other requirements. The conferees fully expect FDA to complete the rulemaking in the 18 months provided.

The bill would require the Secretary to promptly notify each registrant of their registration number. The conferees intend for the Secretary to provide for electronic data submission and use of an electronic database to maintain a current listing of registered facilities. The listing of registered facilities is to be held strictly confidential. Since failure to register would be a violation of the Federal Food, Drug, and Cosmetic Act, prompt issuance of registration numbers under this system is imperative.

The bill would authorize the Secretary to broadly impose the registration requirement to domestic facilities engaged in processing or distributing food for human consumption as the Secretary deems necessary. However, the registration requirement would not authorize registration of farming facilities (including facilities attendant to harvesting of food crops), restaurants or other retail food establishments (including facilities attendant to their operations, which are under the same ownership or management) or most fishing vessels. In addition, the Secretary would be authorized to require registration of a foreign facility, but only if food from such facility is exported to the United States without further processing or packaging outside the U.S. If an article of food that is offered for import is from a foreign facility for which registration has not been submitted, the article would be held at the port of entry until registration is submitted.

The conferees intend for the Secretary to exercise his discretion in the development and implementation of registration regulations to ensure that registration requirements are neither burdensome nor disruptive of the smooth flow of commerce.

MAINTENANCE AND INSPECTION OF RECORDS: SECTION 306 OF THE TITLE

A new Section 414 of the FFDCA would authorize FDA to have access to and to copy certain records in the possession of persons involved in the production and distribution of food. Access to records would occur only if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences. The ''reasonable belief'' standard is intended to make clear that the Secretary must have evidence or information in hand that would cause a reasonable person to conclude that the food is both adulterated and presents a threat of serious adverse health consequences. Once the standard is met, the Secretary would have authority to gain access to and copy only those records needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences.

Records that would be subject to inspection under this authority relate to the manufacture, processing, packing, distribution, receipt, holding, or importation of the food being investigated, regardless of the format or location of the record. This records access would not extend to the most commercially sensitive or confidential records of the record keeper, including recipes (including formulation and preparation or processing techniques), financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales). Clearly, the authority would not permit access to any records regarding employees, research or customers (other than shipment data), nor would it permit access to information such as correspondence or marketing plans.

This new records access authority is responsive to a request of the Department so that investigation may be made of possible threats to the public health, but strictly limited to avoid potential abuse of confidential business information. The managers intend for limitations on records access to be strictly observed. A determination that there is reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences should be made under the direct supervision of senior officials of the FDA.

In addition, the Secretary would be required to take appropriate measures, presumably through rulemaking and assuredly with the benefit of comments from record keepers, to prevent the unauthorized disclosure of trade secret or confidential information obtained by the Secretary. The managers envision procedures whereby no agency personnel will have access to records without a specific need for such access, possession of all copies of records will be strictly controlled, and detailed records regarding all handling and access to these records will be kept. Shortcomings in such procedures or lapses in adherence to them should be viewed as a presumption of unlawful release of the records. Such record protections are to be in place prior to FDA exercising new records access authority.

A conforming amendment to Section 704 of the FFDCA is also included in this section. This conforming amendment would provide the Secretary no greater access to records (either in circumstances during which records access is permitted, the types of records that may be accessed, or protections afforded records that are obtained) than would be authorized under new Section 414.

PRIOR NOTICE: SECTION 307 OF THE TITLE

Amendment to Section 801 of the FFDCA would require that the Secretary promulgate regulations for submission of notice prior to the importation of any food to enable the Secretary to provide for inspection of food imports at ports of entry. The conferees intend for the Secretary to expeditiously promulgate the required regulations so that efficiency of food import inspections may be improved. The Secretary would be required to consult with the Secretary of the Treasury in promulgation of prior notice regulations to assure that smooth coordination is achieved between FDA and U.S. Customs. The managers intended for the Secretary to exercise discretion to ensure that neither the requirements of the notice nor the timing of prior notice be more burdensome than necessary to provide for the availability of food import inspectional personnel. The Secretary should exercise discretion in promulgating and implementing these rules to assure that prior notice requirements never become a barrier to the smooth flow of commerce. If an article of food were offered for import without providing the required prior notice, the article of food would be held at the port of entry until the Secretary has determined that notice is complete, but it would not be held longer than the unelapsed period of prior notice unless there is other basis for doing so. If the Secretary fails to promulgate prior notice regulations within 18 months of enactment, the bill specifies the information to be provided in the notice and that notice must be provided no less than 8 hours, and no more than 5 days, prior to offering the article of food for import. The conferees fully expect FDA to complete the rulemaking within the 18 months provided.

