

107TH CONGRESS
1ST SESSION

S. 1715

To improve the ability of the United States to prepare for and respond
to a biological threat or attack.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 15, 2001

Mr. FRIST (for himself, Mr. KENNEDY, Mr. ALLEN, Mr. DASCHLE, Mr. BOND, Mr. AKAKA, Mr. CHAFEE, Mr. BAYH, Ms. COLLINS, Mr. BIDEN, Mr. DOMENICI, Mr. BREAUX, Mr. DEWINE, Mrs. CARNAHAN, Mr. HAGEL, Mr. CLELAND, Mr. HUTCHINSON, Mrs. CLINTON, Mrs. HUTCHISON, Mr. CORZINE, Mr. ROBERTS, Mr. DODD, Ms. SNOWE, Mr. DURBIN, Mr. VOINOVICH, Mr. EDWARDS, Mr. WARNER, Mrs. FEINSTEIN, Mr. HARKIN, Mr. JEFFORDS, Mr. JOHNSON, Mr. LEAHY, Mr. LIEBERMAN, Ms. MIKULSKI, Mrs. MURRAY, Mr. NELSON of Florida, Mr. REED, Mr. ROCKEFELLER, Mr. SARBANES, Mr. TORRICELLI, and Mr. WELLSTONE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve the ability of the United States to prepare for
and respond to a biological threat or attack.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Bioterrorism Preparedness Act of 2001”.

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

Sec. 1. Short title; table of contents.

TITLE I—NATIONAL GOALS FOR BIOTERRORISM PREPAREDNESS

Sec. 101. Amendment to the Public Health Service Act.

TITLE II—IMPROVING THE FEDERAL RESPONSE TO
BIOTERRORISM

Sec. 201. Additional authorities of the Secretary; Strategic National Pharmaceutical Stockpile.

Sec. 202. Improving the ability of the Centers for Disease Control and Prevention to respond effectively to bioterrorism.

Subtitle B—Coordination of Efforts and Responses

Sec. 211. Assistant Secretary of Emergency Preparedness; National Disaster Medical System.

Sec. 212. Expanded authority of the Secretary of Health and Human Services to respond to public health emergencies.

Sec. 213. Public health preparedness and response to a bioterrorist attack.

Sec. 214. The official Federal Internet site on bioterrorism.

Sec. 215. Technical amendments.

Sec. 216. Regulation of biological agents and toxins.

TITLE III—IMPROVING STATE AND LOCAL PREPAREDNESS

Subtitle A—Emergency Measures To Improve State and Local Preparedness

Sec. 301. State bioterrorism preparedness and response block grant.

Subtitle B—Improving Local Preparedness and Response Capabilities

Sec. 311. Designated bioterrorism response medical centers.

Sec. 312. Designated State public emergency announcement plan.

Sec. 313. Training for pediatric issues surrounding biological agents used in warfare and terrorism.

Sec. 314. General Accounting Office report.

Sec. 315. Additional research.

Sec. 316. Sense of the Senate.

TITLE IV—DEVELOPING NEW COUNTERMEASURES AGAINST
BIOTERRORISM

Sec. 401. Limited antitrust exemption.

Sec. 402. Developing new countermeasures against bioterrorism.

Sec. 403. Sequencing of priority pathogens.

Sec. 404. Accelerated countermeasure research and development.

Sec. 405. Accelerated approval of priority countermeasures.

Sec. 406. Use of animal trials in the approval of priority countermeasures.

Sec. 407. Miscellaneous provisions.

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

Subtitle A—General Provisions To Expand and Upgrade Security

- Sec. 511. Food safety and security strategy.
- Sec. 512. Expansion of Animal and Plant Health Inspection Service activities.
- Sec. 513. Expansion of Food Safety Inspection Service activities.
- Sec. 514. Expansion of Food and Drug Administration activities.
- Sec. 515. Biosecurity upgrades at the Department of Agriculture.
- Sec. 516. Biosecurity upgrades at the Department of Health and Human Services.
- Sec. 517. Agricultural biosecurity.
- Sec. 518. Biosecurity of food manufacturing, processing, and distribution.

Subtitle B—Protection of the Food Supply

- Sec. 531. Administrative detention.
- Sec. 532. Debarment for repeated or serious food import violations.
- Sec. 533. Maintenance and inspection of records for foods.
- Sec. 534. Registration of food manufacturing, processing, and handling facilities.
- Sec. 535. Prior notice of imported food shipments.
- Sec. 536. Authority to mark refused articles.
- Sec. 537. Authority to commission other Federal officials to conduct inspections.
- Sec. 538. Prohibition against port shopping.
- Sec. 539. Grants to States for inspections.
- Sec. 540. Rule of construction.

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

- Sec. 541. Surveillance and information grants and authorities.
- Sec. 542. Agricultural bioterrorism research and development.

1 TITLE I—NATIONAL GOALS FOR

2 BIOTERRORISM PREPAREDNESS

3 SEC. 101. AMENDMENT TO THE PUBLIC HEALTH SERVICE

4 ACT.

5 The Public Health Service Act (42 U.S.C. 201 et

6 seq.) is amended by adding at the end the following:

1 **“TITLE XXVIII—STRENGTHENING**
2 **THE NATION’S PREPARED-**
3 **NESS FOR BIOTERRORISM**

4 **“SEC. 2801. CONGRESSIONAL FINDINGS ON BIOTERRORISM**
5 **PREPAREDNESS.**

6 “Congress finds that the United States should fur-
7 ther develop and implement a coordinated strategy to pre-
8 vent, and if necessary, to respond to biological threats or
9 attacks upon the United States. Such strategy should in-
10 clude measures for—

11 “(1) enabling the Federal Government to pro-
12 vide health care assistance to States and localities in
13 the event of a biological threat or attack;

14 “(2) improving public health, hospital, labora-
15 tory, communications, and emergency response per-
16 sonnel preparedness and responsiveness at the State
17 and local levels;

18 “(3) rapidly developing and manufacturing
19 needed therapies, vaccines, and medical supplies;
20 and

21 “(4) enhancing the protection of the nation’s
22 food supply and protecting agriculture against bio-
23 logical threats or attacks.”.

1 **TITLE II—IMPROVING THE FED-**
 2 **ERAL RESPONSE TO BIOTER-**
 3 **RORISM**

4 **SEC. 201. ADDITIONAL AUTHORITIES OF THE SECRETARY;**
 5 **STRATEGIC NATIONAL PHARMACEUTICAL**
 6 **STOCKPILE.**

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

10 **“Subtitle A—Improving the Federal**
 11 **Response to Bioterrorism**

12 **“SEC. 2811. AUTHORITY OF THE SECRETARY RELATED TO**
 13 **BIOTERRORISM PREPAREDNESS.**

14 “(a) PLAN.—To meet the objectives of this title (and
 15 the amendments made by the Bioterrorism Preparedness
 16 Act of 2001), and to help the United States fully prepare
 17 for a biological threat or attack, the Secretary, consistent
 18 with the recommendations and activities of the working
 19 group established under section 319F(a), shall develop
 20 and implement a coordinated plan to meet such objectives
 21 that are within the jurisdiction of the Secretary. Such plan
 22 shall include the development of specific criteria that will
 23 enable measurements to be made of the progress made at
 24 the national, State, and local levels toward achieving the
 25 national goal of bioterrorism preparedness, including ac-

1 tions to strengthen the preparedness of rural communities
2 for a biological threat or attack.

3 “(b) BIENNIAL REPORTS.—

4 “(1) IN GENERAL.—Not later than 1 year after
5 the date of enactment of this title, and biennially
6 thereafter, the Secretary shall prepare and submit to
7 Congress a report concerning the progress made and
8 the steps taken by the Secretary to further the pur-
9 poses of this title (and the amendments made by the
10 Bioterrorism Preparedness Act of 2001). Such re-
11 port shall include an assessment of the activities
12 conducted under section 319F(c).

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

16 “(A) additional legislative authority that
17 the Secretary determines is necessary to meet
18 the objectives of this title (and the amendments
19 made by the Bioterrorism Preparedness Act of
20 2001); and

21 “(B) additional legislative authority that
22 the Secretary determines is necessary under
23 section 319 to protect the public health in the
24 event that a condition described in section
25 319(a) occurs.

1 “(c) OTHER REPORTS.—Not later than 1 year after
 2 the date of enactment of this title, the Secretary shall pre-
 3 pare and submit to Congress a report concerning—

4 “(1) activities conducted under section
 5 319F(b);

6 “(2) the characteristics that may render a rural
 7 community uniquely vulnerable to a biological threat
 8 or attack, including distance, lack of emergency
 9 transport, hospital or laboratory capacity, lack of in-
 10 tegration of Federal or State public health networks,
 11 workforce deficits, or other relevant conditions;

12 “(3) in any case in which the Secretary deter-
 13 mines that additional legislative authority is nec-
 14 essary to effectively strengthen the preparedness of
 15 rural communities for responding to a biological
 16 threat or attack, the recommendations of the Sec-
 17 retary with respect to such legislative authority; and

18 “(4) the need for and benefits of a National
 19 Disaster Response Medical Volunteer Service that
 20 would be a private-sector, community-based rapid re-
 21 sponse corps of medical volunteers.

22 **“SEC. 2812. STRATEGIC NATIONAL PHARMACEUTICAL**
 23 **STOCKPILE.**

24 “(a) IN GENERAL.—The Secretary, in coordination
 25 with the Secretary of Veterans Affairs, shall maintain a

1 strategic stockpile of vaccines, therapies, and medical sup-
2 plies that are adequate, as determined by the Secretary,
3 to meet the health needs of the United States population,
4 including children and other vulnerable populations, for
5 use at the direction of the Secretary, in the event of a
6 biological threat or attack or other public health emer-
7 gency.

