Public Law 107–188
107th Congress

An Act

June 12, 2002
[H.R. 3448]

To improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.

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

Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
42 USC 201 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002".

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

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TITLE I—NATIONAL PREPAREDNESS FOR BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES

Subtitle A—National Preparedness and Response Planning, Coordinating, and Reporting

SEC. 101. NATIONAL PREPAREDNESS AND RESPONSE.

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

"TITLE XXVIII—NATIONAL PREPAREDNESS FOR BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES

"Subtitle A—National Preparedness and Response Planning, Coordinating, and Reporting

42 USC 300hh.

"SEC. 2801. NATIONAL PREPAREDNESS PLAN.

"(a) IN GENERAL.—

"(1) PREPAREDNESS AND RESPONSE REGARDING PUBLIC HEALTH EMERGENCIES.—The Secretary shall further develop and implement a coordinated strategy, building upon the core public health capabilities established pursuant to section 319A,

for carrying out health-related activities to prepare for and respond effectively to bioterrorism and other public health emergencies, including the preparation of a plan under this section. The Secretary shall periodically thereafter review and, as appropriate, revise the plan.

"(2) NATIONAL APPROACH.—In carrying out paragraph (1), the Secretary shall collaborate with the States toward the goal of ensuring that the activities of the Secretary regarding bioterrorism and other public health emergencies are coordinated with activities of the States, including local governments.

"(3) EVALUATION OF PROGRESS.—The plan under paragraph (1) shall provide for specific benchmarks and outcome measures for evaluating the progress of the Secretary and the States, including local governments, with respect to the plan under paragraph (1), including progress toward achieving the goals specified in subsection (b).

"(b) PREPAREDNESS GOALS.—The plan under subsection (a) should include provisions in furtherance of the following:

"(1) Providing effective assistance to State and local governments in the event of bioterrorism or other public health emergency.

"(2) Ensuring that State and local governments have appropriate capacity to detect and respond effectively to such emergencies, including capacities for the following:

"(A) Effective public health surveillance and reporting mechanisms at the State and local levels.

"(B) Appropriate laboratory readiness.

"(C) Properly trained and equipped emergency response, public health, and medical personnel.

"(D) Health and safety protection of workers responding to such an emergency.

"(E) Public health agencies that are prepared to coordinate health services (including mental health services) during and after such emergencies.

"(F) Participation in communications networks that can effectively disseminate relevant information in a timely and secure manner to appropriate public and private entities and to the public.

"(3) Developing and maintaining medical countermeasures (such as drugs, vaccines and other biological products, medical devices, and other supplies) against biological agents and toxins that may be involved in such emergencies.

"(4) Ensuring coordination and minimizing duplication of Federal, State, and local planning, preparedness, and response activities, including during the investigation of a suspicious disease outbreak or other potential public health emergency.

"(5) Enhancing the readiness of hospitals and other health care facilities to respond effectively to such emergencies.

"(c) REPORTS TO CONGRESS.—

"(1) IN GENERAL.—Not later than one year after the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and biennially thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report concerning progress with respect to the plan under

Deadline.

subsection (a), including progress toward achieving the goals specified in subsection (b).

"(2) ADDITIONAL AUTHORITY.—Reports submitted under paragraph (1) by the Secretary (other than the first report) shall make recommendations concerning—

"(A) any additional legislative authority that the Secretary determines is necessary for fully implementing the plan under subsection (a), including meeting the goals under subsection (b); and

"(B) any additional legislative authority that the Secretary determines is necessary under section 319 to protect the public health in the event of an emergency described in section 319(a).

"(d) RULE OF CONSTRUCTION.—This section may not be construed as expanding or limiting any of the authorities of the Secretary that, on the day before the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, were in effect with respect to preparing for and responding effectively to bioterrorism and other public health emergencies.".

42 USC 247d–6 note. Deadline.

(b) OTHER REPORTS.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report concerning—

(A) the recommendations and findings of the National Advisory Committee on Children and Terrorism under section 319F(c)(2) of the Public Health Service Act;

(B) the recommendations and findings of the EPIC Advisory Committee under section 319F(c)(3) of such Act;

(C) the characteristics that may render a rural community uniquely vulnerable to a biological 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 characteristics;

(D) the characteristics that may render areas or populations designated as medically underserved populations (as defined in section 330 of such Act) uniquely vulnerable to a biological attack, including significant numbers of low-income or uninsured individuals, lack of affordable and accessible health care services, insufficient public and primary health care resources, lack of integration of Federal or State public health networks, workforce deficits, or other relevant characteristics;

(E) the recommendations of the Secretary with respect to additional legislative authority that the Secretary determines is necessary to effectively strengthen rural communities, or medically underserved populations (as defined in section 330 of such Act); and

(F) 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.

(2) STUDY REGARDING LOCAL EMERGENCY RESPONSE METHODS.—The Secretary shall conduct a study of effective methods for the provision of emergency response services through local governments (including through private response contractors and volunteers of such governments) in a consistent manner in response to acts of bioterrorism or other public health emergencies. Not later than 180 days after the date of the enactment of this Act, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the findings of the study.

Deadline.
Reports.

SEC. 102. ASSISTANT SECRETARY FOR PUBLIC HEALTH EMERGENCY PREPAREDNESS; NATIONAL DISASTER MEDICAL SYSTEM.

(a) IN GENERAL.—Title XXVIII of the Public Health Service Act, as added by section 101 of this Act, is amended by adding at the end the following subtitle:

"Subtitle B—Emergency Preparedness and Response

"SEC. 2811. COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.

42 USC 300hh–11.

"(a) ASSISTANT SECRETARY FOR PUBLIC HEALTH EMERGENCY PREPAREDNESS.—

"(1) IN GENERAL.—There is established within the Department of Health and Human Services the position of Assistant Secretary for Public Health Emergency Preparedness. The President shall appoint an individual to serve in such position. Such Assistant Secretary shall report to the Secretary.

Establishment.
President.

"(2) DUTIES.—Subject to the authority of the Secretary, the Assistant Secretary for Public Health Emergency Preparedness shall carry out the following duties with respect to bioterrorism and other public health emergencies:

"(A) Coordinate on behalf of the Secretary—

"(i) interagency interfaces between the Department of Health and Human Services (referred to in this paragraph as the 'Department') and other departments, agencies, and offices of the United States; and

"(ii) interfaces between the Department and State and local entities with responsibility for emergency preparedness.

"(B) Coordinate the operations of the National Disaster Medical System and any other emergency response activities within the Department of Health and Human Services that are related to bioterrorism and other public health emergencies.

"(C) Coordinate the efforts of the Department to bolster State and local emergency preparedness for a bioterrorist attack or other public health emergency, and evaluate the progress of such entities in meeting the benchmarks and other outcome measures contained in the national plan and in meeting the core public health capabilities established pursuant to 319A.

"(D) Any other duties determined appropriate by the Secretary.

"(b) NATIONAL DISASTER MEDICAL SYSTEM.—

"(1) IN GENERAL.—The Secretary shall provide for the operation in accordance with this section of a system to be known as the National Disaster Medical System. The Secretary shall designate the Assistant Secretary for Public Health Emergency Preparedness as the head of the National Disaster Medical System, subject to the authority of the Secretary.

"(2) FEDERAL AND STATE COLLABORATIVE SYSTEM.—

"(A) IN GENERAL.—The National Disaster Medical System shall be a coordinated effort by the Federal agencies specified in subparagraph (B), working in collaboration with the States and other appropriate public or private entities, to carry out the purposes described in paragraph (3).

"(B) PARTICIPATING FEDERAL AGENCIES.—The Federal agencies referred to in subparagraph (A) are the Department of Health and Human Services, the Federal Emergency Management Agency, the Department of Defense, and the Department of Veterans Affairs.

"(3) PURPOSE OF SYSTEM.—

"(A) IN GENERAL.—The Secretary may activate the National Disaster Medical System to—

"(i) provide health services, health-related social services, other appropriate human services, and appropriate auxiliary services to respond to the needs of victims of a public health emergency (whether or not determined to be a public health emergency under section 319); or

"(ii) be present at locations, and for limited periods of time, specified by the Secretary on the basis that the Secretary has determined that a location is at risk of a public health emergency during the time specified.

"(B) ONGOING ACTIVITIES.—The National Disaster Medical System shall carry out such ongoing activities as may be necessary to prepare for the provision of services described in subparagraph (A) in the event that the Secretary activates the National Disaster Medical System for such purposes.

"(C) TEST FOR MOBILIZATION OF SYSTEM.—During the one-year period beginning on the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Secretary shall conduct an exercise to test the capability and timeliness of the National Disaster Medical System to mobilize and otherwise respond effectively to a bioterrorist attack or other public health emergency that affects two or more geographic locations concurrently. Thereafter, the Secretary may periodically conduct such exercises regarding the National Disaster Medical System as the Secretary determines to be appropriate.

"(c) CRITERIA.—

"(1) IN GENERAL.—The Secretary shall establish criteria for the operation of the National Disaster Medical System.

"(2) PARTICIPATION AGREEMENTS FOR NON-FEDERAL ENTITIES.—In carrying out paragraph (1), the Secretary shall establish criteria regarding the participation of States and private entities in the National Disaster Medical System, including criteria regarding agreements for such participation. The criteria shall include the following:

"(A) Provisions relating to the custody and use of Federal personal property by such entities, which may in the discretion of the Secretary include authorizing the custody and use of such property to respond to emergency situations for which the National Disaster Medical System has not been activated by the Secretary pursuant to subsection (b)(3)(A). Any such custody and use of Federal personal property shall be on a reimbursable basis.

"(B) Provisions relating to circumstances in which an individual or entity has agreements with both the National Disaster Medical System and another entity regarding the provision of emergency services by the individual. Such provisions shall address the issue of priorities among the agreements involved.

"(d) INTERMITTENT DISASTER-RESPONSE PERSONNEL.—

"(1) IN GENERAL.—For the purpose of assisting the National Disaster Medical System in carrying out duties under this section, the Secretary may appoint individuals to serve as intermittent personnel of such System in accordance with applicable civil service laws and regulations.

"(2) 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. With respect to the participation of individuals appointed under paragraph (1) in training programs authorized by the Assistant Secretary for Public Health Emergency Preparedness or a comparable official of any Federal agency specified in subsection (b)(2)(B), acts of individuals so appointed that are within the scope of such participation shall be considered within the scope of the appointment under paragraph (1) (regardless of whether the individuals receive compensation for such participation).

"(e) CERTAIN EMPLOYMENT ISSUES REGARDING INTERMITTENT APPOINTMENTS.—

"(1) INTERMITTENT DISASTER-RESPONSE APPOINTEE.—For purposes of this subsection, the term 'intermittent disaster-response appointee' means an individual appointed by the Secretary under subsection (d).

"(2) COMPENSATION FOR WORK INJURIES.—An intermittent disaster-response appointee shall, while acting in the scope of such appointment, be considered to be an employee of the Public Health Service performing medical, surgical, dental, or related functions, and an injury sustained by such an individual 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. With respect to the participation of individuals appointed under subsection (d) in training programs authorized by the Assistant Secretary for Public Health Emergency Preparedness or a comparable official of

any Federal agency specified in subsection (b)(2)(B), injuries sustained by such an individual, while acting within the scope of such participation, also shall be deemed 'in the performance of duty' for purposes of chapter 81 of title 5, United States Code (regardless of whether the individuals receive compensation for such participation). In the event of an injury to such an intermittent disaster-response appointee, the Secretary of Labor shall be responsible for making determinations as to whether the claimant is entitled to compensation or other benefits in accordance with chapter 81 of title 5, United States Code.

"(3) EMPLOYMENT AND REEMPLOYMENT RIGHTS.—

"(A) IN GENERAL.—Service as an intermittent disaster-response appointee when the Secretary activates the National Disaster Medical System or when the individual participates in a training program authorized by the Assistant Secretary for Public Health Emergency Preparedness or a comparable official of any Federal agency specified in subsection (b)(2)(B) shall be deemed 'service in the uniformed services' for purposes of chapter 43 of title 38, United States Code, pertaining to employment and reemployment rights of individuals who have performed service in the uniformed services (regardless of whether the individual receives compensation for such participation). 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.

"(B) NOTICE OF ABSENCE FROM POSITION OF EMPLOYMENT.—Preclusion of giving notice of service by necessity of Service as an intermittent disaster-response appointee when the Secretary activates the National Disaster Medical System 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 such necessity shall be made by the Secretary, in consultation with the Secretary of Defense, and shall not be subject to judicial review.

"(4) LIMITATION.—An intermittent disaster-response appointee shall not be deemed an employee of the Department of Health and Human Services for purposes other than those specifically set forth in this section.

"(f) RULE OF CONSTRUCTION REGARDING USE OF COMMISSIONED CORPS.—If the Secretary assigns commissioned officers of the Regular or Reserve Corps to serve with the National Disaster Medical System, such assignments do not affect the terms and conditions of their appointments as commissioned officers of the Regular or Reserve Corps, respectively (including with respect to pay and allowances, retirement, benefits, rights, privileges, and immunities).

"(g) DEFINITION.—For purposes of this section, the term 'auxiliary services' includes mortuary services, veterinary services, and other services that are determined by the Secretary to be appropriate with respect to the needs referred to in subsection (b)(3)(A).

"(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing for the Assistant Secretary for Public Health Emergency Preparedness and the operations of the National Disaster Medical

System, other than purposes for which amounts in the Public Health Emergency Fund under section 319 are available, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.".

(b) SENSE OF CONGRESS REGARDING RESOURCES OF NATIONAL DISASTER MEDICAL SYSTEM.—It is the sense of the Congress that the Secretary of Health and Human Services should provide sufficient resources to entities tasked to carry out the duties of the National Disaster Medical System for reimbursement of expenses, operations, purchase and maintenance of equipment, training, and other funds expended in furtherance of the National Disaster Medical System.

SEC. 103. IMPROVING ABILITY OF CENTERS FOR DISEASE CONTROL AND PREVENTION.

Section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended to read as follows:

"SEC. 319D. REVITALIZING THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

"(a) FACILITIES; CAPACITIES.—

"(1) FINDINGS.—Congress finds that the Centers for Disease Control and Prevention has an essential role in defending against and combatting public health threats and requires secure and modern facilities, and expanded and improved capabilities related to bioterrorism and other public health emergencies, sufficient to enable such Centers to conduct this important mission.

"(2) FACILITIES.—

"(A) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may design, construct, and equip new facilities, renovate existing facilities (including laboratories, laboratory support buildings, scientific communication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities, in order to better conduct the capacities described in section 319A, and for supporting public health activities.

"(B) MULTIYEAR CONTRACTING AUTHORITY.—For any project of designing, constructing, equipping, or renovating any facility under subparagraph (A), the Director of the Centers for Disease Control and Prevention may enter into a single contract or related contracts that collectively include the full scope of the project, and the solicitation and contract shall contain the clause 'availability of funds' found at section 52.232–18 of title 48, Code of Federal Regulations.

"(3) IMPROVING THE CAPACITIES OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Secretary, taking into account evaluations under section 319B(a), shall expand, enhance, and improve the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies. Activities that may be carried out under the preceding sentence include—

"(A) expanding or enhancing the training of personnel;

"(B) improving communications facilities and networks, including delivery of necessary information to rural areas;

"(C) improving capabilities for public health surveillance and reporting activities, taking into account the integrated system or systems of public health alert communications and surveillance networks under subsection (b); and

"(D) improving laboratory facilities related to bioterrorism and other public health emergencies, including increasing the security of such facilities.

"(b) NATIONAL COMMUNICATIONS AND SURVEILLANCE NETWORKS.—

"(1) IN GENERAL.—The Secretary, directly or through awards of grants, contracts, or cooperative agreements, shall provide for the establishment of an integrated system or systems of public health alert communications and surveillance networks between and among—

"(A) Federal, State, and local public health officials;

"(B) public and private health-related laboratories, hospitals, and other health care facilities; and

"(C) any other entities determined appropriate by the Secretary.

"(2) REQUIREMENTS.—The Secretary shall ensure that networks under paragraph (1) allow for the timely sharing and discussion, in a secure manner, of essential information concerning bioterrorism or another public health emergency, or recommended methods for responding to such an attack or emergency.

Deadline.

"(3) STANDARDS.—Not later than one year after the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Secretary, in cooperation with health care providers and State and local public health officials, shall establish any additional technical and reporting standards (including standards for interoperability) for networks under paragraph (1).

"(c) AUTHORIZATION OF APPROPRIATIONS.—

"(1) FACILITIES; CAPACITIES.—

"(A) FACILITIES.—For the purpose of carrying out subsection (a)(2), there are authorized to be appropriated $300,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.

"(B) MISSION; IMPROVING CAPACITIES.—For the purposes of achieving the mission of the Centers for Disease Control and Prevention described in subsection (a)(1), for carrying out subsection (a)(3), for better conducting the capacities described in section 319A, and for supporting public health activities, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

"(2) NATIONAL COMMUNICATIONS AND SURVEILLANCE NETWORKS.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.".

SEC. 104. ADVISORY COMMITTEES AND COMMUNICATIONS; STUDY REGARDING COMMUNICATIONS ABILITIES OF PUBLIC HEALTH AGENCIES.

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

(1) by striking subsections (b) and (i);

(2) by redesignating subsections (c) through (h) as subsections (e) through (j), respectively; and

(3) by inserting after subsection (a) the following subsections:

"(b) ADVICE TO THE FEDERAL GOVERNMENT.—

"(1) REQUIRED ADVISORY COMMITTEES.—In coordination with the working group under subsection (a), the Secretary shall establish advisory committees in accordance with paragraphs (2) and (3) to provide expert recommendations to assist such working groups in carrying out their respective responsibilities under subsections (a) and (b). Establishment.

"(2) NATIONAL ADVISORY COMMITTEE ON CHILDREN AND TERRORISM.—

"(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the National Advisory Committee on Children and Terrorism (referred to in this paragraph as the 'Advisory Committee'). Establishment.

"(B) DUTIES.—The Advisory Committee shall provide recommendations regarding—

"(i) the preparedness of the health care (including mental 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; and

"(iii) changes, if necessary, to the national stockpile under section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to meet the emergency health security of children.

"(C) COMPOSITION.—The Advisory Committee shall be composed of such Federal officials as may be appropriate to address the special needs of the diverse population groups of children, and child health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines.

"(D) TERMINATION.—The Advisory Committee terminates one year after the date of the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

"(3) EMERGENCY PUBLIC INFORMATION AND COMMUNICATIONS ADVISORY COMMITTEE.—

"(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the Emergency Public Information and Communications Advisory Committee (referred to in this paragraph as the 'EPIC Advisory Committee').

"(B) DUTIES.—The EPIC Advisory Committee shall make recommendations to the Secretary and the working group under subsection (a) and report on appropriate ways

to communicate public health information regarding bioterrorism and other public health emergencies to the public.

"(C) COMPOSITION.—The EPIC Advisory Committee shall be composed of individuals representing a diverse group of experts in public health, medicine, communications, behavioral psychology, and other areas determined appropriate by the Secretary.

"(D) DISSEMINATION.—The Secretary shall review the recommendations of the EPIC Advisory Committee and ensure that appropriate information is disseminated to the public.

"(E) TERMINATION.—The EPIC Advisory Committee terminates one year after the date of the enactment of Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

"(c) STRATEGY FOR COMMUNICATION OF INFORMATION REGARDING BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.—In coordination with working group under subsection (a), the Secretary shall develop a strategy for effectively communicating information regarding bioterrorism and other public health emergencies, and shall develop means by which to communicate such information. The Secretary may carry out the preceding sentence directly or through grants, contracts, or cooperative agreements.

"(d) RECOMMENDATION OF CONGRESS REGARDING 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.".