MARKING REFUSED ARTICLES: SECTION 308 OF THE TITLE

Another amendment to Section 801 of the FFDCA would authorize the Secretary to require that the outermost container of a shipment of certain foods that have been refused admission into the U.S. be marked ''UNITED STATES: REFUSED ENTRY''. The purpose of such a marking would be to alert inspectional personnel at the port of entry of a second attempt to import the refused food shipment. Accordingly, the conferees intend for this authority to be exercised in cases where there is reason to believe that the shipment may be offered for import at another U.S. port of entry. The conferees do not intend for this authority to be used to require markings that are unlikely to be observed at import inspection or that may inhibit the lawful marketing of a product in another country. The Secretary is expected to consult with the Secretary of Treasury regarding development of regulations to implement this provision.

Mr. COMBEST. Mr. Speaker, I would first like to commend Chairman TAUZIN, ranking Member DINGELL and all of the other conferees and their staffs for their hard work on this important legislation. This conference report represents a concerted effort by the Congress, the Bush Administration and numerous constituent groups coming together to tackle, head-on the threat of bioterrorism in the United States.

The attacks of September 11, and the subsequent mailing of Anthrax contaminated mail to the capitol, media outlets, and the devastating release of this deadly organism in postal facilities, led all Americans to reconsider the fundamentals. Members of Congress naturally turned to exploring ways that the public can be protected from potential terrorist attacks.

As Chairman of the Agriculture committee, my responsibility has been to evaluate and safeguard our nation's food supply. The Congress, working with the Executive branch, has a responsibility to farmers, ranchers, processors, retailers, and consumers to ensure appropriate steps are being taken to maintain confidence in our food supply.

Fortunately, the U.S. Department of Agriculture has been in the biosecurity business for a long time. The Animal Plant Health Inspection Service (APHIS) has its origins in the 19th century. The Food Safety Inspection Service (FSIS) started operations at the beginning of the 20th century.

Likewise, other sectors of our economy have recognized the fact that they have had to make wholesale changes in how they function. In some cases, organizations are in the process of being completely retooled or even created out of whole cloth. Thankfully, with regards to the Department of Agriculture, we already have broad legal authorities, plentiful resources, and trained personnel already in place to address the threats of the 21st century.

Nearly 5,000 APHIS employees securing our border from the importation of animal and plant diseases and 7,600 FSIS inspectors in every meat and poultry plant in America are

already working to protect our food production system. Obviously, the events of September 11 have caused these and other agencies of USDA to increase their vigilance, but we are very fortunate to have them. Not unlike our firefighters and police, they do a difficult job every day; a job we appreciate even more during these troubled times.

With this legislation, additional resources will be authorized for the USDA to modernize its Agricultural Research Service laboratory facilities. Likewise, funding is authorized for the USDA to provide grants to agricultural colleges and universities to review their security needs. These grants, coupled with security upgrade grant authority included as part of the recently passed Farm Security and Rural Investment Act of 2002 will strengthen our biosecurity and food safety research capabilities for years to come.

Likewise, authority is granted to expand on USDA's biosecurity research programs, both in the Agricultural Research Service, and those programs involving colleges and universities throughout United States.

This conference report strengthens USDA's regulatory efforts with regard to food safety, and animal and plant health. Specifically, the conference report recognizes the inadequacy of current USDA authorities with regard to the regulation of biological agents and toxins that present a severe threat to plant or animal health, and the products of plants and animals. Based on this recognition, the conference report adopts provisions that would grant nearly identical authorities to the USDA as those granted to the Department of Health and Human Services for the regulation of possession, use or transfer of listed biological agents and toxins.