8 “(b) RULE OF CONSTRUCTION.—Nothing in sub-
9 section (a) shall be construed to prohibit the Secretary
10 from including in the stockpile described in such sub-
11 section such vaccines, therapies, or medical supplies as
12 may be necessary to meet the needs of the United States
13 in the event of a nuclear, radiological, or chemical attack
14 or other public health emergency.

15 “(c) DEFINITION.—In this section, the term ‘stock-
16 pile’ means—

17 “(1) a physical accumulation of the material de-
18 scribed in subsection (a); or

19 “(2) a contractual agreement between the Sec-
20 retary and a vendor or vendors under which such
21 vendor or vendors agree to provide to the Secretary
22 such medical supplies as shall be described in the
23 contract at such time as shall be specified in the
24 contract.

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

3 “(1) ensure that adequate procedures are fol-
4 lowed with respect to the stockpile maintained under
5 subsection (a) for inventory management, account-
6 ing, and for the physical security of such stockpile;
7 and

8 “(2) in consultation with State and local offi-
9 cials, take into consideration the timing and location
10 of special events, including designated national secu-
11 rity events.

12 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
13 is authorized to be appropriated to carry out this section,
14 \$643,000,000 for fiscal year 2002, and such sums as may
15 be necessary for each of fiscal years 2003 through 2006.”.

16 **SEC. 202. IMPROVING THE ABILITY OF THE CENTERS FOR**
17 **DISEASE CONTROL AND PREVENTION TO RE-**
18 **SPOND EFFECTIVELY TO BIOTERRORISM.**

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

22 (1) in subsection (a), by inserting “, and ex-
23 panded, enhanced, and improved capabilities of the
24 Centers related to biological threats or attacks,”
25 after “modern facilities”;

1 (2) in subsection (b)—

2 (A) by inserting “, including preparing for
3 or responding to biological threats or attacks,”
4 after “public health activities”; and

5 (B) by inserting “\$60,000,000 for fiscal
6 year 2002,”; and

7 (3) by adding at the end the following:

8 “(c) IMPROVING PUBLIC HEALTH LABORATORY CA-
9 PACITY.—

10 “(1) IN GENERAL.—The Secretary shall provide
11 for the establishment of a coordinated network of
12 public health laboratories to assist with the detection
13 of and response to a biological threat or attack, that
14 may, at the discretion of the Secretary, include lab-
15 oratories that serve as regional reference labora-
16 tories.

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

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

24 “(4) LOCAL DISCRETION.—Use of regional lab-
25 oratories, if established under paragraph (1), shall

1 be at the discretion of the public health agencies of
2 the States.

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

6 “(A) purchase or improve land or purchase
7 any building or other facility; or

8 “(B) permanently improve any building or
9 other facility.

10 “(6) SUPPLEMENT NOT SUPPLANT.—Funds ap-
11 propriated under this subsection shall be used to
12 supplement and not supplant other Federal, State,
13 and local public funds provided for activities under
14 this subsection.

15 “(7) AUTHORIZATION OF APPROPRIATIONS.—
16 There is authorized to be appropriated to carry out
17 this subsection, \$60,000,000 for fiscal year 2002,
18 and such sums as may be necessary for each of fis-
19 cal years 2003 through 2006.”.

20 (b) EDUCATION AND TRAINING.—Section 319F(e) of
21 the Public Health Service Act (42 U.S.C. 247d6(e)) is
22 amended by adding at the end the following flush sen-
23 tence:

24 “The education and training activities described in this
25 subsection may be carried out through Public Health Pre-

paredness Centers, Noble training facilities, the Emerging Infections Program, and the Epidemic Intelligence Service.”.

Subtitle B—Coordination of Efforts and Responses

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

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

“SEC. 2813. ASSISTANT SECRETARY FOR EMERGENCY PREPAREDNESS.

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

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

“(1) serve as the principal adviser to the Secretary on matters relating to emergency prepared-

1 ness, including preparing for and responding to bio-
 2 logical threats or attacks and for developing policy;
 3 and

4 “(2) coordinate all functions within the Depart-
 5 ment of Health and Human Services relating to
 6 emergency preparedness, including preparing for and
 7 responding to biological threat or attacks.

8 **“SEC. 2814. NATIONAL DISASTER MEDICAL SYSTEM.**

9 “(a) NATIONAL DISASTER MEDICAL SYSTEM.—

10 “(1) IN GENERAL.—There shall be operated a
 11 system to be known as the National Disaster Med-
 12 ical System (in this section referred to as the ‘Na-
 13 tional System’) which shall be coordinated by the
 14 Secretary, in collaboration with the Secretary of De-
 15 fense, the Secretary of Veterans Affairs, and the Di-
 16 rector of the Federal Emergency Management Agen-
 17 cy.

18 “(2) FUNCTIONS.—The National System shall
 19 provide appropriate health services, health-related
 20 social services and, if necessary, auxiliary services
 21 (including mortuary and veterinary services) to re-
 22 spond to the needs of victims of a public health
 23 emergency if the Secretary activates the System with
 24 respect to the emergency. The National System shall

1 carry out such ongoing activities as may be nec-
2 essary to prepare for the provision of such services.

3 “(b) TEMPORARY DISASTER-RESPONSE PER-
4 SONNEL.—

5 “(1) IN GENERAL.—For the purpose of assist-
6 ing the Office of Emergency Preparedness and the
7 National System in carrying out duties under this
8 section, the Secretary may in accordance with this
9 subsection appoint individuals to serve as temporary
10 personnel of such Office or System. The Secretary
11 may make such appointments without regard to the
12 provisions of title 5, United States Code, governing
13 appointments in the competitive service, and without
14 regard to the provisions of chapter 51 and sub-
15 chapter III of chapter 53 of such title relating to
16 classification and General Schedule pay rates.

17 “(2) TRAVEL AND SUBSISTENCE.—An indi-
18 vidual appointed under paragraph (1) shall, in ac-
19 cordance with subchapter I of chapter 57 of title 5,
20 United States Code, be eligible for travel, subsist-
21 ence, and other necessary expenses incurred in car-
22 rying out the duties for which the individual was ap-
23 pointed, including per diem in lieu of subsistence.

24 “(3) LIABILITY.—For purposes of section
25 224(a) and the remedies described in such section,

1 an individual appointed under paragraph (1) shall,
2 while acting within the scope of such appointment,
3 be considered to be an employee of the Public
4 Health Service performing medical, surgical, dental,
5 or related functions. Participation in training pro-
6 grams carried out by the Office of Emergency Pre-
7 paredness or Federal personnel of the National Sys-
8 tem shall be considered within the scope of such an
9 appointment (regardless of whether the individual
10 receives compensation for such participation).

11 “(c) TEMPORARY DISASTER-RESPONSE AP-
12 POINTEE.—For purposes of this section, the term ‘tem-
13 porary disaster-response appointee’ means an individual
14 appointed by the Secretary under subsection (b).

15 “(d) COMPENSATION FOR WORK INJURIES.—A tem-
16 porary disaster-response appointee, as designated by the
17 Secretary, shall be deemed an employee, and an injury
18 sustained by such an individual while actually serving or
19 while participating in a uncompensated training exercise
20 related to such service shall be deemed ‘in the performance
21 of duty’, for purposes of chapter 81 of title 5, United
22 States Code, pertaining to compensation for work injuries.
23 In the event of an injury to such a temporary disaster-
24 response appointee, the Secretary of Labor shall be re-
25 sponsible for making determinations as to whether the

1 claimants are entitled to compensation or other benefits
2 in accordance with chapter 81 of title 5, United States
3 Code.

4 “(e) EMPLOYMENT AND REEMPLOYMENT RIGHTS.—

5 “(1) IN GENERAL.—A temporary disaster-re-
6 sponse appointee, as designated by the Secretary,
7 shall, when performing service as a temporary dis-
8 aster-response appointee or participating in an un-
9 compensated training exercise related to such serv-
10 ice, be deemed a person performing ‘service in the
11 uniformed services’ for purposes of chapter 43 of
12 title 38, United States Code, pertaining to employ-
13 ment and reemployment rights of members in the
14 uniformed services. All rights and obligations of such
15 persons and procedures for assistance, enforcement,
16 and investigation shall be as provided for in chapter
17 43 of title 38, United States Code.

18 “(2) NOTICE OF ABSENCE FROM POSITION OF
19 EMPLOYMENT.—Preclusion of giving notice of serv-
20 ice by disaster response necessity shall be deemed
21 preclusion by ‘military necessity’ for purposes of sec-
22 tion 4312(b) of title 38, United States Code, per-
23 taining to giving notice of absence from a position
24 of employment. A determination of disaster response
25 necessity shall be made pursuant to regulations pre-

1 scribed by the Secretary, in consultation with the
 2 Secretary of Defense, and shall not be subject to ju-
 3 dicial review.

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

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

12 (a) PROVISION OF DECLARATION TO CONGRESS.—
 13 Section 319(a) of the Public Health Service Act (42
 14 U.S.C. 247d(a)) is amended by adding at the end the fol-
 15 lowing: “Not later than 48 hours after a declaration of
 16 a public health emergency under this section, the Sec-
 17 retary shall provide a written declaration to Congress indi-
 18 cating that an emergency under this section has been de-
 19 clared.”.