42 USC 247d–6 note.

(b) STUDY REGARDING COMMUNICATIONS ABILITIES OF PUBLIC HEALTH AGENCIES.—The Secretary of Health and Human Services, in consultation with the Federal Communications Commission, the National Telecommunications and Information Administration, and other appropriate Federal agencies, shall conduct a study to determine whether local public health entities have the ability to maintain communications in the event of a bioterrorist attack or other public health emergency. The study shall examine whether redundancies are required in the telecommunications system, particularly with respect to mobile communications, for public health entities to maintain systems operability and connectivity during such emergencies. The study shall also include recommendations to industry and public health entities about how to implement such redundancies if necessary.

SEC. 105. EDUCATION OF HEALTH CARE PERSONNEL; TRAINING REGARDING PEDIATRIC ISSUES.

42 USC 247d–6.

Section 319F(g) of the Public Health Service Act, as redesignated by section 104(a)(2) of this Act, is amended to read as follows:

"(g) EDUCATION; TRAINING REGARDING PEDIATRIC ISSUES.—

"(1) MATERIALS; CORE CURRICULUM.—The Secretary, in collaboration with members of the working group described

in subsection (b), and professional organizations and societies, shall—

"(A) develop materials for teaching the elements of a core curriculum for the recognition and identification of potential bioweapons and other agents that may create a public health emergency, and for the care of victims of such emergencies, recognizing the special needs of children and other vulnerable populations, to public health officials, medical professionals, emergency physicians and other emergency department staff, laboratory personnel, and other personnel working in health care facilities (including poison control centers);

"(B) develop a core curriculum and materials for community-wide planning by State and local governments, hospitals and other health care facilities, emergency response units, and appropriate public and private sector entities to respond to a bioterrorist attack or other public health emergency;

"(C) develop materials for proficiency testing of laboratory and other public health personnel for the recognition and identification of potential bioweapons and other agents that may create a public health emergency; and

"(D) provide for dissemination and teaching of the materials described in subparagraphs (A) through (C) by appropriate means, which may include telemedicine, long-distance learning, or other such means.

"(2) CERTAIN ENTITIES.—The entities through which education and training activities described in paragraph (1) may be carried out include Public Health Preparedness Centers, the Public Health Service's Noble Training Center, the Emerging Infections Program, the Epidemic Intelligence Service, the Public Health Leadership Institute, multi-State, multi-institutional consortia, other appropriate educational entities, professional organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

"(3) GRANTS AND CONTRACTS.—In carrying out paragraph (1), the Secretary may carry out activities directly and through the award of grants and contracts, and may enter into interagency cooperative agreements with other Federal agencies.

"(4) HEALTH-RELATED ASSISTANCE FOR EMERGENCY RESPONSE PERSONNEL TRAINING.—The Secretary, in consultation with the Attorney General and the Director of the Federal Emergency Management Agency, may provide technical assistance with respect to health-related aspects of emergency response personnel training carried out by the Department of Justice and the Federal Emergency Management Agency.".

SEC. 106. GRANTS REGARDING SHORTAGES OF CERTAIN HEALTH PROFESSIONALS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319G the following section:

"SEC. 319H. GRANTS REGARDING TRAINING AND EDUCATION OF CERTAIN HEALTH PROFESSIONALS. 42 USC 247d–7a.

"(a) IN GENERAL.—The Secretary may make awards of grants and cooperative agreements to appropriate public and nonprofit

private health or educational entities, including health professions schools and programs as defined in section 799B, for the purpose of providing low-interest loans, partial scholarships, partial fellowships, revolving loan funds, or other cost-sharing forms of assistance for the education and training of individuals in any category of health professions for which there is a shortage that the Secretary determines should be alleviated in order to prepare for or respond effectively to bioterrorism and other public health emergencies.

"(b) AUTHORITY REGARDING NON-FEDERAL CONTRIBUTIONS.—The Secretary may require as a condition of an award under subsection (a) that a grantee under such subsection provide non-Federal contributions toward the purpose described in such subsection.

"(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.".

SEC. 107. EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF HEALTH PROFESSIONS VOLUNTEERS.

Part B of title III of the Public Health Service Act, as amended by section 106 of this Act, is amended by inserting after section 319H the following section:

42 USC 247d–7b.

"SEC. 319I. EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF HEALTH PROFESSIONS VOLUNTEERS.

"(a) IN GENERAL.—The Secretary shall, directly or through an award of a grant, contract, or cooperative agreement, establish and maintain a system for the advance registration of health professionals for the purpose of verifying the credentials, licenses, accreditations, and hospital privileges of such professionals when, during public health emergencies, the professionals volunteer to provide health services (referred to in this section as the 'verification system'). In carrying out the preceding sentence, the Secretary shall provide for an electronic database for the verification system.

"(b) CERTAIN CRITERIA.—The Secretary shall establish provisions regarding the promptness and efficiency of the system in collecting, storing, updating, and disseminating information on the credentials, licenses, accreditations, and hospital privileges of volunteers described in subsection (a).

"(c) OTHER ASSISTANCE.—The Secretary may make grants and provide technical assistance to States and other public or nonprofit private entities for activities relating to the verification system developed under subsection (a).

"(d) COORDINATION AMONG STATES.—The Secretary may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide certain health services to provide such health services in the State.

"(e) RULE OF CONSTRUCTION.—This section may not be construed as authorizing the Secretary to issue requirements regarding the provision by the States of credentials, licenses, accreditations, or hospital privileges.

"(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.".

SEC. 108. WORKING GROUP.

Section 319F of the Public Health Service Act, as amended by section 104(a), is amended by striking subsection (a) and inserting the following: 42 USC 247d–6.

"(a) WORKING GROUP ON BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.—

"(1) IN GENERAL.—The Secretary, in coordination with the Secretary of Agriculture, the Attorney General, the Director of Central Intelligence, the Secretary of Defense, the Secretary of Energy, the Administrator of the Environmental Protection Agency, the Director of the Federal Emergency Management Agency, the Secretary of Labor, the Secretary of Veterans Affairs, and with other similar Federal officials as determined appropriate, shall establish a working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies. Such joint working group, or subcommittees thereof, shall meet periodically for the purpose of consultation on, assisting in, and making recommendations on—

"(A) responding to a bioterrorist attack, including the provision of appropriate safety and health training and protective measures for medical, emergency service, and other personnel responding to such attacks;

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

"(C) facilitation of the awarding of grants, contracts, or cooperative agreements for the development, manufacture, distribution, supply-chain management, and purchase of priority countermeasures;

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

"(E) development of shared standards for equipment to detect and to protect against biological agents and toxins;

"(F) assessment of the priorities for and enhancement of 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;

"(G) in the recognition that medical and public health professionals are likely to provide much of the first response to such an attack, development and enhancement of 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—

"(i) local firefighters, ambulance personnel, police and public security officers, or other emergency response personnel (including private response contractors); and

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

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

"(I) ensuring that the activities under this subsection address the health security needs of children and other vulnerable populations;

"(J) strategies for decontaminating facilities contaminated as a result of a biological attack, including appropriate protections for the safety of workers conducting such activities;

"(K) subject to compliance with other provisions of Federal law, clarifying the responsibilities among Federal officials for the investigation of suspicious outbreaks of disease and other potential public health emergencies, and for related revisions of the interagency plan known as the Federal response plan; and

"(L) in consultation with the National Highway Traffic Safety Administration and the U.S. Fire Administration, ways to enhance coordination among Federal agencies involved with State, local, and community based emergency medical services, including issuing a report that—

"(i) identifies needs of community-based emergency medical services; and

"(ii) identifies ways to streamline and enhance the process through which Federal agencies support community-based emergency medical services.

"(2) CONSULTATION WITH EXPERTS.—In carrying out subparagraphs (B) and (C) of paragraph (1), the working group under such paragraph shall consult with the pharmaceutical, biotechnology, and medical device industries, and other appropriate experts.

"(3) USE OF SUBCOMMITTEES REGARDING CONSULTATION REQUIREMENTS.—With respect to a requirement under law that the working group under paragraph (1) be consulted on a matter, the working group may designate an appropriate subcommittee of the working group to engage in the consultation.

"(4) DISCRETION IN EXERCISE OF DUTIES.—Determinations made by the working group under paragraph (1) with respect to carrying out duties under such paragraph are matters committed to agency discretion for purposes of section 701(a) of title 5, Unites States Code.

"(5) RULE OF CONSTRUCTION.—This subsection may not be construed as establishing new regulatory authority for any of the officials specified in paragraph (1), or as having any legal effect on any other provision of law, including the responsibilities and authorities of the Environmental Protection Agency.".

SEC. 109. ANTIMICROBIAL RESISTANCE.

Section 319E of the Public Health Service Act (42 U.S.C. 247d–5) is amended—

(1) in subsection (b)—

(A) by striking "shall conduct and support" and inserting "shall directly or through awards of grants or cooperative agreements to public or private entities provide for the conduct of"; and

(B) by amending paragraph (4) to read as follows:

"(4) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health

in consultation with the task force established under subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy; and";

(2) in subsection (e)(2), by inserting after "societies," the following: "schools or programs that train medical laboratory personnel,"; and

(3) in subsection (g), by striking "and such sums" and all that follows and inserting the following: "$25,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.".

SEC. 110. SUPPLIES AND SERVICES IN LIEU OF AWARD FUNDS.

Part B of title III of the Public Health Service Act, as amended by section 107 of this Act, is amended by inserting after section 319I the following section:

"SEC. 319J. SUPPLIES AND SERVICES IN LIEU OF AWARD FUNDS. 42 USC 247d–7c.

"(a) IN GENERAL.—Upon the request of a recipient of an award under any of sections 319 through 319I or section 319K, the Secretary may, subject to subsection (b), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

"(b) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in subsection (a), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.".

SEC. 111. ADDITIONAL AMENDMENTS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended—

(1) in section 319A(a)(1), by striking "10 years" and inserting "five years"; 42 USC 247d–1.

(2) in section 319B(a), in the first sentence, by striking "10 years" and inserting "five years"; and 42 USC 247d–2.

(3) in section 391F(e)(2), as redesignated by section 104(a)(2) of this Act— 42 USC 247d–6.

(A) by striking "or" after "clinic,"; and

(B) by inserting before the period following: ", professional organization or society, school or program that trains medical laboratory personnel, private accrediting organization, or other nonprofit private institution or entity meeting criteria established by the Secretary".

Subtitle B—Strategic National Stockpile; Development of Priority Countermeasures

SEC. 121. STRATEGIC NATIONAL STOCKPILE. 42 USC 300hh–12.

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), in coordination with the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

(A) consult with the working group under section 319F(a) of the Public Health Service Act;

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

(F) ensure the adequate physical security of the stockpile.

(b) SMALLPOX VACCINE DEVELOPMENT.—

Contracts.

(1) 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 under subsection (a) includes an amount of vaccine against smallpox as determined by the Secretary to be sufficient to meet the health security needs of the United States.

(2) 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) DISCLOSURES.—No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

(d) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

(1) a physical accumulation (at one or more locations) of the supplies 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 supplies described in subsection (a).

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

SEC. 122. ACCELERATED APPROVAL OF PRIORITY COUNTERMEASURES. 21 USC 356–1.

(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 review priority pursuant to section 515(d)(5) of such Act (21 U.S.C. 360e(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(b) 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 pursuant to section 123 may be designated as a fast track product for purposes of this section.

(c) PRIORITY REVIEW OF DRUGS AND BIOLOGICAL PRODUCTS.—A priority countermeasure that is a drug or biological product shall be considered a priority drug or biological product for purposes of performance goals for priority drugs or biological products agreed to by the Commissioner of Food and Drugs.

(d) DEFINITIONS.—For purposes of this title:

(1) The term "priority countermeasure" has the meaning given such term in section 319F(h)(4) of the Public Health Service Act.

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

SEC. 123. ISSUANCE OF RULE ON ANIMAL TRIALS.

Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall complete the process of rulemaking that was commenced under authority of section 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act with the issuance of the proposed rule 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" published in the Federal Register on October 5, 1999 (64 Fed. Reg. 53960), and shall promulgate a final rule. Deadline.

SEC. 124. SECURITY FOR COUNTERMEASURE DEVELOPMENT AND PRODUCTION.

Part B of title III of the Public Health Service Act, as amended by section 110 of this Act, is amended by inserting after section 319J the following section:

42 USC 247d–7d.

"SEC. 319K. 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, production, distribution, or storage of priority countermeasures (as defined in section 319F(h)(4)).

"(b) GUIDELINES.—The Secretary may develop guidelines to enable entities eligible to receive assistance under subsection (a) to secure their facilities against potential terrorist attack.".

SEC. 125. ACCELERATED COUNTERMEASURE RESEARCH AND DEVELOPMENT.

Section 319F(h) of the Public Health Service Act, as redesignated by section 104(a)(2) of this Act, is amended to read as follows:

42 USC 247d–6.

"(h) ACCELERATED RESEARCH AND DEVELOPMENT ON PRIORITY PATHOGENS AND COUNTERMEASURES.—

"(1) IN GENERAL.—With respect to pathogens of potential use in a bioterrorist attack, and other agents that may cause a public health emergency, the Secretary, taking into consideration any recommendations of the working group under subsection (a), shall conduct, and award grants, contracts, or cooperative agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

"(A) the epidemiology and pathogenesis of such pathogens;

"(B) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the working group established in subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy;

"(C) the development of priority countermeasures; and

"(D) other relevant areas of research;

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

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

"(3) ROLE OF DEPARTMENT OF VETERANS AFFAIRS.—In carrying out paragraph (1), the Secretary shall consider using the biomedical research and development capabilities of the Department of Veterans Affairs, in conjunction with that Department's affiliations with health-professions universities. When advantageous to the Government in furtherance of the purposes of such paragraph, the Secretary may enter into cooperative agreements with the Secretary of Veterans Affairs to achieve such purposes.

"(4) PRIORITY COUNTERMEASURES.—For purposes of this section, the term 'priority countermeasure' means a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be—

"(A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to section 351A(a)(1), or harm from any other agent that may cause a public health emergency; or

"(B) a priority to diagnose conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority under subparagraph (A).".

SEC. 126. EVALUATION OF NEW AND EMERGING TECHNOLOGIES REGARDING BIOTERRORIST ATTACK AND OTHER PUBLIC HEALTH EMERGENCIES.

42 USC 300hh–13.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall promptly carry out a program to periodically evaluate new and emerging technologies that, in the determination of the Secretary, are designed to improve or enhance the ability of public health or safety officials to conduct public health surveillance activities relating to a bioterrorist attack or other public health emergency.

(b) CERTAIN ACTIVITIES.—In carrying out this subsection, the Secretary shall, to the extent practicable—

(1) survey existing technology programs funded by the Federal Government for potentially useful technologies;

(2) promptly issue a request, as necessary, for information from non-Federal public and private entities for ongoing activities in this area; and

(3) evaluate technologies identified under paragraphs (1) and (2) pursuant to subsection (c).

(c) CONSULTATION AND EVALUATION.—In carrying out subsection (b)(3), the Secretary shall consult with the working group under section 319F(a) of the Public Health Service Act, as well as other appropriate public, nonprofit, and private entities, to develop criteria for the evaluation of such technologies and to conduct such evaluations.

(d) REPORT.—Not later than 180 days after the date of the enactment of this Act, and periodically thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report on the activities under this section.

Deadline.

SEC. 127. POTASSIUM IODIDE.

42 USC 300hh–12 note.

(a) IN GENERAL.—Through the national stockpile under section 121, the President, subject to subsections (b) and (c), shall make available to State and local governments potassium iodide tablets for stockpiling and for distribution as appropriate to public facilities, such as schools and hospitals, in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant.

(b) STATE AND LOCAL PLANS.—

(1) IN GENERAL.—Subsection (a) applies with respect to a State or local government, subject to paragraph (2), if the government involved meets the following conditions:

(A) Such government submits to the President a plan for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident.

(B) The plan is accompanied by certifications by such government that the government has not already received sufficient quantities of potassium iodide tablets from the Federal Government.

(2) LOCAL GOVERNMENTS.—Subsection (a) applies with respect to a local government only if, in addition to the conditions described in paragraph (1), the following conditions are met:

(A) The State in which the locality involved is located—

(i) does not have a plan described in paragraph (1)(A); or

(ii) has a plan described in such paragraph, but the plan does not address populations at a distance greater than 10 miles from the nuclear power plant involved.

(B) The local government has petitioned the State to modify the State plan to address such populations, not exceeding 20 miles from such plant, and 60 days have elapsed without the State modifying the State plan to address populations at the full distance sought by the local government through the petition.

(C) The local government has submitted its local plan under paragraph (1)(A) to the State, and the State has approved the plan and certified that the plan is not inconsistent with the State emergency plan.

Deadline.

(c) GUIDELINES.—Not later than one year after the date of the enactment of this Act, the President, in consultation with individuals representing appropriate Federal, State, and local agencies, shall establish guidelines for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident. Such tablets may not be made available under subsection (a) until such guidelines have been established.

(d) INFORMATION.—The President shall carry out activities to inform State and local governments of the program under this section.

(e) REPORTS.—

Deadline.

(1) PRESIDENT.—Not later than six months after the date on which the guidelines under subsection (c) are issued, the President shall submit to the Congress a report—

(A) on whether potassium iodide tablets have been made available under subsection (a) or other Federal, State, or local programs, and the extent to which State and local governments have established stockpiles of such tablets; and

(B) the measures taken by the President to implement this section.

(2) NATIONAL ACADEMY OF SCIENCES.—

Contracts.

(A) IN GENERAL.—The President shall request the National Academy of Sciences to enter into an agreement with the President under which the Academy conducts a study to determine what is the most effective and safe way to distribute and administer potassium iodide tablets

on a mass scale. If the Academy declines to conduct the study, the President shall enter into an agreement with another appropriate public or nonprofit private entity to conduct the study.

(B) REPORT.—The President shall ensure that, not later than six months after the date of the enactment of this Act, the study required in subparagraph (A) is completed and a report describing the findings made in the study is submitted to the Congress. Deadline.

(f) APPLICABILITY.—Subsections (a) and (d) cease to apply as requirements if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.

Subtitle C—Improving State, Local, and Hospital Preparedness for and Response to Bioterrorism and Other Public Health Emergencies

SEC. 131. GRANTS TO IMPROVE STATE, LOCAL, AND HOSPITAL PREPAREDNESS FOR AND RESPONSE TO BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319C the following sections:

"SEC. 319C–1. GRANTS TO IMPROVE STATE, LOCAL, AND HOSPITAL PREPAREDNESS FOR AND RESPONSE TO BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES. 42 USC 247d–3a.

"(a) IN GENERAL.—To enhance the security of the United States with respect to bioterrorism and other public health emergencies, the Secretary shall make awards of grants or cooperative agreements to eligible entities to enable such entities to conduct the activities described in subsection (d).

"(b) ELIGIBLE ENTITIES.—

"(1) IN GENERAL.—To be eligible to receive an award under subsection (a), an entity shall—

"(A)(i) be a State; and

"(ii) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require, including an assurance that the State—

"(I) has completed an evaluation under section 319B(a), or an evaluation that is substantially equivalent to an evaluation described in such section (as determined by the Secretary);

"(II) has prepared, or will (within 60 days of receiving an award under this section) prepare, a Bioterrorism and Other Public Health Emergency Preparedness and Response Plan in accordance with subsection (c);

"(III) has established a means by which to obtain public comment and input on the plan prepared under subclause (II), and on the implementation of such plan,

that shall include an advisory committee or other similar mechanism for obtaining comment from the public at large as well as from other State and local stakeholders;

"(IV) will use amounts received under the award in accordance with the plan prepared under subclause (II), including making expenditures to carry out the strategy contained in the plan; and

"(V) with respect to the plan prepared under subclause (II), will establish reasonable criteria to evaluate the effective performance of entities that receive funds under the award and include relevant benchmarks in the plan; or

"(B)(i) be a political subdivision of a State or a consortium of 2 or more such subdivisions; and

"(ii) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require.