Mr. Speaker, I would close by once again thanking all of the conferees who have worked on this legislation. Likewise, I would like to thank the employees of the Department of Agriculture who worked very closely with my staff in hammering out the details of this legislation. Specifically, I would like to mention the outstanding efforts of Dr. Curt Mann and Deb Atwood from the Office of the Secretary, Molly Phillips from the Office of Congressional Relations, Pilar Ruttenberg and Sheila Novak from the Office of General Counsel, Courtney Billet, Dr. Andrea Morgan and Mr. Chuck Schwalbe from the Animal and Plant Health Inspection Service, and Christy Slamowitz from the Office of the Inspector General.

Mr. DINGELL. Mr. Speaker, when the Joint Statement of Managers was filed last night, it inadvertently omitted some important language concerning a Performance Goals Letter for the authorization of the Prescription Drug User Fee Act (PDUFA).

Chairman TAUZIN and Ranking Minority Member DINGELL hereby submit the following additional statement which they view as authoritative legislative history on the provision in question.

PERFORMANCE GOALS LETTER

Authorization of PDUFA is accompanied by a letter entitled ''PDUFA Reauthorization Performance Goals and Procedures.'' The goals letter is unique to PDUFA. It does not have force of law, but nonetheless the Agency views it as a statement of their obligations, and they issue a yearly report on their performance in meeting the goals specified in the letter.

Title IX of the goals letter is entitled ''Independent Consultants for Biotechnology Clinical Trial Protocols.'' Contained in this title, as negotiated by the agency, is a paragraph ''D. Denial of Requests.'' As forwarded to the Congress, this paragraph previously read: ''Except in the most unusual circumstances (for example, it is clearly premature) FDA will honor the request and engage the services of an independent consultant, of FDA's choosing, as soon as practicable. If the Agency denies the request, it will provide a written rationale to the requester within 14 days of receipt.'' Upon agreement of the Conferees, this paragraph shall now read ''D. Denial of Requests: FDA will grant the request unless the Agency determines that engagement of an expert consultant would not serve a useful purpose (for example, it is clearly premature). FDA will engage the services of an independent consultant, of FDA's choosing, as soon as practicable. If the Agency denies the request, it will provide a written rationale to the requester within 14 days of receipt.''

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The goals letter also, for the first time, includes a title on ''Pre- and Peri-NDA/BLA Risk Management Plan Activities'' (Title VIII). The Managers view this title as a strong addition to the PDUFA regimen. Under this title, user fee monies will be available for postmarket surveillance for up to three years for drug and biological products. The Managers strongly support this Title, and upon agreement of the Managers, the title will not include the following additional language at the end Section D of Title VIII: ''FDA will allocate $76,319,879 in user fees over 5 years to the activities covered in this section. FDA will track the specific amounts of user fees spent on these activities and will include in its annual report to Congress an accounting of this spending.''

JOHN D. DINGELL,
Ranking Member.

Mr. Speaker, I commend this conference report to the House, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. LAHOOD). Without objection, the previous question is ordered.

There was no objection.

The SPEAKER pro tempore. The question is on the conference report.

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

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

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

The Sergeant at Arms will notify absent Members.

Pursuant to clause 8 of rule XX, this 15-minute vote on agreeing to the conference report will be followed by two 5-minute votes on motions to suspend the rules that were debated yesterday.

The vote was taken by electronic device, and there were—yeas 425, nays 1, not voting 8, as follows:

[Roll No. 189]