20 (b) WAIVER OF REPORTING DEADLINES.—Section
 21 319 of the Public Health Service Act (42 U.S.C. 247d)
 22 is amended by adding at the end the following:

23 “(d) WAIVER OF DATA SUBMITTAL AND REPORTING
 24 DEADLINES.—In any case in which the Secretary deter-
 25 mines that, wholly or partially as a result of a public

1 health emergency that has been declared pursuant to sub-
 2 section (a), individuals or public or private entities are un-
 3 able to comply with deadlines for the submission to the
 4 Secretary of data or reports required under any law ad-
 5 ministered by the Secretary, the Secretary may, notwith-
 6 standing any other provision of law, grant such extensions
 7 of such deadlines as the circumstances reasonably require,
 8 and may waive any sanctions otherwise applicable to such
 9 failure to comply.”.

10 (c) EMERGENCY DECLARATION PERIOD.—Section
 11 319 of the Public Health Service Act (42 U.S.C. 247d),
 12 as amended by subsection (b), is further amended by add-
 13 ing at the end the following:

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

20 “(1) the Secretary determines that such an ex-
 21 tension is appropriate; and

22 “(2) the Secretary provides a written notifica-
 23 tion to Congress within 48 hours of such exten-
 24 sion.”.

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

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

6 “(a) **WORKING GROUP ON BIOTERRORISM.**—The
7 Secretary, in coordination with the Secretary of Defense,
8 the Director of the Federal Emergency Management
9 Agency, the Attorney General, the Secretary of Veterans
10 Affairs, the Secretary of Labor, and the Secretary of Agri-
11 culture, and with other similar Federal officials as deter-
12 mined appropriate, shall establish a joint interdepart-
13 mental working group on the prevention, preparedness,
14 and response to a biological threat or attack on the civilian
15 population. Such joint working group shall—

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

19 “(2) coordinate and facilitate the awarding of
20 grants, contracts, or cooperative agreements for the
21 development, manufacture, distribution, and pur-
22 chase of priority countermeasures;

23 “(3) coordinate research on pathogens likely to
24 be used in a biological threat or attack on the civil-
25 ian population;

1 “(4) develop shared standards for equipment to
2 detect and to protect against biological agents and
3 toxins;

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

7 “(6) assess the priorities for and enhance the
8 preparedness of public health institutions, providers
9 of medical care, and other emergency service per-
10 sonnel (including firefighters) to detect, diagnose,
11 and respond (including mental health response) to a
12 biological threat or attack;

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

20 “(A) local firefighters, ambulance per-
21 sonnel, police and public security officers, or
22 other emergency response personnel; and

23 “(B) hospitals, primary care facilities, and
24 public health agencies;

1 “(8) coordinate the development of strategies
2 for Federal, State, and local agencies to commu-
3 nicate information to the public regarding biological
4 threats or attacks;

5 “(9) develop methods to decontaminate facilities
6 contaminated as a result of a biological attack, in-
7 cluding appropriate protections for the safety of
8 those conducting such activities; and

9 “(10) ensure that the activities under this sub-
10 section address the needs of children and other vul-
11 nerable populations.

12 The working group shall carry out paragraphs (1) and (2)
13 in consultation with the pharmaceutical, biotechnology,
14 and medical device industries, and other appropriate ex-
15 perts.

16 “(b) ADVICE TO THE FEDERAL GOVERNMENT.—The
17 Secretary shall establish advisory committees to provide
18 expert recommendations to the Secretary to assist the Sec-
19 retary, including the following:

20 “(1) NATIONAL TASK FORCE ON CHILDREN
21 AND TERRORISM.—

22 “(A) IN GENERAL.—The National Task
23 Force on Children and Terrorism, which shall
24 be composed of such Federal officials as may be
25 appropriate to address the special needs of chil-

dren, and child health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines.

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

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

“(ii) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of children with respect to a biological threat or attack; and

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

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

“(A) IN GENERAL.—The Emergency Public Information and Communications (EPIC) Task Force, which shall be composed of individuals with expertise in public health, communica-

tions, behavioral psychology, and other areas determined appropriate by the Secretary.

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

“(3) SUNSET.—Each Task Force established under paragraphs (1) and (3) shall terminate on the date that is 1 year after the date of enactment of the Bioterrorism Preparedness Act of 2001.

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

It is the recommendation of Congress that there should be established an official Federal Internet site on bioterrorism, either directly or through provision of a grant to an entity that has expertise in bioterrorism and the development of websites, that should include information relevant to diverse populations (including messages directed at the general public and such relevant groups

1 as medical personnel, public safety workers, and agricul-
 2 tural workers) and links to appropriate State and local
 3 government sites.

4 **SEC. 215. TECHNICAL AMENDMENTS.**

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

7 (1) in subsection (a), by striking “competitive”;
 8 and

9 (2) in subsection (f), by inserting
 10 “\$420,000,000 for fiscal year 2002,” after “2001,”.

11 **SEC. 216. REGULATION OF BIOLOGICAL AGENTS AND TOX-**
 12 **INS.**

13 (a) BIOLOGICAL AGENTS PROVISIONS OF THE
 14 ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT
 15 OF 1996; CODIFICATION IN THE PUBLIC HEALTH SERV-
 16 ICE ACT, WITH AMENDMENTS.—

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

21 **“SEC. 351A. ENHANCED CONTROL OF BIOLOGICAL AGENTS**
 22 **AND TOXINS.**

23 “(a) REGULATORY CONTROL OF BIOLOGICAL
 24 AGENTS AND TOXINS.—

1 “(1) LIST OF BIOLOGICAL AGENTS AND TOX-
2 INS.—

3 “(A) IN GENERAL.—The Secretary shall by
4 regulation establish and maintain a list of each
5 biological agent and each toxin that has the po-
6 tential to pose a severe threat to public health
7 and safety.

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

11 “(i) consider—

12 “(I) the effect on human health
13 of exposure to the agent or toxin;

14 “(II) the degree of contagious-
15 ness of the agent or toxin and the
16 methods by which the agent or toxin
17 is transferred to humans;

18 “(III) the availability and effec-
19 tiveness of pharmacotherapies and im-
20 munizations to treat and prevent any
21 illness resulting from infection by the
22 agent or toxin; and

23 “(IV) any other criteria, includ-
24 ing the needs of children and other

1 vulnerable populations, that the Sec-
2 retary considers appropriate; and

3 “(ii) consult with appropriate Federal
4 departments and agencies, and scientific
5 experts representing appropriate profes-
6 sional groups, including those with pedi-
7 atric expertise.

8 “(2) BIENNIAL REVIEW.—The Secretary shall
9 review and republish the list under paragraph (1) bi-
10 ennially, or more often as needed, and shall, through
11 rulemaking, revise the list as necessary to incor-
12 porate additions or deletions to ensure public health,
13 safety, and security.

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

16 “(A) attenuated or inactive biological
17 agents or toxins used in biomedical research or
18 for legitimate medical purposes; and

19 “(B) products that are cleared or approved
20 under the Federal Food, Drug, and Cosmetic
21 Act or under the Virus-Serum-Toxin Act, as
22 amended in 1985 by the Food Safety and Secu-
23 rity Act.”;

1 “(b) REGULATION OF TRANSFERS OF LISTED BIO-
2 LOGICAL AGENTS AND TOXINS.—The Secretary shall by
3 regulation provide for—

4 “(1) the establishment and enforcement of safe-
5 ty procedures for the transfer of biological agents
6 and toxins listed pursuant to subsection (a)(1), in-
7 cluding measures to ensure—

8 “(A) proper training and appropriate skills
9 to handle such agents and toxins; and

10 “(B) proper laboratory facilities to contain
11 and dispose of such agents and toxins;

12 “(2) safeguards to prevent access to such
13 agents and toxins for use in domestic or inter-
14 national terrorism or for any other criminal purpose;

15 “(3) the establishment of procedures to protect
16 the public safety in the event of a transfer or poten-
17 tial transfer of a biological agent or toxin in viola-
18 tion of the safety procedures established under para-
19 graph (1) or the safeguards established under para-
20 graph (2); and

21 “(4) appropriate availability of biological agents
22 and toxins for research, education, and other legiti-
23 mate purposes.

24 “(c) POSSESSION AND USE OF LISTED BIOLOGICAL
25 AGENTS AND TOXINS.—The Secretary shall by regulation

1 provide for the establishment and enforcement of stand-
2 ards and procedures governing the possession and use of
3 biological agents and toxins listed pursuant to subsection
4 (a)(1) in order to protect the public health and safety, in-
5 cluding the measures, safeguards, procedures, and avail-
6 ability of such agents and toxins described in paragraphs
7 (1) through (4) of subsection (b), respectively.

8 “(d) REGISTRATION AND TRACEABILITY MECHA-
9 NISMS.—Regulations under subsections (b) and (c) shall
10 require registration of the possession, use, and transfer
11 of biological agents and toxins listed pursuant to sub-
12 section (a)(1), and such registration shall include (if avail-
13 able to the registered person) information regarding the
14 characterization of such biological agents and toxins to fa-
15 cilitate their identification and traceability. The Secretary
16 shall maintain a national database of the location of such
17 biological agents and toxins with information regarding
18 their characterizations.

19 “(e) INSPECTIONS.—The Secretary shall have the au-
20 thority to inspect persons subject to the regulations under
21 subsections (b) and (c) to ensure their compliance with
22 such regulations, including prohibitions on restricted per-
23 sons under subsection (g).

24 “(f) EXEMPTIONS.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish exemptions, including exemptions from the secu-
3 rity provisions for the use of attenuated or inactive
4 biological agents or toxins in biomedical research or
5 for legitimate medical purposes, from the applica-
6 bility of provisions of—

7 “(A) the regulations issued under sub-
8 section (b) when the Secretary determines that
9 the exemptions, including exemptions from the
10 security requirements, are consistent with pro-
11 tecting public health and safety; and

12 “(B) the regulations issued under sub-
13 section (c) when the Secretary determines that
14 the exemptions, including exemptions from the
15 security requirements, are consistent with pro-
16 tecting public health and safety and that the
17 agent or toxin does not present a threat of use
18 in domestic or international terrorism.

