107TH CONGRESS
1ST SESSION

# H. R. 3448

## AN ACT

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*,

**SECTION. 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the ''Public Health Security and Bioterrorism Response Act of 2001''.

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

# 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.**

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

**"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) CONSULTATION.—The Secretary shall carry out paragraph (1) in consultation with the Secretary of Defense, the Director of the Federal Emergency Management Agency, the Secretary of Veterans Affairs, the Attorney General, the Secretary of Agriculture, the Secretary of Energy, the Secretary of Labor, and the Administrator of the Environmental Protection Agency, and with other appropriate public and private entities.

''(3) 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 through local governments, such that there is a national plan for preparedness for and responding effectively to such emergencies.

''(4) EVALUATION OF PROGRESS.—The plan under paragraph (1) shall provide for specific bench-

marks 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) shall include provisions for achieving the following goals with respect to preparedness for and responding effectively to bioterrorism and other public health emergencies:

''(1) Providing effective assistance to State and local governments in the event of such an emergency.

''(2) Ensuring that State and local governments have adequate and 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) Adequate laboratory readiness.

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

''(D) Health and safety protection of workers involved in 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, and medical devices) against biological agents that may be used in such emergencies.

''(4) Ensuring coordination and minimizing duplication of Federal, State, and local planning, preparedness, and response activities, including among agencies during the investigation of a suspicious disease outbreak.

''(5) Ensuring adequate readiness of hospitals and other health care facilities to respond effectively to such emergencies.

''(c) EVALUATION OF USING VA R&D CAPABILITIES.—The Secretary shall evaluate the feasibility of using the biomedical research and development capabilities of the Department of Veterans Affairs, in conjunction with that Department's affiliations with health-professions universities, as a means to assist the Secretary in achieving the goals specified in subsection (b).

''(d) REPORTS TO CONGRESS.—

''(1) INITIAL REPORT TO CONGRESS.—Not later than one year after the date of the enactment of the Public Health Security and Bioterrorism Response Act of 2001, 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 subsection (a), including progress toward achieving the goals specified in subsection (b).

''(2) BIENNIAL REPORTS.—Not later than 2 years after the date on which the report under paragraph (1) is submitted, and biennially thereafter, the Secretary shall submit to each of the committees specified in such paragraph a report concerning the progress made with respect to the plan under subsection (a), including the goals under subsection (b).

''(3) ADDITIONAL AUTHORITY.—Reports submitted under paragraph (2) by the Secretary 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 that a condition described in section 319(a) occurs.

''(e) OTHER REPORTS.—Not later than one year after the date of the enactment of the Public Health Security and Bioterrorism Response Act of 2001, the Secretary shall submit to each of the committees specified in paragraph (1) a report concerning—

''(1) the recommendations and findings of the EPIC Advisory Committee under section 319F(c)(3);

''(2) 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 integra-

tion of Federal or State public health networks, workforce deficits, or other relevant conditions;

''(3) the characteristics that may render areas or populations designated as medically underserved populations (as defined in section 330) 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 conditions; and

''(4) 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).

''(f) 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 Response Act of 2001, were in effect with respect to preparing for and responding effectively to bioterrorism and other public health emergencies.''.

**SEC. 102. ASSISTANT SECRETARY FOR 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.**

''(a) ASSISTANT SECRETARY FOR EMERGENCY PREPAREDNESS.—

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

''(2) DUTIES.—Subject to the authority of the Secretary, the Assistant Secretary for Emergency Preparedness shall carry out the following duties:

''(A) Coordinate on behalf of the Secretary—

''(i) all 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, including the activities of the joint interdepartmental working groups under subsections (a) and (b) of section 319F; and

''(ii) all 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 or 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) Coordinate the activities of the Department with respect to research and development of priority vaccines, other biological products, drugs, and devices useful for detecting or responding to a bioterrorist attack or other public health emergency.

"(E) Coordinate the activities of the Department with respect to public education, awareness, and information relating to bioterrorism or other public health emergencies, including the activities and recommendations of the EPIC Advisory Committee under section 319F(c)(3).

"(F) Coordinate all other functions within the Department of Health and Human Services relating to emergency preparedness, including matters relating to bioterrorism and other public health emergencies that are addressed in the national plan under section 2801.

"(G) 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 (in this section referred to as the 'National System'). The Secretary shall designate the Assistant Secretary for Emergency Preparedness as the head of the National System, subject to the authority of the Secretary.

''(2) FEDERAL AND STATE COLLABORATIVE SYSTEM.—

''(A) IN GENERAL.—The National 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 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 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 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 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 Response Act of 2001, the Secretary shall conduct an exercise to test the capability and timeliness of the Na-

tional 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 System as the Secretary determines to be appropriate.

''(c) CRITERIA.—

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

''(2) EDUCATION AND TRAINING OF PERSONNEL.—In carrying out paragraph (1), the Secretary shall establish criteria regarding the education and training of individuals who provide emergency services through the National System. In the case of permanent, full-time positions in the Department of Health and Human Services that involve significant supervisory roles within the National System, the criteria shall require that individuals in such positions have completed appropriate education or training programs as determined by the Secretary.

''(3) PARTICIPATION AGREEMENTS FOR NONFEDERAL ENTITIES.—In carrying out paragraph (1),

the Secretary shall establish criteria regarding the participation of States and private entities in the National 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 on a reimbursable basis to respond to emergency situations for which the National System has not been activated by the Secretary pursuant to subsection (b)(3)(A).

''(B) Provisions relating to circumstances in which an individual or entity has agreements with both the National 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 System in carrying out duties under this section, the Secretary may appoint indi-

viduals 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 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 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 System or when the individual participates in a training program authorized by the Assistant Secretary for 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 intermit-

tent disaster-response appointee when the Secretary activates the National 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) 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).

''(g) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing for the Assistant Secretary for Emergency Preparedness and the operations of the National 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 SYSTEM.—It is the sense of the Congress that the Secretary of Health and Human Services should provide sufficient resources to individuals and 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 such National System.

**SEC. 103. IMPROVING ABILITY OF CENTERS FOR DISEASE CONTROL AND PREVENTION WITH RESPECT TO BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES; FACILITIES.**

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) FINDINGS.—Congress finds that the Centers for Disease Control and Prevention have an essential role in defending against and combatting public health threats of the 21st century and requires secure and modern facilities, and expanded and improved capabilities related to biologi-

cal threats or attacks or other public health emergencies, sufficient to enable such Centers to conduct this important mission.