"(2) COORDINATION WITH STATEWIDE PLANS.—An award under subsection (a) to an eligible entity described in paragraph (1)(B) may not be made unless the application of such entity is in coordination with, and consistent with, applicable Statewide plans described in subsection (d)(1).

Deadline.

"(c) BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE PLAN.—Not later than 60 days after receiving amounts under an award under subsection (a), an eligible entity described in subsection (b)(1)(A) shall prepare and submit to the Secretary a Bioterrorism and Other Public Health Emergency Preparedness and Response Plan. Recognizing the assessment of public health needs conducted under section 319B, such plan shall include a description of activities to be carried out by the entity to address the needs identified in such assessment (or an equivalent assessment).

"(d) USE OF FUNDS.—An award under subsection (a) may be expended for activities that may include the following and similar activities:

"(1) To develop Statewide plans (including the development of the Bioterrorism and Other Public Health Emergency Preparedness and Response Plan required under subsection (c)), and community-wide plans for responding to bioterrorism and other public health emergencies that are coordinated with the capacities of applicable national, State, and local health agencies and health care providers, including poison control centers.

"(2) To address deficiencies identified in the assessment conducted under section 319B.

"(3) To purchase or upgrade equipment (including stationary or mobile communications equipment), supplies, pharmaceuticals or other priority countermeasures to enhance preparedness for and response to bioterrorism or other public health emergencies, consistent with the plan described in subsection (c).

"(4) To conduct exercises to test the capability and timeliness of public health emergency response activities.

"(5) To develop and implement the trauma care and burn center care components of the State plans for the provision of emergency medical services.

"(6) To improve training or workforce development to enhance public health laboratories.

"(7) To train public health and health care personnel to enhance the ability of such personnel—

"(A) to detect, provide accurate identification of, and recognize the symptoms and epidemiological characteristics of exposure to a biological agent that may cause a public health emergency; and

"(B) to provide treatment to individuals who are exposed to such an agent.

"(8) To develop, enhance, coordinate, or improve participation in systems by which disease detection and information about biological attacks and other public health emergencies can be rapidly communicated among national, State, and local health agencies, emergency response personnel, and health care providers and facilities to detect and respond to a bioterrorist attack or other public health emergency, 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.

"(9) To enhance communication to the public of information on bioterrorism and other public health emergencies, including through the use of 2–1–1 call centers.

"(10) To address the health security needs of children and other vulnerable populations with respect to bioterrorism and other public health emergencies.

"(11) To provide training and develop, enhance, coordinate, or improve methods to enhance the safety of workers and workplaces in the event of bioterrorism.

"(12) To prepare and plan for contamination prevention efforts related to public health that may be implemented in the event of a bioterrorist attack, including training and planning to protect the health and safety of workers conducting the activities described in this paragraph.

"(13) To prepare a plan for triage and transport management in the event of bioterrorism or other public health emergencies.

"(14) To enhance the training of health care professionals to recognize and treat the mental health consequences of bioterrorism or other public health emergencies.

"(15) To enhance the training of health care professionals to assist in providing appropriate health care for large numbers of individuals exposed to a bioweapon.

"(16) To enhance training and planning to protect the health and safety of personnel, including health care professionals, involved in responding to a biological attack.

"(17) To 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 and including early warning and surveillance networks that use advanced information technology to provide early detection of biological threats or attacks.

"(18) To develop, enhance, and coordinate or improve the ability of existing telemedicine programs to provide health care

information and advice as part of the emergency public health response to bioterrorism or other public health emergencies. Nothing in this subsection may be construed as establishing new regulatory authority or as modifying any existing regulatory authority.

"(e) PRIORITIES IN USE OF GRANTS.—

"(1) IN GENERAL.—

"(A) PRIORITIES.—Except as provided in subparagraph (B), the Secretary shall, in carrying out the activities described in this section, address the following hazards in the following priority:

"(i) Bioterrorism or acute outbreaks of infectious diseases.

"(ii) Other public health threats and emergencies.

"(B) DETERMINATION OF THE SECRETARY.—In the case of the hazard involved, the degree of priority that would apply to the hazard based on the categories specified in clauses (i) and (ii) of subparagraph (A) may be modified by the Secretary if the following conditions are met:

"(i) The Secretary determines that the modification is appropriate on the basis of the following factors:

"(I) The extent to which eligible entities are adequately prepared for responding to hazards within the category specified in clause (i) of subparagraph (A).

"(II) There has been a significant change in the assessment of risks to the public health posed by hazards within the category specified in clause (ii) of such subparagraph.

"(ii) Prior to modifying the priority, the Secretary notifies the appropriate committees of the Congress of the determination of the Secretary under clause (i) of this subparagraph.

"(2) AREAS OF EMPHASIS WITHIN CATEGORIES.—The Secretary shall determine areas of emphasis within the category of hazards specified in clause (i) of paragraph (1)(A), and shall determine areas of emphasis within the category of hazards specified in clause (ii) of such paragraph, based on an assessment of the risk and likely consequences of such hazards and on an evaluation of Federal, State, and local needs, and may also take into account the extent to which receiving an award under subsection (a) will develop capacities that can be used for public health emergencies of varying types.

"(f) CERTAIN ACTIVITIES.—In administering activities under section 319C(c)(4) or similar activities, the Secretary shall, where appropriate, give priority to activities that include State or local government financial commitments, that seek to incorporate multiple public health and safety services or diagnostic databases into an integrated public health entity, and that cover geographic areas lacking advanced diagnostic and laboratory capabilities.

"(g) COORDINATION WITH LOCAL MEDICAL RESPONSE SYSTEM.—An eligible entity and local Metropolitan Medical Response Systems shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities that are carried out by local Metropolitan Medical Response Systems.

"(h) COORDINATION OF FEDERAL ACTIVITIES.—In making awards under subsection (a), the Secretary shall—

"(1) annually notify the Director of the Federal Emergency Management Agency, the Director of the Office of Justice Programs, and the Director of the National Domestic Preparedness Office, as to the amount, activities covered under, and status of such awards; and

"(2) coordinate such awards with other activities conducted or supported by the Secretary to enhance preparedness for bioterrorism and other public health emergencies.

"(i) DEFINITION.—For purposes of this section, the term 'eligible entity' means an entity that meets the conditions described in subparagraph (A) or (B) of subsection (b)(1).

"(j) FUNDING.—

"(1) AUTHORIZATIONS OF APPROPRIATIONS.—

"(A) FISCAL YEAR 2003.—

"(i) AUTHORIZATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $1,600,000,000 for fiscal year 2003, of which—

"(I) $1,080,000,000 is authorized to be appropriated for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)); and

"(II) $520,000,000 is authorized to be appropriated—

"(aa) for awards under subsection (a) to States, notwitstanding the eligibility conditions under subsection (b), for the purpose of enhancing the preparedness of hospitals (including children's hospitals), clinics, health centers, and primary care facilities for bioterrorism and other public health emergencies; and

"(bb) for Federal, State, and local planning and administrative activities related to such purpose.

"(ii) CONTINGENT ADDITIONAL AUTHORIZATION.—If a significant change in circumstances warrants an increase in the amount authorized to be appropriated under clause (i) for fiscal year 2003, there are authorized to be appropriated such sums as may be necessary for such year for carrying out this section, in addition to the amount authorized in clause (i).

"(B) OTHER FISCAL YEARS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2006.

"(2) SUPPLEMENT NOT SUPPLANT.—Amounts appropriated under paragraph (1) shall be used to supplement and not supplant other State and local public funds provided for activities under this section.

"(3) STATE BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE BLOCK GRANT FOR FISCAL YEAR 2003.—

"(A) IN GENERAL.—For fiscal year 2003, the Secretary shall, in an amount determined in accordance with subparagraphs (B) through (D), make an award under subsection (a) to each State, notwithstanding the eligibility conditions described in subsection (b), that submits to the Secretary an application for the award that meets the criteria of the Secretary for the receipt of such an award and that meets other implementation conditions established by the Secretary for such awards. No other awards may be made under subsection (a) for such fiscal year, except as provided in paragraph (1)(A)(i)(II) and paragraphs (4) and (5).

"(B) BASE AMOUNT.—In determining the amount of an award pursuant to subparagraph (A) for a State, the Secretary shall first determine an amount the Secretary considers appropriate for the State (referred to in this paragraph as the 'base amount'), except that such amount may not be greater than the minimum amount determined under subparagraph (D).

"(C) INCREASE ON BASIS OF POPULATION.—After determining the base amount for a State under subparagraph (B), the Secretary shall increase the base amount by an amount equal to the product of—

"(i) the amount appropriated under paragraph (1)(A)(i)(I) for the fiscal year, less an amount equal to the sum of all base amounts determined for the States under subparagraph (B), and less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); and

"(ii) subject to paragraph (4)(C), the percentage constituted by the ratio of an amount equal to the population of the State over an amount equal to the total population of the States (as indicated by the most recent data collected by the Bureau of the Census).

"(D) MINIMUM AMOUNT.—Subject to the amount appropriated under paragraph (1)(A)(i)(I), an award pursuant to subparagraph (A) for a State shall be the greater of the base amount as increased under subparagraph (C), or the minimum amount under this subparagraph. The minimum amount under this subparagraph is—

"(i) in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, an amount equal to the lesser of—

"(I) $5,000,000; or

"(II) if the amount appropriated under paragraph (1)(A)(i)(I) is less than $667,000,000, an amount equal to 0.75 percent of the amount appropriated under such paragraph, less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); or

"(ii) in the case of each of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Virgin Islands, an amount determined by the Secretary to be appropriate, except that such amount may not exceed the amount determined under clause (i).

"(4) CERTAIN POLITICAL SUBDIVISIONS.—

"(A) IN GENERAL.—For fiscal year 2003, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1)(A)(i)(I) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. Not more than three political subdivisions may receive awards pursuant to this subparagraph.

"(B) COORDINATION WITH STATEWIDE PLANS.—An award pursuant to subparagraph (A) may not be made unless the application of the political subdivision involved is in coordination with, and consistent with, applicable Statewide plans described in subsection (c).

"(C) RELATIONSHIP TO FORMULA GRANTS.—In the case of a State that will receive an award pursuant to paragraph (3), and in which there is located a political subdivision that will receive an award pursuant to subparagraph (A), the Secretary shall, in determining the amount under paragraph (3)(C) for the State, subtract from the population of the State an amount equal to the population of such political subdivision.

"(D) CONTINUITY OF FUNDING.—In determining whether to make an award pursuant to subparagraph (A) to a political subdivision, the Secretary may consider, as a factor indicating that the award should be made, that the political subdivision received public health funding from the Secretary for fiscal year 2002.

"(5) SIGNIFICANT UNMET NEEDS; DEGREE OF RISK.—

"(A) IN GENERAL.—For fiscal year 2003, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1)(A)(i)(I) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to eligible entities that—

"(i) have a significant need for funds to build capacity to identify, detect, monitor, and respond to a bioterrorist or other threat to the public health, which need will not be met by awards pursuant to paragraph (3); and

"(ii) face a particularly high degree of risk of such a threat.

"(B) RECIPIENTS OF GRANTS.—Awards pursuant to subparagraph (A) may be supplemental awards to States that receive awards pursuant to paragraph (3), or may be awards to eligible entities described in subsection (b)(1)(B) within such States.

"(C) FINDING WITH RESPECT TO DISTRICT OF COLUMBIA.—The Secretary shall consider the District of Columbia to have a significant unmet need for purposes of subparagraph (A), and to face a particularly high degree of risk for such purposes, on the basis of the concentration of entities of national significance located within the District.

"(6) FUNDING OF LOCAL ENTITIES.—For fiscal year 2003, the Secretary shall in making awards under this section ensure that appropriate portions of such awards are made available to political subdivisions, local departments of public health, hospitals (including children's hospitals), clinics, health centers, or primary care facilities, or consortia of such entities.

42 USC 247d–3b.

"SEC. 319C–2. PARTNERSHIPS FOR COMMUNITY AND HOSPITAL PREPAREDNESS.

"(a) GRANTS.—The Secretary shall make awards of grants or cooperative agreements to eligible entities to enable such entities to improve community and hospital preparedness for bioterrorism and other public health emergencies.

"(b) ELIGIBILITY.—To be eligible for an award under subsection (a), an entity shall—

"(1) be a partnership consisting of—

"(A) one or more hospitals (including children's hospitals), clinics, health centers, or primary care facilities; and

"(B)(i) one or more political subdivisions of States;

"(ii) one or more States; or

"(iii) one or more States and one or more political subdivisions of States; and

"(2) 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 described in paragraph (1)(A) is located, and submit to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require.

"(c) REGIONAL COORDINATION.—In making awards under subsection (a), the Secretary shall give preference to eligible entities that submit applications that, in the determination of the Secretary, will—

"(1) enhance coordination—

"(A) among the entities described in subsection (b)(1)(A); and

"(B) between such entities and the entities described in subsection (b)(1)(B); and

"(2) serve the needs of a defined geographic area.

"(d) CONSISTENCY OF PLANNED ACTIVITIES.—An entity described in subsection (b)(1) shall utilize amounts received under an award under subsection (a) in a manner that is coordinated and consistent, as determined by the Secretary, with an applicable State Bioterrorism and Other Public Health Emergency Preparedness and Response Plan.

"(e) USE OF FUNDS.—An award under subsection (a) may be expended for activities that may include the following and similar activities—

"(1) planning and administration for such award;

"(2) preparing a plan for triage and transport management in the event of bioterrorism or other public health emergencies;

"(3) enhancing the training of health care professionals to improve the ability of such professionals to recognize the symptoms of exposure to a potential bioweapon, to make appropriate diagnosis, and to provide treatment to those individuals so exposed;

"(4) enhancing the training of health care professionals to recognize and treat the mental health consequences of bioterrorism or other public health emergencies;

"(5) enhancing the training of health care professionals to assist in providing appropriate health care for large numbers of individuals exposed to a bioweapon;

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

"(7) developing and implementing the trauma care and burn center care components of the State plans for the provision of emergency medical services; or

"(8) conducting such activities as are described in section 319C–1(d) that are appropriate for hospitals (including children's hospitals), clinics, health centers, or primary care facilities.

"(f) LIMITATION ON AWARDS.—A political subdivision of a State shall not participate in more than one partnership described in subsection (b)(1).

"(g) PRIORITIES IN USE OF GRANTS.—

"(1) IN GENERAL.—

"(A) PRIORITIES.—Except as provided in subparagraph (B), the Secretary shall, in carrying out the activities described in this section, address the following hazards in the following priority:

"(i) Bioterrorism or acute outbreaks of infectious diseases.

"(ii) Other public health threats and emergencies.

"(B) DETERMINATION OF THE SECRETARY.—In the case of the hazard involved, the degree of priority that would apply to the hazard based on the categories specified in clauses (i) and (ii) of subparagraph (A) may be modified by the Secretary if the following conditions are met:

"(i) The Secretary determines that the modification is appropriate on the basis of the following factors:

"(I) The extent to which eligible entities are adequately prepared for responding to hazards within the category specified in clause (i) of subparagraph (A).

"(II) There has been a significant change in the assessment of risks to the public health posed by hazards within the category specified in clause (ii) of such subparagraph.

"(ii) Prior to modifying the priority, the Secretary notifies the appropriate committees of the Congress of the determination of the Secretary under clause (i) of this subparagraph.

"(2) AREAS OF EMPHASIS WITHIN CATEGORIES.—The Secretary shall determine areas of emphasis within the category of hazards specified in clause (i) of paragraph (1)(A), and shall determine areas of emphasis within the category of hazards specified in clause (ii) of such paragraph, based on an assessment of the risk and likely consequences of such hazards and on an evaluation of Federal, State, and local needs, and may also take into account the extent to which receiving an award under subsection (a) will develop capacities that can be used for public health emergencies of varying types.

"(h) COORDINATION WITH LOCAL MEDICAL RESPONSE SYSTEM.—An eligible entity and local Metropolitan Medical Response Systems shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities that are carried out by local Metropolitan Medical Response Systems.

"(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2004 through 2006.".

(b) CERTAIN GRANTS.—Section 319C of the Public Health Service Act (42 U.S.C. 247d–3) is amended by striking subsection (f).

Subtitle D—Emergency Authorities; Additional Provisions

SEC. 141. 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) 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 determined 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, wholly or partially, any sanctions otherwise applicable to such failure to comply. Before or promptly after granting such an extension or waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.".

Federal Register, publication.

SEC. 142. STREAMLINING AND CLARIFYING COMMUNICABLE DISEASE QUARANTINE PROVISIONS.

(a) ELIMINATION OF PREREQUISITE FOR NATIONAL ADVISORY HEALTH COUNCIL RECOMMENDATION BEFORE ISSUING QUARANTINE RULES.—

(1) EXECUTIVE ORDERS SPECIFYING DISEASES SUBJECT TO INDIVIDUAL DETENTIONS.—Section 361(b) of the Public Health Act (42 U.S.C. 264(b)) is amended by striking "Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General" and inserting "Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,".

(2) REGULATIONS PROVIDING FOR APPREHENSION OF INDIVIDUALS.—Section 361(d) of the Public Health Act (42 U.S.C. 264(d)) is amended by striking "On recommendation of the National Advisory Health Council, regulations" and inserting "Regulations".

(3) REGULATIONS PROVIDING FOR APPREHENSION OF INDIVIDUALS IN WARTIME.—Section 363 of the Public Health Act (42 U.S.C. 266) is amended by striking "the Surgeon General, on recommendation of the National Advisory Health Council," and

inserting "the Secretary, in consultation with the Surgeon General,".

(b) APPREHENSION AUTHORITY TO APPLY IN CASES OF EXPOSURE TO DISEASE.—

(1) REGULATIONS PROVIDING FOR APPREHENSION OF INDIVIDUALS.—Section 361(d) of the Public Health Act (42 U.S.C. 264(d)), as amended by subsection (a)(2), is further amended—

(A) by striking "(1)" and "(2)" and inserting "(A)" and "(B)", respectively;

(B) by striking "(d)" and inserting "(d)(1)";

(C) in paragraph (1) (as designated by subparagraph (B) of this paragraph), in the first sentence, by striking "in a communicable stage" each place such term appears and inserting "in a qualifying stage"; and

(D) by adding at the end the following paragraph:

"(2) For purposes of this subsection, the term 'qualifying stage', with respect to a communicable disease, means that such disease—

"(A) is in a communicable stage; or

"(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.".

(2) REGULATIONS PROVIDING FOR APPREHENSION OF INDIVIDUALS IN WARTIME.—Section 363 of the Public Health Act (42 U.S.C. 266), as amended by subsection (a)(3), is further amended by striking "in a communicable stage".

(c) STATE AUTHORITY.—Section 361 of the Public Health Act (42 U.S.C. 264) is amended by adding at the end the following:

"(e) Nothing in this section or section 363, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 363.".

SEC. 143. EMERGENCY WAIVER OF MEDICARE, MEDICAID, AND SCHIP REQUIREMENTS.

(a) WAIVER AUTHORITY.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1134 the following new section:

"AUTHORITY TO WAIVE REQUIREMENTS DURING NATIONAL EMERGENCIES

"SEC. 1135. (a) PURPOSE.—The purpose of this section is to enable the Secretary to ensure to the maximum extent feasible, in any emergency area and during an emergency period (as defined in subsection (g)(1))— 42 USC 1320b–5.