19 “(2) CLINICAL LABORATORIES.—The Secretary
20 shall exempt clinical laboratories and other persons
21 that possess, use, or transfer biological agents and
22 toxins listed pursuant to subsection (a)(1) from the
23 applicability of provisions of regulations issued
24 under subsections (b) and (c) only when—

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

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

7 “(C) such agents or toxins are transferred
8 or destroyed in a manner set forth by the Sec-
9 retary in regulation.

10 “(g) SECURITY REQUIREMENTS FOR REGISTERED
11 PERSONS.—

12 “(1) SECURITY.—In carrying out paragraphs
13 (2) and (3) of subsection (b), the Secretary shall es-
14 tablish appropriate security requirements for persons
15 possessing, using, or transferring biological agents
16 and toxins listed pursuant to subsection (a)(1), con-
17 sidering existing standards developed by the Attor-
18 ney General for the security of government facilities,
19 and shall ensure compliance with such requirements
20 as a condition of registration under regulations
21 issued under subsections (b), (c), and (d).

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

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

5 “(B) to provide that registered persons
6 promptly submit the names and other identi-
7 fying information for such individuals to the At-
8 torney General, with which information the At-
9 torney General shall promptly use criminal, im-
10 migration, and national security databases
11 available to the Federal Government to identify
12 whether such individuals—

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

16 “(ii) are named in a warrant issued to
17 a Federal or State law enforcement agency
18 for participation in any domestic or inter-
19 national act of terrorism.

20 “(3) CONSULTATION AND IMPLEMENTATION.—
21 Regulations under subsections (b) and (c) shall be
22 developed in consultation with research-performing
23 organizations, including universities, and imple-
24 mented with timeframes that take into account the
25 need to continue research and education using bio-

1 logical agents and toxins listed pursuant to sub-
2 section (a)(1).

3 “(h) DISCLOSURE OF INFORMATION.—

4 “(1) IN GENERAL.—Any information in the
5 possession of any Federal agency that identifies a
6 person, or the geographic location of a person, who
7 is registered pursuant to regulations under this sec-
8 tion (including regulations promulgated before the
9 effective date of this subsection), or any site-specific
10 information relating to the type, quantity, or charac-
11 terization of a biological agent or toxin listed pursu-
12 ant to subsection (a)(1) or the site-specific security
13 mechanisms in place to protect such agents and tox-
14 ins, including the national database required in sub-
15 section (d), shall not be disclosed under section
16 552(a) of title 5, United States Code.

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

21 “(A) from making disclosures of informa-
22 tion described in paragraph (1) for purposes of
23 protecting the public health and safety; or

24 “(B) from making disclosures of such in-
25 formation to any committee or subcommittee of

1 the Congress with appropriate jurisdiction,
2 upon request.

3 “(i) CIVIL PENALTY.—In addition to any other pen-
4 alties that may apply under law, any person who violates
5 any provision of a regulation issued under subsection (b)
6 or (c) shall be subject to the United States for a civil pen-
7 alty in an amount not exceeding \$250,000 in the case of
8 an individual and \$500,000 in the case of any other per-
9 son.

10 “(j) DEFINITIONS.—For purposes of this section, the
11 terms ‘biological agent’ and ‘toxin’ have the same meaning
12 as in section 178 of title 18, United States Code.”.

13 (2) REGULATIONS.—

14 (A) DATE CERTAIN FOR PROMULGATION;
15 EFFECTIVE DATE REGARDING CRIMINAL AND
16 CIVIL PENALTIES.—Not later than 180 days
17 after the date of the enactment of this title, the
18 Secretary of Health and Human Services shall
19 promulgate an interim final rule for carrying
20 out section 351A(c) of the Public Health Serv-
21 ice Act, which amends the Antiterrorism and
22 Effective Death Penalty Act of 1996. Such in-
23 terim final rule will take effect 60 days after
24 the date on which such rule is promulgated, in-
25 cluding for purposes of—

1 (i) section 175(b) of title 18, United
 2 States Code (relating to criminal pen-
 3 alties), as added by subsection (b)(1)(B) of
 4 this section; and

5 (ii) section 351A(i) of the Public
 6 Health Service Act (relating to civil pen-
 7 alties).

8 (B) SUBMISSION OF REGISTRATION APPLI-
 9 CATIONS.—A person required to register for
 10 possession under the interim final rule promul-
 11 gated under subparagraph (A), shall submit an
 12 application for such registration not later than
 13 60 days after the date on which such rule is
 14 promulgated.

15 (3) CONFORMING AMENDMENT.—Subsections
 16 (d), (e), (f), and (g) of section 511 of the
 17 Antiterrorism and Effective Death Penalty Act of
 18 1996 (42 U.S.C. 262 note) are repealed.

19 (4) EFFECTIVE DATE.—Paragraph (1) shall
 20 take effect as if incorporated in the Antiterrorism
 21 and Effective Death Penalty Act of 1996, and any
 22 regulations, including the list under subsection
 23 (d)(1) of section 511 of that Act, issued under sec-
 24 tion 511 of that Act shall remain in effect as if

1 issued under section 351A of the Public Health
2 Service Act.

3 (b) SELECT AGENTS.—

4 (1) IN GENERAL.—Section 175 of title 18,
5 United States Code, as amended by the Uniting and
6 Strengthening America by Providing Appropriate
7 Tools Required to Intercept and Obstruct Terrorism
8 (USA PATRIOT ACT) Act of 2001 (Public Law
9 107–56) is amended—

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

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

14 “(b) SELECT AGENTS.—

15 “(1) UNREGISTERED FOR POSSESSION.—Who-
16 ever knowingly possesses a biological agent or toxin
17 where such agent or toxin is a select agent for which
18 such person has not obtained a registration required
19 by regulation issued under section 351A(c) of the
20 Public Health Service Act shall be fined under this
21 title, or imprisoned for not more than 5 years, or
22 both.

23 “(2) TRANSFER TO UNREGISTERED PERSON.—
24 Whoever transfers a select agent to a person who
25 the transferor has reasons to believe has not ob-

1 tained a registration required by regulations issued
 2 under section 351A(b) or (c) of the Public Health
 3 Service Act shall be fined under this title, or impris-
 4 oned for not more than 5 years, or both.”.

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

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

10 “(1) The terms ‘biological agent’ and ‘toxin’
 11 have the meanings given such terms in section 178,
 12 except that, for purposes of subsections (b) and (c),
 13 such terms do not encompass any biological agent or
 14 toxin that is in its naturally occurring environment,
 15 if the biological agent or toxin has not been cul-
 16 tivated, cultured, collected, or otherwise extracted
 17 from its natural source.

18 “(2) The term ‘for use as a weapon’ includes
 19 the development, production, transfer, acquisition,
 20 retention, or possession of any biological agent,
 21 toxin, or delivery system, other than for prophy-
 22 lactic, protective, or other peaceful purposes.

23 “(3) The term ‘select agent’ means a biological
 24 agent or toxin, as defined in paragraph (1), that is
 25 on the list that is in effect pursuant to section

1 511(d)(1) of the Antiterrorism and Effective Death
2 Penalty Act of 1996 (Public Law 104–132), or as
3 subsequently revised under section 351A(a) of the
4 Public Health Service Act.”.

5 (3) CONFORMING AMENDMENT.—

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

10 (B) Section 175(c) of title 18, United
11 States Code, (as redesignated by paragraph
12 (1)), is amended by striking the second sen-
13 tence.

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

19 (1) describes the extent to which there has been
20 compliance by governmental and private entities
21 with applicable regulations under section 351A of
22 the Public Health Service Act, including the extent
23 of compliance before the date of the enactment of
24 this Act, and including the extent of compliance with

1 regulations promulgated after such date of enact-
 2 ment;

3 (2) describes the actions to date and future
 4 plans of the Secretary for updating the list of bio-
 5 logical agents and toxins under section 351A(a)(1)
 6 of the Public Health Service Act;

7 (3) describes the actions to date and future
 8 plans of the Secretary for determining compliance
 9 with regulations under such section 351A of the
 10 Public Health Service Act and for taking appro-
 11 priate enforcement actions; and

12 (4) provides any recommendations of the Sec-
 13 retary for administrative or legislative initiatives re-
 14 garding such section 351A of the Public Health
 15 Service Act.

16 **TITLE III—IMPROVING STATE**
 17 **AND LOCAL PREPAREDNESS**
 18 **Subtitle A—Emergency Measures**
 19 **to Improve State and Local Pre-**
 20 **paredness**

21 **SEC. 301. STATE BIOTERRORISM PREPAREDNESS AND RE-**
 22 **SPONSE BLOCK GRANT.**

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

1 “(c) STATE BIOTERRORISM PREPAREDNESS AND RE-
2 SPONSE BLOCK GRANTS.—

3 “(1) IN GENERAL.—The Secretary shall estab-
4 lish the State Bioterrorism Preparedness and Re-
5 sponse Block Grant Program (referred to in this
6 subsection as the ‘Program’) under which the Sec-
7 retary shall award grants to or enter into coopera-
8 tive agreements with States, the District of Colum-
9 bia, and territories (referred to in this section as ‘eli-
10 gible entities’) to enable such entities to prepare for
11 and respond to biological threats or attacks. The
12 Secretary shall ensure that activities conducted
13 under this section are coordinated with the activities
14 conducted under this section and section 319C.