''(b) IMPROVING THE CAPACITIES OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION.—

''(1) IN GENERAL.—The Secretary 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;

''(C) improving capabilities for public health surveillance and reporting activities;

''(D) improving laboratory facilities related to bioterrorism, including increasing the security of such facilities; and

''(E) such other activities as the Secretary determines appropriate.

''(2) IMPROVING PUBLIC HEALTH LABORATORY CAPACITY.—

''(A) IN GENERAL.—The Secretary, directly or through awards of grants, contracts, or cooperative agreements, shall provide for the establishment of a coordinated network of public health laboratories, that may, at the discretion of the Secretary, include laboratories that serve as regional reference laboratories.

''(B) PRIORITY.—In carrying out subparagraph (A), the Secretary shall give priority to projects 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 or regional reference laboratory, and that cover geographic areas lacking advanced diagnostic and safety-level laboratory capabilities.

''(3) NATIONAL PUBLIC HEALTH COMMUNICATIONS AND SURVEILLANCE NETWORK.—

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

''(i) Federal, State, and local public health officials;

''(ii) public and private health-related laboratories, hospitals, and other health care facilities; and

''(iii) any other entities determined appropriate by the Secretary.

''(B) REQUIREMENTS.—The Secretary shall ensure that networks under subparagraph (A) allow for the timely sharing and discussion, in a secure manner, of essential information concerning a bioterrorist attack or other public health emergency, or recommended methods for responding to such an attack or emergency.

''(4) CONTINUITY OF EFFORT.—To the maximum extent practicable, the Secretary, in conducting activities under paragraphs (1) through (3), shall administer such activities in a manner that intensifies, expands, or enhances activities being carried out on the date of enactment of this subsection.

''(c) FACILITIES.—

''(1) 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 related public health activities.

''(2) MULTIYEAR CONTRACTING AUTHORITY.—For any project of designing, constructing, equipping, or renovating any facility under paragraph (1), 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.

''(d) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—For the purposes of achieving the mission of the Centers for Disease Control and Prevention described in subsection (a), for carrying out subsection (b), for better conducting the capacities described in section 319A, and for supporting related 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) FACILITIES.—For the purpose of carrying out subsection (c), 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.''.

**SEC. 104. ADVISORY COMMITTEES AND COMMUNICATIONS.**

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

(1) by redesignating subsections (c) through (i) as subsections (e) through (k), respectively; and

(2) by inserting after subsection (b) the following subsections:

''(c) ADVICE TO THE FEDERAL GOVERNMENT.—

''(1) REQUIRED ADVISORY COMMITTEES.—In coordination with the working groups under subsections (a) and (b), 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).

''(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').

''(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 Response Act of 2001 to meet the special needs of children.

''(C) COMPOSITION.—The Advisory Committee shall be composed of such Federal officials as may be appropriate to address the spe-

cial 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 Response Act of 2001.

''(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 and report on appropriate ways to communicate public-health information regarding biological attacks to the public.

''(C) COMPOSITION.—The EPIC Advisory Committee shall be composed of individuals representing a diverse group of experts in public health, communications, behavioral psychology,

and other areas determined appropriate by the Secretary.

''(D) DISSEMINATION.—The Secretary shall ensure that the recommendations of the EPIC Advisory Committee are widely disseminated to the media, State and local governments, poison control centers, and others as the Secretary determines appropriate.

''(E) TERMINATION.—The EPIC Advisory Committee terminates one year after the date of the enactment of the Public Health Security and Bioterrorism Response Act of 2001.

''(d) STRATEGY FOR COMMUNICATION OF INFORMATION REGARDING BIOLOGICAL ATTACK.—In coordination with the joint interdepartmental working group under subsection (b), the Secretary, acting through the Assistant Secretary for Emergency Preparedness, shall develop a strategy for effectively communicating information regarding a biological attack, 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.''.

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

Section 319F(g) of the Public Health Service Act, as redesignated by section 104(1) 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 (including proficiency testing) 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) provide for dissemination and teaching of the materials described in subparagraphs (A) and (B) by all appropriate means, including telemedicine, long-distance learning, or other such means; and

''(D) to the extent practicable, establish and maintain an electronic database of individuals participating in training or education programs carried out under this section, for the purpose of providing continuing education materials and information to such participants.

''(2) GRANTS.—In carrying out paragraph (1), the Secretary may award grants to, or enter into cooperative agreements with, professional organizations and societies, private accrediting organizations, or other nonprofit institutions or entities meeting criteria established by the Secretary, and may enter into interagency cooperative agreements with other Federal agencies.

''(3) 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 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.**

''(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 VERIFICATION OF CREDENTIALS 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:

**''SEC. 319I. EMERGENCY SYSTEM FOR VERIFICATION 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 verifying the credentials, licenses, accreditations, and hospital privi-

leges of individuals, who during public health emergencies volunteer to serve as health professionals (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 criteria regarding the verification system under subsection (a), including 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) ADVANCE REGISTRATION OF VOLUNTEERS.—In order to facilitate the availability of health professionals during a public health emergency, the Secretary shall provide for the advance registration with the system of health professionals who are willing to serve as volunteers described in subsection (a), and may carry out activities to encourage health professionals to register with the system.

''(d) 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).

''(e) COORDINATION AMONG STATES.—The Secretary shall 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.

''(f) 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.

''(g) 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. ENHANCING PREPAREDNESS ACTIVITIES FOR BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.**

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

(1) by amending subsection (a) to read as follows:

''(a) WORKING GROUP ON PREPAREDNESS FOR ACTS OF BIOTERRORISM.—The Secretary, in coordination with the Secretary of Defense, the Director of the Federal Emergency Management Agency, the Attorney General,

the Secretary of Veterans Affairs, the Secretary of Agriculture, the Secretary of Energy, and the Administrator of the Environmental Protection Agency shall establish a joint interdepartmental working group on preparedness and readiness for the medical and public health effects of a bioterrorist attack on the civilian population. Such joint working group shall—

''(1) coordinate and prioritize research on, and the development of countermeasures against, pathogens likely to be used in a bioterrorist attack on the civilian population;

''(2) facilitate the development, production, and regulatory review of priority countermeasures (as defined in subsection (h)(2)(C)) for a bioterrorist attack on the civilian population;

''(3) coordinate research and development into equipment to detect pathogens likely to be used in a bioterrorist attack on the civilian population and protect against infection from such pathogens;

''(4) develop shared standards for equipment to detect and to protect against infection from pathogens likely to be used in a bioterrorist attack on the civilian population; and