"(1) that sufficient health care items and services are available to meet the needs of individuals in such area enrolled in the programs under titles XVIII, XIX, and XXI; and

"(2) that health care providers (as defined in subsection (g)(2)) that furnish such items and services in good faith, but that are unable to comply with one or more requirements described in subsection (b), may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

"(b) SECRETARIAL AUTHORITY.—To the extent necessary to accomplish the purpose specified in subsection (a), the Secretary

is authorized, subject to the provisions of this section, to temporarily waive or modify the application of, with respect to health care items and services furnished by a health care provider (or classes of health care providers) in any emergency area (or portion of such an area) during any portion of an emergency period, the requirements of titles XVIII, XIX, or XXI, or any regulation thereunder (and the requirements of this title other than this section, and regulations thereunder, insofar as they relate to such titles), pertaining to—

"(1)(A) conditions of participation or other certification requirements for an individual health care provider or types of providers,

"(B) program participation and similar requirements for an individual health care provider or types of providers, and

"(C) pre-approval requirements;

"(2) requirements that physicians and other health care professionals be licensed in the State in which they provide such services, if they have equivalent licensing in another State and are not affirmatively excluded from practice in that State or in any State a part of which is included in the emergency area;

"(3) sanctions under section 1867 (relating to examination and treatment for emergency medical conditions and women in labor) for a transfer of an individual who has not been stabilized in violation of subsection (c) of such section if the transfer arises out of the circumstances of the emergency;

"(4) sanctions under section 1877(g) (relating to limitations on physician referral);

"(5) deadlines and timetables for performance of required activities, except that such deadlines and timetables may only be modified, not waived; and

"(6) limitations on payments under section 1851(i) for health care items and services furnished to individuals enrolled in a Medicare+Choice plan by health care professionals or facilities not included under such plan.

Insofar as the Secretary exercises authority under paragraph (6) with respect to individuals enrolled in a Medicare+Choice plan, to the extent possible given the circumstances, the Secretary shall reconcile payments made on behalf of such enrollees to ensure that the enrollees do not pay more than would be required had they received services from providers within the network of the plan and may reconcile payments to the organization offering the plan to ensure that such organization pays for services for which payment is included in the capitation payment it receives under part C of title XVIII.

"(c) AUTHORITY FOR RETROACTIVE WAIVER.—A waiver or modification of requirements pursuant to this section may, at the Secretary's discretion, be made retroactive to the beginning of the emergency period or any subsequent date in such period specified by the Secretary.

"(d) CERTIFICATION TO CONGRESS.—The Secretary shall provide a certification and advance written notice to the Congress at least two days before exercising the authority under this section with respect to an emergency area. Such a certification and notice shall include—

"(1) a description of—

"(A) the specific provisions that will be waived or modified;

"(B) the health care providers to whom the waiver or modification will apply;

"(C) the geographic area in which the waiver or modification will apply; and

"(D) the period of time for which the waiver or modification will be in effect; and

"(2) a certification that the waiver or modification is necessary to carry out the purpose specified in subsection (a).

"(e) DURATION OF WAIVER.—

"(1) IN GENERAL.—A waiver or modification of requirements pursuant to this section terminates upon—

"(A) the termination of the applicable declaration of emergency or disaster described in subsection (g)(1)(A);

"(B) the termination of the applicable declaration of public health emergency described in subsection (g)(1)(B); or

"(C) subject to paragraph (2), the termination of a period of 60 days from the date the waiver or modification is first published (or, if applicable, the date of extension of the waiver or modification under paragraph (2)).

"(2) EXTENSION OF 60-DAY PERIODS.—The Secretary may, by notice, provide for an extension of a 60-day period described in paragraph (1)(C) (or an additional period provided under this paragraph) for additional period or periods (not to exceed, except as subsequently provided under this paragraph, 60 days each), but any such extension shall not affect or prevent the termination of a waiver or modification under subparagraph (A) or (B) of paragraph (1).

"(f) REPORT TO CONGRESS.—Within one year after the end of the emergency period in an emergency area in which the Secretary exercised the authority provided under this section, the Secretary shall report to the Congress regarding the approaches used to accomplish the purposes described in subsection (a), including an evaluation of such approaches and recommendations for improved approaches should the need for such emergency authority arise in the future.

"(g) DEFINITIONS.—For purposes of this section:

"(1) EMERGENCY AREA; EMERGENCY PERIOD.—An 'emergency area' is a geographical area in which, and an 'emergency period' is the period during which, there exists—

"(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

"(B) a public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.

"(2) HEALTH CARE PROVIDER.—The term 'health care provider' means any entity that furnishes health care items or services, and includes a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall be effective on and after September 11, 2001.

42 USC 1320b–5 note.

SEC. 144. PROVISION FOR EXPIRATION OF PUBLIC HEALTH EMERGENCIES.

(a) IN GENERAL.—Section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)), is amended by adding at the end the following new sentence: "Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination.".

42 USC 247d note.

(b) APPLICABILITY.—The amendment made by subsection (a) applies to any public health emergency under section 319(a) of the Public Health Service Act, including any such emergency that was in effect as of the day before the date of the enactment of this Act. In the case of such an emergency that was in effect as of such day, the 90-day period described in such section with respect to the termination of the emergency is deemed to begin on such date of enactment.

Subtitle E—Additional Provisions

SEC. 151. 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.".

42 USC 7257d.

SEC. 152. EXPANDED RESEARCH BY SECRETARY OF ENERGY.

(a) DETECTION AND IDENTIFICATION RESEARCH.—

(1) IN GENERAL.—In conjunction with the working group under section 319F(a) of the Public Health Service Act, the Secretary of Energy and the Administrator of the National Nuclear Security Administration shall expand, enhance, and intensify research relevant to the rapid detection and identification of pathogens likely to be used in a bioterrorism attack or other agents that may cause a public health emergency.

(2) AUTHORIZED ACTIVITIES.—Activities carried out under paragraph (1) may include—

(A) the improvement of methods for detecting biological agents or toxins of potential use in a biological attack and the testing of such methods under variable conditions;

(B) the improvement or pursuit of methods for testing, verifying, and calibrating new detection and surveillance tools and techniques; and

(C) carrying out other research activities in relevant areas.

(3) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Administrator of the National Nuclear Security Administration shall submit to the Committee on Energy and Natural Resources and the Committee on Armed Services of the Senate, and the Committee on Energy and Commerce and the Committee on Armed Services of the House of Representatives, a report setting forth the programs and projects that will be funded prior to the obligation of funds appropriated under subsection (b). Deadline.

(b) AUTHORIZATION.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary in each of fiscal years 2002 through 2006.

SEC. 153. EXPANDED RESEARCH ON WORKER HEALTH AND SAFETY. 29 USC 669a.

The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Director of the National Institute of Occupational Safety and Health, shall enhance and expand research as deemed appropriate on the health and safety of workers who are at risk for bioterrorist threats or attacks in the workplace, including research on the health effects of measures taken to treat or protect such workers for diseases or disorders resulting from a bioterrorist threat or attack. Nothing in this section may be construed as establishing new regulatory authority for the Secretary or the Director to issue or modify any occupational safety and health rule or regulation.

SEC. 154. ENHANCEMENT OF EMERGENCY PREPAREDNESS OF DEPARTMENT OF VETERANS AFFAIRS. 38 USC note prec. 8101.

(a) READINESS OF DEPARTMENT MEDICAL CENTER.—(1) The Secretary of Veterans Affairs shall take appropriate actions to enhance the readiness of Department of Veterans Affairs medical centers to protect the patients and staff of such centers from chemical or biological attack or otherwise to respond to such an attack and so as to enable such centers to fulfil their obligations as part of the Federal response to public health emegencies.

(2) Actions under paragraph (1) shall include—

(A) the provision of decontamination equipment and personal protection equipment at Department medical centers; and

(B) the provision of training in the use of such equipment to staff of such centers.

(b) SECURITY AT DEPARTMENT MEDICAL AND RESEARCH FACILITIES.—(1) Not later than 180 days after the date of the enactment of this Act, the Secretary shall carry out an evaluation of the security needs at Department medical centers and research facilities. The evaluation shall address the following needs: Deadline.

(A) Needs for the protection of patients and medical staff during emergencies, including a chemical or biological attack or other terrorist attack.

(B) Needs, if any, for screening personnel engaged in research relating to biological pathogens or agents, including work associated with such research.

(C) Needs for securing laboratories or other facilities engaged in research relating to biological pathogens or agents.

(D) Any other needs the Secretary considers appropriate.

(2) The Secretary shall take appropriate actions to enhance the security of Department medical centers and research facilities, including staff and patients at such centers and facilities. In taking

such actions, the Secretary shall take into account the results of the evaluation required by paragraph (1).

(c) TRACKING OF PHARMACEUTICALS AND MEDICAL SUPPLIES AND EQUIPMENT.—The Secretary shall develop and maintain a centralized system for tracking the current location and availability of pharmaceuticals, medical supplies, and medical equipment throughout the Department health care system in order to permit the ready identification and utilization of such pharmaceuticals, supplies, and equipment for a variety of purposes, including response to a chemical or biological attack or other terrorist attack.

(d) TRAINING.—The Secretary shall ensure that the Department medical centers, in consultation with the accredited medical school affiliates of such medical centers, develop and implement curricula to train resident physicians and health care personnel in medical matters relating to biological, chemical, or radiological attacks.

(e) PARTICIPATION IN NATIONAL DISASTER MEDICAL SYSTEM.—(1) The Secretary shall, in consultation with the Secretary of Defense, the Secretary of Health and Human Services, and the Director of the Federal Emergency Management Agency, establish and maintain a training program to facilitate the participation of the staff of Department medical centers, and of the community partners of such centers, in the National Disaster Medical System.

(2) The Secretary shall establish and maintain the training program under paragraph (1) in accordance with the recommendations of the working group under section 319F(a) of the Public Health Service Act.

(f) MENTAL HEALTH COUNSELING.—(1) With respect to activities conducted by personnel serving at Department medical centers, the Secretary shall, in consultation with the Secretary of Health and Human Services, the American Red Cross, and the working group under section 319F(a) of the Public Health Service Act, develop and maintain various strategies for providing mental health counseling and assistance, including counseling and assistance for post-traumatic stress disorder, to local and community emergency response providers, veterans, active duty military personnel, and individuals seeking care at Department medical centers following a bioterrorist attack or other public health emergency.

(2) The strategies under paragraph (1) shall include the following:

(A) Training and certification of providers of mental health counseling and assistance.

(B) Mechanisms for coordinating the provision of mental health counseling and assistance to emergency response providers referred to in that paragraph.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is hereby authorized to be appropriated for the Department of Veterans Affairs amounts as follows:

(1) To carry out activities required by subsection (a)—

(A) $100,000,000 for fiscal year 2002; and

(B) such sums as may be necessary for each of fiscal years 2003 through 2006.

(2) To carry out activities required by subsections (b) through (f)—

(A) $33,000,000 for fiscal year 2002; and

(B) such sums as may be necessary for each of fiscal years 2003 through 2006.

SEC. 155. REAUTHORIZATION OF EXISTING PROGRAM.

Section 582(f) of the Public Health Service Act (42 U.S.C. 290hh-1(f)) is amended by striking "2002 and 2003" and inserting "2003 through 2006".

SEC. 156. SENSE OF CONGRESS.

It is the sense of the Congress 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 this Act and the amendments made by this Act; and

(4) the Secretary of Health and Human Services should, as appropriate, recognize the importance of existing public and private university-based research, training, public awareness, and safety related biological defense programs when the Secretary makes awards of grants and contracts in accordance with this Act and the amendments made by this Act.

SEC. 157. GENERAL ACCOUNTING OFFICE REPORT.

42 USC 300hh note.

(a) IN GENERAL.—The Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report that describes—

(1) Federal activities primarily related to research on, preparedness for, and the management of the public health and medical consequences of a bioterrorist attack against the civilian population;

(2) the coordination of the activities described in paragraph (1);

(3) the effectiveness of such efforts in preparing national, State, and local authorities to address the public health and medical consequences of a potential bioterrorist attack against the civilian population;

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

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

(6) the ability of private sector contractors to enhance governmental responses to biological threats or attacks.

SEC. 158. CERTAIN AWARDS.

Section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)) is amended in the matter after and below paragraph (2) by striking "grants and" and inserting "grants, providing awards for expenses, and".

Community Access to Emergency Defibrillation Act of 2002.
42 USC 201 note.
42 USC 244 note.

SEC. 159. PUBLIC ACCESS DEFIBRILLATION PROGRAMS AND PUBLIC ACCESS DEFIBRILLATION DEMONSTRATION PROJECTS.

(a) SHORT TITLE.—This section may be cited as the "Community Access to Emergency Defibrillation Act of 2002".

(b) FINDINGS.—Congress makes the following findings:

(1) Over 220,000 Americans die each year from cardiac arrest. Every 2 minutes, an individual goes into cardiac arrest in the United States.

(2) The chance of successfully returning to a normal heart rhythm diminishes by 10 percent each minute following sudden cardiac arrest.

(3) Eighty percent of cardiac arrests are caused by ventricular fibrillation, for which defibrillation is the only effective treatment.

(4) Sixty percent of all cardiac arrests occur outside the hospital. The average national survival rate for out-of-hospital cardiac arrest is only 5 percent.

(5) Communities that have established and implemented public access defibrillation programs have achieved average survival rates for out-of-hospital cardiac arrest as high as 50 percent.

(6) According to the American Heart Association, wide use of defibrillators could save as many as 50,000 lives nationally each year.

(7) Successful public access defibrillation programs ensure that cardiac arrest victims have access to early 911 notification, early cardiopulmonary resuscitation, early defibrillation, and early advanced care.

(c) PUBLIC ACCESS DEFIBRILLATION PROGRAMS AND PROJECTS.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by Public Law 106–310, is amended by adding after section 311 the following:

42 USC 244.

"SEC. 312. PUBLIC ACCESS DEFIBRILLATION PROGRAMS.

Grants.

"(a) IN GENERAL.—The Secretary shall award grants to States, political subdivisions of States, Indian tribes, and tribal organizations to develop and implement public access defibrillation programs—

"(1) by training and equipping local emergency medical services personnel, including firefighters, police officers, paramedics, emergency medical technicians, and other first responders, to administer immediate care, including cardiopulmonary resuscitation and automated external defibrillation, to cardiac arrest victims;

"(2) by purchasing automated external defibrillators, placing the defibrillators in public places where cardiac arrests are likely to occur, and training personnel in such places to administer cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims;

"(3) by setting procedures for proper maintenance and testing of such devices, according to the guidelines of the manufacturers of the devices;

"(4) by providing training to members of the public in cardiopulmonary resuscitation and automated external defibrillation;

"(5) by integrating the emergency medical services system with the public access defibrillation programs so that emergency

medical services personnel, including dispatchers, are informed about the location of automated external defibrillators in their community; and

"(6) by encouraging private companies, including small businesses, to purchase automated external defibrillators and provide training for their employees to administer cardiopulmonary resuscitation and external automated defibrillation to cardiac arrest victims in their community.

"(b) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall give a preference to a State, political subdivision of a State, Indian tribe, or tribal organization that—

"(1) has a particularly low local survival rate for cardiac arrests, or a particularly low local response rate for cardiac arrest victims; or

"(2) demonstrates in its application the greatest commitment to establishing and maintaining a public access defibrillation program.

"(c) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) may use funds received through such grant to—

"(1) purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration;

"(2) provide automated external defibrillation and basic life support training in automated external defibrillator usage through nationally recognized courses;

"(3) provide information to community members about the public access defibrillation program to be funded with the grant;

"(4) provide information to the local emergency medical services system regarding the placement of automated external defibrillators in public places;

"(5) produce materials to encourage private companies, including small businesses, to purchase automated external defibrillators; and

"(6) further develop strategies to improve access to automated external defibrillators in public places.

"(d) APPLICATION.—

"(1) IN GENERAL.—To be eligible to receive a grant under subsection (a), a State, political subdivision of a State, Indian tribe, or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

"(2) CONTENTS.—An application submitted under paragraph (1) shall—

"(A) describe the comprehensive public access defibrillation program to be funded with the grant and demonstrate how such program would make automated external defibrillation accessible and available to cardiac arrest victims in the community;

"(B) contain procedures for implementing appropriate nationally recognized training courses in performing cardiopulmonary resuscitation and the use of automated external defibrillators;

"(C) contain procedures for ensuring direct involvement of a licensed medical professional and coordination with

the local emergency medical services system in the oversight of training and notification of incidents of the use of the automated external defibrillators;

"(D) contain procedures for proper maintenance and testing of the automated external defibrillators, according to the labeling of the manufacturer;

"(E) contain procedures for ensuring notification of local emergency medical services system personnel, including dispatchers, of the location and type of devices used in the public access defibrillation program; and

"(F) provide for the collection of data regarding the effectiveness of the public access defibrillation program to be funded with the grant in affecting the out-of-hospital cardiac arrest survival rate.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.

42 USC 245.

"SEC. 313. PUBLIC ACCESS DEFIBRILLATION DEMONSTRATION PROJECTS.

"(a) IN GENERAL.—The Secretary shall award grants to political subdivisions of States, Indian tribes, and tribal organizations to develop and implement innovative, comprehensive, community-based public access defibrillation demonstration projects that—

"(1) provide cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims in unique settings;

"(2) provide training to community members in cardiopulmonary resuscitation and automated external defibrillation; and

"(3) maximize community access to automated external defibrillators.

"(b) USE OF FUNDS.—A recipient of a grant under subsection (a) shall use the funds provided through the grant to—

"(1) purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration;

"(2) provide basic life training in automated external defibrillator usage through nationally recognized courses;

"(3) provide information to community members about the public access defibrillation demonstration project to be funded with the grant;

"(4) provide information to the local emergency medical services system regarding the placement of automated external defibrillators in the unique settings; and

"(5) further develop strategies to improve access to automated external defibrillators in public places.

"(c) APPLICATION.—

"(1) IN GENERAL.—To be eligible to receive a grant under subsection (a), a political subdivision of a State, Indian tribe, or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

"(2) CONTENTS.—An application submitted under paragraph (1) may—

"(A) describe the innovative, comprehensive, community-based public access defibrillation demonstration project to be funded with the grant;

"(B) explain how such public access defibrillation demonstration project represents innovation in providing public access to automated external defibrillation; and

"(C) provide for the collection of data regarding the effectiveness of the demonstration project to be funded with the grant in—

"(i) providing emergency cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims in the setting served by the demonstration project; and

"(ii) affecting the cardiac arrest survival rate in the setting served by the demonstration project.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2002 through 2006. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.".

TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

Subtitle A—Department of Health and Human Services

SEC. 201. REGULATION OF CERTAIN 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.—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 DANGEROUS BIOLOGICAL AGENTS AND TOXINS. 42 USC 262a.

"(a) REGULATORY CONTROL OF CERTAIN 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 with scientific experts representing appropriate professional groups, including groups 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 by regulation revise the list as necessary in accordance with such paragraph.

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

"(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, 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) the establishment and enforcement of safeguard and security measures 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 such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures 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 AGENTS AND TOXINS.—The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect the public health and safety.

"(d) REGISTRATION; IDENTIFICATION; DATABASE.—

"(1) REGISTRATION.—Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

"(2) IDENTIFICATION; DATABASE.—Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their

identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

"(e) SAFEGUARD AND SECURITY REQUIREMENTS FOR REGISTERED PERSONS.—

"(1) IN GENERAL.—Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including the risk of use in domestic or international terrorism). The Secretary shall establish such requirements in consultation with the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

"(2) LIMITING ACCESS TO LISTED AGENTS AND TOXINS.—Requirements under paragraph (1) shall include provisions to ensure that registered persons—

"(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

"(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years;

"(C) deny access to such agents and toxins by individuals whom the Attorney General has identified as restricted persons; and

"(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

"(3) SUBMITTED NAMES; USE OF DATABASES BY ATTORNEY GENERAL.—

"(A) IN GENERAL.—Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

"(B) CERTAIN INDIVIDUALS.—For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

"(i) the individual is a restricted person; or

"(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

"(I) committing a crime set forth in section 2332b(g)(5) of title 18, United States Code;

"(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence; or

"(III) being an agent of a foreign power (as defined in section 1801 of title 50, United States Code).

