In the Senate of the United States,

December 20 (legislative day, December 18), 2001.

Resolved, That the bill from the House of Representatives (H.R. 3448) entitled ''An Act to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.'', do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Bioterrorism Preparedness Act of 2001''.

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

TITLE I—NATIONAL GOALS FOR BIOTERRORISM PREPAREDNESS

SEC. 101. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

"TITLE XXVIII—STRENGTHENING THE NATION'S PREPAREDNESS FOR BIOTERRORISM

"SEC. 2801. CONGRESSIONAL FINDINGS ON BIOTERRORISM PREPAREDNESS.

"Congress finds that the United States should further develop and implement a coordinated strategy to prevent, and if necessary, to respond to biological threats or attacks upon the United States. Such strategy should include measures for—

"(1) enabling the Federal Government to provide health care assistance to States and localities in the event of a biological threat or attack;

"(2) improving public health, hospital, laboratory, communications, and emergency response personnel preparedness and responsiveness at the State and local levels;

"(3) rapidly developing and manufacturing needed therapies, vaccines, and medical supplies; and

"(4) enhancing the protection of the nation's food supply and protecting agriculture against biological threats or attacks.".

TITLE II—IMPROVING THE FEDERAL RESPONSE TO BIOTERRORISM

Subtitle A—Additional Authorities

SEC. 201. ADDITIONAL AUTHORITIES OF THE SECRETARY; STRATEGIC NATIONAL PHARMACEUTICAL STOCKPILE.

Title XXVIII of the Public Health Service Act, as added by section 101, is amended by adding at the end the following:

"Subtitle A—Improving the Federal Response to Bioterrorism

"SEC. 2811. AUTHORITY OF THE SECRETARY RELATED TO BIOTERRORISM PREPAREDNESS.

"(a) PLAN.—To meet the objectives of this title (and the amendments made by the Bioterrorism Preparedness Act of 2001), and to help the United States fully prepare for a biological threat or attack, the Secretary, consistent with the recommendations and activities of the working group established under section 319F(a), shall develop and implement a coordinated plan to meet such objectives that are within the jurisdiction of the Secretary. Such plan shall include the development of specific criteria that will enable measurements to be made of the progress made at the national, State, and local levels toward achieving the national

goal of bioterrorism preparedness, including actions to strengthen the preparedness of rural communities for a biological threat or attack.

"(b) BIENNIAL REPORTS.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this title, and biennially thereafter, the Secretary shall prepare and submit to Congress a report concerning the progress made and the steps taken by the Secretary to further the purposes of this title (and the amendments made by the Bioterrorism Preparedness Act of 2001). Such report shall include an assessment of the activities conducted under section 319F(c).

"(2) ADDITIONAL AUTHORITY.—In the biennial report submitted under paragraph (1), the Secretary may make recommendations concerning—

"(A) additional legislative authority that the Secretary determines is necessary to meet the objectives of this title (and the amendments made by the Bioterrorism Preparedness Act of 2001); and

"(B) additional legislative authority that the Secretary determines is necessary under section 319 to protect the public health in the event

that a condition described in section 319(a) occurs.

"(c) OTHER REPORTS.—Not later than 1 year after the date of enactment of this title, the Secretary shall prepare and submit to Congress a report concerning—

"(1) activities conducted under section 319F(b);

"(2) the characteristics that may render a rural community uniquely vulnerable to a biological threat or attack, including distance, lack of emergency transport, hospital or laboratory capacity, lack of integration of Federal or State public health networks, workforce deficits, or other relevant conditions;

"(3) in any case in which the Secretary determines that additional legislative authority is necessary to effectively strengthen the preparedness of rural communities for responding to a biological threat or attack, the recommendations of the Secretary with respect to such legislative authority; and

"(4) the need for and benefits of a National Disaster Response Medical Volunteer Service that would be a private-sector, community-based rapid response corps of medical volunteers.

"SEC. 2812. STRATEGIC NATIONAL PHARMACEUTICAL STOCKPILE.

"(a) IN GENERAL.—The Secretary, in coordination with the Secretary of Veterans Affairs, shall maintain a strategic stockpile of vaccines, therapies, and medical supplies that are adequate, as determined by the Secretary, to meet the health needs of the United States population, including children and other vulnerable populations, for use at the direction of the Secretary, in the event of a biological threat or attack or other public health emergency.

"(b) RULE OF CONSTRUCTION.—Nothing in subsection (a) shall be construed to prohibit the Secretary from including in the stockpile described in such subsection such vaccines, therapies, or medical supplies as may be necessary to meet the needs of the United States in the event of a nuclear, radiological, or chemical attack or other public health emergency.

"(c) DEFINITION.—In this section, the term 'stockpile' means—

"(1) a physical accumulation of the material described in subsection (a); or

"(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to the Secretary such medical supplies as shall be described in the contract at such time as shall be specified in the contract.

"(d) PROCEDURES.—The Secretary, in managing the stockpile under this section, shall—

"(1) ensure that adequate procedures are followed with respect to the stockpile maintained under subsection (a) for inventory management, accounting, and for the physical security of such stockpile; and

"(2) in consultation with State and local officials, take into consideration the timing and location of special events, including designated national security events.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.".

SEC. 202. IMPROVING THE ABILITY OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION TO RESPOND EFFECTIVELY TO BIOTERRORISM.

(a) REVITALIZING THE CDC.—Section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended—

(1) in subsection (a), by inserting ", and expanded, enhanced, and improved capabilities of the Centers related to biological threats or attacks," after "modern facilities";

(2) in subsection (b)—

(A) by inserting ", including preparing for or responding to biological threats or attacks," after "public health activities"; and

(B) by inserting "$60,000,000 for fiscal year 2002,"; and

(3) by adding at the end the following:

"(c) IMPROVING PUBLIC HEALTH LABORATORY CAPACITY.—

"(1) IN GENERAL.—The Secretary shall provide for the establishment of a coordinated network of public health laboratories to assist with the detection of and response to a biological threat or attack, that may, at the discretion of the Secretary, include laboratories that serve as regional reference laboratories.

"(2) AUTHORITY.—The Secretary may award grants, contracts, or cooperative agreements to carry out paragraph (1).

"(3) COORDINATION.—To the maximum extent practicable, the Secretary shall ensure that activities conducted under paragraph (1) are coordinated with existing laboratory preparedness activities.

"(4) LOCAL DISCRETION.—Use of regional laboratories, if established under paragraph (1), shall be at the discretion of the public health agencies of the States.

"(5) PROHIBITED USES.—An eligible entity may not use amounts received under this subsection to—

"(A) purchase or improve land or purchase any building or other facility; or

"(B) construct, repair, or alter any building or other facility.

"(6) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this subsection shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this subsection.

"(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $59,500,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.".

(b) EDUCATION AND TRAINING.—Section 319F(e) of the Public Health Service Act (42 U.S.C. 247d6(e)) is amended by adding at the end the following flush sentence: "The education and training activities described in this subsection may be carried out through Public Health Preparedness Centers, Noble training facilities, the Emerging Infections Program, and the Epidemic Intelligence Service.".

Subtitle B—Coordination of Efforts and Responses

SEC. 211. ASSISTANT SECRETARY FOR EMERGENCY PREPAREDNESS; NATIONAL DISASTER MEDICAL SYSTEM.

Title XXVIII of the Public Health Service Act, as added by section 101, and amended by section 201, is further amended by adding at the end the following:

"SEC. 2813. ASSISTANT SECRETARY FOR EMERGENCY PREPAREDNESS.

"(a) APPOINTMENT OF ASSISTANT SECRETARY FOR EMERGENCY PREPAREDNESS.—The President, with the advice and consent of the Senate, shall appoint an individual to serve as the Assistant Secretary for Emergency Preparedness who shall head the Office for Emergency Preparedness. Such Assistant Secretary shall report to the Secretary.

"(b) DUTIES.—Subject to the authority of the Secretary, the Assistant Secretary for Emergency Preparedness shall—

"(1) serve as the principal adviser to the Secretary on matters relating to emergency preparedness, including preparing for and responding to biological threats or attacks and for developing policy; and

"(2) coordinate all functions within the Department of Health and Human Services relating to

emergency preparedness, including preparing for and responding to biological threats or attacks.

"SEC. 2814. NATIONAL DISASTER MEDICAL SYSTEM.

"(a) NATIONAL DISASTER MEDICAL SYSTEM.—

"(1) IN GENERAL.—There shall be operated a system to be known as the National Disaster Medical System (in this section referred to as the 'National System') which shall be coordinated by the Secretary, in collaboration with the Secretary of Defense, the Secretary of Veterans Affairs, and the Director of the Federal Emergency Management Agency.

"(2) FUNCTIONS.—The National System shall provide appropriate health services, health-related social services and, if necessary, auxiliary services (including mortuary and veterinary services) to respond to the needs of victims of a public health emergency if the Secretary activates the System with respect to the emergency. The National System shall carry out such ongoing activities as may be necessary to prepare for the provision of such services.

"(b) TEMPORARY DISASTER-RESPONSE PERSONNEL.—

"(1) IN GENERAL.—For the purpose of assisting the Office of Emergency Preparedness and the National System in carrying out duties under this sec-

tion, the Secretary may in accordance with section 316.401 of title 5, Code of Federal Regulations (including revisions to such section), and notwithstanding the eligibility requirements set forth in paragraphs (1) through (8) of section 316.402(b) of such title (including revisions), make temporary appointments of individuals to intermittent positions to serve as personnel of such Office or System.

"(2) TRAVEL AND SUBSISTENCE.—An individual appointed under paragraph (1) shall, in accordance with subchapter I of chapter 57 of title 5, United States Code, be eligible for travel, subsistence, and other necessary expenses incurred in carrying out the duties for which the individual was appointed, including per diem in lieu of subsistence.

"(3) LIABILITY.—For purposes of section 224(a) and the remedies described in such section, an individual appointed under paragraph (1) shall, while acting within the scope of such appointment, be considered to be an employee of the Public Health Service performing medical, surgical, dental, or related functions. Participation in training programs carried out by the Office of Emergency Preparedness or Federal personnel of the National System shall be considered within the scope of such an appointment (regardless

of whether the individual receives compensation for such participation).

"(c) TEMPORARY DISASTER-RESPONSE APPOINTEE.—For purposes of this section, the term 'temporary disaster-response appointee' means an individual appointed by the Secretary under subsection (b).