YEAS—425

Abercrombie
Ackerman
Aderholt
Akin
Allen
Andrews
Armey
Baca
Bachus
Baird
Baker
Baldacci
Baldwin
Ballenger
Barcia
Barr
Barrett
Bartlett
Barton
Bass
Becerra
Bentsen
Bereuter
Berkley
Berman
Berry
Biggert
Bilirakis
Bishop
Blagojevich
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonior
Bono
Boozman
Borski
Boswell
Boucher
Boyd
Brady (PA)
Brady (TX)
Brown (FL)
Brown (OH)
Brown (SC)
Bryant
Burr
Buyer
Callahan
Calvert
Camp
Cannon
Cantor
Capito
Capps
Capuano
Cardin
Carson (IN)
Carson (OK)
Castle
Chabot
Chambliss
Clay
Clayton
Clement
Clyburn
Coble
Collins
Combest
Condit
Conyers
Costello
Cox
Coyne
Cramer
Crane
Crenshaw
Crowley
Cubin
Culberson
Cummings
Cunningham
Davis (CA)
Davis (FL)
Davis (IL)
Davis, Jo Ann
Davis, Tom
Deal
DeFazio
DeGette
Delahunt
DeLauro
DeLay
DeMint
Diaz-Balart
Dicks
Dingell
Doggett
Dooley
Doolittle
Doyle
Dreier
Duncan
Dunn
Edwards
Ehlers
Ehrlich
Engel
English
Eshoo
Etheridge
Evans
Everett
Farr
Fattah
Ferguson
Filner
Flake
Fletcher
Foley
Forbes
Ford
Fossella
Frank
Frelinghuysen
Frost
Gallegly
Ganske
Gekas
Gephardt
Gibbons
Gilchrest
Gillmor
Gilman
Gonzalez
Goode
Goodlatte
Gordon
Goss
Graham
Granger
Graves
Green (TX)
Green (WI)
Greenwood
Grucci
Gutierrez
Gutknecht
Hall (OH)
Hall (TX)
Hansen
Harman
Hart
Hastings (FL)
Hastings (WA)
Hayes
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Herger
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Hilleary
Hilliard
Hinchey
Hinojosa
Hobson
Hoeffel
Hoekstra
Holden
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Honda
Hooley
Horn
Hostettler
Houghton
Hoyer
Hulshof
Hunter
Hyde
Inslee
Isakson
Israel
Issa
Istook
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Jenkins
John
Johnson (CT)
Johnson (IL)
Johnson, E. B.
Johnson, Sam
Jones (NC)
Jones (OH)
Kanjorski
Kaptur
Keller
Kelly
Kennedy (MN)
Kennedy (RI)
Kerns
Kildee
Kilpatrick
Kind (WI)
King (NY)
Kingston
Kirk
Kleczka
Knollenberg
Kolbe
Kucinich
LaFalce
LaHood
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Leach
Lee
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Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
LoBiondo
Lofgren
Lowey
Lucas (KY)
Lucas (OK)
Luther
Lynch
Maloney (CT)
Maloney (NY)
Manzullo
Markey
Matheson
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCrery
McDermott
McGovern
McHugh
McInnis
McIntyre
McKeon
McKinney
McNulty
Meehan
Meek (FL)
Meeks (NY)
Menendez
Mica
Millender-McDonald
Miller, Dan
Miller, Gary
Miller, George
Miller, Jeff
Mink
Mollohan
Moore
Moran (KS)
Moran (VA)
Morella
Murtha
Myrick
Nadler
Napolitano
Neal
Nethercutt
Ney
Northup
Norwood
Nussle
Oberstar
Obey
Olver
Ortiz
Osborne
Ose
Otter
Owens
Oxley
Pallone
Pascrell
Pastor
Payne
Pelosi
Pence
Peterson (MN)
Peterson (PA)
Petri
Phelps
Pickering
Pitts
Platts
Pombo
Pomeroy
Portman
Price (NC)

Pryce (OH)
Putnam
Quinn
Radanovich
Rahall
Ramstad
Rangel
Regula
Rehberg
Reyes
Reynolds
Rivers
Rodriguez
Roemer
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Ross
Rothman
Roukema
Roybal-Allard
Royce
Rush
Ryan (WI)
Ryun (KS)
Sabo
Sanchez
Sanders
Sandlin
Sawyer
Saxton
Schaffer
Schakowsky
Schiff
Schrock
Scott
Sensenbrenner
Serrano
Sessions
Shadegg
Shaw
Shays
Sherman
Sherwood
Shimkus
Shows
Shuster
Simmons
Simpson
Skeen
Skelton
Slaughter
Smith (MI)
Smith (NJ)
Smith (TX)
Smith (WA)
Snyder
Solis
Souder
Spratt
Stark
Stearns
Stenholm
Strickland
Stump
Stupak
Sullivan
Sununu
Sweeney
Tancredo
Tanner
Tauscher
Tauzin
Taylor (MS)
Taylor (NC)
Terry
Thomas
Thompson (CA)
Thompson (MS)
Thornberry
Thune
Thurman
Tiahrt
Tiberi
Tierney
Toomey
Towns
Turner
Udall (CO)
Udall (NM)
Upton
Velazquez
Visclosky
Vitter
Walden
Walsh
Wamp
Waters
Watkins (OK)
Watson (CA)
Watt (NC)
Waxman
Weiner
Weldon (FL)
Weldon (PA)
Weller
Wexler
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Woolsey
Wu
Wynn
Young (AK)
Young (FL)