"(C) NOTIFICATION BY ATTORNEY GENERAL REGARDING SUBMITTED NAMES.—After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

"(4) NOTIFICATIONS BY SECRETARY.—The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

"(5) EXPEDITED REVIEW.—Regulations under subsections (b) and (c) shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

"(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and

"(B) expedite the notification of the registered person by the Secretary under paragraph (4).

"(6) PROCESS REGARDING PERSONS SEEKING TO REGISTER.—

"(A) INDIVIDUALS.—Regulations under subsections (b) and (c) shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

"(B) OTHER PERSONS.—Regulations under subsections (b) and (c) shall provide that, in determining whether to deny or revoke registration by a person other than an individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs

(2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

"(7) REVIEW.—

"(A) ADMINISTRATIVE REVIEW.—

"(i) IN GENERAL.—Regulations under subsections (b) and (c) shall provide for an opportunity for a review by the Secretary—

"(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

"(II) when requested by the person involved, of a determination under paragraph (6) to deny or revoke registration for such person.

"(ii) EX PARTE REVIEW.—During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

"(iii) FINAL AGENCY ACTION.—The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5, United States Code.

"(B) CERTAIN PROCEDURES.—

"(i) SUBMISSION OF EX PARTE MATERIALS IN JUDICIAL PROCEEDINGS.—When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18, United States Code (relating to interlocutory appeal and expedited consideration).

"(ii) DISCLOSURE OF INFORMATION.—In a review under subparagraph (A), and in any judical proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to

disclose to the public any information that under subsection (h) shall not be disclosed under section 552 of title 5, United States Code.

"(8) NOTIFICATIONS REGARDING THEFT OR LOSS OF AGENTS.—Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

"(9) TECHNICAL ASSISTANCE FOR REGISTERED PERSONS.—The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

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

"(g) EXEMPTIONS.—

"(1) CLINICAL OR DIAGNOSTIC LABORATORIES.—Regulations under subsections (b) and (c) shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

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

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

"(2) PRODUCTS.—

"(A) IN GENERAL.—Regulations under subsections (b) and (c) shall exempt products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in subparagraph (B), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) to a specific product is necessary to protect public health and safety.

"(B) RELEVANT LAWS.—For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:

"(i) The Federal Food, Drug, and Cosmetic Act.

"(ii) Section 351 of this Act.

"(iii) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading 'Bureau of Animal Industry' in the Act of March 4, 1913; 21 U.S.C. 151–159).

"(iv) The Federal Insecticide, Fungicide, and Rodenticide Act.

"(C) INVESTIGATIONAL USE.—

"(i) IN GENERAL.—The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection

(b) or (c) to such product is not necessary to protect public health and safety.

"(ii) CERTAIN PROCESSES.—Regulations under subsections (b) and (c) shall set forth the procedures for applying for an exemption under clause (i). In the case of investigational products authorized under any of the Acts specified in subparagraph (B), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption: Deadline.

"(I) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

"(II) The person has notified the Secretary that the investigation has been authorized under such an Act.

"(3) PUBLIC HEALTH EMERGENCIES.—The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 319(a) or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

"(4) AGRICULTURAL EMERGENCIES.—Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

"(h) DISCLOSURE OF INFORMATION.—

"(1) NONDISCLOSURE OF CERTAIN INFORMATION.—No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5, United States Code, any of the following:

"(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

"(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b)

and (c) to the extent that such compilation discloses site-specific registration or transfer information.

"(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

"(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.

"(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

"(2) COVERED AGENCIES.—For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

"(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

"(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

"(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

"(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

"(3) OTHER EXEMPTIONS.—This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, United States Code, except as to subsection 552(b)(3) of such title, to any of the information specified in paragraph (1).

"(4) RULE OF CONSTRUCTION.—Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, United States Code, or the obligation of any Federal agency to disclose under section 552 of title 5, United States Code, any information, including information relating to—

"(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

"(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

"(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

"(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

"(5) DISCLOSURES TO CONGRESS; OTHER DISCLOSURES.—This subsection may not be construed as providing any authority—

"(A) to withhold information from the Congress or any committee or subcommittee thereof; or

"(B) to withhold information from any person under any other Federal law or treaty.

"(i) CIVIL MONEY PENALTY.—

"(1) IN GENERAL.—In addition to any other penalties that may apply under law, any person who violates any provision of regulations 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.

"(2) APPLICABILITY OF CERTAIN PROVISIONS.—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)) shall apply to a civil money penalty under paragraph (1) 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 subsection in the same manner as provided in section 1128A(j)(2) of the Social Security Act, and such authority shall include all powers as contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

"(j) NOTIFICATION IN EVENT OF RELEASE.—Regulations under subsections (b) and (c) shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin (as defined in subsection (l)), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

"(k) REPORTS.—The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases).

"(l) DEFINITIONS.—For purposes of this section:

"(1) The terms 'biological agent' and 'toxin' have the meanings given such terms in section 178 of title 18, United States Code.

"(2) The term 'listed agents and toxins' means biological agents and toxins listed pursuant to subsection (a)(1).

"(3) The term 'listed agents or toxins' means biological agents or toxins listed pursuant to subsection (a)(1).

"(4) The term 'overlap agents and toxins' means biological agents and toxins that—

"(A) are listed pursuant to subsection (a)(1); and

"(B) are listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002.

"(5) The term 'overlap agent or toxin' means a biological agent or toxin that—

"(A) is listed pursuant to subsection (a)(1); and

"(B) is listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002.

"(6) The term 'person' includes Federal, State, and local governmental entities.

"(7) The term 'registered person' means a person registered under regulations under subsection (b) or (c).

"(8) The term 'restricted person' has the meaning given such term in section 175b of title 18, United States Code.

"(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2007.".

Deadline. 42 USC 262a note.

(b) REPORT TO CONGRESS.—Not later than one 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 (as added by subsection (a) of this section), 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 such section 351A;

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

(4) evaluates the impact of such section 351A on research on biological agents and toxins listed pursuant to such section; and

(5) provides any recommendations of the Secretary for administrative or legislative initiatives regarding such section 351A.

Deadlines. 42 USC 262a note.

SEC. 202. IMPLEMENTATION BY DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(a) DATE CERTAIN FOR NOTICE OF POSSESSION.—Not later than 90 days after the date of the enactment of this Act, all persons (unless exempt under subsection (g) of section 351A of the Public Health Service Act, as added by section 201 of this Act) in possession of biological agents or toxins listed under such section 351A of the Public Health Service Act shall notify the Secretary of Health and Human Services of such possession. Not later than 30 days after such date of enactment, the Secretary shall provide written guidance on how such notice is to be provided to the Secretary.

Guidelines.

Rules.

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

(1) section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

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

(c) TRANSITIONAL PROVISION REGARDING CURRENT RESEARCH AND EDUCATION.—The interim final rule under subsection (b) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act and that were underway as of the effective date of such rule.

SEC. 203. EFFECTIVE DATES.

42 USC 262a note.

(a) IN GENERAL.—Regulations promulgated by the Secretary of Health and Human Services under section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 are deemed to have been promulgated under section 351A of the Public Health Service Act, as added by section 201 of this Act. Such regulations, including the list under subsection (d)(1) of such section 511, that were in effect on the day before the date of the enactment of this Act remain in effect until modified by the Secretary in accordance with such section 351A and with section 202 of this Act.

(b) EFFECTIVE DATE REGARDING DISCLOSURE OF INFORMATION.—Subsection (h) of section 351A of the Public Health Service Act, as added by section 201 of this Act, is deemed to have taken effect on the effective date of the Antiterrorism and Effective Death Penalty Act of 1996.

SEC. 204. 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.

Subtitle B—Department of Agriculture

Agricultural Bioterrorism Protection Act of 2002.
7 USC 8401 note.

SEC. 211. SHORT TITLE.

This subtitle may be cited as the "Agricultural Bioterrorism Protection Act of 2002".

SEC. 212. REGULATION OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.

7 USC 8401.

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

(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—

(A) IN GENERAL.—The Secretary of Agriculture shall by regulation establish and maintain a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.

(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 of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;

(II) the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;

(III) the availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and

(IV) any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups.

Publication.

(2) BIENNIAL REVIEW.—The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

Safety.

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

(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, 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) the establishment and enforcement of safeguard and security measures 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 animal and plant health, and animal and plant products, in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures 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 AGENTS AND TOXINS.—The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect animal and plant health, and animal and plant products.

(d) REGISTRATION; IDENTIFICATION; DATABASE.—

(1) REGISTRATION.—Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

(2) IDENTIFICATION; DATABASE.—Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their

identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins. Records.

(e) SAFEGUARD AND SECURITY REQUIREMENTS FOR REGISTERED PERSONS.—

(1) IN GENERAL.—Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to animal and plant health, and animal and plant products (including the risk of use in domestic or international terrorism). The Secretary shall establish such requirements in consultation with the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

(2) LIMITING ACCESS TO LISTED AGENTS AND TOXINS.—Requirements under paragraph (1) shall include provisions to ensure that registered persons—

(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years; and

(C)(i) in the case of listed agents and toxins that are not overlap agents and toxins (as defined in subsection (g)(1)(A)(ii)), limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General; and

(ii) in the case of listed agents and toxins that are overlap agents—

(I) deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category referred to in paragraph (3)(B)(i); and

(II) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

(3) SUBMITTED NAMES; USE OF DATABASES BY ATTORNEY GENERAL.—

(A) IN GENERAL.—Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the

categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

(B) CERTAIN INDIVIDUALS.—For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

(i) the individual is within any of the categories described in section 175b(d)(1) of title 18, United States Code (relating to restricted persons); or

(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

(I) committing a crime set forth in section 2332b(g)(5) of title 18, United States Code;

(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence; or

(III) being an agent of a foreign power (as defined in section 1801 of title 50, United States Code).

(C) NOTIFICATION BY ATTORNEY GENERAL REGARDING SUBMITTED NAMES.—After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

(4) NOTIFICATIONS BY SECRETARY.—The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

(5) EXPEDITED REVIEW.—Regulations under subsections (b) and (c) shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and

(B) expedite the notification of the registered person by the Secretary under paragraph (4).

(6) PROCESS REGARDING PERSONS SEEKING TO REGISTER.—

(A) INDIVIDUALS.—Regulations under subsections (b) and (c) shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

(B) OTHER PERSONS.—Regulations under subsections (b) and (c) shall provide that, in determining whether to deny or revoke registration by a person other than an

individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is within any of the categories described in section 175b(d)(1) of title 18, United States Code (relating to restricted persons), or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

(7) REVIEW.—

(A) ADMINISTRATIVE REVIEW.—

(i) IN GENERAL.—Regulations under subsections (b) and (c) shall provide for an opportunity for a review by the Secretary—

(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

(II) when requested by the person involved, of a determination under under paragraph (6) to deny or revoke registration for such person.

(ii) EX PARTE REVIEW.—During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

(iii) FINAL AGENCY ACTION.—The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5, United States Code.

(B) CERTAIN PROCEDURES.—

(i) SUBMISSION OF EX PARTE MATERIALS IN JUDICIAL PROCEEDINGS.—When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by

any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18, United States Code (relating to interlocutory appeal and expedited consideration).

(ii) DISCLOSURE OF INFORMATION.—In a review under subparagraph (A), and in any judical proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (h) shall not be disclosed under section 552 of title 5, United States Code.

(8) NOTIFICATIONS REGARDING THEFT OR LOSS OF AGENTS.—Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

(9) TECHNICAL ASSISTANCE FOR REGISTERED PERSONS.—The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

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

(g) EXEMPTIONS.—

(1) OVERLAP AGENTS AND TOXINS.—

(A) IN GENERAL.—

(i) LIMITATION.—In the case of overlap agents and toxins, exemptions from the applicability of provisions of regulations under subsection (b) or (c) may be granted only to the extent provided in this paragraph.

(ii) DEFINITIONS.—For purposes of this section:

(I) The term "overlap agents and toxins" means biological agents and toxins that—

(aa) are listed pursuant to subsection (a)(1); and

(bb) are listed pursuant to section 315A(a)(1) of the Public Health Service Act.

(II) The term "overlap agent or toxin" means a biological agent or toxin that—

(aa) is listed pursuant to subsection (a)(1); and

(bb) is listed pursuant to section 315A(a)(1) of the Public Health Service Act.

(B) CLINICAL OR DIAGNOSTIC LABORATORIES.—Regulations under subsections (b) and (c) shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer overlap agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

(i) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and

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

(C) PRODUCTS.—

(i) IN GENERAL.—Regulations under subsections (b) and (c) shall exempt products that are, bear, or contain overlap agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in clause (ii), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) to a specific product is necessary to protect animal or plant health, or animal or plant products.

(ii) RELEVANT LAWS.—For purposes of clause (i), the Acts specified in this clause are the following:

(I) The Federal Food, Drug, and Cosmetic Act.

(II) Section 351 of the Public Health Service Act.

(III) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading "Bureau of Animal Industry" in the Act of March 4, 1913; 21 U.S.C. 151–159).

(IV) The Federal Insecticide, Fungicide, and Rodenticide Act.

(iii) INVESTIGATIONAL USE.—

(I) IN GENERAL.—The Secretary may exempt an investigational product that is, bears, or contains an overlap agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection (b) or (c) to such product is not necessary to protect animal and plant health, and animal and plant products.

(II) CERTAIN PROCESSES.—Regulations under subsections (b) and (c) shall set forth the procedures for applying for an exemption under subclause (I). In the case of investigational products authorized under any of the Acts specified in clause (ii), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption:

(aa) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

(bb) The person has notified the Secretary that the investigation has been authorized under such an Act.

(D) AGRICULTURAL EMERGENCIES.—The Secretary may temporarily exempt a person from the applicability of the

requirements of this section with respect to an overlap agent or toxin, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign agricultural emergency that involves such an agent or toxin. With respect to the emergency involved, the exemption under this subparagraph for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(E) PUBLIC HEALTH EMERGENCIES.—Upon request of the Secretary of Health and Human Services, after the granting by such Secretary of an exemption under 351A(g)(3) of the Public Health Service Act pursuant to a finding that there is a public health emergency, the Secretary of Agriculture may temporarily exempt a person from the applicability of the requirements of this section with respect to an overlap agent or toxin, in whole or in part, to provide for the timely participation of the person in a response to the public health emergency. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that upon request of the Secretary of Health and Human Services, the Secretary of Agriculture may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

(2) GENERAL AUTHORITY FOR EXEMPTIONS NOT INVOLVING OVERLAP AGENTS OR TOXINS.—In the case of listed agents or toxins that are not overlap agents or toxins, the Secretary may grant exemptions from the applicability of provisions of regulations under subsection (b) or (c) if the Secretary determines that such exemptions are consistent with protecting animal and plant health, and animal and plant products.

(h) DISCLOSURE OF INFORMATION.—

(1) NONDISCLOSURE OF CERTAIN INFORMATION.—No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5, United States Code, any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c), or permits issued prior to the date of the enactment of this Act, for the possession, use or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used or transferred by a specific person or discloses the identity or location of a specific person.

(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.

(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any

notification of theft or loss submitted under such subsections.

(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger animal or plant health, or animal or plant products.

(2) COVERED AGENCIES.—For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

(3) OTHER EXEMPTIONS.—This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, United States Code, except as to subsection 552(b)(3) of such title, to any of the information specified in paragraph (1).

(4) RULE OF CONSTRUCTION.—Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, United States Code, or the obligation of any Federal agency to disclose under section 552 of title 5, United States Code, any information, including information relating to—

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

(5) DISCLOSURES TO CONGRESS; OTHER DISCLOSURES.—This subsection may not be construed as providing any authority—

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

(i) CIVIL MONEY PENALTY.—

(1) IN GENERAL.—In addition to any other penalties that may apply under law, any person who violates any provision of regulations 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.

(2) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of sections 423 and 425(2) of the Plant Protection Act (7 U.S.C. 7733 and 7735(2)) shall apply to a civil money penalty or activity under paragraph (1) in the same manner as such provisions apply to a penalty or activity under the Plant Protection Act.

(j) NOTIFICATION IN EVENT OF RELEASE.—Regulations under subsections (b) and (c) shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to animal or plant health, or animal or plant products, the Secretary shall take appropriate action to notify relevant Federal, State, and local authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin, the Secretary shall promptly notify the Secretary of Health and Human Services upon notification by the registered person.

(k) REPORTS.—The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases).

(l) DEFINITIONS.—For purposes of this section:

(1) The terms "biological agent" and "toxin" have the meanings given such terms in section 178 of title 18, United States Code.

(2) The term "listed agents and toxins" means biological agents and toxins listed pursuant to subsection (a)(1).

(3) The term "listed agents or toxins" means biological agents or toxins listed pursuant to subsection (a)(1).

(4) The terms "overlap agents and toxins" and "overlap agent or toxin" have the meaning given such terms in subsection (g)(1)(A)(ii).

(5) The term "person" includes Federal, State, and local governmental entities.

(6) The term "registered person" means a person registered under regulations under subsection (b) or (c).

(7) The term "Secretary" means the Secretary of Agriculture.

(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2007, in addition to other funds that may be available.

Deadlines.

SEC. 213. IMPLEMENTATION BY DEPARTMENT OF AGRICULTURE.

Rules.
7 USC 8401 note.

(a) DATE CERTAIN FOR PROMULGATION OF LIST.—Not later than 60 days after the date of the enactment of this Act, the Secretary of Agriculture (referred to in this section as the "Secretary") shall promulgate an interim final rule that establishes the initial list

under section 212(a)(1). In promulgating such rule, the Secretary shall provide written guidance on the manner in which the notice required in subsection (b) is to be provided to the Secretary. Guidelines.

(b) DATE CERTAIN FOR NOTICE OF POSSESSION.—Not later than 60 days after the date on which the Secretary promulgates the interim final rule under subsection (a), all persons (unless exempt under section 212(g)) in possession of biological agents or toxins included on the list referred to in subsection (a) shall notify the Secretary of such possession.

(c) DATE CERTAIN FOR PROMULGATION; EFFECTIVE DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall promulgate an interim final rule for carrying out section 212, other than for the list referred to in subsection (a) of this section (but such rule may incorporate by reference provisions promulgated pursuant to subsection (a)). Such interim final rule shall take effect 60 days after the date on which such rule is promulgated, including for purposes of— Rules.

(1) section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

(2) section 212(i) of this Act (relating to civil penalties).

(d) TRANSITIONAL PROVISION REGARDING CURRENT RESEARCH AND EDUCATION.—The interim final rule under subsection (c) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 212(a)(1) and that were underway as of the effective date of such rule.

Subtitle C—Interagency Coordination Regarding Overlap Agents and Toxins

SEC. 221. INTERAGENCY COORDINATION. 7 USC 8411.

(a) IN GENERAL.—

(1) COORDINATION.—The Secretary of Agriculture and the Secretary of Health and Human Services shall in accordance with this section coordinate activities regarding overlap agents and toxins.

(2) OVERLAP AGENTS AND TOXINS; OTHER TERMS.—For purposes of this section:

(A) The term "overlap agent or toxin" means a biological agent or toxin that—

(i) is listed pursuant to section 315A(a)(1) of the Public Health Service Act, as added by section 201 of this Act; and

(ii) is listed pursuant to section 212(a)(1) of this Act.

(B) The term "section 351A program" means the program under section 351A of the Public Health Service Act.

(C) The term "section 212 program" means the program under section 212 of this Act.