"(d) COMPENSATION FOR WORK INJURIES.—A temporary disaster-response appointee, as designated by the Secretary, shall be deemed an employee, and an injury sustained by such an individual while actually serving or while participating in a uncompensated training exercise related to such service shall be deemed 'in the performance of duty', for purposes of chapter 81 of title 5, United States Code, pertaining to compensation for work injuries. In the event of an injury to such a temporary disaster-response appointee, the Secretary of Labor shall be responsible for making determinations as to whether the claimants are entitled to compensation or other benefits in accordance with chapter 81 of title 5, United States Code.

"(e) EMPLOYMENT AND REEMPLOYMENT RIGHTS.—

"(1) IN GENERAL.—A temporary disaster-response appointee, as designated by the Secretary, shall, when performing service as a temporary disaster-response appointee or participating in an uncompensated training exercise related to such service,

be deemed a person performing 'service in the uniformed services' for purposes of chapter 43 of title 38, United States Code, pertaining to employment and reemployment rights of members in the uniformed services. All rights and obligations of such persons and procedures for assistance, enforcement, and investigation shall be as provided for in chapter 43 of title 38, United States Code.

"(2) NOTICE OF ABSENCE FROM POSITION OF EMPLOYMENT.—Preclusion of giving notice of service by disaster response necessity shall be deemed preclusion by 'military necessity' for purposes of section 4312(b) of title 38, United States Code, pertaining to giving notice of absence from a position of employment. A determination of disaster response necessity shall be made pursuant to regulations prescribed by the Secretary, in consultation with the Secretary of Defense, and shall not be subject to judicial review.

"(f) LIMITATION.—A temporary disaster-response appointee shall not be deemed an employee of the Public Health Service or the Office of Emergency Preparedness for purposes other than those specifically set forth in this section.".

SEC. 212. EXPANDED AUTHORITY OF THE SECRETARY OF HEALTH AND HUMAN SERVICES TO RESPOND TO PUBLIC HEALTH EMERGENCIES.

(a) PROVISION OF DECLARATION TO CONGRESS.—Section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)) is amended by adding at the end the following: "Not later than 48 hours after a declaration of a public health emergency under this section, the Secretary shall provide a written declaration to Congress indicating that an emergency under this section has been declared.".

(b) WAIVER OF REPORTING DEADLINES.—Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

"(d) WAIVER OF DATA SUBMITTAL AND REPORTING DEADLINES.—In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been declared pursuant to subsection (a), individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive any sanctions otherwise applicable to such failure to comply.".

(c) EMERGENCY DECLARATION PERIOD.—Section 319 of the Public Health Service Act (42 U.S.C. 247d), as amended by subsection (b), is further amended by adding at the end the following:

"(e) EMERGENCY DECLARATION PERIOD.—A determination by the Secretary under subsection (a) that a public health emergency exists shall remain in effect for not longer than the 180-day period beginning on the date of the determination. Such period may be extended by the Secretary if—

"(1) the Secretary determines that such an extension is appropriate; and

"(2) the Secretary provides a written notification to Congress within 48 hours of such extension.".

SEC. 213. PUBLIC HEALTH PREPAREDNESS AND RESPONSE TO A BIOTERRORIST ATTACK.

Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended by striking subsections (a) and (b), and inserting the following:

"(a) WORKING GROUP ON BIOTERRORISM.—The Secretary, in coordination with the Secretary of Defense, the Director of the Federal Emergency Management Agency, the Attorney General, the Secretary of Veterans Affairs, the Secretary of Labor, and the Secretary of Agriculture, and with other similar Federal officials as determined appropriate,

shall establish a joint interdepartmental working group on the prevention, preparedness, and response to a biological threat or attack on the civilian population. Such joint working group shall—

"(1) prioritize countermeasures required to treat, prevent, or identify exposure to a biological agent or toxin pursuant to section 351A;

"(2) coordinate and facilitate the awarding of grants, contracts, or cooperative agreements for the development, manufacture, distribution, and purchase of priority countermeasures;

"(3) coordinate research on pathogens likely to be used in a biological threat or attack on the civilian population;

"(4) develop shared standards for equipment to detect and to protect against biological agents and toxins;

"(5) coordinate the development, maintenance, and procedures for the release of materials from the Strategic National Pharmaceutical Stockpile;

"(6) assess the priorities for and enhance the preparedness of public health institutions, providers of medical care, and other emergency service personnel (including firefighters) to detect, diagnose, and

respond (including mental health response) to a biological threat or attack;

"(7) in the recognition that medical and public health professionals are likely to provide much of the first response to such an attack, develop, coordinate, enhance, and assure the quality of joint planning and training programs that address the public health and medical consequences of a biological threat or attack on the civilian population between—

"(A) local firefighters, ambulance personnel, police and public security officers, or other emergency response personnel; and

"(B) hospitals, primary care facilities, and public health agencies;

"(8) coordinate the development of strategies for Federal, State, and local agencies to communicate information to the public regarding biological threats or attacks;

"(9) develop methods to decontaminate facilities contaminated as a result of a biological attack, including appropriate protections for the safety of those conducting such activities; and

"(10) ensure that the activities under this subsection address the needs of children and other vulnerable populations.

The working group shall carry out paragraphs (1) and (2) in consultation with the pharmaceutical, biotechnology, and medical device industries, and other appropriate experts.

"(b) ADVICE TO THE SECRETARY.—The Secretary shall establish advisory committees to provide expert recommendations to the Secretary to assist the Secretary, including the following:

"(1) NATIONAL TASK FORCE ON CHILDREN AND TERRORISM.—

"(A) IN GENERAL.—The National Task Force on Children and Terrorism, which shall be composed of such Federal officials as may be appropriate to address the special needs of children, and child health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines.

"(B) DUTIES.—The task force described in subparagraph (A) shall provide recommendations to the Secretary regarding—

"(i) the preparedness of the health care system to respond to bioterrorism as it relates to children;

"(ii) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet

the special needs of children with respect to a biological threat or attack; and

"(iii) changes, if necessary, to the Strategic National Pharmaceutical Stockpile, to meet the special needs of children.

"(2) EMERGENCY PUBLIC INFORMATION AND COMMUNICATIONS TASK FORCE.—

"(A) IN GENERAL.—The Emergency Public Information and Communications (EPIC) Task Force, which shall be composed of individuals with expertise in public health, communications, behavioral psychology, and other areas determined appropriate by the Secretary.

"(B) DUTIES.—The task force described in subparagraph (A) shall make recommendations and report to the Secretary on appropriate ways to communicate information regarding biological threats or attacks to the public, including public service announcements or other appropriate means to communicate in a manner that maximizes information and minimizes panic, and includes information relevant to children and other vulnerable populations.

"(3) SUNSET.—Each Task Force established under paragraphs (1) and (2) shall terminate on the

date that is 1 year after the date of enactment of the Bioterrorism Preparedness Act of 2001.".

SEC. 214. THE OFFICIAL FEDERAL INTERNET SITE ON BIOTERRORISM.

It is the recommendation of Congress that there should be established an official Federal Internet site on bioterrorism, either directly or through provision of a grant to an entity that has expertise in bioterrorism and the development of websites, that should include information relevant to diverse populations (including messages directed at the general public and such relevant groups as medical personnel, public safety workers, and agricultural workers) and links to appropriate State and local government sites.

SEC. 215. TECHNICAL AMENDMENTS.

Section 319C of the Public Health Service Act (42 U.S.C. 247d–3) is amended—

(1) in subsection (a), by striking "competitive"; and

(2) in subsection (f), by inserting "$420,000,000 for fiscal year 2002," after "2001,".

SEC. 216. REGULATION OF BIOLOGICAL AGENTS AND TOXINS.

(a) BIOLOGICAL AGENTS PROVISIONS OF THE ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT OF

1996; CODIFICATION IN THE PUBLIC HEALTH SERVICE ACT, WITH AMENDMENTS.—

(1) PUBLIC HEALTH SERVICE ACT.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by inserting after section 351 the following:

"SEC. 351A. ENHANCED CONTROL OF BIOLOGICAL AGENTS AND TOXINS.

"(a) REGULATORY CONTROL OF BIOLOGICAL AGENTS AND TOXINS.—

"(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—

"(A) IN GENERAL.—The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

"(B) CRITERIA.—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

"(i) consider—

"(I) the effect on human health of exposure to the agent or toxin;

"(II) the degree of contagiousness of the agent or toxin and the methods

by which the agent or toxin is transferred to humans;

"(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

"(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

"(ii) consult with appropriate Federal departments and agencies, and scientific experts representing appropriate professional groups, including those with pediatric expertise.

"(2) BIENNIAL REVIEW.—The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall, through rulemaking, revise the list as necessary to incorporate additions or deletions to ensure public health, safety, and security.

"(3) EXEMPTIONS.—The Secretary may exempt from the list under paragraph (1)—

"(A) attenuated or inactive biological agents or toxins used in biomedical research or for legitimate medical purposes; and

"(B) products that are cleared or approved under the Federal Food, Drug, and Cosmetic Act or under the Virus-Serum-Toxin Act, as amended in 1985 by the Food Safety and Security Act.";

"(b) REGULATION OF TRANSFERS OF LISTED BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall by regulation provide for—

"(1) the establishment and enforcement of safety procedures for the transfer of biological agents and toxins listed pursuant to subsection (a)(1), including measures to ensure—

"(A) proper training and appropriate skills to handle such agents and toxins; and

"(B) proper laboratory facilities to contain and dispose of such agents and toxins;

"(2) safeguards to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

"(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of a biological agent or toxin in violation

of the safety procedures established under paragraph (1) or the safeguards established under paragraph (2); and

"(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

"(c) POSSESSION AND USE OF LISTED BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of biological agents and toxins listed pursuant to subsection (a)(1) in order to protect the public health and safety, including the measures, safeguards, procedures, and availability of such agents and toxins described in paragraphs (1) through (4) of subsection (b), respectively.

"(d) REGISTRATION AND TRACEABILITY MECHANISMS.—Regulations under subsections (b) and (c) shall require registration for the possession, use, and transfer of biological agents and toxins listed pursuant to subsection (a)(1), and such registration shall include (if available to the registered person) information regarding the characterization of such biological agents and toxins to facilitate their identification and traceability. The Secretary shall maintain a national database of the location of such bio-

logical agents and toxins with information regarding their characterizations.