''(5) coordinate the development, maintenance, and procedures for the release and distribution of

strategic reserves of vaccines, drugs, and medical supplies which may be needed rapidly after a bioterrorist attack upon the civilian population, including consideration of vulnerable populations (such as children, the elderly, and individuals with disabilities).'';

(2) in subsection (b)(1), by striking ''The Secretary'' and all that follows through ''shall establish'' and inserting the following: ''The Secretary, in collaboration with the Secretary of Defense, the Director of the Federal Emergency Management Agency, the Attorney General, the Secretary of Veterans Affairs, the Secretary of Agriculture, the Secretary of Labor, and the Administrator of the Environmental Protection Agency, shall establish'';

(3) in subsection (b)(2)—

(A) in subparagraph (A), by striking ''respond to a bioterrorist attack; and'' and inserting the following: ''respond 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) in subparagraph (B), by striking the period and inserting ''; and''; and

(C) by adding at the end the following subparagraph:

''(C) subject to compliance with other provisions of Federal law, clarify the responsibilities among Federal officials for the investigation of suspicious outbreaks of disease, and revise the interagency plan known as the Federal response plan accordingly.'';

(4) in subsection (b)(3), by striking ''Assistant Secretary for Health'' and inserting ''Assistant Secretary for Emergency Preparedness''; and

(5) in subsection (e) (as redesignated by section 104(1) of this Act)—

(A) in paragraph (1), by striking ''The Secretary'' and all that follows and inserting the following: ''In consultation with the working group established under subsection (b), the Secretary shall, based on criteria established by the Secretary, award grants to or enter into cooperative agreements with eligible entities to increase their capacity to detect, diagnose, and respond to acts of bioterrorism upon the civilian population.'';

(B) in paragraph (2)—

(i) by striking ''or'' after ''clinic,''; and

(ii) by inserting before the period the following: '', professional organizations and societies, schools or programs that train medical laboratory personnel, private accrediting organizations, or other nonprofit institutions or entities meeting criteria established by the Secretary'';

(C) in paragraph (3)—

(i) in the matter preceding subparagraph (A), by striking ''the priorities'' and inserting ''any priorities''; and

(ii) by striking subparagraphs (A) through (D) and inserting the following:

''(A) developing community-wide plans involving the public and private health care infrastructure to respond to bioterrorism or other public health emergencies, which are coordinated with the capacities of applicable national, State, and local health agencies;

''(B) training health care professionals and public health personnel to enhance the ability of such personnel to recognize the symptoms and epidemiological characteristics of exposure to a

potential bioweapon, or other agents that may cause a public health emergency;

"(C) addressing rapid and accurate identification of potential bioweapons, or other agents that may cause a public health emergency;

"(D) coordinating medical care for individuals during public health emergencies, including bioterrorism;

"(E) conducting exercises to test the capability and timeliness of public health emergency response activities;

"(F) facilitating and coordinating rapid communication of data generated from a bioterrorist attack or public health emergency among national, State, and local health agencies, emergency response personnel, and health care providers and facilities; and

"(G) purchasing or upgrading equipment, supplies, pharmaceuticals or other countermeasures to enhance preparedness for and response to bioterrorism or other public health emergencies, consistent with a plan described in subparagraph (A)."; and

(D) in paragraph (4)—

(i) in subparagraph (A), by striking ''and'' after the semicolon at the end;

(ii) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following subparagraph:

''(C) coordinate grants under this subsection with grants under 319C.''.

**SEC. 109. IMPROVING STATE AND LOCAL CORE PUBLIC HEALTH CAPACITIES.**

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

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

(2) in subsection (c)—

(A) in paragraph (3), by striking ''health care providers; and'' and inserting ''health care providers, including poison control centers;'';

(B) by redesignating paragraph (4) as paragraph (7); and

(C) by inserting after paragraph (3) the following paragraphs:

''(4) purchase or upgrade equipment, supplies, pharmaceuticals or other countermeasures to en-

hance preparedness for and response to bioterrorism or other public health emergencies, consistent with a plan described in paragraph (3);

''(5) conduct exercises to test the capability and timeliness of public health emergency response activities;

''(6) within the meaning of part B of title XII, develop and implement the trauma care component of the State plan for the provision of emergency medical services; and'';

**SEC. 110. ANTIMICROBIAL RESISTANCE PROGRAM.**

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 appropriate DNA analysis, or other necessary 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. 111. 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 ensure that 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 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. 112. 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**

''(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 Sec-

retary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.''.

**SEC. 113. 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''; and

(2) in section 319B(a), in the first sentence, by striking ''10 years'' and inserting ''five years''.

**SEC. 114. STUDY REGARDING LOCAL EMERGENCY RESPONSE METHODS.**

The Secretary of Health and Human Services shall conduct a study of best-practices methods for the provision of emergency response services through local governments (including through 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 Congress a report describing the findings of the study.

# Subtitle B—National Stockpile; Development of Priority Countermeasures

**SEC. 121. NATIONAL STOCKPILE.**

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') 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 adequate to meet the health security needs of the United States, including consideration of vulnerable populations (such as children, the elderly, and individuals with disabilities), in the event of a bioterrorist attack or other public health emergency.

(b) PROCEDURES.—The Secretary, in managing the stockpile under subsection (a), shall—

(1) consult with the Director of the Federal Emergency Management Agency, the Secretary of Defense, the Secretary of Veterans Affairs, the Attorney General, the Secretary of Energy, and the Administrator of the Environmental Protection Agency;

(2) ensure that adequate procedures are followed with respect to such stockpile for inventory

management and accounting, and for the physical security of the stockpile;

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

(4) 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; and

(5) devise plans for the effective and timely distribution of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure.

(c) 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).

(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $1,155,000,000 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.**

(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). Such a designation may be made prior to the submission of—

(1) a request for designation by the sponsor; 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 from declining such a designation.

(b) REVIEW OF PRIORITY COUNTERMEASURE NOT DESIGNATED AS FAST-TRACK PRODUCT.—A priority countermeasure shall be subject to the performance goals established by the Commissioner of Food and Drugs, unless it is designated as a fast-track product.

(c) DEFINITION.—For purposes of this section, the term ''priority countermeasure'' means a drug or biological product that is a countermeasure to treat, identify, or prevent infection by a biological agent or toxin listed pur-

suant to section 351A(a)(1) or harm from any other agent that may cause a public health emergency.

**SEC. 123. USE OF ANIMAL TRIALS IN APPROVAL OF CERTAIN DRUGS AND BIOLOGICS; ISSUANCE OF RULE.**

Not later than 180 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 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).