(b) CERTAIN MATTERS.—In carrying out the section 351A program and the section 212 program, the Secretary of Health and Human Services and the Secretary of Agriculture shall, to the

greatest extent practicable, coordinate activities to achieve the following purposes:

(1) To minimize any conflicts between the regulations issued under, and activities carried out under, such programs.

(2) To minimize the administrative burden on persons subject to regulation under both of such programs.

(3) To ensure the appropriate availability of biological agents and toxins for legitimate biomedical, agricultural or veterinary research, education, or other such purposes.

(4) To ensure that registration information for overlap agents and toxins under the section 351A and section 212 programs is contained in both the national database under the section 351A program and the national database under the section 212 program.

(c) MEMORANDUM OF UNDERSTANDING.—

(1) IN GENERAL.—Promptly after the date of the enactment of this Act, the Secretary of Agriculture and the Secretary of Health and Human Services shall enter into a memorandum of understanding regarding overlap agents and toxins that is in accordance with paragraphs (2) through (4) and contains such additional provisions as the Secretary of Agriculture and the Secretary of Health and Human Services determine to be appropriate.

(2) SINGLE REGISTRATION SYSTEM REGARDING REGISTERED PERSONS.—The memorandum of understanding under paragraph (1) shall provide for the development and implementation of a single system of registration for persons who possess, use, or transfer overlap agents or toxins and are required to register under both the section 351A program and the section 212 program. For purposes of such system, the memorandum shall provide for the development and implementation of the following:

(A) A single registration form through which the person submitting the form provides all information that is required for registration under the section 351A program and all information that is required for registration under the section 212 program.

(B) A procedure through which a person may choose to submit the single registration form to the agency administering the section 351A program (in the manner provided under such program), or to the agency administering the section 212 program (in the manner provided under such program).

(C) A procedure through which a copy of a single registration form received pursuant to subparagraph (B) by the agency administering one of such programs is promptly provided to the agency administering the other program.

(D) A procedure through which the agency receiving the single registration form under one of such programs obtains the concurrence of the agency administering the other program that the requirements for registration under the other program have been met.

(E) A procedure through which—

(i) the agency receiving the single registration form under one of such programs informs the agency administering the other program whether the receiving agency has denied the registration; and

(ii) each of such agencies ensures that registrations are entered into the national database of registered persons that is maintained by each such agency.

(3) PROCESS OF IDENTIFICATION.—With respect to the process of identification under the section 351A program and the section 212 program for names and other identifying information submitted to the Attorney General (relating to certain categories of individuals and entities), the memorandum of understanding under paragraph (1) shall provide for the development and implementation of the following:

(A) A procedure through which a person who is required to submit information pursuant to such process makes (in addition to the submission to the Attorney General) a submission, at the option of the person, to either the agency administering the section 351A program or the agency administering the section 212 program, but not both, which submission satisfies the requirement of submission for both of such programs.

(B) A procedure for the sharing by both of such agencies of information received from the Attorney General by one of such agencies pursuant to the submission under subparagraph (A).

(C) A procedure through which the agencies administering such programs concur in determinations that access to overlap agents and toxins will be granted.

(4) COORDINATION OF INSPECTIONS AND ENFORCEMENT.—The memorandum of understanding under paragraph (1) shall provide for the development and implementation of procedures under which Federal personnel under the section 351A program and the section 212 program may share responsibilities for inspections and enforcement activities under such programs regarding overlap agents and toxins. Activities carried out under such procedures by one of such programs on behalf of the other may be carried out with or without reimbursement by the agency that administers the other program.

(5) DATE CERTAIN FOR IMPLEMENTATION.—The memorandum of understanding under paragraph (1) shall be implemented not later than 180 days after the date of the enactment of this Act. Until the single system of registration under paragraph (2) is implemented, persons who possess, use, or transfer overlap agents or toxins shall register under both the section 351A program and the section 212 program. Deadline.

(d) JOINT REGULATIONS.—Not later than 18 months after the date on which the single system of registration under subsection (c)(2) is implemented, the Secretary of Health and Human Services and the Secretary of Agriculture shall jointly issue regulations for the possession, use, and transfer of overlap agents and toxins that meet the requirements of both the section 351A program and the section 212 program. Deadline.

Subtitle D—Criminal Penalties Regarding Certain Biological Agents and Toxins

SEC. 231. CRIMINAL PENALTIES.

(a) IN GENERAL.—Section 175b of title 18, United States Code, as added by section 817 of Public Law 107–56, is amended—

(1) by striking "(a)" and inserting "(a)(1)";

(2) by transferring subsection (c) from the current placement of the subsection and inserting the subsection before subsection (b);

(3) by striking "(c)" and inserting "(2);

(4) by redesignating subsection (b) as subsection (d); and

(5) by inserting before subsection (d) (as so redesignated) the following subsections:

"(b) TRANSFER TO UNREGISTERED PERSON.—

"(1) SELECT AGENTS.—Whoever transfers a select agent to a person who the transferor knows or has reasonable cause to believe is not registered as required by regulations under subsection (b) or (c) of section 351A of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

"(2) CERTAIN OTHER BIOLOGICAL AGENTS AND TOXINS.—Whoever transfers a biological agent or toxin listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 to a person who the transferor knows or has reasonable cause to believe is not registered as required by regulations under subsection (b) or (c) of section 212 of such Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

"(c) UNREGISTERED FOR POSSESSION.—

"(1) SELECT AGENTS.—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 regulations 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) CERTAIN OTHER BIOLOGICAL AGENTS AND TOXINS.—Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a biological agent or toxin listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 for which such person has not obtained a registration required by regulations under section 212(c) of such Act shall be fined under this title, or imprisoned for not more than 5 years, or both.".

(b) CONFORMING AMENDMENTS.—Chapter 10 of title 18, United States Code, is amended—

(1) in section 175b (as added by section 817 of Public Law 107–56 and amended by subsection (a) of this section)—

(A) in subsection (d)(1), by striking "The term" and all that follows through "does not include" and inserting the following: "The term 'select agent' means a biological agent or toxin to which subsection (a) applies. Such term (including for purposes of subsection (a)) does not include"; and

(B) in the heading for the section, by striking "**Possession by restricted persons**" and inserting "**Select agents; certain other agents**"; and

(2) in the chapter analysis, in the item relating to section 175b, by striking "Possession by restricted persons." and inserting "Select agents; certain other agents.".

(c) TECHNICAL CORRECTIONS.—Chapter 10 of title 18, United States Code, as amended by section 817 of Public Law 107–56 and subsections (a) and (b) of this section, is amended—

(1) in section 175(c), by striking "protective" and all that follows and inserting "protective, bona fide research, or other peaceful purposes.";

(2) in section 175b—

(A) in subsection (a)(1), by striking "described in subsection (b)" and all that follows and inserting the following: "shall ship or transport in or affecting interstate or foreign commerce, or possess in or affecting interstate or foreign commerce, any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent in Appendix A of part 72 of title 42, Code of Federal Regulations, pursuant to section 351A of the Public Health Service Act, and is not exempted under subsection (h) of section 72.6, or Appendix A of part 72, of title 42, Code of Federal Regulations."; and

(B) in subsection (d)(3), by striking "section 1010(a)(3)" and inserting "section 101(a)(3)";

(3) in section 176(a)(1)(A), by striking "exists by reason of" and inserting "pertains to"; and

(4) in section 178—

(A) in paragraph (1), by striking "means any microorganism" and all that follows through "product, capable of" and inserting the following: "means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of";

(B) in paragraph (2), by striking "means the toxic" and all that follows through "including—" and inserting the following: "means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes—"; and

(C) in paragraph (4), by striking "recombinant molecule," and all that follows through "biotechnology," and inserting "recombinant or synthesized molecule,".

(d) ADDITIONAL TECHNICAL CORRECTION.—Section 2332a of title 18, United States Code, is amended—

(1) in subsection (a), in the matter preceding paragraph (1), by striking "section 229F)" and all that follows through "section 178)—" and inserting "section 229F)—"; and

(2) in subsection (c)(2)(C), by striking "a disease organism" and inserting "a biological agent, toxin, or vector (as those terms are defined in section 178 of this title)".

TITLE III—PROTECTING SAFETY AND SECURITY OF FOOD AND DRUG SUPPLY

Subtitle A—Protection of Food Supply

21 USC 341 note.

SEC. 301. FOOD SAFETY AND SECURITY STRATEGY.

(a) IN GENERAL.—The President's Council on Food Safety (as established by Executive Order No. 13100) shall, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, 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; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of implementing the strategy developed under subsection (a), there are authorized to be appropriated $750,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 302. PROTECTION AGAINST ADULTERATION OF FOOD.

(a) INCREASING INSPECTIONS FOR DETECTION OF ADULTERATION OF FOOD.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following subsection:

"(h)(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.".

(b) IMPROVEMENTS TO INFORMATION MANAGEMENT SYSTEMS.—Section 801(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section, is amended by adding at the end the following paragraph:

"(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this Act.".

(c) LINKAGES WITH APPROPRIATE PUBLIC ENTITIES.—Section 801(h) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b) of this section, is amended by adding at the end the following paragraph:

"(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages

with the States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))).".

(d) TESTING FOR RAPID DETECTION OF ADULTERATION OF FOOD.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a) of this section, is amended by adding at the end the following:

"(i)(1) For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

"(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

"(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

"(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

"(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

"(4) The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).". Reports.

(e) ASSESSMENT OF THREAT OF INTENTIONAL ADULTERATION OF FOOD.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall ensure that, not later than six months after the date of the enactment of this Act— Deadline.

(1) the assessment that (as of such date of enactment) is being conducted on the threat of the intentional adulteration of food is completed; and

(2) a report describing the findings of the assessment is submitted to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Health, Education, Labor, and Pensions of the Senate. Reports.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section and the amendments made by this section, there are authorized to be appropriated $100,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006, in addition to other authorizations of appropriations that are available for such purpose.

SEC. 303. 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 subsection:

"(h) ADMINISTRATIVE DETENTION OF FOODS.—

"(1) DETENTION AUTHORITY.—

"(A) IN GENERAL.—An 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 such article presents a threat of serious adverse health consequences or death to humans or animals.

"(B) SECRETARY'S APPROVAL.—An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

"(2) PERIOD OF DETENTION.—An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

Regulation.

"(3) SECURITY OF DETAINED ARTICLE.—An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

"(4) APPEAL OF DETENTION ORDER.—

"(A) IN GENERAL.—With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

"(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 302 regarding the article of food involved.".

(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:

"(bb) The transfer 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 to identify the article as detained.".

(c) TEMPORARY HOLDS AT PORTS OF ENTRY.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 302(d)of this Act, is amended by adding at the end the following: 21 USC 381.

"(j)(1) If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and such officer or qualified employee is unable to inspect, examine, or investigate such article upon the article being offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

"(2) The Secretary shall request the Secretary of Treasury to remove an article held pursuant to paragraph (1) to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held.

"(3) An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

"(4) With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that such article is being held under this subsection.".

SEC. 304. 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) in subparagraph (A), by striking "or" after the comma at the end;

(B) in subparagraph (B), by striking the period at the end and inserting ", or"; and

(C) by adding at the end the following subparagraph:

"(C) a person from importing an article of food or offering such an article for import into the United States.".

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

(A) in paragraph (2), in the matter preceding subparagraph (A), by inserting "subparagraph (A) or (B) of" before "paragraph (1)";

(B) by redesignating paragraph (3) as paragraph (4); and

(C) by inserting after paragraph (2) the following paragraph:

"(3) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; FOOD IMPORTATION.—A person is subject to debarment under paragraph (1)(C) if—

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

"(B) 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.".

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

(1) in subsection (a), in the heading for the subsection, by striking "MANDATORY DEBARMENT.—" and inserting "MANDATORY DEBARMENT; CERTAIN DRUG APPLICATIONS.—";

(2) in subsection (b)—

(A) in the heading for the subsection, by striking "PERMISSIVE DEBARMENT.—" and inserting "PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS; FOOD IMPORTS.—"; and

(B) in paragraph (2), in the heading for the paragraph, by striking "PERMISSIVE DEBARMENT.—" and inserting "PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS.—";

(3) in subsection (c)(2)(A)(iii), by striking "subsection (b)(2)" and inserting "paragraph (2) or (3) of subsection (b)";

(4) in subsection (d)(3)—

(A) in subparagraph (A)(i), by striking "or (b)(2)(A)" and inserting " or paragraph (2)(A) or (3) of subsection (b)";

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

(C) in subparagraph (B), in each of clauses (i) and (ii), by inserting "or subsection (b)(3)" after "subsection (b)(2)(B)"; and

(D) in subparagraph (B)(ii), by inserting before the period the following: "or the food importation process, as the case may be".

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

(1) in the first sentence—

(A) by striking "and" after "subsection (b)(2),"; and

(B) by inserting ", and subsection (b)(3)(A)" after "subsection (b)(2)(B)"; and

(2) in the second sentence, by inserting ", subsection (b)(3)(B)," after "subsection (b)(2)(B)".

(d) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 303(b) of this Act, is amended by adding at the end the following:

"(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 306(b)(3).".

(e) IMPORTATION BY DEBARRED PERSONS.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 303(c) of this Act, is amended by adding at the end the following subsection: 21 USC 381.

"(k)(1) If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person who has been debarred under section 306(b)(3), such article shall be held at the port of entry for the article, and may not be delivered to such person. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

"(2) An article of food held under paragraph (1) may be delivered to a person who is not a debarred person under section 306(b)(3) if such person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this Act, as determined by the Secretary.".

SEC. 305. REGISTRATION OF FOOD FACILITIES.

(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. 415. REGISTRATION OF FOOD FACILITIES. 21 USC 350d.

"(a) REGISTRATION.—

"(1) IN GENERAL.—The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. To be registered— Regulations.

"(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 registration 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, packed, or held at such facility. The registrant shall notify the Secretary in a timely manner of changes to such information. Notification.

"(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. Notification.

"(4) LIST.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. Such list and any registration documents submitted pursuant Records.

to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code. Information derived from such list or registration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered person.

"(b) FACILITY.—For purposes of this section:

"(1) The term 'facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).

"(2) The term 'domestic facility' means a facility located in any of the States or Territories.

"(3)(A) The term 'foreign facility' means a facility that manufacturers, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States.

"(B) A food may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the food.

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

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 304(d) of this Act, is amended by adding at the end the following:

"(dd) The failure to register in accordance with section 415.".

(c) IMPORTATION; FAILURE TO REGISTER.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 304(e) of this Act, is amended by adding at the end the following subsection:

21 USC 381.

"(l)(1) If an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415, such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.".

21 USC 350d note.

(d) ELECTRONIC FILING.—For the purpose of reducing paperwork and reporting burdens, the Secretary of Health and Human Services may provide for, and encourage the use of, electronic methods of submitting to the Secretary registrations required pursuant to this section. In providing for the electronic submission of

such registrations, the Secretary shall ensure adequate authentication protocols are used to enable identification of the registrant and validation of the data as appropriate.

(e) RULEMAKING; EFFECTIVE DATE.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed and final regulations for the requirement of registration under section 415 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section). Such requirement of registration takes effect— Deadline.

(1) upon the effective date of such final regulations; or

(2) upon the expiration of such 18-month period if the final regulations have not been made effective as of the expiration of such period, subject to compliance with the final regulations when the final regulations are made effective.

SEC. 306. MAINTENANCE AND INSPECTION OF RECORDS FOR FOODS.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 305 of this Act, is amended by inserting before section 415 the following section:

"SEC. 414. MAINTENANCE AND INSPECTION OF RECORDS. 21 USC 350c.

"(a) RECORDS INSPECTION.—If the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article 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 copy all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The requirement under the preceding sentence applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location. Applicability.

"(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

"(c) PROTECTION OF SENSITIVE INFORMATION.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

"(d) LIMITATIONS.—This section shall not be construed—

"(1) to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of 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 have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code; or

"(4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).".

(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 inserting after the first sentence the following new sentence: "In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d).."; 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 paragraph (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 paragraph (j), by inserting "414," after "412,".

Deadline. 21 USC 350c note.

(d) EXPEDITED RULEMAKING.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall promulgate proposed and final regulations establishing recordkeeping requirements under subsection 414(b) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

SEC. 307. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 305(c) of this Act, is amended by adding at the end the following subsection:

Regulations.

"(m)(1) In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be

provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

"(2)(A) Regulations under paragraph (1) shall require that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration. Nothing in the preceding sentence may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

"(B)(i) If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary, and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1). Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

"(ii) In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

"(3)(A) This subsection may not be construed as limiting the authority of the Secretary to obtain information under any other provision of this Act.

"(B) This subsection may not be construed as authorizing 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.).".

21 USC 331.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 305(b) of this Act, is amended by adding at the end the following:

"(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m).".

21 USC 351 note.
Deadline.

(c) RULEMAKING; EFFECTIVE DATE.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed and final regulations for the requirement of providing notice in accordance with section 801(m) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section). Such requirement of notification takes effect—

(A) upon the effective date of such final regulations; or

(B) upon the expiration of such 18-month period if the final regulations have not been made effective as of the expiration of such period, subject to compliance with the final regulations when the final regulations are made effective.

(2) DEFAULT; MINIMUM PERIOD OF ADVANCE NOTICE.—If under paragraph (1) the requirement for providing notice in accordance with section 801(m) of the Federal Food, Drug, and Cosmetic Act takes effect without final regulations having been made effective, then for purposes of such requirement, the specified period of time that the notice is required to be made in advance of the time of the importation of the article of food involved or the offering of the food for import shall be not fewer than eight hours and not more than five days, which shall remain in effect until the final regulations are made effective.

SEC. 308. AUTHORITY TO MARK ARTICLES REFUSED ADMISSION INTO UNITED STATES.

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended by section 307(a) of this Act, is amended by adding at the end the following:

"(n)(1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, the Secretary may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: 'UNITED STATES: REFUSED ENTRY'.

"(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.

"(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this Act.".

(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:

"(v) If—

"(1) it fails to bear a label required by the Secretary under section 801(n)(1) (relating to food refused admission into the United States);

"(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

"(3) upon or after notifying the owner or consignee involved that the label is required under section 801, the Secretary informs the owner or consignee that the food presents such a threat.".

(c) RULE OF CONSTRUCTION.—With respect to articles of food that are imported or offered for import into the United States, 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 of food under any other provision of law. 21 USC 381 note.

SEC. 309. PROHIBITION AGAINST PORT SHOPPING.

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 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. 310. NOTICES TO STATES REGARDING IMPORTED FOOD.

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 section:

"SEC. 908. NOTICES TO STATES REGARDING IMPORTED FOOD. 21 USC 398.

"(a) IN GENERAL.—If the Secretary has credible evidence or information indicating that a shipment of imported food or portion thereof presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall provide notice regarding such threat to the States in which the food is held or will be held, and to the States in which the manufacturer, packer, or distributor of the food is located, to the extent that the Secretary has knowledge of which States are so involved. In providing notice to a State, the Secretary shall request the State to take such action as the State considers appropriate, if any, to protect the public health regarding the food involved.

"(b) RULE OF CONSTRUCTION.—Subsection (a) may not be construed as limiting the authority of the Secretary with respect to food under any other provision of this Act.".

SEC. 311. GRANTS TO STATES FOR INSPECTIONS.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as amended by section 310 of this Act, is amended by adding at the end the following section:

"SEC. 909. GRANTS TO STATES FOR INSPECTIONS. 21 USC 399.

"(a) IN GENERAL.—The Secretary is authorized to make grants to States, territories, and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) 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) NOTICES REGARDING ADULTERATED IMPORTED FOOD.—The Secretary may make grants to the States for the purpose of assisting the States with the costs of taking appropriate action to protect the public health in response to notification under section 908, including planning and otherwise preparing to take such action.