"(e) INSPECTIONS.—The Secretary shall have the authority to inspect persons subject to the regulations under subsections (b) and (c) to ensure their compliance with such regulations, including prohibitions on restricted persons under subsection (g).

"(f) EXEMPTIONS.—

"(1) IN GENERAL.—The Secretary shall establish exemptions, including exemptions from the security provisions, from the applicability of provisions of—

"(A) the regulations issued under subsections (b) and (c) when the Secretary determines that the exemptions, including exemptions from the security requirements for the use of attenuated or inactive biological agents or toxins in biomedical research or for legitimate medical purposes, are consistent with protecting public health and safety; and

"(B) the regulations issued under subsection (c).

"(2) CLINICAL LABORATORIES.—The Secretary shall exempt clinical laboratories and other persons that possess, use, or transfer biological agents and toxins listed pursuant to subsection (a)(1) from the ap-

plicability of provisions of regulations issued under subsections (b) and (c) only when—

"(A) such agents or toxins are presented for diagnosis, verification, or proficiency testing;

"(B) the identification of such agents and toxins is, when required under Federal or State law, reported to the Secretary or other public health authorities; and

"(C) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary in regulation.

"(g) SECURITY REQUIREMENTS FOR REGISTERED PERSONS.—

"(1) SECURITY.—In carrying out paragraphs (2) and (3) of subsection (b), the Secretary shall establish appropriate security requirements for persons possessing, using, or transferring biological agents and toxins listed pursuant to subsection (a)(1), considering existing standards developed by the Attorney General for the security of government facilities, and shall ensure compliance with such requirements as a condition of registration under regulations issued under subsections (b) and (c).

"(2) LIMITING ACCESS TO LISTED AGENTS AND TOXINS.—Regulations issued under subsections (b) and (c) shall include provisions—

"(A) to restrict access to biological agents and toxins listed pursuant to subsection (a)(1) only to those individuals who need to handle or use such agents or toxins; and

"(B) to provide that registered persons promptly submit the names and other identifying information for such individuals to the Attorney General, with which information the Attorney General shall promptly use criminal, immigration, and national security databases available to the Federal Government to identify whether such individuals—

"(i) are restricted persons, as defined in section 175b of title 18, United States Code; or

"(ii) are named in a warrant issued to a Federal or State law enforcement agency for participation in any domestic or international act of terrorism.

"(3) CONSULTATION AND IMPLEMENTATION.—Regulations under subsections (b) and (c) shall be developed in consultation with research-performing or-

ganizations, including universities, and implemented with timeframes that take into account the need to continue research and education using biological agents and toxins listed pursuant to subsection (a)(1).

"(h) DISCLOSURE OF INFORMATION.—

"(1) IN GENERAL.—Any information in the possession of any Federal agency that identifies a person, or the geographic location of a person, who is registered pursuant to regulations under this section (including regulations promulgated before the effective date of this subsection), or any site-specific information relating to the type, quantity, or characterization of a biological agent or toxin listed pursuant to subsection (a)(1) or the site-specific security mechanisms in place to protect such agents and toxins, including the national database required in subsection (d), shall not be disclosed under section 552(a) of title 5, United States Code.

"(2) DISCLOSURES FOR PUBLIC HEALTH AND SAFETY; CONGRESS.—Nothing in this section may be construed as preventing the head of any Federal agency—

"(A) from making disclosures of information described in paragraph (1) for purposes of protecting the public health and safety; or

"(B) from making disclosures of such information to any committee or subcommittee of the Congress with appropriate jurisdiction, upon request.

"(i) CIVIL MONEY PENALTY.—Any person who violates a regulation under subsection (b) or (c) shall be subject to the United States for a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of any other person. The provisions of section 1128A of the Social Security Act (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f) of such section) shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act. The Secretary may delegate authority under this section in the same manner as provided in section 1128A(j)(2) of such Act and such authority shall include all powers described in section 6 of the Inspector General Act of 1978 (5 U.S.C. App. 2)

"(j) DEFINITIONS.—For purposes of this section, the terms 'biological agent' and 'toxin' have the same meaning as in section 178 of title 18, United States Code.".

(2) REGULATIONS.—

(A) DATE CERTAIN FOR PROMULGATION; EFFECTIVE DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—Not later than 180 days after the date of the enactment of this title, the Secretary of Health and Human Services shall promulgate an interim final rule for carrying out section 351A(c) of the Public Health Service Act, which amends the Antiterrorism and Effective Death Penalty Act of 1996. Such interim final rule will take effect 60 days after the date on which such rule is promulgated, including for purposes of—

(i) section 175(b) of title 18, United States Code (relating to criminal penalties), as added by subsection (b)(1)(B) of this section; and

(ii) section 351A(i) of the Public Health Service Act (relating to civil penalties).

(B) SUBMISSION OF REGISTRATION APPLICATIONS.—A person required to register for possession under the interim final rule promulgated under subparagraph (A) shall submit an application for such registration not later than 60

days after the date on which such rule is promulgated.

(3) CONFORMING AMENDMENT.—Subsections (d), (e), (f), and (g) of section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (42 U.S.C. 262 note) are repealed.

(4) EFFECTIVE DATE.—Paragraph (1) shall take effect as if incorporated in the Antiterrorism and Effective Death Penalty Act of 1996, and any regulations, including the list under subsection (d)(1) of section 511 of that Act, issued under section 511 of that Act shall remain in effect as if issued under section 351A of the Public Health Service Act.

(b) SELECT AGENTS.—

(1) IN GENERAL.—Section 175 of title 18, United States Code, as amended by the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001 (Public Law 107–56), is amended—

(A) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(B) by inserting after subsection (a) the following:

"(b) SELECT AGENTS.—

"(1) UNREGISTERED FOR POSSESSION.—Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a select agent for which such person has not obtained a registration required by regulation issued under section 351A(c) of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

"(2) TRANSFER TO UNREGISTERED PERSON.—Whoever transfers a select agent to a person who the transferor has reason to believe has not obtained a registration required by regulations issued under section 351A(b) or (c) of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both.".

(2) DEFINITIONS.—Section 175 of title 18, United States Code, as amended by paragraph (1), is further amended by striking subsection (d) and inserting the following:

"(d) DEFINITIONS.—As used in this section:

"(1) The terms 'biological agent' and 'toxin' have the meanings given such terms in section 178, except that, for purposes of subsections (b) and (c), such terms do not encompass any biological agent or toxin that is in its naturally occurring environment, if the biological agent or toxin has not been cultivated, cul-

tured, collected, or otherwise extracted from its natural source.

"(2) The term 'for use as a weapon' includes the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system, other than for prophylactic, protective, or other peaceful purposes.

"(3) The term 'select agent' means a biological agent or toxin, as defined in paragraph (1), that is on the list that is in effect pursuant to section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104–132), or as subsequently revised under section 351A(a) of the Public Health Service Act.".

(3) CONFORMING AMENDMENT.—

(A) Section 175(a) of title 18, United States Code, is amended in the second sentence by striking "under this section" and inserting "under this subsection".

(B) Section 175(c) of title 18, United States Code, (as redesignated by paragraph (1)), is amended by striking the second sentence.

(c) REPORT TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, after consultation with

other appropriate Federal agencies, shall submit to the Congress a report that—

(1) describes the extent to which there has been compliance by governmental and private entities with applicable regulations under section 351A of the Public Health Service Act, including the extent of compliance before the date of the enactment of this Act, and including the extent of compliance with regulations promulgated after such date of enactment;

(2) describes the actions to date and future plans of the Secretary for updating the list of biological agents and toxins under section 351A(a)(1) of the Public Health Service Act;

(3) describes the actions to date and future plans of the Secretary for determining compliance with regulations under such section 351A of the Public Health Service Act and for taking appropriate enforcement actions; and

(4) provides any recommendations of the Secretary for administrative or legislative initiatives regarding such section 351A of the Public Health Service Act.

TITLE III—IMPROVING STATE AND LOCAL PREPAREDNESS

Subtitle A—Emergency Measures to Improve State and Local Preparedness

SEC. 301. STATE BIOTERRORISM PREPAREDNESS AND RESPONSE BLOCK GRANT.

(a) IN GENERAL.—Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended by striking subsection (c) and inserting the following:

"(c) STATE BIOTERRORISM PREPAREDNESS AND RESPONSE BLOCK GRANTS.—

"(1) IN GENERAL.—The Secretary shall establish the State Bioterrorism Preparedness and Response Block Grant Program (referred to in this subsection as the 'Program') under which the Secretary shall award grants to or enter into cooperative agreements with States, the District of Columbia, and territories (referred to in this section as 'eligible entities') to enable such entities to prepare for and respond to biological threats or attacks. The Secretary shall ensure that activities conducted under this section are coordinated with the activities conducted under this section and section 319C.

"(2) ELIGIBILITY.—To be eligible to receive amounts under paragraph (1), a State, the District of Columbia, or a territory shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the entity will—

"(A) not later than 180 days after the date on which a grant or contract is received under this subsection, prepare and submit to the Secretary a Bioterrorism Preparedness and Response Plan in accordance with subsection (c);

"(B) not later than 180 days after the date on which a grant or contract is received under this subsection, complete an assessment under section 319B(a), or an assessment that is substantially equivalent as determined by the Secretary unless such assessment has already been performed; and

"(C) establish a means by which to obtain public comment and input on the plan and plan implementation that shall include an advisory committee or other similar mechanism for obtaining input from the public at large as well as other stakeholders;

"(D) use amounts received under paragraph (1) in accordance with the plan submitted under paragraph (3), including making expenditures to carry out the strategy contained in the plan;

"(E) use amounts received under paragraph (1) to supplement and not supplant funding at levels in existence prior to September 11, 2001 for public health capacities or bioterrorism preparedness; and

"(F) with respect to the plan under paragraph (3), establish reasonable criteria to evaluate the effective performance of entities that receive funds under the grant or agreement and shall include relevant benchmarks in the plan.