15 “(2) ELIGIBILITY.—To be eligible to receive
16 amounts under paragraph (1), a State, the District
17 of Columbia, or a territory shall prepare and submit
18 to the Secretary an application at such time, in such
19 manner, and containing such information as the Sec-
20 retary may require, including an assurance that the
21 entity will—

22 “(A) not later than 180 days after the date
23 on which a grant or contract is received under
24 this subsection, prepare and submit to the Sec-
25 retary a State Bioterrorism Preparedness and

1 Response Plan in accordance with subsection
2 (c);

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

10 “(C) establish a means by which to obtain
11 public comment and input on the plan and plan
12 implementation that shall include an advisory
13 committee or other similar mechanism for ob-
14 taining input from the public at large as well as
15 other stakeholders;

16 “(D) use amounts received under para-
17 graph (1) in accordance with the plan sub-
18 mitted under paragraph (3), including making
19 expenditures to carry out the strategy contained
20 in the plan;

21 “(E) use amounts received under para-
22 graph (1) to supplement and not supplant fund-
23 ing at levels in existence prior to and on Sep-
24 tember 11, 2001 for public health capacities or
25 bioterrorism preparedness; and

1 “(F) with respect to the plan under para-
2 graph (3), establish reasonable criteria to evalu-
3 ate the effective performance of entities that re-
4 ceive funds under the grant or agreement and
5 shall include relevant benchmarks in the plan.

6 “(3) BIOTERRORISM PREPAREDNESS AND RE-
7 SPONSE PLAN.—Not later than 180 days after re-
8 ceiving amounts under this subsection, and 1 year
9 after such date, a State, the District of Columbia,
10 or a territory shall prepare and submit to the Sec-
11 retary a Bioterrorism Preparedness and Response
12 Plan for responding to biological threats or attacks.
13 Recognizing the assessment of public health capacity
14 conducted under section 319B, such plan shall
15 include—

16 “(A) a description of the program that the
17 eligible entity will adopt to achieve the core ca-
18 pacities developed under section 319A, includ-
19 ing measures that meet the needs of children
20 and other vulnerable populations;

21 “(B) a description (including amounts ex-
22 pended by the eligible entity for such purpose)
23 of the programs, projects, and activities that
24 the eligible entity will implement using amounts
25 received in order to detect and respond to bio-

1 logical threats or attacks, including the manner
2 in which the eligible entity will manage State
3 surveillance and response efforts and coordinate
4 such efforts with national efforts;

5 “(C) a description of the training initia-
6 tives that the eligible entity has carried out to
7 improve its ability to detect and respond to a
8 biological threat or attack, including training
9 and planning to protect the health and safety of
10 those conducting such detection and response
11 activities;

12 “(D) a description of the cleanup and con-
13 tamination prevention efforts that may be im-
14 plemented in the event of a biological threat or
15 attack;

16 “(E) a description of efforts to ensure that
17 hospitals and health care providers have ade-
18 quate capacity and plans in place to provide
19 health care items and services (including mental
20 health services and services to meet the needs
21 of children and other vulnerable populations
22 that may include the provision of telehealth
23 services) in the event of a biological threat or
24 attack; and

1 “(F) other information the Secretary may
2 by regulation require.

3 “Nothing in subparagraph (E) shall be con-
4 strued to require or recommend that States establish
5 or maintain stockpiles of vaccines, therapies, or
6 other medical supplies.

7 “(4) USE OF FUNDS.—

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

12 “(i) conduct the assessment under
13 section 319B to achieve the capacities de-
14 scribed in section 319A, if the assessment
15 has not previously been conducted;

16 “(ii) achieve the public health capac-
17 ities developed under section 319A; and

18 “(iii) carry out the plan under para-
19 graph (3).

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

24 “(i) improve surveillance, detection,
25 and response activities to prepare for

1 emergency response activities including bi-
2 ological threats or attacks, including train-
3 ing personnel in these and other necessary
4 functions;

5 “(ii) carry out activities to improve
6 communications and coordination efforts
7 within the eligible entity and between the
8 eligible entity and the Federal Govern-
9 ment, including activities to improve infor-
10 mation technology and communications
11 equipment available to health care and
12 public health officials for use in responding
13 to a biological threat or attack or other
14 public health emergency and including
15 early warning and surveillance networks
16 that use advanced information technology
17 to provide early detection of biological
18 threats or attacks;

19 “(iii) plan for triage and transport
20 management in the event of a biological
21 threat or attack;

22 “(iv) meet the special needs of chil-
23 dren and other vulnerable populations dur-
24 ing and after a biological threat or attack,
25 including the expansion of 2–1–1 call cen-

1 ters or other universal hotlines, or an al-
2 ternative communication plan to assist vic-
3 tims and their families in receiving timely
4 information;

5 “(v) improve the ability of hospitals
6 and other health care facilities to provide
7 effective health care (including mental
8 health care) during and after a biological
9 threat or attack, including the development
10 of model hospital preparedness plans by a
11 hospital accreditation organization or simi-
12 lar organizations; and

13 “(vi) enhance the safety of workplaces
14 in the event of a biological threat or at-
15 tack, except that nothing in this clause
16 shall be construed to create a new, or devi-
17 ate from an existing, authority to regulate,
18 modify, or otherwise effect safety and
19 health rules and standards.

20 “(C) PROHIBITED USES.—An eligible enti-
21 ty may not use amounts received under this
22 subsection to—

23 “(i) provide inpatient services;

24 “(ii) make cash payments to intended
25 recipients of health services;

1 “(iii) purchase or improve land or
2 purchase any building or other facility;

3 “(iv) permanently improve any build-
4 ing or other facility; or

5 “(v) satisfy any requirement for the
6 expenditure of non-Federal funds as a con-
7 dition for the receipt of Federal funds.

8 “(5) AMOUNT OF GRANT.—

9 “(A) IN GENERAL.—Except as provided in
10 paragraph (2), the amount awarded to a State,
11 the District of Columbia, or a territory under
12 this subsection for a fiscal year shall be an
13 amount that bears the same ratio to the
14 amount appropriated under paragraph (9) for
15 such fiscal year (and remaining after amounts
16 are made available under subparagraphs (C)
17 and (D)) as the total population of the State,
18 District, or territory bears to the total popu-
19 lation of the United States.

20 “(B) EXCEPTIONS.—

21 “(i) MINIMUM AMOUNT WITH RE-
22 SPECT TO STATES.—Notwithstanding sub-
23 paragraph (A) and subject to the extent of
24 amounts made available under paragraph
25 (9), a State may not receive an award

1 under this subsection for a fiscal year in
2 an amount that is less than—

3 “(I) \$5,000,000 for any fiscal
4 year in which the total amount appro-
5 priated under this subsection equals
6 or exceeds \$667,000,000; or

7 “(II) 0.75 percent of the total
8 amount appropriated under this sub-
9 section for any fiscal year in which
10 such total amount is less than
11 \$667,000,000.

12 “(ii) EXTRAORDINARY NEEDS.—

13 “(I) IN GENERAL.—Notwith-
14 standing subparagraph (A) and sub-
15 ject to the extent of amounts made
16 available under paragraph (9), the
17 Secretary may provide additional
18 funds to a State, District, or territory
19 under this subsection if the Secretary
20 determines that such State, District,
21 or territory has extraordinary needs
22 with respect to bioterrorism prepared-
23 ness.

24 “(II) FINDING WITH RESPECT TO
25 THE DISTRICT OF COLUMBIA.—As a

1 result of the concentration of entities
2 of national significance located within
3 the District of Columbia, Congress
4 finds that the District of Columbia
5 has extraordinary needs with respect
6 to bioterrorism preparedness, and the
7 Secretary shall recognize such finding
8 for purposes of subclause (I).

9 “(C) RULE WITH RESPECT TO UNEX-
10 PENDED FUNDS.—To the extent that all the
11 funds appropriated under paragraph (9) for a
12 fiscal year and available in such fiscal year are
13 not otherwise paid to eligible entities because—

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

18 “(ii) one or more eligible entities have
19 notified the Secretary that they do not in-
20 tend to use the full amount awarded under
21 this subsection; or

22 “(iii) some eligible entity amounts are
23 offset or repaid;

24 such excess shall be provided to each of the re-
25 maining eligible entities in proportion to the

1 amount otherwise provided to such entities
 2 under this paragraph for the fiscal year without
 3 regard to this subparagraph.

4 “(D) AVAILABILITY OF FUNDS.—Any
 5 amount paid to an eligible entity for a fiscal
 6 year under this subsection and remaining unob-
 7 ligated at the end of such year shall remain
 8 available for the next fiscal year to such entity
 9 for the purposes for which it was made.

10 “(6) INDIAN TRIBES.—

11 “(A) IN GENERAL.—If the Secretary—

12 “(i) receives a request from the gov-
 13 erning body of an Indian tribe or tribal or-
 14 ganization within any State that funds
 15 under this subsection be provided directly
 16 by the Secretary to such tribe or organiza-
 17 tion; and

18 “(ii) determines that the members of
 19 such tribe or tribal organization would be
 20 better served by means of grants or agree-
 21 ments made directly by the Secretary
 22 under this subsection;

23 the Secretary shall reserve from amounts which
 24 would otherwise be provided to such State

1 under this subsection for the fiscal year the
2 amount determined under subparagraph (B).

3 “(B) AMOUNT.—The Secretary shall re-
4 serve for the purpose of subparagraph (A) from
5 amounts that would otherwise be paid to such
6 State under paragraph (1) an amount equal to
7 the amount which bears the same ratio to the
8 amount awarded to the State for the fiscal year
9 involved as the population of the Indian tribe or
10 the individuals represented by the tribal organi-
11 zation bears to the total population of the
12 State.

13 “(C) GRANT.—The amount reserved by the
14 Secretary on the basis of a determination under
15 this paragraph shall be granted to the Indian
16 tribe or tribal organization serving the individ-
17 uals for whom such a determination has been
18 made.