NAYS—1

Paul

NOT VOTING—8

Burton
Cooksey
Deutsch
Emerson
Mascara
Riley
Traficant
Watts (OK)

□ 1335

So the conference report was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid upon the table.

Stated for:

Mr. Speaker, on rollcall No. 189 I was unavoidably detained and unable to record my vote. Had I been able, I would have voted "yea."

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. LAHOOD). Pursuant to clause 8 of rule XX, the Chair will now put the question on motions to suspend the rules on which further proceedings were postponed on Tuesday, May 21, in the order in which that motion was entertained.

Votes will be taken in the following order:

H.R. 3717, by the yeas and nays;

H. Res. 424, by the yeas and nays.

The Chair will reduce to 5 minutes the time for each of these two votes.

FEDERAL DEPOSIT INSURANCE REFORM ACT OF 2002

The SPEAKER pro tempore. The unfinished business is the question of suspending the rules and passing the bill, H.R. 3717, as amended.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Ohio (Mr. OXLEY) that the House suspend the rules and pass the bill, H.R. 3717, as amended, on which the yeas and nays are ordered.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 408, nays 18, not voting 8, as follows:

[Roll No. 190]

YEAS—408

Abercrombie
Ackerman
Aderholt
Akin
Allen
Andrews
Armey
Baca
Bachus
Baird
Baker
Baldacci
Baldwin
Ballenger
Barcia
Barr
Barrett
Bartlett
Barton
Bass
Becerra
Bentsen
Bereuter
Berkley
Berman
Berry
Biggert
Bilirakis
Bishop
Blagojevich
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonior
Bono
Boozman
Borski
Boswell
Boucher
Boyd
Brady (PA)
Brady (TX)
Brown (FL)
Brown (OH)
Brown (SC)
Bryant
Burr
Buyer
Callahan
Calvert
Camp
Cannon
Cantor
Capito
Capps
Cardin
Carson (IN)
Carson (OK)
Castle
Chabot
Chambliss
Clay
Clayton
Clement
Clyburn
Coble
Collins
Combest
Condit
Conyers
Cooksey
Costello
Cox
Coyne
Cramer
Crane
Crenshaw
Crowley
Cubin
Culberson
Cummings
Cunningham
Davis (CA)
Davis (FL)
Davis (IL)
Davis, Tom
Deal
DeGette
Delahunt
DeLauro
DeLay
DeMint
Diaz-Balart
Dicks
Dingell
Doggett
Dooley
Doolittle
Doyle
Dreier
Duncan
Dunn
Edwards
Ehlers
Ehrlich
Engel
English
Eshoo
Etheridge
Evans
Everett
Farr
Fattah
Ferguson
Filner
Fletcher
Foley
Ford
Fossella
Frelinghuysen
Frost
Gallegly
Ganske
Gekas
Gephardt
Gibbons
Gilchrest
Gillmor
Gilman
Gonzalez
Goodlatte
Gordon
Goss
Graham
Granger
Graves
Green (TX)
Green (WI)
Greenwood
Grucci
Gutierrez
Gutknecht
Hall (OH)
Hall (TX)
Hansen
Harman
Hart
Hastings (FL)
Hastings (WA)
Hayes
Hayworth
Hefley
Herger
Hill
Hilleary
Hilliard
Hinchey
Hinojosa
Hobson
Hoeffel
Hoekstra
Holden
Holt
Honda
Hooley
Horn
Hostettler
Houghton
Hoyer
Hulshof
Hunter
Hyde
Inslee
Isakson
Israel
Issa
Istook