"(3) BIOTERRORISM PREPAREDNESS AND RESPONSE PLAN.—Not later than 180 days after receiving amounts under this subsection, and 1 year after such date, a State, the District of Columbia, or a territory shall prepare and submit to the Secretary a Bioterrorism Preparedness and Response Plan for responding to biological threats or attacks. Recognizing the assessment of public health capacity conducted under section 319B, such plan shall include—

"(A) a description of the program that the eligible entity will adopt to achieve the core ca-

pacities developed under section 319A, including measures that meet the needs of children and other vulnerable populations;

"(B) a description (including amounts expended by the eligible entity for such purpose) of the programs, projects, and activities that the eligible entity will implement using amounts received in order to detect and respond to biological threats or attacks, including the manner in which the eligible entity will manage State surveillance and response efforts and coordinate such efforts with national efforts;

"(C) a description of the training initiatives that the eligible entity has carried out to improve its ability to detect and respond to a biological threat or attack, including training and planning to protect the health and safety of those conducting such detection and response activities;

"(D) a description of the cleanup and contamination prevention efforts that may be implemented in the event of a biological threat or attack;

"(E) a description of efforts to ensure that hospitals and health care providers have ade-

quate capacity and plans in place to provide health care items and services (including mental health services and services to meet the needs of children and other vulnerable populations that may include the provision of telehealth services) in the event of a biological threat or attack; and

"(F) other information the Secretary may by regulation require.

"Nothing in subparagraph (E) shall be construed to require or recommend that States establish or maintain stockpiles of vaccines, therapies, or other medical supplies.

"(4) USE OF FUNDS.—

"(A) IN GENERAL.—In coordination with the activities conducted under this section, an eligible entity shall use amounts received under this section to—

"(i) conduct the assessment under section 319B to achieve the capacities described in section 319A, if the assessment has not previously been conducted;

"(ii) achieve the public health capacities developed under section 319A; and

"(iii) carry out the plan under paragraph (3).

"(B) ADDITIONAL USES.—In addition to the activities described in subparagraph (A), an eligible entity may use amounts received under this subsection to—

"(i) improve surveillance, detection, and response activities to prepare for emergency response activities including biological threats or attacks, including training personnel in these and other necessary functions;

"(ii) carry out activities to improve communications and coordination efforts within the eligible entity and between the eligible entity and the Federal Government, including activities to improve information technology and communications equipment available to health care and public health officials for use in responding to a biological threat or attack or other public health emergency and including early warning and surveillance networks that use advanced information technology to provide early detection of biological threats or attacks;

"(iii) plan for triage and transport management in the event of a biological threat or attack;

"(iv) meet the special needs of children and other vulnerable populations during and after a biological threat or attack, including the expansion of 2–1–1 call centers or other universal hotlines, or an alternative communication plan to assist victims and their families in receiving timely information;

"(v) improve the ability of hospitals and other health care facilities to provide effective health care (including mental health care) during and after a biological threat or attack, including the development of model hospital preparedness plans by a hospital accreditation organization or similar organizations; and

"(vi) enhance the safety of workplaces in the event of a biological threat or attack, except that nothing in this clause shall be construed to create a new, or deviate from an existing, authority to regulate, modify,

or otherwise effect safety and health rules and standards.

"(C) PROHIBITED USES.—An eligible entity may not use amounts received under this subsection to—

"(i) provide inpatient services;

"(ii) make cash payments to intended recipients of health services;

"(iii) purchase or improve land or purchase any building or other facility;

"(iv) construct, repair, or alter any building or other facility; or

"(v) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

"(5) AMOUNT OF GRANT.—

"(A) IN GENERAL.—Except as provided in paragraph (2), the amount awarded to a State, the District of Columbia, or a territory under this subsection for a fiscal year shall be an amount that bears the same ratio to the amount appropriated under paragraph (9) for such fiscal year (and remaining after amounts are made available under subparagraphs (C) and (D)) as the total population of the State, District, or ter-

ritory bears to the total population of the United States.

"(B) EXCEPTIONS.—

"(i) MINIMUM AMOUNT WITH RESPECT TO STATES.—Notwithstanding subparagraph (A) and subject to the extent of amounts made available under paragraph (9), a State may not receive an award under this subsection for a fiscal year in an amount that is less than—

"(I) $5,000,000 for any fiscal year in which the total amount appropriated under this subsection equals or exceeds $667,000,000; or

"(II) 0.75 percent of the total amount appropriated under this subsection for any fiscal year in which such total amount is less than $667,000,000.

"(ii) EXTRAORDINARY NEEDS.—

"(I) IN GENERAL.—Notwithstanding subparagraph (A) and subject to the extent of amounts made available under paragraph (9), the Secretary may provide additional funds to

a State, District, or territory under this subsection if the Secretary determines that such State, District, or territory has extraordinary needs with respect to bioterrorism preparedness.

"(II) FINDING WITH RESPECT TO THE DISTRICT OF COLUMBIA.—As a result of the concentration of entities of national significance located within the District of Columbia, Congress finds that the District of Columbia has extraordinary needs with respect to bioterrorism preparedness, and the Secretary shall recognize such finding for purposes of subclause (I).

"(C) RULE WITH RESPECT TO UNEXPENDED FUNDS.—To the extent that all the funds appropriated under paragraph (9) for a fiscal year and available in such fiscal year are not otherwise paid to eligible entities because—

"(i) one or more eligible entities have not submitted an application or public health disaster plan in accordance with paragraphs (2) and (3) for the fiscal year;

"(ii) one or more eligible entities have notified the Secretary that they do not intend to use the full amount awarded under this subsection; or

"(iii) some eligible entity amounts are offset or repaid;

such excess shall be provided to each of the remaining eligible entities in proportion to the amount otherwise provided to such entities under this paragraph for the fiscal year without regard to this subparagraph.

"(D) AVAILABILITY OF FUNDS.—Any amount paid to an eligible entity for a fiscal year under this subsection and remaining unobligated at the end of such year shall remain available for the next fiscal year to such entity for the purposes for which it was made.

"(6) INDIAN TRIBES.—

"(A) IN GENERAL.—If the Secretary—

"(i) receives a request from the governing body of an Indian tribe or tribal organization within any State that funds under this subsection be provided directly by the Secretary to such tribe or organization; and

"(ii) determines that the members of such tribe or tribal organization would be better served by means of grants or agreements made directly by the Secretary under this subsection;

the Secretary shall reserve from amounts which would otherwise be provided to such State under this subsection for the fiscal year the amount determined under subparagraph (B).

"(B) AMOUNT.—The Secretary shall reserve for the purpose of subparagraph (A) from amounts that would otherwise be paid to such State under paragraph (1) an amount equal to the amount which bears the same ratio to the amount awarded to the State for the fiscal year involved as the population of the Indian tribe or the individuals represented by the tribal organization bears to the total population of the State.

"(C) GRANT.—The amount reserved by the Secretary on the basis of a determination under this paragraph shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.

"(D) PLAN.—In order for an Indian tribe or tribal organization to be eligible for a grant for a fiscal year under this paragraph, it shall submit to the Secretary a plan for such fiscal year which meets such criteria as the Secretary may prescribe.

"(E) DEFINITIONS.—In this paragraph, the terms 'Indian tribe' and 'tribal organization' have the same meaning given such terms in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act.

"(7) WITHHOLDING.—

"(A) REQUIREMENTS.—

"(i) IN GENERAL.—The Secretary shall, after adequate notice and an opportunity for a hearing conducted within the affected eligible entity, withhold or recoup funds from any such entity that does not use amounts received under this subsection in accordance with the requirements of this subsection. The Secretary shall withhold or recoup such funds until the Secretary finds that the reason for the withholding or recoupment has been removed and there is reasonable assurance that it will not recur.

"(ii) INVESTIGATION.—The Secretary may not institute proceedings to withhold or recoup funds under clause (i) unless the Secretary has conducted an investigation concerning whether the eligible entity has used grant or agreement amounts in accordance with the requirements of this subsection. Investigations required by this clause shall be conducted within the affected entity by qualified investigators.

"(iii) RESPONSE TO COMPLAINTS.—The Secretary shall respond in an expeditious manner to complaints of a substantial or serious nature that an eligible entity has failed to use funds in accordance with the requirements of this subsection.

"(iv) MINOR FAILURES.—The Secretary may not withhold or recoup funds under clause (i) from an eligible entity for a minor failure to comply with the requirements of this subsection.

"(B) AVAILABILITY OF INFORMATION FOR INSPECTION.—Each eligible entity, and other entity which has received funds under this section, shall make appropriate books, documents, pa-

pers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefore.

"(C) LIMITATION ON REQUESTS FOR INFORMATION.—

"(i) IN GENERAL.—In conducting any investigation in an eligible entity, the Secretary or the Comptroller General of the United States may not make a request for any information not readily available to such eligible entity, or an entity which has received funds under this subsection, or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

"(ii) JUDICIAL PROCEEDINGS.—Clause (i) does not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

"(8) DEFINITION.—In this subsection, the term 'State' means any of the several States.

"(9) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $667,000,000 for fiscal year 2002, and such sums as may be necessary for fiscal year 2003, and no funds are authorized to be appropriated for subsequent fiscal years.".

(b) REAUTHORIZATION OF OTHER PROGRAMS.—Section 319F(i) of the Public Health Service Act (42 U.S.C. 247d–6(i)) is amended to read as follows:

"(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

"(1) to carry out subsection (d), $370,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year through 2006; and

"(2) to carry out subsections (a), (b), and (e) through (i), such sums as may be necessary for each of fiscal years 2002 through 2006.".

Subtitle B—Improving Local Preparedness and Response Capabilities

SEC. 311. DESIGNATED BIOTERRORISM RESPONSE MEDICAL CENTERS.

Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended—

(1) by redesignating subsections (d) through (h) and (i), as subsections (e) through (i) and (l), respectively; and

(2) by inserting after subsection (c), the following:

"(d) DESIGNATED BIOTERRORISM RESPONSE MEDICAL CENTERS.—

"(1) GRANTS.—The Secretary shall award project grants to eligible entities to enable such entities, in a manner consistent with applicable provisions of the Bioterrorism Preparedness and Response Plan, to improve local and bioterrorism response medical center preparedness.