**SEC. 124. SECURITY FOR COUNTERMEASURE DEVELOPMENT AND PRODUCTION.**

Part B of title III of the Public Health Service Act, as amended by section 112 of this Act, is amended by inserting after section 319J the following section:

**''SEC. 319K. SECURITY FOR COUNTERMEASURE DEVELOPMENT AND PRODUCTION.**

''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)(2)(C)).''.

**SEC. 125. ACCELERATED COUNTERMEASURE RESEARCH AND DEVELOPMENT.**

Section 319F(h) of the Public Health Service Act, as redesignated by section 104(1) of this Act, is amended—

(1) by redesignating paragraphs (1) through (4), as subparagraphs (A) through (D), respectively;

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

''(1) IN GENERAL.—The Secretary'';

(3) by moving each of subparagraphs (A) through (D) (as so redesignated) two ems to the right; and

(4) by adding at the end the following:

''(2) ACCELERATED COUNTERMEASURE RESEARCH AND DEVELOPMENT.—

''(A) 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 coopera-

tive agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

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

"(ii) the development of new vaccines and therapeutics for use against such pathogens and other agents;

"(iii) the development of diagnostic tests to detect such pathogens and other agents; and

"(iv) other relevant areas of research; with consideration given to the needs of children and other vulnerable populations.

"(B) ROLE OF DEPARTMENT OF VETERANS AFFAIRS.—In carrying out subparagraph (A), 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 subparagraph, the Secretary may enter into cooperative agree-

ments with the Secretary of Veterans Affairs to achieve such purposes.

''(C) PRIORITY COUNTERMEASURES.—For purposes of this paragraph, the term 'priority countermeasure' means a countermeasure, including a drug, medical or other technological device, biological product, or diagnostic test, 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.''.

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

(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 evaluate new and emerging technologies that are designed to improve or enhance the ability of public health or safety officials to detect, identify, diagnose, or 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—

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

(2) promptly issue a request 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 joint interdepartmental 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, 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 that provides a list of priority technologies whose development or deployment or both should be accelerated, and the estimated cost of doing so.

**SEC. 127. POTASSIUM IODIDE.**

(a) IN GENERAL.—Through the national stockpile under section 121, the Secretary of Health and Human Services (in this section referred to as the ''Secretary''), subject to subsection (b), 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, that are within 20 miles of a nuclear power plant, in quantities sufficient to provide adequate protection for the populations within such miles.

(b) STATE AND LOCAL PLANS.—Subsection (a) applies with respect to a State or local government if the government involved meets the following conditions:

(1) Such government submits to the Secretary, and to the Director of the Federal Emergency Management Agency, 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.

(2) The plan is accompanied by certifications by such government that—

(A) the government has not received sufficient quantities of potassium iodide tablets from the Nuclear Regulatory Commission; and

(B) in the case of a local government, such government has submitted the plan to the State involved.

(c) GUIDELINES.—In consultation with the Director of the Federal Emergency Management Agency and with the Nuclear Regulatory Commission, the Secretary 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.

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

(e) REPORT.—Not later than six months after the date of the enactment of this Act, the Secretary shall submit to the Congress a report—

(1) on whether potassium iodide tablets have been made available under subsection (a) and the extent to which State and local governments have established stockpiles of such tablets; and

(2) the measures taken by the Secretary to implement this section.

(f) APPLICABILITY.—Subsections (a) and (d) cease to apply as requirements if the Secretary determines that there is an alternative and more effective medical treatment to address adverse thyroid conditions that may re-

sult from the release of radionuclides from nuclear power plants.

# Subtitle C—Emergency Authorities; Additional Provisions

## SEC. 131. EXPANDED AUTHORITY OF SECRETARY OF HEALTH AND HUMAN SERVICES TO RESPOND TO PUBLIC HEALTH EMERGENCIES.

(a) TRANSFERS OF FUNDS.—Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

''(d) TRANSFERS OF FUNDS BETWEEN PROGRAMS AND ACCOUNTS.—

''(1) IN GENERAL.—At any time during a public health emergency declared by the Secretary under subsection (a), the Secretary may, subject to paragraph (2), transfer funds, to the extent authorized by law, between appropriations accounts administered by the Secretary under this Act, without regard to any waiting period imposed by any other provision of law, including any provision of an appropriations Act, except as provided in paragraphs (3) and (4).

''(2) AMOUNT OF TRANSFERS.—With respect to the public health emergency involved:

"(A) The Secretary may not make a transfer under paragraph (1) in an amount exceeding a reasonable estimate by the Secretary of the amount necessary to respond to the emergency involved for a period of 60 days.

"(B) Subsequent transfers under paragraph (1) may be made by the Secretary, subject to compliance with subparagraph (A).

"(3) NOTIFICATION.—Not later than 48 hours prior to making a transfer under paragraph (1), the Secretary shall submit a notice of the intent to make such transfer to the Committee on Appropriations of the House of Representatives, the Committee on Energy and Commerce of the House of Representatives, the Committee on Appropriations of the Senate, and the Committee on Health, Education, Labor, and Pensions of the Senate.

"(4) SCOPE.—Paragraph (1) shall apply, notwithstanding any other provision of law including any provision of an appropriations Act and any Act enacted after the date of enactment of this subsection, unless such provision specifically refers to and overrides this subsection.".

(b) REPORTING DEADLINES.—Section 319 of the Public Health Service Act (42 U.S.C. 247d), as amended

by subsection (a), is further amended by adding at the end the following:

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

**SEC. 132. 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 by inserting ''or exposed to'' after ''to be infected with''.

(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 inserting ''or exposed to'' after ''to be infected with''.

(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. 133. 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:

**''SEC. 1135. AUTHORITY TO WAIVE REQUIREMENTS DURING NATIONAL EMERGENCIES.**

''(a) PURPOSE.—

''(1) IN GENERAL.—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—

''(A) 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

''(B) that health care providers (as defined in subsection (g)) 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.

''(2) EMERGENCY AREA; EMERGENCY PERIOD.—For purposes of this section, 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.

''(b) SECRETARIAL AUTHORITY.—To the extent necessary to accomplish the purposes 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 in any emergency area (or portion of such an area) during an emergency period, the requirements of titles XVIII, XIX, or XXI, or any regulation thereunder (and the requirements of this title, and regulations thereunder, insofar as they relate to such titles), pertaining to—

''(1) conditions of participation or other certification requirements for an individual health care provider or types of providers; program participation and similar requirements for an individual health care provider or types of providers; and 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;

''(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); and

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

''(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) NOTIFICATION OF CONGRESS.—The Secretary shall provide 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 notice shall include a description of the specific provisions that will be waived or modified, the health care providers to whom the waiver or modification will apply, the geographic area in which the waiver or modification will apply, and the period of time for which the waiver or modification will be in effect.