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Jenkins
John
Johnson (CT)
Johnson (IL)
Johnson, E. B.
Johnson, Sam
Jones (NC)
Jones (OH)
Kanjorski
Kaptur
Keller
Kelly
Kennedy (MN)
Kennedy (RI)
Kerns
Kildee
Kilpatrick
Kind (WI)
King (NY)
Kingston
Kirk
Kleczka
Knollenberg
Kolbe
Kucinich
LaFalce
LaHood
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Leach
Lee
Levin
Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
LoBiondo
Lofgren
Lowey
Lucas (KY)
Lucas (OK)
Luther
Lynch
Maloney (CT)
Maloney (NY)
Manzullo
Matheson
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCrery
McDermott
McHugh
McInnis
McIntyre
McKeon
McKinney
McNulty
Meehan
Meek (FL)
Meeks (NY)
Menendez
Mica
Millender-McDonald
Miller, Dan
Miller, Gary
Miller, Jeff
Mink
Mollohan
Moore
Moran (KS)
Moran (VA)
Morella
Murtha
Myrick
Nadler
Napolitano
Neal
Nethercutt
Ney
Northup
Norwood
Nussle
Oberstar
Obey
Ortiz
Osborne
Otter
Owens
Oxley
Pallone
Pascrell
Pastor
Payne
Pelosi
Pence
Peterson (MN)
Peterson (PA)
Petri
Phelps
Pickering
Pitts
Platts
Pombo
Pomeroy
Portman
Price (NC)
Pryce (OH)
Putnam
Quinn
Radanovich
Rahall
Ramstad
Rangel
Regula
Rehberg
Reyes
Reynolds
Rivers
Rodriguez
Roemer
Rogers (KY)
Rogers (MI)
Ros-Lehtinen
Ross
Rothman
Roukema
Roybal-Allard
Rush
Ryan (WI)
Ryun (KS)
Sabo
Sanchez
Sanders
Sandlin
Sawyer
Saxton
Schaffer
Schakowsky
Schiff
Schrock
Scott
Sensenbrenner
Serrano
Sessions
Shadegg
Shaw
Shays
Sherman
Sherwood
Shimkus
Shows
Shuster
Simmons
Skeen
Skelton
Slaughter
Smith (MI)
Smith (NJ)
Smith (TX)
Smith (WA)
Snyder
Solis
Souder
Spratt
Stearns
Stenholm
Strickland
Stump
Stupak
Sullivan
Sununu
Sweeney
Tancredo
Tanner
Tauscher
Tauzin
Taylor (NC)
Terry
Thomas
Thompson (CA)
Thompson (MS)
Thornberry
Thune
Thurman
Tiahrt
Tiberi
Toomey
Towns
Turner
Udall (CO)
Udall (NM)
Upton
Velazquez
Visclosky
Vitter
Walden
Walsh
Wamp
Waters
Watkins (OK)
Watson (CA)
Watt (NC)
Waxman
Weiner
Weldon (FL)
Weldon (PA)
Weller
Wexler
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Woolsey
Wu
Wynn
Young (AK)
Young (FL)

NAYS—18

Capuano
Davis, Jo Ann
DeFazio
Flake
Forbes
Frank
Goode
Markey
McGovern
Olver
Ose
Paul
Rohrabacher
Royce
Simpson
Stark
Taylor (MS)
Tierney

NOT VOTING—8

Burton
Deutsch
Emerson
Mascara
Miller, George
Riley
Traficant
Watts (OK)

□ 1345

Mr. MCGOVERN, Mr. OLVER, and Mr. TIERNEY changed their vote from "yea" to "nay."

So (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

PAYING TRIBUTE TO WORKERS IN NEW YORK CITY FOR RESCUE, RECOVERY, AND CLEAN-UP EFFORTS AT SITE OF WORLD TRADE CENTER

The SPEAKER pro tempore. The unfinished business is the question of suspending the rules and agreeing to the resolution, H. Res. 424.

The Clerk read the title of the resolution.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from California (Mr.