"(2) ELIGIBILITY.—To be eligible for a grant under paragraph (1), an entity shall—

"(A) be a consortium that consists of at least one entity from each of the following categories—

"(i) a hospital including children's hospitals, clinic, health center, or primary care facility;

"(ii) a political subdivision of a State; and

"(iii) a department of public health;

"(B) prepare, in consultation with the Chief Executive Officer of the State, District, or territory in which the hospital, clinic, health center, or primary care facility is located, and submits to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require;

"(C) within a reasonable period of time after receiving a grant under paragraph (1), meet such technical guidelines as may be applicable under paragraph (4); and

"(D) provide assurances satisfactory to the Secretary that such entity shall, upon the request of the Secretary or the Chief Executive Officer of the State, District, or territory in which the entity is located, during the emergency period, serve the needs of the emergency area, including providing adequate health care capacity, serving as a regional resource in the diagnosis, treatment, or care for persons, including children and other vulnerable populations, exposed to a biological threat or attack, and accepting the transfer of patients, where appropriate.

"(3) USE OF FUNDS.—An entity that receives a grant under paragraph (1) shall use funds received under the grant for activities that include—

"(A) the training of health care professionals to enhance the ability of such personnel to recognize the symptoms of exposure to a potential biological threat or attack and to provide treatment to those so exposed;

"(B) the training of health care professionals to recognize and treat the mental health consequences of a biological threat or attack;

"(C) increasing the capacity of such entity to provide appropriate health care for large numbers of individuals exposed to a biological threat or attack;

"(D) the purchase of reserves of vaccines, therapies, and other medical supplies to be used until materials from the Strategic National Pharmaceutical Stockpile arrive;

"(E) training and planning to protect the health and safety of personnel involved in responding to a biological threat or attack; or

"(F) other activities determined appropriate by the Secretary.

"(4) PROHIBITED USES.—An eligible entity may not use amounts received under this subsection to—

"(A) purchase or improve land or purchase any building or other facility; or

"(B) construct, repair, or alter any building or facility.

"(6) TECHNICAL ASSISTANCE.—Not later than 180 days after the date of enactment of the Bioterrorism Preparedness Act of 2001, the Secretary shall develop and publish technical guidelines relating to equipment, training, treatment, capacity, and personnel, relevant to the status as a bioterrorism response medical center and the Secretary may provide technical assistance to eligible entities, including assistance to address the needs of children and other vulnerable populations.".

SEC. 312. DESIGNATED STATE PUBLIC EMERGENCY ANNOUNCEMENT PLAN.

Section 613(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5196b(b)) is amended—

(1) in paragraph (5), by striking "and" at the end;

(2) in paragraph (6), by striking the period and inserting "; and"; and

(3) by adding at the end the following:

"(7) include a plan for providing information to the public in a coordinated manner.".

SEC. 313. TRAINING FOR PEDIATRIC ISSUES SURROUNDING BIOLOGICAL AGENTS USED IN WARFARE AND TERRORISM.

Section 319F(f) of the Public Health Service Act (42 U.S.C. 247d–6(e)), as so redesignated by section 311, is amended—

(1) in paragraph (1)—

(A) by inserting "(including mental health care)" after "and care"; and

(B) by striking "and" at the end;

(2) in paragraph (2), by striking the period and inserting "; and"; and

(3) by adding at the end the following:

"(3) develop educational programs for health care professionals, recognizing the special needs of children and other vulnerable populations.".

SEC. 314. GENERAL ACCOUNTING OFFICE REPORT.

Section 319F(h) of the Public Health Service Act (42 U.S.C. 247d–6(g)), as so redesignated by section 311, is amended—

(1) by striking "Not later than 180 days after the date of the enactment of this section, the" and inserting "The";

(2) in paragraph (3), by striking "and" at the end;

(3) in paragraph (4), by striking the period and inserting a semicolon; and

(4) by adding at the end the following:

"(5) the activities and cost of the Civil Support Teams of the National Guard in responding to biological threats or attacks against the civilian population;

"(6) the activities of the working group described in subsection (a) and the efforts made by such group to carry out the activities described in such subsection;

"(7) the activities and cost of the 2–1–1 call centers and other universal hotlines; and

"(8) the activities and cost of the development and improvement of public health laboratory capacity.".

SEC. 315. ADDITIONAL RESEARCH.

Section 22 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 671) is amended by adding at the end the following:

"(h) RESEARCH RELATING TO BIOLOGICAL THREATS OR ATTACKS IN THE WORKPLACE.—The Director shall enhance and expand research as deemed appropriate by the Director on the health and safety of workers who are at risk for biological threats or attacks in the workplace.".

SEC. 316. SENSE OF THE SENATE.

It is the sense of the Senate that—

(1) many excellent university-based programs are already functioning and developing important biodefense products and solutions throughout the United States;

(2) accelerating the crucial work done at university centers and laboratories will contribute significantly to the United States capacity to defend against any biological threat or attack;

(3) maximizing the effectiveness of, and extending the mission of, established university programs would be one appropriate use of the additional resources provided for in the Bioterrorism Preparedness Act of 2001; and

(4) Congress recognizes the importance of existing public and private university-based research, training, public awareness, and safety related biological defense programs in the awarding of grants and contracts made in accordance with this Act.

TITLE IV—DEVELOPING NEW COUNTERMEASURES AGAINST BIOTERRORISM

SEC. 401. LIMITED ANTITRUST EXEMPTION.

Section 2 of the Clayton Act (15 U.S.C. 13) is amended by adding at the end the following:

"(g) LIMITED ANTITRUST EXEMPTION.—

"(1) COUNTERMEASURES DEVELOPMENT MEETINGS.—

"(A) COUNTERMEASURES DEVELOPMENT MEETINGS AND CONSULTATIONS.—The Secretary may conduct meetings and consultations with parties involved in the development of priority countermeasures for the purpose of the development, manufacture, distribution, purchase, or sale of priority countermeasures consistent with the purposes of this title. The Secretary shall give notice of such meetings and consultations to the Attorney General and the Chairperson of the Federal Trade Commission (referred to in this subsection as the 'Chairperson').

"(B) MEETING AND CONSULTATION CONDITIONS.—A meeting or consultation conducted under subparagraph (A) shall—

"(i) be chaired or, in the case of a consultation, facilitated by the Secretary;

"(ii) be open to parties involved in the development, manufacture, distribution, purchase, or sale of priority countermeasures, as determined by the Secretary;

"(iii) be open to the Attorney General and the Chairperson;

"(iv) be limited to discussions involving the development, manufacture, distribution, or sale of priority countermeasures, consistent with the purposes of this title; and

"(v) be conducted in such manner as to ensure that national security, confidential, and proprietary information is not disclosed outside the meeting or consultation.

"(C) MINUTES.—The Secretary shall maintain minutes of meetings and consultations under this subsection, which shall not be disclosed under section 552 of title 5, United States Code.

"(D) EXEMPTION.—The antitrust laws shall not apply to meetings and consultations under this paragraph, except that any agreement or

conduct that results from a meeting or consultation and that does not receive an exemption pursuant to this subsection shall be subject to the antitrust laws.

"(2) WRITTEN AGREEMENTS.—The Secretary shall file a written agreement regarding covered activities, made pursuant to meetings or consultations conducted under paragraph (1) and that is consistent with this paragraph, with the Attorney General and the Chairperson for a determination of the compliance of such agreement with antitrust laws. In addition to the proposed agreement itself, any such filing shall include—

"(A) an explanation of the intended purpose of the agreement;

"(B) a specific statement of the substance of the agreement;

"(C) a description of the methods that will be utilized to achieve the objectives of the agreement;

"(D) an explanation of the necessity of a cooperative effort among the particular participating parties to achieve the objectives of the agreement; and

"(E) any other relevant information determined necessary by the Secretary in consultation with the Attorney General and the Chairperson.

"(3) DETERMINATION.—The Attorney General, in consultation with the Chairperson, shall determine whether an agreement regarding covered activities referred to in paragraph (2) would likely—

"(A) be in compliance with the antitrust laws, and so inform the Secretary and the participating parties; or

"(B) violate the antitrust laws, in which case, the filing shall be deemed to be a request for an exemption from the antitrust laws, limited to the performance of the agreement consistent with the purposes of this title.

"(4) ACTION ON REQUEST FOR EXEMPTION.—

"(A) IN GENERAL.—The Attorney General, in consultation with the Chairperson, shall grant, deny, grant in part and deny in part, or propose modifications to a request for exemption from the antitrust laws under paragraph (3) within 15 days of the receipt of such request.

"(B) EXTENSION.—The Attorney General may extend the 15-day period referred to in subparagraph (A) for an additional period of not to

exceed 10 days. Such additional period may be further extended only by the United States district court, upon an application by the Attorney General after notice to the Secretary and the parties involved.

"(C) DETERMINATION.—In granting an exemption under this paragraph, the Attorney General, in consultation with the Chairperson and the Secretary—

(i) must find—

"(I) that the agreement involved is necessary to ensure the availability of priority countermeasures;

"(II) that the exemption from the antitrust laws would promote the public interest; and

"(III) that there is no substantial competitive impact to areas not directly related to the purposes of the agreement; and

"(ii) may consider any other factors determined relevant by the Attorney General and the Chairperson.

"(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4)

shall be limited to covered activities, and shall expire on the date that is 3 years after the date on which the exemption becomes effective (and at 3 year intervals thereafter, if renewed) unless the Attorney General in consultation with the Chairperson determines that the exemption should be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

"(6) LIMITATION ON PARTIES.—The use of any information acquired under an exempted agreement by the parties to such an agreement for any purposes other than those specified in the antitrust exemption granted by the Attorney General shall be subject to the antitrust laws and any other applicable laws.

"(7) GUIDELINES.—The Attorney General and the Chairperson may develop and issue guidelines to implement this subsection.

"(8) REPORT.—Not later than 1 year after the date of enactment of the Bioterrorism Preparedness Act of 2001, and annually thereafter, the Attorney General and the Chairperson shall report to Congress on the use and continuing need for the exemption from the antitrust laws provided by this subsection.

"(9) SUNSET.—The authority of the Attorney General to grant or renew a limited antitrust exemp-

tion under this subsection shall expire at the end of the 6-year period that begins on the date of enactment of the Bioterrorism Preparedness Act of 2001.

"(h) DEFINITIONS.—In this section and title XXVIII of the Public Health Service Act:

"(1) ANTITRUST LAWS.—The term 'antitrust laws'—

"(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes the Act of June 19, 1936 (15 U.S.C. 13 et seq.) commonly known as the Robinson-Patman Act), and section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

"(B) includes any State law similar to the laws referred to in subparagraph (A).