''(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 (a)(2)(B);

''(B) the termination of the applicable declaration of public health emergency described in subsection (a)(2)(B); or

''(C) subject to paragraph (2), the termination of a period of 90 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 90-DAY PERIODS.—The Secretary may, by notice, provide for an extension of a 90-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, 90 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 the success of such approaches and recommendations for improved approaches should the need for such emergency authority arise in the future.

''(g) HEALTH CARE PROVIDER DEFINED.—For purposes of this section, 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 amendments made by subsection (a) shall be effective on and after September 11, 2001.

**SEC. 134. PROVISION FOR EXPIRATION OF PUBLIC HEALTH EMERGENCIES.**

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.''.

**SEC. 135. DESIGNATED STATE PUBLIC EMERGENCY ANNOUNCEMENT PLAN.**

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

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

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

(3) by adding at the end the following:

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

**SEC. 136. EXPANDED RESEARCH BY SECRETARY OF ENERGY.**

(a) IN GENERAL.—In coordination with the joint interdepartmental 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.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2002 through 2006.

**SEC. 137. AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY.**

(a) IN GENERAL.—In planning for and responding to bioterrorism and other public health emergencies, including assisting State health departments, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall take into account the role and expertise of the Agency for Toxic Substances and Disease Registry (in this section referred to as ''ATSDR'').

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing resources (including increased personnel, as appropriate) for ATSDR to use authorities under section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 to assist the Secretary in planning for or responding to bioterrorism or other public health emergencies, there are authorized to be appropriated to the Secretary such sums

as may be necessary for each of the fiscal years 2002 through 2006, in addition to any other authorizations of appropriations that are available for such purpose.

**SEC. 138. EXPANDED RESEARCH ON WORKER HEALTH AND SAFETY.**

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.

**SEC. 139. TECHNOLOGY OPPORTUNITIES PROGRAM SUPPORT.**

For fiscal years 2003 and 2004, all of the information infrastructure grants provided by the National Telecommunications and Information Administration (under the program also known as the Technology Opportunities Program) shall be used to provide grants to health providers to facilitate participation in the national public health communications and surveillance networks authorized under section 319D(b)(3) of the Public Health Service Act.

# Subtitle D—Authorization of Appropriations

**SEC. 151. AUTHORIZATION OF APPROPRIATIONS.**

(a) IN GENERAL.—For the purpose of carrying out activities of the Department of Health and Human Services in accordance with the provisions referred to in subsection (b), including making awards of grants, cooperative agreements, or contracts and providing other assistance to States and other public or private entities, there are authorized to be appropriated $2,720,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.

(b) RELEVANT PROVISIONS.—For purposes of this section, the provisions referred to in this subsection are—

(1) the provisions of this title;

(2) sections 319A through 319K of the Public Health Service Act;

(3) title XXVIII of such Act; and

(4) section 301 of such Act, to the extent that such section is used as the authority of the Secretary of Health and Human Services to carry out activities to supplement the activities carried out under the provisions referred to in paragraphs (1) through (3);

except that this section does not have any applicability with respect to the use of section 301 of such Act as authority for activities of the National Institutes of Health.

(c) FISCAL YEAR 2002.—

(1) IN GENERAL.—The aggregate amount of authorizations of appropriations under this title and under the Public Health Service Act for fiscal year 2002 for the purpose described in subsection (a) does not exceed the amount specified for fiscal year 2002 in such subsection, notwithstanding other authorizations of appropriations.

(2) ALLOCATIONS OF AUTHORIZATIONS.—Of the amount that is authorized to be appropriated under subsection (a) for fiscal year 2002, the following authorizations of appropriations for such fiscal year for the purpose described in such subsection apply:

(A) For making awards of grants, cooperative agreements, or contracts and providing other assistance to States and other public or private entities, $1,000,000,000 is authorized, of which—

(i) $455,000,000 is authorized for grants under section 319C of the Public Health Service Act;

(ii) $455,000,000 is authorized for grants or cooperative agreements under section 319F of such Act; and

(iii) $40,000,000 is authorized for grants or cooperative agreements under section 319H of the Public Health Service Act, as added by section 106 of this Act (relating to shortages of certain health professionals).

(B) For the national stockpile under section 121 of this Act, other than activities of the National Institutes of Health regarding smallpox vaccine, $1,155,000,000 is authorized, of which $509,000,0000 is authorized for the acquisition of smallpox vaccine.

(C) For the Centers for Disease Control and Prevention, other than purposes to which the authorization established in subparagraph (A) applies, $450,000,000, of which $300,000,000 is authorized for facilities of such Centers for purposes described in section 399D(c) of the Public Health Service Act.

(D) For activities on antimicrobial resistance under section 319E of such Act, $25,000,000 is authorized.

# TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

## 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.—

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

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

''(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 immunizations to prevent and treatments for any illness resulting from infection by the agent or toxin; and

''(IV) any other criteria that the Secretary considers appropriate; and

''(ii) consult with scientific experts representing appropriate professional groups.

''(2) BIENNIAL PUBLICATION.—The Secretary shall publish the list under paragraph (1) biennially, or at such more frequent intervals as the Secretary determines to be appropriate. Before publishing the list, the Secretary shall review the list, and shall

make such revisions as are appropriate to protect the public health and safety. In reviewing and revising the list, the Secretary shall consider the needs of vulnerable populations, including children, and shall consult with appropriate Federal agencies and State and local public health officials.

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

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

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

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

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

''(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of a biological agent or toxin in violation of the safety procedures established under para-

graph (1) or the safeguards established under paragraph (2); and

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

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

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

''(e) INSPECTIONS.—The Secretary may conduct inspections to ensure that persons subject to regulations under subsection (b) or (c) are in compliance with such regulations, including provisions regarding security and restrictions on access under subsection (g).

''(f) EXEMPTIONS.—The Secretary may establish exemptions from the applicability of provisions of regulations under subsection (b) or (c) if the Secretary determines that such exemptions are consistent with protecting the public health and safety. In the case of a clinical laboratory that is in possession of a biological agent or toxin listed pursuant to subsection (a)(1), such an exemption may be provided only if such agent or toxin has been presented for diagnosis, verification, or proficiency testing, and upon identification or verification of the agent or toxin, such laboratory—

''(1) promptly notifies the Secretary or other public health authorities when required under Federal or State law; and

''(2) transfers or destroys the agent or toxin in accordance with such regulations.