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

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

“(7) WITHHOLDING.—

“(A) REQUIREMENTS.—

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

“(ii) INVESTIGATION.—The Secretary may not institute proceedings to withhold or recoup funds under clause (i) unless the Secretary has conducted an investigation concerning whether the eligible entity has

1 used grant or agreement amounts in ac-
2 cordance with the requirements of this
3 subsection. Investigations required by this
4 clause shall be conducted within the af-
5 fected entity by qualified investigators.

6 “(iii) RESPONSE TO COMPLAINTS.—

7 The Secretary shall respond in an expedi-
8 tious manner to complaints of a substan-
9 tial or serious nature that an eligible entity
10 has failed to use funds in accordance with
11 the requirements of this subsection.

12 “(iv) MINOR FAILURES.—The Sec-

13 retary may not withhold or recoup funds
14 under clause (i) from an eligible entity for
15 a minor failure to comply with the require-
16 ments of this subsection.

17 “(B) AVAILABILITY OF INFORMATION FOR

18 INSPECTION.—Each eligible entity, and other
19 entity which has received funds under this sec-
20 tion, shall make appropriate books, documents,
21 papers, and records available to the Secretary
22 or the Comptroller General of the United
23 States, or any of their duly authorized rep-
24 resentatives, for examination, copying, or me-
25 chanical reproduction on or off the premises of

1 the appropriate entity upon a reasonable re-
 2 quest therefore.

3 “(C) LIMITATION ON REQUESTS FOR IN-
 4 FORMATION.—

5 “(i) IN GENERAL.—In conducting any
 6 investigation in an eligible entity, the Sec-
 7 retary or the Comptroller General of the
 8 United States may not make a request for
 9 any information not readily available to
 10 such eligible entity, or an entity which has
 11 received funds under this subsection, or
 12 make an unreasonable request for informa-
 13 tion to be compiled, collected, or trans-
 14 mitted in any form not readily available.

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

19 “(8) DEFINITION.—In this subsection, the term
 20 ‘State’ means any of the several States.

21 “(9) AUTHORIZATION OF APPROPRIATIONS.—
 22 There is authorized to be appropriated to carry out
 23 this subsection, \$670,000,000 for fiscal year 2002,
 24 and such sums as may be necessary for fiscal year

1 2003, and no funds are authorized to be appro-
 2 priated for subsequent fiscal years.”.

3 (b) REAUTHORIZATION OF OTHER PROGRAMS.—Sec-
 4 tion 319F(i) of the Public Health Service Act (42 U.S.C.
 5 247d–6(i)) is amended to read as follows:

6 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
 7 are authorized to be appropriated—

8 “(1) to carry out subsection (d), \$370,000,000
 9 for fiscal year 2002, and such sums as may be nec-
 10 essary for each subsequent fiscal year through 2006;
 11 and

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

15 **Subtitle B—Improving Local Pre-**
 16 **paredness and Response Capa-**
 17 **bilities**

18 **SEC. 311. DESIGNATED BIOTERRORISM RESPONSE MED-**
 19 **ICAL CENTERS.**

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

22 (1) by redesignating subsections (d) through (h)
 23 and (i), as subsections (e) through (i) and (l), re-
 24 spectively; and

1 (2) by inserting after subsection (c), the fol-
 2 lowing:

3 “(d) DESIGNATED BIOTERRORISM RESPONSE MED-
 4 ICAL CENTERS.—

5 “(1) GRANTS.—The Secretary shall award
 6 project grants to eligible entities to enable such enti-
 7 ties, in a manner consistent with applicable provi-
 8 sions of the State Bioterrorism Preparedness and
 9 Response Plan, to improve local and bioterrorism re-
 10 sponse medical center preparedness.

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

13 “(A) be a consortium that consists of at
 14 least one entity from each of the following
 15 categories—

16 “(i) a hospital including children’s
 17 hospitals, clinic, health center, or primary
 18 care facility;

19 “(ii) a political subdivision of a State;
 20 and

21 “(iii) a department of public health;

22 “(B) prepare, in consultation with the Gov-
 23 ernor or Governors of the State or States in
 24 which the hospital, clinic, health center, or pri-
 25 mary care facility is located, and submits to the

1 Secretary, an application at such time, in such
2 manner, and containing such information as the
3 Secretary may require;

4 “(C) within a reasonable period of time
5 after receiving a grant under paragraph (1),
6 meet such technical guidelines as may be appli-
7 cable under paragraph (4); and

8 “(D) provide assurances satisfactory to the
9 Secretary that such entity shall, upon the re-
10 quest of the Secretary or the Governor or Gov-
11 ernor of the State or States in which the entity
12 is located, during the emergency period, serve
13 the needs of the emergency area, including pro-
14 viding adequate health care capacity, serving as
15 a regional resource in the diagnosis, treatment,
16 or care for persons, including children and
17 other vulnerable populations, exposed to a bio-
18 logical attack, and accepting the transfer of pa-
19 tients, where appropriate.

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

23 “(A) the training of health care profes-
24 sionals to enhance the ability of such personnel
25 to recognize the symptoms of exposure to a po-

1 tential biological threat or attack and to provide
2 treatment to those so exposed;

3 “(B) the training of health care profes-
4 sionals to recognize and treat the mental health
5 consequences of a biological threat or attack;

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

10 “(D) the purchase of reserves of vaccines,
11 therapies, and other medical supplies to be used
12 until materials from the National Pharma-
13 ceutical Stockpile arrive;

14 “(E) training and planning to protect the
15 health and safety of personnel involved in re-
16 sponding to a biological threat or attack; or

17 “(F) other activities determined appro-
18 priate by the Secretary.

19 “(4) PROHIBITED USES.—An eligible entity
20 may not use amounts received under this subsection
21 to—

22 “(A) purchase or improve land or purchase
23 any building or other facility; or

24 “(B) permanently improve any building or
25 facility.

1 “(6) TECHNICAL ASSISTANCE.—Not later than
 2 180 days after the date of enactment of the Bioter-
 3 rorism Preparedness Act of 2001, the Secretary
 4 shall develop and publish technical guidelines relat-
 5 ing to equipment, training, treatment, capacity, and
 6 personnel, relevant to the status as a bioterrorism
 7 response medical center and the Secretary may pro-
 8 vide technical assistance to eligible entities, including
 9 assistance to address the needs of children and other
 10 vulnerable populations.”.

11 **SEC. 312. DESIGNATED STATE PUBLIC EMERGENCY AN-**
 12 **NOUNCEMENT PLAN.**

13 Section 613(b) of the Robert T. Stafford Disaster Re-
 14 lief and Emergency Assistance Act (42 U.S.C. 5196b(b))
 15 is amended—

16 (1) in paragraph (5), by striking “and” at the
 17 end;

18 (2) in paragraph (6), by striking the period and
 19 inserting “; and”; and

20 (3) by adding at the end the following:

21 “(7) include a plan for providing information to
 22 the public in a coordinated manner.”.

1 **SEC. 313. TRAINING FOR PEDIATRIC ISSUES SURROUNDING**
2 **BIOLOGICAL AGENTS USED IN WARFARE AND**
3 **TERRORISM.**

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

7 (1) in paragraph (1)—

8 (A) by inserting “(including mental health
9 care)” after “and care”; and

10 (B) by striking “and” at the end;

11 (2) in paragraph (2), by striking the period and
12 inserting “; and”; and

13 (3) by adding at the end the following:

14 “(3) develop educational programs for health
15 care professionals, recognizing the special needs of
16 children and other vulnerable populations.”.

17 **SEC. 314. GENERAL ACCOUNTING OFFICE REPORT.**

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

21 (1) by striking “Not later than 180 days after
22 the date of the enactment of this section, the” and
23 inserting “The”;

24 (2) in paragraph (3), by striking “and” at the
25 end;

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

3 (4) by adding at the end the following:

4 “(5) the activities and cost of the Civil Support
 5 Teams of the National Guard in responding to bio-
 6 logical threats or attacks against the civilian popu-
 7 lation;

8 “(6) the activities of the working group de-
 9 scribed in subsection (a) and the efforts made by
 10 such group to carry out the activities described in
 11 such subsection;

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

14 “(8) the activities and cost of the development
 15 and improvement of public health laboratory capac-
 16 ity.”.

17 **SEC. 315. ADDITIONAL RESEARCH.**

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

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

1 **SEC. 316. SENSE OF THE SENATE.**

2 It is the sense of the Senate that—

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

7 (2) accelerating the crucial work done at uni-
8 versity centers and laboratories will contribute sig-
9 nificantly to the United States capacity to defend
10 against any biological threat;

11 (3) maximizing the effectiveness of, and extend-
12 ing the mission of, established university programs
13 would be one appropriate use of the additional re-
14 sources provided for in the Bioterrorism Prepared-
15 ness Act of 2001; and

16 (4) Congress recognizes the importance of exist-
17 ing public university-based research, training, public
18 awareness, and safety related biological defense pro-
19 grams in the awarding of grants and contracts made
20 in accordance with this Act.

21 **TITLE IV—DEVELOPING NEW**
22 **COUNTERMEASURES**
23 **AGAINST BIOTERRORISM**

24 **SEC. 401. LIMITED ANTITRUST EXEMPTION.**

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

1 “(g) LIMITED ANTITRUST EXEMPTION.—

2 “(1) COUNTERMEASURES DEVELOPMENT MEET-
3 INGS.—

4 “(A) COUNTERMEASURES DEVELOPMENT
5 MEETINGS AND CONSULTATIONS.—The Sec-
6 retary may conduct meetings and consultations
7 with parties involved in the development of pri-
8 ority countermeasures for the purpose of the
9 development, manufacture, distribution, pur-
10 chase, or sale of priority countermeasures con-
11 sistent with the purposes of this title. The Sec-
12 retary shall give notice of such meetings and
13 consultations to the Attorney General and the
14 Chairperson of the Federal Trade Commission
15 (referred to in this subsection as the ‘Chair-
16 person’).