"(2) COVERED ACTIVITIES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered activities' means any group of activities or conduct, including attempting to make, making, or performing a contract or agreement or engaging in other conduct, for the purpose of—

"(i) theoretical analysis, experimentation, or the systematic study of phenomena or observable facts necessary to the development of priority countermeasures;

"(ii) the development or testing of basic engineering techniques necessary to the development of priority countermeasures;

"(iii) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes necessary to the development of priority countermeasures;

"(iv) the production, distribution, or marketing of a product, process, or service that is a priority countermeasures;

"(v) the testing in connection with the production of a product, process, or services necessary to the development of priority countermeasures;

"(vi) the collection, exchange, and analysis of research or production informa-

tion necessary to the development of priority countermeasures; or

"(vii) any combination of the purposes described in clauses (i) through (vi);

and such term may include the establishment and operation of facilities for the conduct of covered activities described in clauses (i) through (vi), the conduct of such covered activities on a protracted and proprietary basis, and the processing of applications for patents and the granting of licenses for the results of such covered activities.

"(B) EXCEPTION.—The term 'covered activities' shall not include the following activities involving 2 or more persons:

"(i) Exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution of any product, process, or service if such information is not reasonably necessary to carry out the purposes of covered activities.

"(ii) Entering into any agreement or engaging in any other conduct—

"(I) to restrict or require the sale, licensing, or sharing of inventions, de-

velopments, products, processes, or services not developed through, produced by, or distributed or sold through such covered activities; or

"(II) to restrict or require participation by any person who is a party to such covered activities in other research and development activities, that is not reasonably necessary to prevent the misappropriation of proprietary information contributed by any person who is a party to such covered activities or of the results of such covered activities.

"(iii) Entering into any agreement or engaging in any other conduct allocating a market with a competitor that is not expressly exempted from the antitrust laws by a determination under subsection (i)(4).

"(iv) Exchanging information among competitors relating to production (other than production by such covered activities) of a product, process, or service if such information is not reasonably necessary to

carry out the purpose of such covered activities.

"(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not so expressly exempted from the antitrust laws by a determination under subsection (i)(4).

"(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person who is a party to such activities, in any unilateral or joint activity that is not reasonably necessary to carry out the purpose of such covered activities.

"(3) DEVELOPMENT.—The term 'development' includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval, and any other actions related to preparation of a countermeasure.

"(4) PERSON.—The term 'person' has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)).

"(5) PRIORITY COUNTERMEASURE.—The term 'priority countermeasure' means a countermeasure, including a drug, medical device, biological product, or diagnostic test to treat, identify, or prevent infection by a biological agent or toxin on the list developed under section 351A(a)(1) and prioritized under subsection (a)(1).".

SEC. 402. DEVELOPING NEW COUNTERMEASURES AGAINST BIOTERRORISM.

Title XXVIII of the Public Health Service Act, as added by section 101 and amended by section 201, is further amended by adding at the end the following:

"Subtitle B—Developing New Countermeasures Against Bioterrorism

"SEC. 2841. SMALLPOX VACCINE AND OTHER VACCINE DEVELOPMENT.

"(a) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile described in section 2812 shall include the number of doses of vaccine against smallpox and

other such vaccines determined by the Secretary to be sufficient to meet the needs of the population of the United States.

"(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

"SEC. 2842. CONTRACT AUTHORITY FOR PRIORITY COUNTERMEASURES.

"(a) IN GENERAL.—The Secretary shall, to the extent the Secretary determines necessary to achieve the purposes of this title, enter into long-term contracts and comparable grants or cooperative agreements, for the purpose of—

"(1) ensuring the development of priority countermeasures that are necessary to prepare for a bioterrorist attack or other significant disease emergency;

"(2) securing the manufacture, distribution, and adequate supply of such countermeasures, including through the development of novel production methods for such countermeasures;

"(3) maintaining the Strategic National Pharmaceutical Stockpile under section 2812; and

"(4) carrying out such other activities determined appropriate by the Secretary to achieve the purposes of this title.

"(b) TERMS OF CONTRACTS.—Notwithstanding any other provision of law, the Secretary may enter into a contract or cooperative agreement under subsection (a) prior to the development, approval, or clearance of the countermeasure that is the subject of the contract. The contract or cooperative agreement may provide for its termination for the convenience of the Federal Government if the contractor does not develop the countermeasure involved. Such a contract or cooperative agreement may—

"(1) involve one or more aspects of the development, manufacture, purchase, or distribution of one or more uses of one or more countermeasures; and

"(2) set forth guaranteed minimum quantities of products and negotiated unit prices.

"SEC. 2843. SECURITY FOR COUNTERMEASURE DEVELOPMENT AND PRODUCTION.

"(a) IN GENERAL.—The Secretary, in consultation with the Attorney General and the Secretary of Defense, may provide technical or other assistance, to provide security to persons or facilities that conduct development, pro-

duction, distribution, or storage of priority countermeasures.

"(b) BEST PRACTICES.—The Secretary shall develop guidelines and best practices to enable entities eligible to receive assistance under this section to secure their facilities against potential terrorist attack.".

SEC. 403. SEQUENCING OF PRIORITY PATHOGENS.

Section 319F(g) of the Public Health Service Act (42 U.S.C. 247d–6(f)), as so redesignated by section 311, is amended—

(1) in paragraph (3), by striking "and" at the end;

(2) by redesignating paragraph (4) as paragraph (5); and

(3) by inserting after paragraph (3), the following:

"(4) the sequencing of the genomes of priority pathogens as determined appropriate by the Director of the National Institutes of Health, in consultation with the working group established in subsection (a); and".

SEC. 404. ACCELERATED COUNTERMEASURE RESEARCH AND DEVELOPMENT.

Section 319F(g) of the Public Health Service Act (42 U.S.C. 247d–6(f)), as so redesignated by section 311 and amended by section 403, is further amended—

(1) by redesignating paragraphs (1) through (5), as subparagraphs (A) through (E), respectively and indenting appropriately;

(2) by striking "The Secretary" and inserting the following:

"(1) IN GENERAL.—The Secretary"; and

(3) by adding at the end the following:

"(2) ACCELERATED COUNTERMEASURE RESEARCH AND DEVELOPMENT.—

"(A) IN GENERAL.—The Secretary shall conduct, and award grants, contracts, or cooperative agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

"(i) the epidemiology and pathogenesis of biological agents or toxins of potential use in a bioterrorist attack;

"(ii) the development of new vaccines and therapeutics for use against biological agents or toxins of potential use in a bioterrorist attack;

"(iii) the development of diagnostic tests to detect biological agents or toxins of potential use in a bioterrorist attack; and

"(iv) other relevant areas of research;

with consideration given to the needs of children and other vulnerable populations.

"(B) PRIORITY.—The Secretary shall give priority under this paragraph to the funding of research and other studies related to priority countermeasures.".

SEC. 405. ACCELERATED APPROVAL OF PRIORITY COUNTERMEASURES.

(a) IN GENERAL.—The Secretary of Health and Human Services may designate a priority countermeasure as a fast-track product pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) or as a device granted priority review pursuant to section 515(d)(5) of such Act (21 U.S.C. 366e(d)(5)). Such a designation may be made prior to the submission of—

(1) a request for designation by the sponsor or applicant; or

(2) an application for the investigation of the drug under section 505(i) of such Act or section 351(a)(3) of the Public Health Service Act.

Nothing in this subsection shall be construed to prohibit a sponsor or applicant from declining such a designation.

(b) USE OF ANIMAL TRIALS.—A drug for which approval is sought under section 505(d) of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act on the basis of evidence of effectiveness that is derived from animal studies under section 406 may be designated as a fast track product for purposes of this section.

(c) PRIORITY REVIEW.—

(1) IN GENERAL.—A priority countermeasure that is a drug or biological product shall be subject to the performance goals established by the Commissioner of Food and Drugs for priority drugs or biological products.

(2) DEFINITION.—In this subsection the term "priority drugs or biological products" means a drug or biological product that is the subject of a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997.

SEC. 406. USE OF ANIMAL TRIALS IN THE APPROVAL OF PRIORITY COUNTERMEASURES.

Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final rule for the proposal entitled "New Drug and Biological Drug Products; Evidence Needed to Demonstrate

Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot be Conducted" as published in the Federal Register on October 5, 1999 (64 Fed. Reg.).

SEC. 407. MISCELLANEOUS PROVISIONS.

Title XXVIII of the Public Health Service Act, as added by section 101 and amended by section 403, is further amended by adding at the end the following:

"Subtitle C—Miscellaneous Provisions

"SEC. 2851. SUPPLEMENT NOT SUPPLANT.

"A State or local government, or other entity to which a grant, contract, or cooperative agreement is awarded under this title, may not use amounts received under the grant, contract, or cooperative agreement to supplant expenditures by the entity for activities provided for under this title, but shall use such amounts only to supplement such expenditures at a level at least equal to the level of such expenditures for fiscal year 2001 (excluding those additional, extraordinary expenditures that may have been made after September 10, 2001).".

TITLE V—PROTECTING THE SAFETY AND SECURITY OF THE FOOD SUPPLY

Subtitle A—General Provisions to Expand and Upgrade Security

SEC. 511. FOOD SAFETY AND SECURITY STRATEGY.

(a) IN GENERAL.—The President's Council on Food Safety (as established by Executive Order 13100), the Secretary of Commerce, and the Secretary of Transportation, shall, in consultation with the food industry and consumer and producer groups, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. Such strategy shall address threat assessments, response and notification procedures, and risks communications to the public.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, $500,000 for fiscal year 2002, and such sums as may be necessary in each subsequent fiscal year to implement the strategy developed under subsection (a) in cooperation with the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency.

SEC. 512. EXPANSION OF ANIMAL AND PLANT HEALTH INSPECTION SERVICE ACTIVITIES.