"(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.".

SEC. 312. 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:

42 USC 247b–20.

"SEC. 317R. FOOD SAFETY GRANTS.

"(a) IN GENERAL.—The Secretary may award grants to States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

"(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $19,500,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.".

7 USC 8319.

SEC. 313. SURVEILLANCE OF ZOONOTIC DISEASES.

The Secretary of Health and Human Services, through the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture shall coordinate the surveillance of zoonotic diseases.

SEC. 314. 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—

(1) by striking "(a)" and inserting "(a)(1)";

(2) by striking "In the case of food packed" and inserting the following:

"(3) In the case of food packed";

(3) by striking "For the purposes of this subsection" and inserting the following:

"(4) For the purposes of this subsection,"; and

(4) by inserting after paragraph (1) (as designated by paragraph (1) of this section) the following paragraph:

"(2)(A) In addition to the authority established in paragraph (1), the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal department or agency, is authorized to conduct examinations and investigations for the purposes of this Act through the officers and employees of such other department or agency, subject to subparagraph (B). Such a memorandum shall include provisions to ensure adequate training of such officers and employees to conduct the examinations

and investigations. The memorandum of understanding shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other department or agency.

"(B) A memorandum of understanding under subparagraph (A) between the Secretary and another Federal department or agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and such department or agency.

"(C) For any fiscal year in which the Secretary and the head of another Federal department or agency carries out one or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of such department or agency shall with respect to their respective departments or agencies submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for such year— Reports.

"(i) the number of officers or employees that carried out one or more programs, projects, or activities under such memorandum;

"(ii) the number of additional articles that were inspected or examined as a result of such memorandum; and

"(iii) the number of additional examinations or investigations that were carried out pursuant to such memorandum.".

SEC. 315. RULE OF CONSTRUCTION. 21 USC 331 note.

Nothing in this title, or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations.

Subtitle B—Protection of Drug Supply

SEC. 321. ANNUAL REGISTRATION OF FOREIGN MANUFACTURERS; SHIPPING INFORMATION; DRUG AND DEVICE LISTING.

(a) ANNUAL REGISTRATION; LISTING.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

(1) in subsection (i)(1)—

(A) by striking "Any establishment" and inserting "On or before December 31 of each year, any establishment"; and

(B) by striking "shall register" and all that follows and inserting the following: "shall, through electronic means in accordance with the criteria of the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation."; and

(2) in subsection (j)(1), in the first sentence, by striking "or (d)" and inserting "(d), or (i)".

(b) IMPORTATION; STATEMENT REGARDING REGISTRATION OF MANUFACTURER.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 308(a) of this Act, is amended by adding at the end the following subsection:

"(o) If an article that is a drug or device is being imported or offered for import into the United States, and the importer, owner, or consignee of such article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 510(i) of each establishment that with respect to such article is required under such section to register with the Secretary, the article may be refused admission. If the article is refused admission for failure to submit such a statement, the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such a statement is submitted to the Secretary. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.".

(2) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 307(b) of this Act, is amended by adding at the end the following:

"(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).".

21 USC 331 note.

(c) EFFECTIVE DATE.—The amendments made by this section take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act.

SEC. 322. REQUIREMENT OF ADDITIONAL INFORMATION REGARDING IMPORT COMPONENTS INTENDED FOR USE IN EXPORT PRODUCTS.

(a) IN GENERAL.—Section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)(3)) is amended to read as follows:

"(3)(A) Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

"(i) The importer of such article of a drug or device or importer of such article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

"(I) Such statement provides that such article is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive,

color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

"(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

"(III) The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an article described in paragraph (4).

"(ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

"(iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

"(iv) The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary. Records.

"(v) Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph. Reports.

"(B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

"(C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation.".

(b) PROHIBITED ACT.—Section 301(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(w)) is amended to read as follows:

"(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in

accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.".

21 USC 331 note.

(c) EFFECTIVE DATE.—The amendments made by this section take effect upon the expiration of the 90-day period beginning on the date of the enactment of this Act.

Subtitle C—General Provisions Relating to Upgrade of Agricultural Security

7 USC 8320.

SEC. 331. EXPANSION OF ANIMAL AND PLANT HEALTH INSPECTION SERVICE ACTIVITIES.

(a) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the "Secretary") may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Animal and Plant Health Inspection Service to conduct 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) develop new and improve existing 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 improve the capacity of the Service to protect against the threat of bioterrorism.

(b) AUTOMATED RECORDKEEPING SYSTEM.—The Administrator of the Animal and Plant Health Inspection Service may 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.

(c) 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. 332. EXPANSION OF FOOD SAFETY INSPECTION SERVICE ACTIVITIES. 21 USC 679c.

(a) IN GENERAL.—The Secretary of Agriculture may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Food Safety Inspection Service to conduct 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 (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) 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. 333. BIOSECURITY UPGRADES AT THE DEPARTMENT OF AGRICULTURE. Appropriation authorization. State listing.

There is authorized to be appropriated for fiscal year 2002, $180,000,000 for the purpose of enabling the Agricultural Research Service to conduct building upgrades to modernize existing facilities, of which (1) $100,000,000 shall be 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 shall be allocated for the Agricultural Research Service/Animal and Plant Health Inspection Service facility in Ames, Iowa. There are authorized to be appropriated such sums as may be necessary for fiscal years 2003 through 2006 for the purpose described in the preceding sentence, for the planning and design of an Agricultural Research Service biocontainment laboratory for poultry research in Athens, Georgia, and for the planning, updating, and renovation of the Arthropod-Borne Animal Disease Laboratory in Laramie, Wyoming.

SEC. 334. AGRICULTURAL BIOSECURITY. 7 USC 3353.

(a) SECURITY AT COLLEGES AND UNIVERSITIES.—

(1) GRANTS.—The Secretary of Agriculture (referred to in this section as the "Secretary") may award grants to covered entities to review security standards and practices at their facilities in order to protect against bioterrorist attacks.

(2) COVERED ENTITIES.—Covered entities under this subsection are colleges or universities that—

(A) are colleges or universities as defined in section 1404 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3103); and

(B) have programs in food and agricultural sciences, as defined in such section.

(3) LIMITATION.—Each individual covered entity may be awarded one grant under paragraph (1), the amount of which shall not exceed $50,000.

(4) CONTRACT AUTHORITY.—Colleges and universities receiving grants under paragraph (1) may use such grants to enter into contracts with independent private organizations with established and demonstrated security expertise to conduct the security reviews specified in such paragraph.

(b) GUIDELINES FOR AGRICULTURAL BIOSECURITY.—

(1) IN GENERAL.—The Secretary may award grants to associations of food producers or consortia of such associations for the development and implementation of educational programs to improve biosecurity on farms in order to ensure the security of farm facilities against potential bioterrorist attacks.

(2) LIMITATION.—Each individual association eligible under paragraph (1) may be awarded one grant under such paragraph, the amount of which shall not exceed $100,000. Each consortium eligible under paragraph (1) may be awarded one grant under such paragraph, the amount of which shall not exceed $100,000 per association participating in the consortium.

(3) CONTRACT AUTHORITY.—Associations of food producers receiving grants under paragraph (1) may use such grants to enter into contracts with independent private organizations with established and demonstrated expertise in biosecurity to assist in the development and implementation of educational programs to improve biosecurity specified in such paragraph.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each fiscal year.

7 USC 3354.

SEC. 335. AGRICULTURAL BIOTERRORISM RESEARCH AND DEVELOPMENT.

(a) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the "Secretary") may utilize existing research authorities and research programs to protect the food supply of the United States by conducting and supporting research activities to—

(1) enhance the capability of the Secretary to respond in a timely manner to emerging or existing bioterrorist threats to the food and agricultural system of the United States;

(2) develop new and continue partnerships with institutions of higher education and other institutions to help form stable, long-term programs to enhance the biosecurity and food safety of the United States, including the coordination of the development, implementation, and enhancement of diverse capabilities for addressing threats to the nation's agricultural economy and food supply, with special emphasis on planning, training, outreach, and research activities related to vulnerability analyses, incident response, detection, and prevention technologies;

(3) strengthen coordination with the intelligence community to better identify research needs and evaluate materials or information acquired by the intelligence community relating to potential threats to United States agriculture;

(4) expand the involvement of the Secretary with international organizations dealing with plant and animal disease control;

(5) continue research to develop rapid detection field test kits to detect biological threats to plants and animals and to provide such test kits to State and local agencies preparing for or responding to bioterrorism;

(6) develop an agricultural bioterrorism early warning surveillance system through enhancing the capacity of and coordination between State veterinary diagnostic laboratories, Federal and State agricultural research facilities, and public health agencies; and

(7) otherwise improve the capacity of the Secretary 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.

SEC. 336. ANIMAL ENTERPRISE TERRORISM PENALTIES.

(a) IN GENERAL.—Section 43(a) of title 18, United States Code, is amended to read as follows:

"(a) OFFENSE.—Whoever—

"(1) travels in interstate or foreign commerce, or uses or causes to be used the mail or any facility in interstate or foreign commerce for the purpose of causing physical disruption to the functioning of an animal enterprise; and

"(2) intentionally damages or causes the loss of any property (including animals or records) used by the animal enterprise, or conspires to do so,

shall be punished as provided for in subsection (b).".

(b) PENALTIES.—Section 43(b) of title 18, United States Code, is amended to read as follows:

"(b) PENALTIES.—

"(1) ECONOMIC DAMAGE.—Any person who, in the course of a violation of subsection (a), causes economic damage not exceeding $10,000 to an animal enterprise shall be fined under this title or imprisoned not more than 6 months, or both.

"(2) MAJOR ECONOMIC DAMAGE.—Any person who, in the course of a violation of subsection (a), causes economic damage exceeding $10,000 to an animal enterprise shall be fined under this title or imprisoned not more than 3 years, or both.

"(3) SERIOUS BODILY INJURY.—Any person who, in the course of a violation of subsection (a), causes serious bodily injury to another individual shall be fined under this title or imprisoned not more than 20 years, or both.

"(4) DEATH.—Any person who, in the course of a violation of subsection (a), causes the death of an individual shall be fined under this title and imprisoned for life or for any term of years.".

(c) RESTITUTION.—Section 43(c) of title 18, United States Code, is amended—

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

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

(3) by adding at the end the following:

"(3) for any other economic damage resulting from the offense.".

TITLE IV—DRINKING WATER SECURITY AND SAFETY

SEC. 401. TERRORIST AND OTHER INTENTIONAL ACTS.

The Safe Drinking Water Act (title XIV of the Public Health Service Act) is amended by inserting the following new section after section 1432:

42 USC 300i–2.

"SEC. 1433. TERRORIST AND OTHER INTENTIONAL ACTS.

"(a) VULNERABILITY ASSESSMENTS.—(1) Each community water system serving a population of greater than 3,300 persons shall conduct an assessment of the vulnerability of its system to a terrorist attack or other intentional acts intended to substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water. The vulnerability assessment shall include, but not be limited to, a review of pipes and constructed conveyances, physical barriers, water collection, pretreatment, treatment, storage and distribution facilities, electronic, computer or other automated systems which are utilized by the public water system, the use, storage, or handling of various chemicals, and the operation and maintenance of such system. The Administrator, not later than August 1, 2002, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall provide baseline information to community water systems required to conduct vulnerability assessments regarding which kinds of terrorist attacks or other intentional acts are the probable threats to—

Deadline.

"(A) substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water; or

"(B) otherwise present significant public health concerns.

Certification. Deadlines.

"(2) Each community water system referred to in paragraph (1) shall certify to the Administrator that the system has conducted an assessment complying with paragraph (1) and shall submit to the Administrator a written copy of the assessment. Such certification and submission shall be made prior to:

"(A) March 31, 2003, in the case of systems serving a population of 100,000 or more.

"(B) December 31, 2003, in the case of systems serving a population of 50,000 or more but less than 100,000.

"(C) June 30, 2004, in the case of systems serving a population greater than 3,300 but less than 50,000.

"(3) Except for information contained in a certification under this subsection identifying the system submitting the certification and the date of the certification, all information provided to the Administrator under this subsection and all information derived therefrom shall be exempt from disclosure under section 552 of title 5 of the United States Code.

"(4) No community water system shall be required under State or local law to provide an assessment described in this section to any State, regional, or local governmental entity solely by reason of the requirement set forth in paragraph (2) that the system submit such assessment to the Administrator.

Deadlines. Protocols.

"(5) Not later than November 30, 2002, the Administrator, in consultation with appropriate Federal law enforcement and intelligence officials, shall develop such protocols as may be necessary to protect the copies of the assessments required to be submitted

under this subsection (and the information contained therein) from unauthorized disclosure. Such protocols shall ensure that—

"(A) each copy of such assessment, and all information contained in or derived from the assessment, is kept in a secure location;

"(B) only individuals designated by the Administrator may have access to the copies of the assessments; and

"(C) no copy of an assessment, or part of an assessment, or information contained in or derived from an assessment shall be available to anyone other than an individual designated by the Administrator.

At the earliest possible time prior to November 30, 2002, the Administrator shall complete the development of such protocols for the purpose of having them in place prior to receiving any vulnerability assessments from community water systems under this subsection.

"(6)(A) Except as provided in subparagraph (B), any individual referred to in paragraph (5)(B) who acquires the assessment submitted under paragraph (2), or any reproduction of such assessment, or any information derived from such assessment, and who knowingly or recklessly reveals such assessment, reproduction, or information other than—

"(i) to an individual designated by the Administrator under paragraph (5),

"(ii) for purposes of section 1445 or for actions under section 1431, or

"(iii) for use in any administrative or judicial proceeding to impose a penalty for failure to comply with this section,

shall upon conviction be imprisoned for not more than one year or fined in accordance with the provisions of chapter 227 of title 18, United States Code, applicable to class A misdemeanors, or both, and shall be removed from Federal office or employment.

"(B) Notwithstanding subparagraph (A), an individual referred to in paragraph (5)(B) who is an officer or employee of the United States may discuss the contents of a vulnerability assessment submitted under this section with a State or local official.

"(7) Nothing in this section authorizes any person to withhold any information from Congress or from any committee or subcommittee of Congress.

"(b) EMERGENCY RESPONSE PLAN.—Each community water system serving a population greater than 3,300 shall prepare or revise, where necessary, an emergency response plan that incorporates the results of vulnerability assessments that have been completed. Each such community water system shall certify to the Administrator, as soon as reasonably possible after the enactment of this section, but not later than 6 months after the completion of the vulnerability assessment under subsection (a), that the system has completed such plan. The emergency response plan shall include, but not be limited to, plans, procedures, and identification of equipment that can be implemented or utilized in the event of a terrorist or other intentional attack on the public water system. The emergency response plan shall also include actions, procedures, and identification of equipment which can obviate or significantly lessen the impact of terrorist attacks or other intentional actions on the public health and the safety and supply of drinking water provided to communities and individuals. Community water systems

Certification.
Deadline.

shall, to the extent possible, coordinate with existing Local Emergency Planning Committees established under the Emergency Planning and Community Right-to-Know Act (42 U.S.C. 11001 et seq.) when preparing or revising an emergency response plan under this subsection.

"(c) RECORD MAINTENANCE.—Each community water system shall maintain a copy of the emergency response plan completed pursuant to subsection (b) for 5 years after such plan has been certified to the Administrator under this section.

"(d) GUIDANCE TO SMALL PUBLIC WATER SYSTEMS.—The Administrator shall provide guidance to community water systems serving a population of less than 3,300 persons on how to conduct vulnerability assessments, prepare emergency response plans, and address threats from terrorist attacks or other intentional actions designed to disrupt the provision of safe drinking water or significantly affect the public health or significantly affect the safety or supply of drinking water provided to communities and individuals.

"(e) FUNDING.—(1) There are authorized to be appropriated to carry out this section not more than $160,000,000 for the fiscal year 2002 and such sums as may be necessary for the fiscal years 2003 through 2005.

"(2) The Administrator, in coordination with State and local governments, may use funds made available under paragraph (1) to provide financial assistance to community water systems for purposes of compliance with the requirements of subsections (a) and (b) and to community water systems for expenses and contracts designed to address basic security enhancements of critical importance and significant threats to public health and the supply of drinking water as determined by a vulnerability assessment conducted under subsection (a). Such basic security enhancements may include, but shall not be limited to the following:

"(A) the purchase and installation of equipment for detection of intruders;

"(B) the purchase and installation of fencing, gating, lighting, or security cameras;

"(C) the tamper-proofing of manhole covers, fire hydrants, and valve boxes;

"(D) the rekeying of doors and locks;

"(E) improvements to electronic, computer, or other automated systems and remote security systems;

"(F) participation in training programs, and the purchase of training manuals and guidance materials, relating to security against terrorist attacks;

"(G) improvements in the use, storage, or handling of various chemicals; and

"(H) security screening of employees or contractor support services.

Funding under this subsection for basic security enhancements shall not include expenditures for personnel costs, or monitoring, operation, or maintenance of facilities, equipment, or systems.

"(3) The Administrator may use not more than $5,000,000 from the funds made available under paragraph (1) to make grants to community water systems to assist in responding to and alleviating any vulnerability to a terrorist attack or other intentional acts intended to substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water (including

sources of water for such systems) which the Administrator determines to present an immediate and urgent security need.

"(4) The Administrator may use not more than $5,000,000 from the funds made available under paragraph (1) to make grants to community water systems serving a population of less than 3,300 persons for activities and projects undertaken in accordance with the guidance provided to such systems under subsection (d).

SEC. 402. OTHER SAFE DRINKING WATER ACT AMENDMENTS.

The Safe Drinking Water Act (title XIV of the Public Health Service Act) is amended by inserting the following new sections after section 1433 (as added by section 401 of this Act):

"SEC. 1434. CONTAMINANT PREVENTION, DETECTION AND RESPONSE. 42 USC 300i–3.

"(a) IN GENERAL.—The Administrator, in consultation with the Centers for Disease Control and, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall review (or enter into contracts or cooperative agreements to provide for a review of) current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for community water systems, including each of the following: Contracts.

"(1) Methods, means and equipment, including real time monitoring systems, designed to monitor and detect various levels of chemical, biological, and radiological contaminants or indicators of contaminants and reduce the likelihood that such contaminants can be successfully introduced into public water systems and source water intended to be used for drinking water.

"(2) Methods and means to provide sufficient notice to operators of public water systems, and individuals served by such systems, of the introduction of chemical, biological or radiological contaminants and the possible effect of such introduction on public health and the safety and supply of drinking water.

"(3) Methods and means for developing educational and awareness programs for community water systems.

"(4) Procedures and equipment necessary to prevent the flow of contaminated drinking water to individuals served by public water systems.

"(5) Methods, means, and equipment which could negate or mitigate deleterious effects on public health and the safety and supply caused by the introduction of contaminants into water intended to be used for drinking water, including an examination of the effectiveness of various drinking water technologies in removing, inactivating, or neutralizing biological, chemical, and radiological contaminants.

"(6) Biomedical research into the short-term and long-term impact on public health of various chemical, biological and radiological contaminants that may be introduced into public water systems through terrorist or other intentional acts.

"(b) FUNDING.—For the authorization of appropriations to carry out this section, see section 1435(e).

42 USC 300i–4.

"SEC. 1435. SUPPLY DISRUPTION PREVENTION, DETECTION AND RESPONSE.

Contracts.

"(a) DISRUPTION OF SUPPLY OR SAFETY.—The Administrator, in coordination with the appropriate departments and agencies of the Federal Government, shall review (or enter into contracts or cooperative agreements to provide for a review of) methods and means by which terrorists or other individuals or groups could disrupt the supply of safe drinking water or take other actions against water collection, pretreatment, treatment, storage and distribution facilities which could render such water significantly less safe for human consumption, including each of the following:

"(1) Methods and means by which pipes and other constructed conveyances utilized in public water systems could be destroyed or otherwise prevented from providing adequate supplies of drinking water meeting applicable public health standards.