17 “(B) MEETING AND CONSULTATION CON-
18 DITIONS.—A meeting or consultation conducted
19 under subparagraph (A) shall—

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

22 “(ii) be open to parties involved in the
23 development, manufacture, distribution,
24 purchase, or sale of priority counter-
25 measures, as determined by the Secretary;

1 “(iii) be open to the Attorney General
2 and the Chairperson;

3 “(iv) be limited to discussions involv-
4 ing the development, manufacture, dis-
5 tribution, or sale of priority counter-
6 measures, consistent with the purposes of
7 this title; and

8 “(v) be conducted in such manner as
9 to ensure that national security, confiden-
10 tial, and proprietary information is not dis-
11 closed outside the meeting or consultation.

12 “(C) MINUTES.—The Secretary shall
13 maintain minutes of meetings and consultations
14 under this subsection, which shall not be dis-
15 closed under section 552 of title 5, United
16 States Code.

17 “(D) EXEMPTION.—The antitrust laws
18 shall not apply to meetings and consultations
19 under this paragraph, except that any agree-
20 ment or conduct that results from a meeting or
21 consultation and that does not receive an ex-
22 emption pursuant to this subsection shall be
23 subject to the antitrust laws.

24 “(2) WRITTEN AGREEMENTS.—The Secretary
25 shall file a written agreement regarding covered ac-

1 tivities, made pursuant to meetings or consultations
2 conducted under paragraph (1) and that is con-
3 sistent with this paragraph, with the Attorney Gen-
4 eral and the Chairperson for a determination of the
5 compliance of such agreement with antitrust laws.
6 In addition to the proposed agreement itself, any
7 such filing shall include—

8 “(A) an explanation of the intended pur-
9 pose of the agreement;

10 “(B) a specific statement of the substance
11 of the agreement;

12 “(C) a description of the methods that will
13 be utilized to achieve the objectives of the
14 agreement;

15 “(D) an explanation of the necessity of a
16 cooperative effort among the particular partici-
17 pating parties to achieve the objectives of the
18 agreement; and

19 “(E) any other relevant information deter-
20 mined necessary by the Secretary in consulta-
21 tion with the Attorney General and the Chair-
22 person.

23 “(3) DETERMINATION.—The Attorney General,
24 in consultation with the Chairperson, shall determine

1 whether an agreement regarding covered activities
2 referred to in paragraph (2) would likely—

3 “(A) be in compliance with the antitrust
4 laws, and so inform the Secretary and the par-
5 ticipating parties; or

6 “(B) violate the antitrust laws, in which
7 case, the filing shall be deemed to be a request
8 for an exemption from the antitrust laws, lim-
9 ited to the performance of the agreement con-
10 sistent with the purposes of this title.

11 “(4) ACTION ON REQUEST FOR EXEMPTION.—

12 “(A) IN GENERAL.—The Attorney General,
13 in consultation with the Chairperson, shall
14 grant, deny, grant in part and deny in part, or
15 propose modifications to a request for exemp-
16 tion from the antitrust laws under paragraph
17 (3) within 15 days of the receipt of such re-
18 quest.

19 “(B) EXTENSION.—The Attorney General
20 may extend the 15-day period referred to in
21 subparagraph (A) for an additional period of
22 not to exceed 10 days. Such additional period
23 may be further extended only by the United
24 States district court, upon an application by the

1 Attorney General after notice to the Secretary
2 and the parties involved.

3 “(C) DETERMINATION.—In granting an
4 exemption under this paragraph, the Attorney
5 General, in consultation with the Chairperson
6 and the Secretary—

7 (i) must find—

8 “(I) that the agreement involved
9 is necessary to ensure the availability
10 of priority countermeasures;

11 “(II) that the exemption from
12 the antitrust laws would promote the
13 public interest; and

14 “(III) that there is no substantial
15 competitive impact to areas not di-
16 rectly related to the purposes of the
17 agreement; and

18 “(ii) may consider any other factors
19 determined relevant by the Attorney Gen-
20 eral and the Chairperson.

21 “(5) LIMITATION ON AND RENEWAL OF EXEMP-
22 TIONS.—An exemption granted under paragraph (4)
23 shall be limited to covered activities, and shall expire
24 on the date that is 3 years after the date on which
25 the exemption becomes effective (and at 3 year in-

1 tervals thereafter, if renewed) unless the Attorney
2 General in consultation with the Chairperson deter-
3 mines that the exemption should be renewed (with
4 modifications, as appropriate) considering the fac-
5 tors described in paragraph (4).

6 “(6) LIMITATION ON PARTIES.—The use of any
7 information acquired under an exempted agreement
8 by the parties to such an agreement for any pur-
9 poses other than those specified in the antitrust ex-
10 emption granted by the Attorney General shall be
11 subject to the antitrust laws and any other applica-
12 ble laws.

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

16 “(8) REPORT.—Not later than 1 year after the
17 date of enactment of the Bioterrorism Preparedness
18 Act of 2001, and annually thereafter, the Attorney
19 General and the Chairperson shall report to Con-
20 gress on the use and continuing need for the exemp-
21 tion from the antitrust laws provided by this sub-
22 section.

23 “(9) SUNSET.—The authority of the Attorney
24 General to grant or renew a limited antitrust exemp-
25 tion under this subsection shall expire at the end of

1 the 6-year period that begins on the date of enact-
 2 ment of the Bioterrorism Preparedness Act of 2001.

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

5 “(1) ANTITRUST LAWS.—The term ‘antitrust
 6 laws’—

7 “(A) has the meaning given such term in
 8 subsection (a) of the first section of the Clayton
 9 Act (15 U.S.C. 12(a)), except that such term
 10 includes the Act of June 19, 1936 (15 U.S.C.
 11 13 et seq.) commonly known as the Robinson-
 12 Patman Act), and section 5 of the Federal
 13 Trade Commission Act (15 U.S.C. 45) to the
 14 extent such section 5 applies to unfair methods
 15 of competition; and

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

18 “(2) COVERED ACTIVITIES.—

19 “(A) IN GENERAL.—Except as provided in
 20 subparagraph (B), the term ‘covered activities’
 21 means any group of activities or conduct, in-
 22 cluding attempting to make, making, or per-
 23 forming a contract or agreement or engaging in
 24 other conduct, for the purpose of—

1 “(i) theoretical analysis, experimen-
2 tation, or the systematic study of phe-
3 nomena or observable facts necessary to
4 the development of priority counter-
5 measures;

6 “(ii) the development or testing of
7 basic engineering techniques necessary to
8 the development of priority counter-
9 measures;

10 “(iii) the extension of investigative
11 findings or theory of a scientific or tech-
12 nical nature into practical application for
13 experimental and demonstration purposes,
14 including the experimental production and
15 testing of models, prototypes, equipment,
16 materials, and processes necessary to the
17 development of priority countermeasures;

18 “(iv) the production, distribution, or
19 marketing of a product, process, or service
20 that is a priority countermeasures;

21 “(v) the testing in connection with the
22 production of a product, process, or serv-
23 ices necessary to the development of pri-
24 ority countermeasures;

1 “(vi) the collection, exchange, and
2 analysis of research or production informa-
3 tion necessary to the development of pri-
4 ority countermeasures; or

5 “(vii) any combination of the purposes
6 described in clauses (i) through (vi);

7 and such term may include the establishment
8 and operation of facilities for the conduct of
9 covered activities described in clauses (i)
10 through (vi), the conduct of such covered activi-
11 ties on a protracted and proprietary basis, and
12 the processing of applications for patents and
13 the granting of licenses for the results of such
14 covered activities.

15 “(B) EXCEPTION.—The term ‘covered ac-
16 tivities’ shall not include the following activities
17 involving 2 or more persons:

18 “(i) Exchanging information among
19 competitors relating to costs, sales, profit-
20 ability, prices, marketing, or distribution of
21 any product, process, or service if such in-
22 formation is not reasonably necessary to
23 carry out the purposes of covered activi-
24 ties.

1 “(ii) Entering into any agreement or
2 engaging in any other conduct—

3 “(I) to restrict or require the
4 sale, licensing, or sharing of inven-
5 tions, developments, products, proc-
6 esses, or services not developed
7 through, produced by, or distributed
8 or sold through such covered activi-
9 ties; or

10 “(II) to restrict or require par-
11 ticipation by any person who is a
12 party to such covered activities in
13 other research and development activi-
14 ties, that is not reasonably necessary
15 to prevent the misappropriation of
16 proprietary information contributed
17 by any person who is a party to such
18 covered activities or of the results of
19 such covered activities.

20 “(iii) Entering into any agreement or
21 engaging in any other conduct allocating a
22 market with a competitor that is not ex-
23 pressly exempted from the antitrust laws
24 by a determination under subsection (i)(4).

1 “(iv) Exchanging information among
2 competitors relating to production (other
3 than production by such covered activities)
4 of a product, process, or service if such in-
5 formation is not reasonably necessary to
6 carry out the purpose of such covered ac-
7 tivities.

8 “(v) Entering into any agreement or
9 engaging in any other conduct restricting,
10 requiring, or otherwise involving the pro-
11 duction of a product, process, or service
12 that is not so expressly exempted from the
13 antitrust laws by a determination under
14 subsection (i)(4).

15 “(vi) Except as otherwise provided in
16 this subsection, entering into any agree-
17 ment or engaging in any other conduct to
18 restrict or require participation by any per-
19 son who is a party to such activities, in
20 any unilateral or joint activity that is not
21 reasonably necessary to carry out the pur-
22 pose of such covered activities.