(a) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the "Secretary") shall enhance and expand the capacity of the Animal and Plant Health Inspection Service through the conduct of activities to—

(1) increase the inspection capacity of the Service at international points of origin;

(2) improve surveillance at ports of entry and customs;

(3) enhance methods of protecting against the introduction of plant and animal disease organisms by terrorists;

(4) adopt new strategies and technologies for dealing with intentional outbreaks of plant and animal disease arising from acts of terrorism or from unintentional introduction, including—

(A) establishing cooperative agreements among Veterinary Services of the Animal and Plant Health Inspection Service, State animal health commissions and regulatory agencies for livestock and poultry health, and private veterinary practitioners to enhance the preparedness and ability of Veterinary Services and the commissions and agencies to respond to outbreaks of such animal diseases; and

(B) strengthening planning and coordination with State and local agencies, including—

(i) State animal health commissions and regulatory agencies for livestock and poultry health; and

(ii) State agriculture departments; and

(5) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) HIGH-TECH AGRICULTURE EARLY WARNING AND EMERGENCY RESPONSE SYSTEM.—

(1) IN GENERAL.—To provide the agricultural system of the United States with a new, enhanced level of protection and biosecurity that does not exist on the date of enactment of this Act, the Secretary of Agriculture, in coordination with the Secretary of Health and Human Services, shall implement a fully secure surveillance and response system that utilizes, or is capable of utilizing, field test devices capable of detecting biological threats to animals and plants and that electronically integrates the devices and the tests on a real-time basis into a comprehensive surveillance, incident management, and emergency response system.

(2) EXPANSION OF SYSTEM.—The Secretary shall expand the system implemented under paragraph (1)

as soon as practicable to include other Federal agencies and the States where appropriate and necessary to enhance the protection of the food and agriculture system of the United States. To facilitate the expansion of the system, the Secretary shall award grants to States.

(c) AUTOMATED RECORDKEEPING SYSTEM.—The Administrator of the Animal and Plant Health Inspection Service shall implement a central automated recordkeeping system to provide for the reliable tracking of the status of animal and plant shipments, including those shipments on hold at ports of entry and customs. The Secretary shall ensure that such a system shall be fully accessible to or fully integrated with the Food Safety Inspection Service.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $30,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 513. EXPANSION OF FOOD SAFETY INSPECTION SERVICE ACTIVITIES.

(a) IN GENERAL.—The Secretary of Agriculture shall enhance and expand the capacity of the Food Safety Inspection Service through the conduct of activities to—

(1) enhance the ability of the Service to inspect and ensure the safety and wholesomeness of meat and poultry products;

(2) improve the capacity of the Service to inspect international meat and meat products, poultry and poultry products, and egg products at points of origin and at ports of entry;

(3) strengthen the ability of the Service to collaborate with relevant agencies within the Department of Agriculture and with other entities in the Federal Government, the States, and Indian tribes through the sharing of information and technology; and

(4) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $15,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 514. EXPANSION OF FOOD AND DRUG ADMINISTRATION ACTIVITIES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall expand the capacity of the Food and Drug Administration to—

(1) increase inspections to ensure the safety of the food supply consistent with the amendments made by subtitle B; and

(2) improve linkages between the Agency and other regulatory agencies of the Federal Government, the States, and Indian tribes with shared responsibilities.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $59,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 515. BIOSECURITY UPGRADES AT THE DEPARTMENT OF AGRICULTURE.

There is authorized to be appropriated for fiscal year 2002, $180,000,000 to enable the Agricultural Research Service to conduct building upgrades to modernize existing facilities, of which (1) $100,000,000 is allocated for renovation, updating, and expansion of the Biosafety Level 3 laboratory and animal research facilities at the Plum Island Animal Disease Center (Greenport, New York), and of which (2) $80,000,000 is allocated for the Agricultural Research Service/Animal and Plant Health Inspection Service facility in Ames, Iowa. There is authorized to be appropriated such sums as may be necessary in fiscal years 2003 through 2006 for (1), (2) and the planning and design of

an Agricultural Research Service biocontainment laboratory for poultry research in Athens, Georgia, and the planning, updating, and renovation of the Arthropod-Borne Animal Disease Laboratory in Laramie, Wyoming.

SEC. 516. BIOSECURITY UPGRADES AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

The Secretary of Health and Human Services shall take such actions as may be necessary to secure existing facilities of the Department of Health and Human Services where potential animal and plant pathogens are housed or researched.

SEC. 517. AGRICULTURAL BIOSECURITY.

(a) LAND GRANT ASSESSMENTS.—

(1) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the "Secretary") shall establish minimum security standards and award grants to land grant universities to conduct security needs assessments and to plan for improvement of—

(A) the security of all facilities where hazardous biological agents and toxins are stored or used for agricultural research purposes; and

(B) communication networks that transmit information about hazardous biological agents and toxins.

(2) AVAILABILITY OF STANDARDS.—Not later than 45 days after the establishment of security standards under paragraph (1), the Secretary shall make such standards available to land grant universities.

(3) GRANTS.—Not later than 45 days after the date of enactment of this Act, the Secretary shall award grants, not to exceed $50,000 each, to land grant universities to enable such universities to conduct a security needs assessment and plan activities to improve security. Such an assessment shall be completed not later than 45 days after the date on which such grant funds are received.

(b) NATIONAL HAZARDOUS AGENT INVENTORY.—The Secretary shall carry out activities necessary to develop a national inventory of hazardous biological agents and toxins contained in agricultural research facilities. Such activities shall include developing and distributing a model inventory procedure, developing secure means of transmitting inventory information, and conducting annual inventory activities. The inventory shall be developed in coordination with, or as a component of, similar systems in existence on the date of enactment of this Act.

(c) SCREENING PROTOCOL.—The Secretary shall establish a national protocol for the screening of individuals

who require access to agricultural research facilities in a manner that provides for the protection of personal privacy.

(d) INDUSTRY-ON-FARM EDUCATION.—

(1) IN GENERAL.—The Secretary shall develop and implement a program to provide education relating to farms, livestock confinement operations, and livestock auction biosecurity to prevent the intentional or accidental introduction of a foreign animal disease and to attempt to discover the introduction of such a disease before it can spread into an outbreak. Biosecurity for livestock includes animal quarantine procedures, blood testing of new arrivals, farm locations, control of human movement onto farms and holding facilities, control of vermin, and movement of vehicles onto farms.

(2) QUARANTINE AND TESTING.—The Secretary shall develop and disseminate through educational programs animal quarantine and testing guidelines to enable farmers and producers to better monitor new arrivals. Any educational seminars and training carried out by the Secretary under this paragraph shall emphasize the economic benefits of biosecurity and the profound negative impact of an outbreak.

(3) CROP GUIDELINES.—The Secretary may develop guidelines and educational materials relating to

biosecurity issues to be distributed to local crop producers and facilities that handle, process, or transport crops.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year, of which not less than $5,000,000 shall be made available in fiscal year 2002 for activities under subsection (a).

SEC. 518. BIOSECURITY OF FOOD MANUFACTURING, PROCESSING, AND DISTRIBUTION.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), in consultation with the Attorney General, may award grants, contracts, or cooperative agreements to enable food manufacturers, food processors, food distributors, and other entities regulated by the Secretary to ensure the safety of food through the development and implementation of educational programs to ensure the security of their facilities and modes of transportation against potential bioterrorist attack.

(b) BEST PRACTICES.—The Secretary may develop best practices to enable entities eligible for funding under this section to secure their facilities and modes of transportation against potential bioterrorist attacks.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $500,000 in fiscal year 2002, and such sums as may be necessary for each fiscal year thereafter.

Subtitle B—Protection of the Food Supply

SEC. 531. ADMINISTRATIVE DETENTION.

(a) EXPANDED AUTHORITY.—Section 304 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 334) is amended by adding at the end the following:

"(h) ADMINISTRATIVE DETENTION OF FOODS.—

"(1) AUTHORITY.—Any officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that the article is in violation of this Act and presents a threat of serious adverse health consequences or death to humans or animals.

"(2) PERIOD OF DETENTION; APPROVAL BY SECRETARY OR SECRETARY'S DESIGNEE.—

"(A) DURATION.—An article of food may be detained under this subsection for a reasonable period, not to exceed 20 days, unless a greater period of time, not to exceed 30 days, is necessary to enable the Secretary to institute an action under subsection (a) or section 302.

"(B) SECRETARY'S APPROVAL.—Before an article of food may be ordered detained under this subsection, the Secretary or an officer or qualified employee designated by the Secretary must approve such order, after determining that the article presents a threat of serious adverse health consequences or death to humans or animals.

"(3) SECURITY OF DETAINED ARTICLE.—A detention order under this subsection with respect to an article of food may require that the article be labeled or marked as detained, and may require that the article be removed to a secure facility. An article subject to a detention order under this subsection shall not be moved by any person from the place at which it is ordered detained until released by the Secretary, or the expiration of the detention period applicable to such order, whichever occurs first.

"(4) APPEAL OF DETENTION ORDER.—Any person who would be entitled to claim a detained article if it were seized under subsection (a) may appeal to the Secretary the detention order under this subsection. Within 15 days after such an appeal is filed, the Secretary, after affording opportunity for an informal hearing, shall by order confirm the detention order or revoke it.

"(5) PERISHABLE FOODS.—The Secretary shall provide in regulation or in guidance for procedures for instituting and appealing on an expedited basis administrative detention of perishable foods.".

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following new subsection:

"(bb) The movement of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order in order to identify the article as detained.".

SEC. 532. DEBARMENT FOR REPEATED OR SERIOUS FOOD IMPORT VIOLATIONS.

(a) DEBARMENT AUTHORITY.—

(1) PERMISSIVE DEBARMENT.—Section 306(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)(1)) is amended—

(A) by striking the period at the end of subparagraph (B) and inserting "; or"; and

(B) by adding at the end the following:

"(C) a person from importing a food or offering a food for import into the United States if—

"(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any food; or

"(ii) the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.".

(2) CONFORMING AMENDMENT.—Section 306(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)(2)) is amended—

(A) in the paragraph heading, by inserting "RELATING TO DRUG APPLICATIONS" after "DEBARMENT"; and

(B) in the matter preceding subparagraph (A), by striking "paragraph (1)" and inserting "subparagraphs (A) and (B) of paragraph (1)".

(3) DEBARMENT PERIOD.—Section 306(c)(2)(A)(iii) of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 335a(c)(2)(A)(iii)) is amended by striking "subsection (b)(2)" and inserting "subsection (b)(1)(C) or (b)(2)".

(4) TERMINATION OF DEBARMENT.—Section 306(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(d)(3)) is amended—

(A) in subparagraph (A)(i), by striking "or (b)(2)(A)" and inserting ", or (b)(2)(A), or (b)(1)(C)";

(B) in subparagraph (A)(ii)(II), by inserting "in applicable cases," before "sufficient audits"; and

(C) in subparagraph (B), in each of clauses (i) and (ii), by inserting "or (b)(1)(C)" after "(b)(2)(B)".