"(2) Methods and means by which collection, pretreatment, treatment, storage and distribution facilities utilized or used in connection with public water systems and collection and pretreatment storage facilities used in connection with public water systems could be destroyed or otherwise prevented from providing adequate supplies of drinking water meeting applicable public health standards.

"(3) Methods and means by which pipes, constructed conveyances, collection, pretreatment, treatment, storage and distribution systems that are utilized in connection with public water systems could be altered or affected so as to be subject to cross-contamination of drinking water supplies.

"(4) Methods and means by which pipes, constructed conveyances, collection, pretreatment, treatment, storage and distribution systems that are utilized in connection with public water systems could be reasonably protected from terrorist attacks or other acts intended to disrupt the supply or affect the safety of drinking water.

"(5) Methods and means by which information systems, including process controls and supervisory control and data acquisition and cyber systems at community water systems could be disrupted by terrorists or other groups.

"(b) ALTERNATIVE SOURCES.—The review under this section shall also include a review of the methods and means by which alternative supplies of drinking water could be provided in the event of the destruction, impairment or contamination of public water systems.

"(c) REQUIREMENTS AND CONSIDERATIONS.—In carrying out this section and section 1434—

"(1) the Administrator shall ensure that reviews carried out under this section reflect the needs of community water systems of various sizes and various geographic areas of the United States; and

"(2) the Administrator may consider the vulnerability of, or potential for forced interruption of service for, a region or service area, including community water systems that provide service to the National Capital area.

"(d) INFORMATION SHARING.—As soon as practicable after reviews carried out under this section or section 1434 have been evaluated, the Administrator shall disseminate, as appropriate as determined by the Administrator, to community water systems

information on the results of the project through the Information Sharing and Analysis Center, or other appropriate means.

"(e) FUNDING.—There are authorized to be appropriated to carry out this section and section 1434 not more than $15,000,000 for the fiscal year 2002 and such sums as may be necessary for the fiscal years 2003 through 2005.".

SEC. 403. MISCELLANEOUS AND TECHNICAL AMENDMENTS.

The Safe Drinking Water Act is amended as follows:

(1) Section 1414(i)(1) is amended by inserting "1433" after "1417". 42 USC 300g–3.

(2) Section 1431 is amended by inserting in the first sentence after "drinking water" the following: ", or that there is a threatened or potential terrorist attack (or other intentional act designed to disrupt the provision of safe drinking water or to impact adversely the safety of drinking water supplied to communities and individuals), which". 42 USC 300i.

(3) Section 1432 is amended as follows: 42 USC 300i–1.

(A) By striking "5 years" in subsection (a) and inserting "20 years".

(B) By striking "3 years" in subsection (b) and inserting "10 years".

(C) By striking "$50,000" in subsection (c) and inserting "$1,000,000".

(D) By striking "$20,000" in subsection (c) and inserting "$100,000".

(4) Section 1442 is amended as follows: 42 USC 300j–1.

(A) By striking "this subparagraph" in subsection (b) and inserting "this subsection".

(B) By amending subsection (d) to read as follows:

"(d) There are authorized to be appropriated to carry out subsection (b) not more than $35,000,000 for the fiscal year 2002 and such sums as may be necessary for each fiscal year thereafter.". Appropriation authorization.

TITLE V—ADDITIONAL PROVISIONS

Subtitle A—Prescription Drug User Fees

Prescription Drug User Fee Amendments of 2002.

SEC. 501. SHORT TITLE. 21 USC 301 note.

This subtitle may be cited as the "Prescription Drug User Fee Amendments of 2002".

SEC. 502. FINDINGS. 21 USC 379g note.

The Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of human drug applications and the assurance of drug safety;

(3) the provisions added by the Prescription Drug User Fee Act of 1992, as amended by the Food and Drug Administration Modernization Act of 1997, have been successful in

substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration, including—

(i) strengthening and improving the review and monitoring of drug safety;

(ii) considering greater interaction between the agency and sponsors during the review of drugs and biologics intended to treat serious diseases and life-threatening diseases; and

(iii) developing principles for improving first-cycle reviews; and

(4) the fees authorized by amendments made in this subtitle will be dedicated towards expediting the drug development process and the process for the review of human drug applications as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the chairman of the Committee on Energy and Commerce of the House of Representatives and the chairman of the Committee on Health, Education, Labor and Pensions of the Senate, as set forth in the Congressional Record.

SEC. 503. DEFINITIONS.

Section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) is amended—

(1) in paragraph (1), in the matter after and below subparagraph (C), by striking "licensure, as described in subparagraph (D)" and inserting "licensure, as described in subparagraph (C)";

(2) in paragraph (3)—

(A) in subparagraph (A), by striking "and" at the end;

(B) in subparagraph (B), by striking the period and inserting ", and";

(C) by inserting after subparagraph (B) the following subparagraph:

"(C) which is on the list of products described in section 505(j)(7)(A) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act."; and

(D) in the matter after and below subparagraph (C) (as added by subparagraph (C) of this paragraph), by striking "Service Act," and all that follows through "biological product" and inserting the following: "Service Act. Such term does not include a biological product";

(3) in paragraph (6), by adding at the end the following subparagraph:

"(F) In the case of drugs approved after October 1, 2002, under human drug applications or supplements: collecting, developing, and reviewing safety information on the drugs, including adverse event reports, during a period

of time after approval of such applications or supplements, not to exceed three years."; and

(4) in paragraph (8)—

(A) by striking the matter after and below subparagraph (B);

(B) by striking subparagraph (B);

(C) by striking "is the lower of" and all that follows through "Consumer Price Index" and inserting "is the Consumer Price Index"; and

(D) by striking "1997, or" and inserting "1997.".

SEC. 504. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking "fiscal year 1998" and inserting "fiscal year 2003";

(2) in paragraph (1)(A)—

(A) in each of clauses (i) and (ii), by striking "in subsection (b)" and inserting "under subsection (c)(4)"; and

(B) in clause (ii), by adding at the end the following sentence: "Such fee shall be half of the amount of the fee established under clause (i).";

(3) in paragraph (2)(A), in the matter after and below clause (ii)—

(A) by striking "in subsection (b)" and inserting "under subsection (c)(4)"; and

(B) by striking "payable on or before January 31" and inserting "payable on or before October 1"; and

(4) in paragraph (3)—

(A) by amending subparagraph (A) to read as follows:

"(A) IN GENERAL.—Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under subsection (c)(4). Such fee shall be payable on or before October 1 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable."; and

(B) in subparagraph (B), by striking "The listing" and all that follows through "filed under section 505(b)(2)" and inserting the following: "A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 505(j)(7)(A) with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 505(b)".

(b) FEE AMOUNTS.—Section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts:

"Type of Fee Revenue	Fiscal Year 2003	Fiscal Year 2004	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007
Application/Supplement	$74,300,000	$77,000,000	$84,000,000	$86,434,000	$86,434,000
Establishment	$74,300,000	$77,000,000	$84,000,000	$86,433,000	$86,433,000
Product	$74,300,000	$77,000,000	$84,000,000	$86,433,000	$86,433,000
Total Fee Revenue	$222,900,000	$231,000,000	$252,000,000	$259,300,000	$259,300,000

If, after the date of the enactment of the Prescription Drug User Fee Amendments of 2002, legislation is enacted requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of human drug applications.".

(c) ADJUSTMENTS.—Section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking "fees and total fee revenues" and inserting "revenues";

(B) in subparagraph (A)—

(i) by striking "during the preceding fiscal year"; and

(ii) by striking ", or" and inserting the following: "for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or";

(C) in subparagraph (B), by striking "for such fiscal year" and inserting "for the previous fiscal year"; and

(D) in the matter after and below subparagraph (B), by striking "fiscal year 1997"; and inserting "fiscal year 2003";

(2) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively;

(3) by inserting after paragraph (1) the following paragraphs:

Effective date.

"(2) WORKLOAD ADJUSTMENT.—Beginning with fiscal year 2004, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

"(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications, commercial investigational new drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

Federal Register, publication.

"(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for the fiscal year established in subsection (b), as adjusted for inflation under paragraph (1).

"(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of human drug applications for the first three months of fiscal year 2008. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2007. If the Secretary has carryover balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made."; and

(4) in paragraph (4) (as redesignated by paragraph (2) of this subsection), by amending such paragraph to read as follows:

"(4) ANNUAL FEE SETTING.—The Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2002, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.". Effective date.

(d) FEE WAIVER OR REDUCTION.—Section 736(d)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (C), by inserting "or" after the comma at the end;

(B) by striking subparagraph (D); and

(C) by redesignating subparagraph (E) as subparagraph (D); and

(2) in paragraph (3), in each of subparagraphs (A) and (B), by striking "paragraph (1)(E)" each place such term appears and inserting "paragraph (1)(D)".

(e) ASSESSMENT OF FEES.—Section 736(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)) is amended—

(1) in the heading for the subsection, by striking "ASSESSMENT OF FEES.—" and inserting "LIMITATIONS.—"; and

(2) in paragraph (1), by striking the heading for the paragraph and all that follows through "fiscal year beginning" and inserting the following: "IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning".

(f) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Section 736(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(1)) is amended by striking "Fees collected for a fiscal year" and all that follows through "fiscal year limitation." and inserting the following: "Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.".

(2) COLLECTIONS AND APPROPRIATION ACTS.—Section 736(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(2)) is amended—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(B) by striking "(2) COLLECTIONS" and all that follows through "the amount specified" in clause (i) (as so redesignated) and inserting the following:

"(2) COLLECTIONS AND APPROPRIATION ACTS.—

"(A) IN GENERAL.—The fees authorized by this section—

"(i) shall be retained in each fiscal year in an amount not to exceed the amount specified";

(C) by moving clause (ii) (as so redesignated) two ems to the right; and

(D) by adding at the end the following subparagraph:

"(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

"(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

"(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

"(II) such costs are not more than 5 percent below the level specified in such subparagraph.".

(3) AUTHORIZATION OF APPROPRIATIONS.—Section 736(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(3)) is amended by striking subparagraphs (A) through (E) and inserting the following:

"(A) $222,900,000 for fiscal year 2003;

"(B) $231,000,000 for fiscal year 2004;

"(C) $252,000,000 for fiscal year 2005;

"(D) $259,300,000 for fiscal year 2006; and

"(E) $259,300,000 for fiscal year 2007;".

Effective dates. Deadlines. 21 USC 379g note.

SEC. 505. ACCOUNTABILITY AND REPORTS.

(a) PUBLIC ACCOUNTABILITY.—

(1) CONSULTATION.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of human drug applications for the fiscal years after fiscal year 2007, and for the reauthorization of sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.

Federal Register, publication.

(2) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under paragraph (1), after negotiations with the regulated industry; shall present such recommendations to the congressional committees specified in such paragraph; shall hold a meeting at which the public may present its views on such recommendations; and shall provide

for a period of 30 days for the public to provide written comments on such recommendations.

(b) PERFORMANCE REPORT.—Beginning with fiscal year 2003, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 502(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(c) FISCAL REPORT.—Beginning with fiscal year 2003, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (b), the Secretary of Health and Human Services shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 506. REPORTS OF POSTMARKETING STUDIES.

Section 506B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356b) is amended by adding at the end the following subsections:

"(d) DISCLOSURE.—If a sponsor fails to complete an agreed upon study required by this section by its original or otherwise negotiated deadline, the Secretary shall publish a statement on the Internet site of the Food and Drug Administration stating that the study was not completed and, if the reasons for such failure to complete the study were not satisfactory to the Secretary, a statement that such reasons were not satisfactory to the Secretary.

"(e) NOTIFICATION.—With respect to studies of the type required under section 506(b)(2)(A) or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as each of such sections was in effect on the day before the effective date of this subsection, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of such sections of such type for a drug or biological product (including such a study conducted after such effective date) notify practitioners who prescribe such drug or biological product of the failure to complete such study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete such study. Nothing in this subsection shall be construed as altering the requirements of the types of studies required under section 506(b)(2)(A) or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as so in effect, or as prohibiting the Secretary from modifying such sections of title 21 of such Code to provide for studies in addition to those of such type.".

21 USC 379g note.

SEC. 507. SAVINGS CLAUSE.

Notwithstanding section 107 of the Food and Drug Administration Modernization Act of 1997, and notwithstanding the amendments made by this subtitle, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, continues to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that, on or after October 1, 1997, but before October 1, 2002, were accepted by the Food and Drug Administration for filing and with respect to assessing and collecting any fee required by such Act for a fiscal year prior to fiscal year 2003.

21 USC 356b note.

SEC. 508. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect October 1, 2002.

21 USC 379g note.

SEC. 509. SUNSET CLAUSE.

The amendments made by sections 503 and 504 cease to be effective October 1, 2007, and section 505 ceases to be effective 120 days after such date.

Subtitle B—Funding Provisions Regarding Food and Drug Administration

SEC. 521. OFFICE OF DRUG SAFETY.

Of the amounts appropriated for the Food and Drug Administration for a fiscal year, the Secretary of Health and Human Services shall reserve for the Office of Drug Safety (within such Administration), the following amounts:

(1) For fiscal year 2003, an amount equal to the sum of $5,000,000 and the amount made available under appropriations Acts for such Office for fiscal year 2002.

(2) For fiscal year 2004, an amount equal to the sum of $10,000,000 and the amount made available under appropriations Acts for such Office for fiscal year 2002.

(3) For each subsequent fiscal year, an amount equal to the sum of the amount made available under appropriations Acts for such Office for fiscal year 2004 and an amount sufficient to offset the effects of inflation occurring after the beginning of fiscal year 2004.

Appropriation authorization.

SEC. 522. DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS.

For the Division of Drug Marketing, Advertising, and Communications (within the Office of Medical Policy, Food and Drug Administration), there are authorized to be appropriated the following amounts, stated as increases above the amount made available under appropriations Acts for such Division for fiscal year 2002:

(1) For fiscal year 2003, an increase of $2,500,000.
(2) For fiscal year 2004, an increase of $4,000,000.
(3) For fiscal year 2005, an increase of $5,500,000.
(4) For fiscal year 2006, an increase of $7,500,000.
(5) For fiscal year 2007, an increase of $7,500,000.

SEC. 523. OFFICE OF GENERIC DRUGS.

Appropriation authorization.

For the Office of Generic Drugs (within the Food and Drug Administration), there are authorized to be appropriated the following amounts, stated as increases above the amount made available under appropriations Acts for such Office for fiscal year 2002:

(1) For fiscal year 2003, an increase of $3,000,000.
(2) For fiscal year 2004, an increase of $6,000,000.
(3) For fiscal year 2005, an increase of $9,000,000.
(4) For fiscal year 2006, an increase of $12,000,000.
(5) For fiscal year 2007, an increase of $15,000,000.

Subtitle C—Additional Provisions

SEC. 531. TRANSITION TO DIGITAL TELEVISION.

47 USC 336 note.

Deadline.

(a) PAIR ASSIGNMENT REQUIRED.—In order to further promote the orderly transition to digital television, and to promote the equitable allocation and use of digital channels by television broadcast permittees and licensees, the Federal Communications Commission, at the request of an eligible licensee or permittee, shall, within 90 days after the date of enactment of this Act, allot, if necessary, and assign a paired digital television channel to that licensee or permittee, provided that—

(1) such channel can be allotted and assigned without further modification of the tables of allotments as set forth in sections 73.606 and 73.622 of the Commission's regulations (47 CFR 73.606, 73.622); and

(2) such allotment and assignment is otherwise consistent with the Commission's rules (47 CFR part 73).

(b) ELIGIBLE TRANSITION LICENSEE OR PERMITTEE.—For purposes of subsection (a), the term "eligible licensee or permittee" means only a full power television broadcast licensee or permittee (or its successor in interest) that—

(1) had an application pending for an analog television station construction permit as of October 24, 1991, which application was granted after April 3, 1997; and

(2) as of the date of enactment of this Act, is the permittee or licensee of that station.

(c) REQUIREMENTS ON LICENSEE OR PERMITTEE.—

(1) CONSTRUCTION DEADLINE.—Any licensee or permittee receiving a paired digital channel pursuant to this section—

(A) shall be required to construct the digital television broadcast facility within 18 months of the date on which the Federal Communications Commission issues a construction permit therefore, and

(B) shall be prohibited from obtaining or receiving an extension of time from the Commission beyond the construction deadline established by paragraph (1).

(2) PROHIBITION OF ANALOG OPERATION USING DIGITAL PAIR.—Any licensee or permittee receiving a paired digital channel pursuant to this section shall be prohibited from giving up its current paired analog assignment and becoming a single-channel broadcaster and operating in analog on such paired digital channel.

(d) RELIEF RESTRICTED.—Any paired digital allotment and assignment made under this section shall not be available to any

other applicant unless such applicant is an eligible licensee or permittee within the meaning of subsection (b).

SEC. 532. 3-YEAR DELAY IN LOCK IN PROCEDURES FOR MEDICARE+CHOICE PLANS; CHANGE IN CERTAIN MEDICARE+CHOICE DEADLINES AND ANNUAL, COORDINATED ELECTION PERIOD FOR 2003, 2004, AND 2005.

(a) LOCK-IN DELAY.—Section 1851(e) of the Social Security Act (42 U.S.C. 1395w–21(e)) is amended—

(1) in paragraph (2)(A), by striking "THROUGH 2001" and "during 1998, 1999, 2000, and 2001" and inserting "THROUGH 2004" and "during the period beginning January 1, 1998, and ending on December 31, 2004", respectively;

(2) in the heading to paragraph (2)(B), by striking "DURING 2002" and inserting "DURING 2005";

(3) in paragraphs (2)(B)(i) and (2)(C)(i), by striking "2002" and inserting "2005" each place it appears;

(4) in paragraph (2)(D), by striking "2001" and inserting "2004"; and

(5) in paragraph (4), by striking "2002" and inserting "2005" each place it appears.

(b) CHANGE IN REPORTING DEADLINE.—

(1) IN GENERAL.—Section 1854(a)(1) of such Act (42 U.S.C. 1395w–24(a)(1)) is amended by striking "Not later than July 1 of each year" and inserting "Not later than the second Monday in September of 2002, 2003, and 2004 (or July 1 of each other year)".

Applicability. 42 USC 1395w–24 note.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to information submitted for years beginning with 2003.

(c) DELAY IN ANNUAL, COORDINATED ELECTION PERIOD.—

(1) IN GENERAL.—Section 1851(e) of such Act (42 U.S.C. 1395w–21(e)) is amended—

(A) in paragraph (3)(B), by striking "means" and all that follows and inserting the following: "means, with respect to a year before 2003 and after 2005, the month of November before such year and with respect to 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year."; and

(B) in paragraph (6)(A), by striking "each subsequent year (as provided in paragraph (3))" and inserting "during the annual, coordinated election period under paragraph (3) for each subsequent year".

Applicability. 42 USC 1395w–21 note.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to the annual, coordinated election period for years beginning with 2003.

(d) CHANGE TO ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—

(1) IN GENERAL.—Section 1853(b)(1) of such Act (42 U.S.C. 1395w–23(b)(1)) is amended by striking "not later than March 1 before the calendar year concerned" and inserting "for years before 2004 and after 2005 not later than March 1 before the calendar year concerned and for 2004 and 2005 not later than the second Monday in May before the respective calendar year".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall first apply to announcements for years after 2003.

Applicability. 42 USC 1395w–23 note.

Approved June 12, 2002.

LEGISLATIVE HISTORY—H.R. 3448:

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Dec. 20, considered and passed Senate, amended.
Vol. 148 (2002): May 22, House agreed to conference report.
May 23, Senate agreed to conference report.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 38 (2002):
June 12, Presidential remarks.