''(g) SECURITY REQUIREMENTS FOR REGISTERED PERSONS.—

''(1) IN GENERAL.—In carrying out the provisions of subsections (b) and (c) that relate to safe-

guards, the Secretary, in consultation with the Attorney General, shall by regulation establish appropriate security requirements for persons possessing, using, or transferring biological agents or toxins listed pursuant to subsection (a)(1), and ensure compliance with such requirements as a condition of registration under subsection (b) or (c).

''(2) LIMITING ACCESS TO LISTED AGENTS AND TOXINS.—

''(A) IN GENERAL.—Regulations issued under subsections (b) and (c) shall include provisions—

''(i) to restrict access to biological agents and toxins listed pursuant to subsection (a)(1) to only those individuals who have a legitimate need for access, as determined according to the purposes for which the registration under such regulations is provided; and

''(ii) to ensure that individuals granted such access are not—

''(I) restricted persons, as defined in section 175b of title 18, United States Code;

"(II) named in a warrant issued to a Federal or State law enforcement agency for participation in any domestic or international act of terrorism or other act of violence;

"(III) under investigation for involvement with a domestic or international terrorist or criminal organization by any Federal law enforcement or intelligence agency; or

"(IV) suspected by any Federal law enforcement or intelligence agency of seeking to obtain covertly information relating to biological agents or toxins on behalf of the intelligence or military operations of a foreign nation.

"(B) SCREENING PROTOCOL.—To carry out subparagraph (A), the Secretary shall require that registered persons promptly submit the names and other identifying information for individuals described in subparagraph (A)(i) to the Secretary and the Attorney General, with which information the Attorney General shall promptly use criminal, immigration, and na-

tional security databases available to the Federal Government to identify whether such individuals satisfy the conditions for access under subparagraph (A)(ii). The Secretary, in consultation with the Attorney General and other Federal agencies, shall periodically review and as appropriate revise the protocol for screening individuals for purposes of subparagraph (A), and may require by regulation additional screening measures if determined necessary to achieve the purposes of this section.

''(3) ASSISTANCE FOR CERTAIN ENTITIES.—The Secretary, in consultation with the Attorney General, may make awards of grants, contracts, or cooperative agreements to public and nonprofit private entities (other than Federal agencies), and may provide technical assistance to such entities, to improve security of the facilities of registered persons.

''(h) DISCLOSURE OF INFORMATION.—

''(1) IN GENERAL.—Any information in the possession of any Federal agency that identifies a person, or the geographic location of a person, who is registered pursuant to regulations under this section (including regulations promulgated before the effective date of this subsection), and any site-spe-

cific information relating to the type, quantity, or identity of a biological agent or toxin listed pursuant to subsection (a)(1) or the site-specific security mechanisms in place to protect such agents and toxins, shall not be disclosed under section 552(a) of title 5, United States Code.

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

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

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

''(i) CIVIL MONEY PENALTY.—

''(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.

''(j) COORDINATION WITH REGULATIONS UNDER VIRUS-SERUM-TOXIN ACT.—

''(1) IN GENERAL.—In establishing and enforcing regulations under subsections (b) and (c), the Secretary shall consult with the Secretary of Agriculture to ensure that such activities are coordinated, to the greatest extent practicable, with regulations governing certain biological agents and toxins listed pursuant to subsection (a)(1) issued by the Secretary of Agriculture under the Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading 'Bureau of Animal In-

dustry' in the Act of March 4, 1913; 21 U.S.C. 151-159) (in this subsection referred to as the 'VST Act'). The purpose of such coordination shall be—

"(A) to minimize any conflicts between the regulations issued by, or the activities of, the Secretary of Health and Human Services and the Secretary of Agriculture with respect to such agents and toxins;

"(B) to minimize the administrative burden on persons subject to regulations under both this section and the VST Act;

"(C) to ensure the appropriate availability of such agents and toxins for legitimate agricultural or veterinary research, education, or other such purposes; and

"(D) to ensure the establishment of a national database of such agents or toxins pursuant to subsection (d).

"(2) PERSONS REGULATED BY DEPARTMENT OF AGRICULTURE.—With respect to persons possessing or using biological agents or toxins listed pursuant to subsection (a)(1) who, as of the date of enactment of the Public Health Security and Bioterrorism Response Act of 2001, possess an unexpired, unrevoked, and unsuspended permit or license from

the Department of Agriculture for such possession or use, such persons may, for purposes of registration under subsection (b) or (c), submit to the Secretary of Health and Human Services the same information previously provided to the Secretary of Agriculture to obtain such permit or license, provided that the information so submitted is accurate as of the time of submittal to the Secretary of Health and Human Services, and provided further that such Secretary may, after review of such submission, request such additional information as the Secretary determines to be necessary to achieve the purposes of this section.

''(3) SAVINGS PROVISION.—Nothing in this section shall be construed as limiting any authority of the Secretary of Agriculture under the VST Act or any regulations issued thereunder.

''(k) 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 'registered person' means a person registered under regulations under subsection (b) or (c).

''(l) 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.''.

(2) RELATION TO OTHER LAWS.—

(A) RULE OF CONSTRUCTION.—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 paragraph (1) of this subsection. 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 (including any revisions required under subsection (a)(2) of such section 351A).

(B) 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.

(3) DATE CERTAIN FOR PROMULGATION OF CERTAIN REGULATIONS; EFFECTIVE DATE REGARD-

ING CRIMINAL AND CIVIL PENALTIES.—With respect to section 351A of the Public Health Service Act (as added by paragraph (1) of this subsection):

(A) Not later than 30 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate an interim final rule requiring all persons in possession of biological agents or toxins listed pursuant to subsection (a)(1) of such section (unless exempt under subsection (e) of such section) to provide notice to the Secretary of such possession, and to include in the notice such additional information as the Secretary may require for compliance with subsection (d) of such section or any other provision of such section, by not later than 30 days after the date on which such rule is promulgated. Such interim final rule takes effect on the date on which the rule is promulgated, except as follows:

(i) For purposes of section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by subsection (a)(1)(E) of this section, the rule takes ef-

fect 60 days after the date on which the rule is promulgated.

(ii) For purposes of subsection (i) of such section 351A (relating to civil penalties), the rule takes effect 60 days after the date on which the rule is promulgated.