(5) EFFECTIVE DATES.—Section 306(l)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(l)(2)) is amended—

(A) in the first sentence, by inserting "and subsection (b)(1)(C)" after "subsection (b)(2)(B)"; and

(B) in the second sentence, by striking "and subsections (f) and (g) of this section" and inserting "subsections (f) and (g), and subsection (b)(1)(C)".

(b) CONFORMING AMENDMENT.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

"(h) If it is an article of food imported or offered for import into the United States by, with the assistance of, or at the direction of, a person debarred under section 306(b)(1)(C).".

SEC. 533. MAINTENANCE AND INSPECTION OF RECORDS FOR FOODS.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 414. MAINTENANCE AND INSPECTION OF RECORDS.

"(a) IN GENERAL.—If the Secretary has reason to believe that an article of food is adulterated or misbranded under this Act and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding restaurants and farms) that manufactures, processes, packs, distributes, receives, holds, or imports such food shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and to copy all records relating to such food that

may assist the Secretary to determine the cause and scope of the violation. This requirement applies to all records relating to such manufacture, processing, packing, distribution, receipt, holding, or importation of such food maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

"(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary shall promulgate regulations regarding the maintenance and retention of records for inspection for not longer than 2 years by persons (excluding restaurants and farms) that manufacture, process, pack, transport, distribute, receive, hold, or import food, as may be needed to allow the Secretary—

"(1) to promptly trace the source and chain of distribution of food and its packaging to address threats of serious adverse health consequences or death to humans or animals; or

"(2) to determine whether food manufactured, processed, packed, or held by the person may be adulterated or misbranded to the extent that it presents a threat of serious adverse health consequences or death to humans or animals under this Act.

The Secretary may impose reduced requirements under such regulations for small businesses with 50 or fewer employees.

"(c) LIMITATIONS.—Nothing in this section shall be construed—

"(1) to limit the authority of the Secretary to inspect records or to require maintenance of records under any other provision of or regulations issued under this Act;

"(2) to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

"(3) to extend to recipes for food, financial data, sales data other than shipment data, pricing data, personnel data, or research data; or

"(4) to alter, amend, or affect in any way the disclosure or nondisclosure under section 552 of title 5, United States Code, of information copied or collected under this section, or its treatment under section 1905 of title 18, United States Code.".

(b) FACTORY INSPECTION.—Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended—

(1) in paragraph (1), by adding after the first sentence the following: "In the case of any person (excluding restaurants and farms) that manufactures, processes, packs, transports, distributes, receives, holds, or imports foods, the inspection shall extend to all records and other information described in section 414(a), or required to be maintained pursuant to section 414(b)."; and

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking "second sentence" and inserting "third sentence".

(c) PROHIBITED ACT.—Section 301 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsection (e)—

(A) by striking "by section 412, 504, or 703" and inserting "by section 412, 414, 504, 703, or 704(a)"; and

(B) by striking "under section 412" and inserting "under section 412, 414(b)"; and

(2) in section (j), by inserting "414," after "412,".

(d) EXPEDITED RULEMAKING.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate proposed and final regulations estab-

lishing recordkeeping requirements under subsection 414(b)(1) of the Federal Food, Drug, and Cosmetic Act.

SEC. 534. REGISTRATION OF FOOD MANUFACTURING, PROCESSING, AND HANDLING FACILITIES.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.), as amended by section 533, is further amended by adding at the end the following:

"SEC. 415. REGISTRATION OF FOOD MANUFACTURING, PROCESSING, AND HANDLING FACILITIES.

"(a) REGISTRATION.—

"(1) IN GENERAL.—Any facility engaged in manufacturing, processing, or handling food for consumption in the United States shall be registered with the Secretary. To be registered—

"(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and

"(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

"(2) REGISTRATION.—An entity (referred to in this section as the 'registrant') shall submit a reg-

istration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, or handled at such facility. The registrant shall notify the Secretary in a timely manner of changes to such information.

"(3) PROCEDURE.—Upon receipt of a completed registration described in paragraph (1), the Secretary shall notify the registrant of the receipt of such registration and assign a registration number to each registered facility.

"(4) LIST.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. Such list and other information required to be submitted under this subsection shall not be subject to the disclosure requirements of section 552 of title 5, United States Code.

"(b) EXEMPTION AUTHORITY.—The Secretary may by regulation exempt types of retail establishments or farms from the requirements of subsection (a) if the Secretary de-

termines that the registration of such facilities is not needed for effective enforcement of chapter IV and any regulations issued under such chapter.

"(c) FACILITY.—In this section, the term 'facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer), that manufactures, handles, or processes food. Such term does not include restaurants.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process.".

(b) MISBRANDED FOODS.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

"(t) If it is a food from a facility for which registration has not been submitted to the Secretary under section 415(a).".

(c) EFFECTIVE DATE.—The amendment made by subsection (b) shall take effect 180 days after the date of enactment of this Act.

SEC. 535. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

"(j) PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.—

"(1) IN GENERAL.—At least 4 hours before a food is imported or offered for importation into the United States, the producer, manufacturer, or shipper of the food shall provide documentation to the Secretary of the Treasury and the Secretary of Health and Human Services that—

"(A) identifies—

"(i) the food;

"(ii) the countries of origin of the food; and

"(iii) the quantity to be imported; and

"(B) includes such other information as the Secretary of Health and Human Services may require by regulation.

"(2) REFUSAL OF ADMISSION.—If documentation is not provided as required by paragraph (1) at least 4 hours before the food is imported or offered for importation, the food may be refused admission.

"(3) LIMITATION.—Nothing in this subsection shall be construed to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal

Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).".

(b) PROHIBITION OF KNOWINGLY MAKING FALSE STATEMENTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 531(b), is further amended by inserting after subsection (bb) the following:

"(cc) Knowingly making a false statement in documentation required under section 801(j).".

SEC. 536. AUTHORITY TO MARK REFUSED ARTICLES.

(a) MISBRANDED FOODS.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343), as amended by section 534(b), is further amended by adding at the end the following:

"(u) If—

"(1) it has been refused admission under section 801(a);

"(2) it has not been required to be destroyed under section 801(a);

"(3) the packaging of it does not bear a label or labeling described in section 801(a); and

"(4) it presents a threat of serious adverse health consequences or death to humans or animals.".

(b) REQUIREMENT.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by adding at the end the following: "The Secretary of Health and Human Services may require the owner or consignee of a food that has been refused admission under this section, and has not been required to be destroyed, to affix to the packaging of the food a label or labeling that—

"(1) clearly and conspicuously bears the statement: 'United States: Refused Entry';

"(2) is affixed to the packaging until the food is brought into compliance with this Act; and

"(3) has been provided at the expense of the owner or consignee of the food.".

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary of Health and Human Services or the Secretary of the Treasury to require the marking of refused articles under any other provision of law.

SEC. 537. AUTHORITY TO COMMISSION OTHER FEDERAL OFFICIALS TO CONDUCT INSPECTIONS.

Section 702(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 372(a)) is amended in the first sentence—

(1) by inserting "qualified" before "employees"; and

(2) by inserting "or of other Federal Departments or agencies, notwithstanding any other provision of law restricting the use of a Department's or agency's officers, employees, or funds," after "officers and qualified employees of the Department".

SEC. 538. PROHIBITION AGAINST PORT SHOPPING.

Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), as amended by section 532(b), is further amended by adding at the end the following:

"(i) If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 801(a), unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this Act, as determined by the Secretary.".

SEC. 539. GRANTS TO STATES FOR INSPECTIONS.

Chapter IX of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 910. GRANTS TO STATES FOR INSPECTIONS.

"(a) IN GENERAL.—The Secretary is authorized to make grants to States, territories, and Federally recognized Indian tribes that undertake examinations, inspections, and investigations, and related activities under section 702.

The funds provided under such grants shall only be available for the costs of conducting such examinations, inspections, investigations, and related activities.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $10,000,000 for fiscal year 2002, and such sums as may be necessary to carry out this section for each subsequent fiscal year.".

SEC. 540. RULE OF CONSTRUCTION.

Nothing in this title, or an amendment made by this title, shall be construed to—

(1) provide the Food and Drug Administration with additional authority related to the regulation of meat, poultry, and egg products; or

(2) limit the authority of the Secretary of Agriculture with respect to such products.

Subtitle C—Research and Training to Enhance Food Safety and Security

SEC. 541. SURVEILLANCE AND INFORMATION GRANTS AND AUTHORITIES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317P the following:

"SEC. 317Q. FOOD SAFETY GRANTS.

"(a) IN GENERAL.—The Secretary may award food safety grants to States to expand the number of States participating in Pulsenet, the Foodborne Diseases Active Surveillance Network, and other networks to enhance Federal, State, and local food safety efforts.

"(b) USE OF FUNDS.—Funds awarded under this section shall be used by States to assist such States in meeting the costs of establishing and maintaining the food safety surveillance, technical and laboratory capacity needed to participate in Pulsenet, Foodborne Diseases Active Surveillance Network, and other networks to enhance Federal, State, and local food safety efforts.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $19,500,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

"SEC. 317R. SURVEILLANCE OF ANIMAL AND HUMAN HEALTH.

"The Secretary, through the Commissioner of the Food and Drug Administration and the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture shall develop and implement a plan for coordinating the surveillance for zoonotic disease and human disease.".

SEC. 542. AGRICULTURAL BIOTERRORISM RESEARCH AND DEVELOPMENT.

(a) IN GENERAL.—The Secretary of Agriculture, to the maximum extent practicable, shall utilize existing authorities to expand Agricultural Research Service, and Cooperative State Research Education and Extension Service, programs to protect the food supply of the United States by conducting activities to—

(1) enhance the capability of the Service to respond immediately to the needs of Federal regulatory agencies involved in protecting the food and agricultural system;

(2) continue existing partnerships with institutions of higher education (including partnerships with 3 institutions of higher education that are national centers for countermeasures against agricultural bioterrorism and 7 additional institutions with existing programs related to bioterrorism) to help form stable, long-term programs of research, development, and evaluation of options to enhance the biosecurity of United States agriculture;

(3) strengthen linkages with the intelligence community to better identify research needs and evaluate acquired materials;

(4) expand Service involvement with international organizations dealing with plant and animal disease control; and

(5) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $190,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

Attest:

Secretary.

107TH CONGRESS
1ST SESSION

H. R. 3448

AMENDMENT