(B) Not later than 120 days after the date of enactment of this Act, such Secretary shall promulgate an interim final rule for carrying out subsections (b) and (c) of such section 351A. Such interim final rule takes effect 60 days after the date on which the rule is promulgated.

(4) EFFECTIVE DATE REGARDING DISCLOSURE OF INFORMATION.—Subsection (h) of section 351A of the Public Health Service Act, as added by paragraph (1) of this subsection, is deemed to have taken effect on the effective date of the Antiterrorism and Effective Death Penalty Act of 1996.

(b) CRIMINAL PENALTIES REGARDING SELECT AGENTS.—

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

(A) by striking ''(a)'' and inserting ''(a)(1)'';

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

(C) by striking ''(c)'' and inserting ''(2);

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

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

''(b) TRANSFER TO UNREGISTERED PERSON.—Whoever knowingly transfers a select agent to a person without first verifying with the Secretary of Health and Human Services that the person has obtained a registration 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.

''(c) UNREGISTERED FOR POSSESSION.—Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a select agent for which such person has not obtained a registration required by 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) CONFORMING AMENDMENTS.—Chapter 10 of title 18, United States Code, is amended—

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

(i) 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

(ii) in the heading for the section, by striking ''**Possession by restricted persons**'' and inserting ''**Select agents**''; and

(B) in the chapter analysis, in the item relating to section 175b, by striking ''Possession by restricted persons.'' and inserting ''Select agents.''.

(3) TECHNICAL CORRECTIONS.—Chapter 10 of title 18, United States Code, as amended by section 817 of Public Law 107–56 and paragraphs (1) and (2) of this subsection, is amended—

(A) in section 175—

(i) in subsection (a), in the second sentence, by striking ''this section'' and inserting ''this subsection''; and

(ii) in subsection (c), by striking ''protective'' and all that follows and inserting ''protective, bona fide research, or other peaceful purposes.'';

(B) in section 175b—

(i) 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

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

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

(D) in section 178—

(i) in paragraph (1), by striking ''means any micro-organism'' and all that follows through ''product, capable of'' and inserting the following: ''means any micro-organism (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'';

(ii) 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, vi-

ruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes—''; and

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

(4) ADDITIONAL TECHNICAL CORRECTION.—Section 2332a of title 18, United States Code, is amended—

(A) 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

(B) 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)''.

(c) SECURITY UPGRADES AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—For the purpose of enabling the Secretary of Health and Human Services to secure existing facilities of the Department of Health and Human Services where biological agents or toxins listed

under section 351A(a)(1) of the Public Health Service Act are housed or researched, or where vaccines are housed or researched, there are authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year.

(d) REPORT TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, after consultation with other appropriate Federal agencies, shall submit to the Congress a report that—

(1) describes the extent to which there has been compliance by governmental and private entities with applicable regulations under section 351A of the Public Health Service Act (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; and

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

# TITLE III-AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

## Subtitle A—Protection of Food Supply

### SEC. 301. PROTECTION AGAINST INTENTIONAL ADULTERATION OF FOOD.

(a) INCREASING INSPECTIONS FOR DETECTION OF INTENTIONAL 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 paragraphs:

''(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.

''(3) 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, periodic reports describing the activities of the Secretary under paragraphs (1) and (2).''.

(c) TESTING FOR RAPID DETECTION OF INTENTIONAL 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).".

(d) 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—

(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.

(e) 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. 302. 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.

''(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 may require that the article be removed to a secure facility. 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.

''(4) APPEAL OF DETENTION ORDER.—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 72 hours 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 72-hour period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.''.

(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 301(c) of this Act, is amended by adding at the end the following:

''(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.

''(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. 303. PERMISSIVE DEBARMENT REGARDING FOOD IMPORTATION.**

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

(1) in paragraph (1)—

(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) in paragraph (2), in the matter preceding subparagraph (A), by inserting ''subparagraph (A) or (B) of'' before ''paragraph (1)'';

(3) by redesignating paragraph (3) as paragraph (4); and

(4) 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 article of food; or

''(B)(i) the person has repeatedly imported or offered for import adulterated articles of food; and

''(ii) the person knew, or should have known, that such articles were adulterated.''.

(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''; and

(C) in subparagraph (B), in each of clauses (i) and (ii), by inserting ''or subsection (b)(3)'' after ''subsection (b)(2)(B).

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

(1) in the first sentence—

(A) by striking ''and'' after ''subsection (b)(2)''; and

(B) by inserting '', and subsection (b)(3)'' after ''subsection (b)(2)(B)''; and

(2) in the second sentence, by inserting '', subsection (b)(3),'' after ''subsection (b)(2)(B)''.

(d) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section

302(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)(1)(C).''.

**SEC. 304. MAINTENANCE AND INSPECTION OF RECORDS FOR FOODS.**

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

**''SEC. 414. MAINTENANCE AND INSPECTION OF RECORDS.**

''(a) RECORDS INSPECTION.—If the Secretary 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, 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 investigating

such credible evidence or information. 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.

''(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 maintenance of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, as may be necessary to trace the source and chain of distribution of food and 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 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 credible evidence or information indicating that an article of food 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(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended—

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

(2) by striking ''under section 412'' and inserting ''under section 412, 414(b)''.

**SEC. 305. REGISTRATION.**

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.), as

amended by section 304 of this Act, is amended by adding at the end the following:

**"SEC. 415. REGISTRATION.**

"(a) REGISTRATION.—

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

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

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

"(2) REGISTRATION.—An entity (referred to in this section as the 'registrant') shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the identity 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, or successor 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.

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

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

''(b) EXEMPTION.—The Secretary shall by regulation exempt types of retail establishments from the requirements of subsection (a) only if the Secretary determines that the registration of such facilities is not needed for effective enforcement of this chapter and any regulations issued under this chapter.

''(c) FACILITY.—For purposes of this section, the term 'facility' includes any factory, warehouse, or estab-

lishment (including a factory, warehouse, or establishment of an importer), that manufactures, processes, packs, or holds food. Such term does not include restaurants or other establishments in which food is served solely for immediate human consumption.

''(d) 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.—

(1) IN GENERAL.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 303(d) of this Act, is amended by adding at the end the following:

''(dd) The failure to register in accordance with section 415.''.

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

''(t) If it is manufactured, processed, packed, or held in a facility that is not registered in accordance with section 415.''.

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

(d) NOTICE.—Not later than 60 days after the date of the enactment of this Act, the Secretary of Health and Human Services, after consultation with appropriate State and local officials, shall take sufficient measures to notify entities that manufacture, process, pack, or hold food for consumption in the United States of the requirement pursuant to this section that facilities be registered with the Secretary. The Secretary shall develop guidance, as needed, to identify facilities required to register under this section.

(e) 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.

(f) SAVINGS CLAUSE.—This section may not be construed as authorizing the Secretary of Health and Human Services 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).

**SEC. 306. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.**

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 302(c) of this Act, is amended by adding at the end the following subsection:

''(k)(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, and 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 regulations 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, not fewer than 24 hours, in advance of the time of the importation of the article of food involved or the offering of the food for import, except that the advance period so required may not exceed 72 hours.

''(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 subparagraph (A), 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 regulations under paragraph (1). The preceding sentence may not be construed as authorizing such delivery pursuant to the execution of a bond, pending such a determination by the Secretary.

''(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).''.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 305(b)(1) 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 regulations under section 801(k).''.

**SEC. 307. 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 306(a) of this Act, is amended by adding at the end the following:

''(l)(1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, and the Secretary determines that the food presents a threat of serious adverse health consequences or death to humans or animals, 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), as amended by section 305(b)(2) of this Act, is amended by adding at the end the following:

''(u) If it fails to bear a label required by the Secretary under section 801(l)(1) (relating to food refused admission into the United States).''.

(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.

**SEC. 308. PROHIBITION AGAINST PORT SHOPPING FOR IMPORTATION.**

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 such article 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 is not adulterated, as determined by the Secretary.''.

**SEC. 309. 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 new section:

**''SEC. 908. NOTICES TO STATES REGARDING IMPORTED FOOD.**

''(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 the 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 adulterated food under any other provision of this Act.''.

**SEC. 310. GRANTS TO STATES FOR INSPECTIONS; RESPONSE TO NOTICE REGARDING ADULTERATED IMPORTED FOOD.**

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.), as amended by section 309 of this Act, is amended by adding at the end the following new section:

**"SEC. 909. GRANTS TO STATES REGARDING FOOD INSPECTIONS.**

"(a) IN GENERAL.—The Secretary may make grants to States and Territories for the purpose of conducting with respect to food examinations, inspections, investigations, and related activities under section 702 through individuals who, under subsection (a) of such section, are duly commissioned by the Secretary as officers of the Department.

"(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 notices 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 such sums as may be necessary for each of the fiscal years 2002 through 2006.".

# Subtitle B—Protection of Drug Supply

**SEC. 311. ANNUAL REGISTRATION OF FOREIGN MANUFACTURERS; SHIPPING INFORMATION; DRUG AND DEVICE LISTING.**

(a) ANNUAL REGISTRATION; LISTING.—

(1) IN GENERAL.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

(A) in subsection (i)(1)—

(i) by striking ''Any establishment'' and inserting ''On or before December 31 of each year, any establishment'';

(ii) by striking ''establishment and the name'' and inserting ''establishment, the name''; and

(iii) by inserting before the period the following: '', 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 carrier used by the establishment in transporting such drug or device to the United States for purposes of importation''; and

(B) in subsection (j)(1), in the first sentence, by striking ''or (d)'' and inserting ''(d), or (i)''.

(2) MISBRANDING.—Section 502(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(o)) is amended by striking ''in any State''.

(b) IMPORTATION; STATEMENT REGARDING REGISTRATION OF MANUFACTURER.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 307(a) of this Act, is amended by adding at the end the following subsection:

''(m) A drug or device that is imported or offered for import into the United States may be refused admission if the importer of the drug or device does not, at the time of offering the drug or device for import, submit to the Secretary a statement that identifies the registration under section 510(i) of each establishment that with respect to such drug or device is required under such section to register with the Secretary.''.

(2) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 306(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 an order of the Secretary to submit to the Secretary a statement under section 801(m).''.

(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. 312. 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, carrier, 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.

''(ii) If such article is known to be, or to contain or bear, any chemical substance or biological substance, the statement under clause (i) is accompanied by such certificates of analysis as are necessary to identify each such substance.

''(iii) 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.

''(iv) 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.

''(v) 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.

''(vi) 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.

''(B) Subparagraph (A) does not apply to the import or offering for import into the United States of an article if the Secretary determines that there is credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

''(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 sub-

paragraph (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.''.

(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.

# TITLE IV-DRINKING WATER SECURITY AND SAFETY

**SEC. 401. AMENDMENT OF THE SAFE DRINKING WATER ACT.**

The Safe Drinking Water Act (title XIV of the Public Health Service Act) is amended as follows:

(1) By inserting the following new sections after section 1432:

**"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 March 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—

''(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.

''(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) prior to:

''(A) December 31, 2002, in the case of systems serving a population of 100,000 or more.

''(B) June 30, 2003, in the case of systems serving a population of 50,000 or more but less than 100,000.

''(C) December 31, 2003, in the case of systems serving a population greater than 3,300 but less than 50,000.

''(b) EMERGENCY RESPONSE PLAN.—Each community water system serving a population greater than 3,300 shall prepare or revise, where necessary, an emergency re-

sponse 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 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) 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 or drinking water provided to communities and individuals.

''(d) FUNDING.—There are authorized to be appropriated to carry out this section not more than $120,000,000 for the fiscal year 2002 and such sums as may be necessary for fiscal year 2003 and fiscal year 2004. The Administrator, in coordination with State and local governments, may 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 under subsection (a).

**''SEC. 1434. CONTAMINANT PREVENTION, DETECTION AND RESPONSE.**

''(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:

''(1) Methods, means and equipment designed to monitor and detect chemical, biological, and radiological contaminants and reduce the likelihood that such contaminants can be successfully introduced into water supplies 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) Procedures and equipment necessary to prevent the flow of contaminated drinking water to individuals served by public water systems.

''(4) 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.

''(5) 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 of other intentional acts.

''(b) FUNDING.—For the authorization of appropriations to carry out this section, see section 1435(c).

**''SEC. 1435. SUPPLY DISRUPTION PREVENTION, DETECTION AND RESPONSE.**

''(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 signifi-

cantly 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.

''(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) 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 fiscal year 2003 and fiscal year 2004.''.

(2) Section 1414(i)(1) is amended by inserting ''1433'' after ''1417''.

(3) 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''.

(4) Section 1432 is amended as follows:

(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''.

(5) Section 1442 is amended as follows:

(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.''.

Passed the House of Representatives December 12, 2001.

Attest:

*Clerk.*

107TH CONGRESS
1ST SESSION

# H. R. 3448

# AN ACT

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