23 “(3) DEVELOPMENT.—The term ‘development’
24 includes the identification of suitable compounds or
25 biological materials, the conduct of preclinical and

1 clinical studies, the preparation of an application for
 2 marketing approval, and any other actions related to
 3 preparation of a countermeasure.

4 “(4) PERSON.—The term ‘person’ has the
 5 meaning given such term in subsection (a) of the
 6 first section of the Clayton Act (15 U.S.C. 12(a)).

7 “(5) PRIORITY COUNTERMEASURE.—The term
 8 ‘priority countermeasure’ means a countermeasure,
 9 including a drug, medical device, biological product,
 10 or diagnostic test to treat, identify, or prevent infec-
 11 tion by a biological agent or toxin on the list devel-
 12 oped under section 351A(a)(1) and prioritized under
 13 subsection (a)(1).”.

14 **SEC. 402. DEVELOPING NEW COUNTERMEASURES AGAINST**
 15 **BIOTERRORISM.**

16 Title XXVIII of the Public Health Service Act, as
 17 added by section 101 and amended by section 201, is fur-
 18 ther amended by adding at the end the following:

19 **“Subtitle B—Developing New**
 20 **Countermeasures Against Bio-**
 21 **terrorism**

22 **“SEC. 2841. SMALLPOX VACCINE AND OTHER VACCINE DE-**
 23 **VELOPMENT.**

24 “(a) IN GENERAL.—The Secretary shall award con-
 25 tracts, enter into cooperative agreements, or carry out

1 such other activities as may reasonably be required in
 2 order to ensure that the stockpile described in section
 3 2812 shall include the number of doses of vaccine against
 4 smallpox and other such vaccines determined by the Sec-
 5 retary to be sufficient to meet the needs of the population
 6 of the United States.

7 “(b) RULE OF CONSTRUCTION.—Nothing in this sec-
 8 tion shall be construed to limit the private distribution,
 9 purchase, or sale of vaccines from sources other than the
 10 stockpile described in subsection (a).

11 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
 12 is authorized to be appropriated to carry out this section,
 13 \$509,000,000 for fiscal year 2002, and such sums as may
 14 be necessary for each of fiscal years 2003 through 2006.

15 **“SEC. 2842. CONTRACT AUTHORITY FOR PRIORITY COUN-**
 16 **TERMEASURES.**

17 “(a) IN GENERAL.—The Secretary shall, to the ex-
 18 tent the Secretary determines necessary to achieve the
 19 purposes of this title, enter into long-term contracts and
 20 comparable grants or cooperative agreements, for the pur-
 21 pose of—

22 “(1) ensuring the development of priority coun-
 23 termeasures that are necessary to prepare for a bio-
 24 terrorist attack or other significant disease emer-
 25 gency;

1 “(2) securing the manufacture, distribution,
2 and adequate supply of such countermeasures, in-
3 cluding through the development of novel production
4 methods for such countermeasures;

5 “(3) maintaining the Strategic National Phar-
6 maceutical Stockpile under section 2812; and

7 “(4) carrying out such other activities deter-
8 mined appropriate by the Secretary to achieve the
9 purposes of this title.

10 “(b) TERMS OF CONTRACTS.—Notwithstanding any
11 other provision of law, the Secretary may enter into a con-
12 tract or cooperative agreement under subsection (a) prior
13 to the development, approval, or clearance of the counter-
14 measure that is the subject of the contract. The contract
15 or cooperative agreement may provide for its termination
16 for the convenience of the Federal Government if the con-
17 tractor does not develop the countermeasure involved.
18 Such a contract or cooperative agreement may—

19 “(1) involve one or more aspects of the develop-
20 ment, manufacture, purchase, or distribution of one
21 or more uses of one or more countermeasures; and

22 “(2) set forth guaranteed minimum quantities
23 of products and negotiated unit prices.

1 **“SEC. 2843. SECURITY FOR COUNTERMEASURE DEVELOP-**
 2 **MENT AND PRODUCTION.**

3 “(a) IN GENERAL.—The Secretary, in consultation
 4 with the Attorney General and the Secretary of Defense,
 5 may provide technical or other assistance, to provide secu-
 6 rity to persons or facilities that conduct development, pro-
 7 duction, distribution, or storage of priority counter-
 8 measures.

9 “(b) BEST PRACTICES.—The Secretary shall develop
 10 guidelines and best practices to enable entities eligible for
 11 funding under this section to secure their facilities against
 12 potential terrorist attack.”.

13 **SEC. 403. SEQUENCING OF PRIORITY PATHOGENS.**

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

17 (1) in paragraph (3), by striking “and” at the
 18 end;

19 (2) by redesignating paragraph (4) as para-
 20 graph (5); and

21 (3) by inserting after paragraph (3), the fol-
 22 lowing:

23 “(4) the sequencing of the genomes of priority
 24 pathogens as determined appropriate by the Director
 25 of the National Institutes of Health, in consultation

1 with the working group established in subsection (a);
 2 and”.

3 **SEC. 404. ACCELERATED COUNTERMEASURE RESEARCH**
 4 **AND DEVELOPMENT.**

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

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

11 (2) by striking “The Secretary” and inserting
 12 the following:

13 “(1) IN GENERAL.—The Secretary”; and

14 (3) by adding at the end the following:

15 “(2) ACCELERATED COUNTERMEASURE RE-
 16 SEARCH AND DEVELOPMENT.—

17 “(A) IN GENERAL.—The Secretary shall
 18 conduct, and award grants, contracts, or coop-
 19 erative agreements for, research, investigations,
 20 experiments, demonstrations, and studies in the
 21 health sciences relating to—

22 “(i) the epidemiology and patho-
 23 genesis of biological agents or toxins of po-
 24 tential use in a bioterrorist attack;

1 “(ii) the development of new vaccines
2 and therapeutics for use against biological
3 agents or toxins of potential use in a bio-
4 terrorist attack;

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

8 “(iv) other relevant areas of research;
9 with consideration given to the needs of chil-
10 dren and other vulnerable populations.

11 “(B) PRIORITY.—The Secretary shall give
12 priority under this paragraph to the funding of
13 research and other studies related to priority
14 countermeasures.”.

15 **SEC. 405. ACCELERATED APPROVAL OF PRIORITY COUN-**
16 **TERMEASURES.**

17 (a) IN GENERAL.—The Secretary of Health and
18 Human Services may designate a priority countermeasure
19 as a fast-track product pursuant to section 506 of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356)
21 or as a device granted priority review pursuant to section
22 515(d)(5) of such Act (21 U.S.C. 366e(d)(5)). Such a des-
23 ignation may be made prior to the submission of—

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

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

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

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

13 (c) PRIORITY REVIEW.—

14 (1) IN GENERAL.—A priority countermeasure
15 that is a drug or biological product shall be subject
16 to the performance goals established by the Commis-
17 sioner of Food and Drugs for priority drugs or bio-
18 logical products.

19 (2) DEFINITION.—In this subsection the term
20 “priority drugs or biological products” means a drug
21 or biological product that is the subject of a drug
22 application referred to in section 101(4) of the Food
23 and Drug Administration Modernization Act of
24 1997.

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

3 Not later than 30 days after the date of enactment
4 of this Act, the Secretary of Health and Human Services
5 shall issue a final rule for the proposal entitled “New
6 Drug and Biological Drug Products; Evidence Needed to
7 Demonstrate Efficacy of New Drugs for Use Against Le-
8 thal or Permanently Disabling Toxic Substances When Ef-
9 ficacy Studies in Humans Ethically Cannot be Conducted”
10 as published in the Federal Register on October 5, 1999
11 (64 Fed. Reg.).

12 **SEC. 407. MISCELLANEOUS PROVISIONS.**

13 Title XXVIII of the Public Health Service Act, as
14 added by section 101 and amended by section 403, is fur-
15 ther amended by adding at the end the following:

16 **“Subtitle C—Miscellaneous**
17 **Provisions**

18 **“SEC. 2851. SUPPLEMENT NOT SUPPLANT.**

19 “Funds appropriated under this title shall be used
20 to supplement and not supplant other Federal, State, and
21 local public funds provided for activities under this title.”.

1 **TITLE V—PROTECTING THE**
2 **SAFETY AND SECURITY OF**
3 **THE FOOD SUPPLY**

4 **Subtitle A—General Provisions to**
5 **Expand and Upgrade Security**

6 **SEC. 511. FOOD SAFETY AND SECURITY STRATEGY.**

7 (a) IN GENERAL.—The President’s Council on Food
8 Safety (as established by Executive Order 13100), the
9 Secretary of Commerce, and the Secretary of Transpor-
10 tation, shall, in consultation with the food industry and
11 consumer and producer groups, and the States, develop
12 a crisis communications and education strategy with re-
13 spect to bioterrorist threats to the food supply. Such strat-
14 egy shall address threat assessments, response and notifi-
15 cation procedures, and risks communications to the public.

16 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
17 authorized to be appropriated, \$500,000 for fiscal year
18 2002, and such sums as may be necessary in each subse-
19 quent fiscal year to implement the strategy developed
20 under subsection (a) in cooperation with the Secretary of
21 Agriculture, the Secretary of Health and Human Services,
22 and the Administrator of the Environmental Protection
23 Agency.

1 **SEC. 512. EXPANSION OF ANIMAL AND PLANT HEALTH IN-**
2 **SPECTION SERVICE ACTIVITIES.**

3 (a) IN GENERAL.—The Secretary of Agriculture (re-
4 ferred to in this section as the “Secretary”) shall enhance
5 and expand the capacity of the Animal and Plant Health
6 Inspection Service through the conduct of activities to—

7 (1) increase the inspection capacity of the Serv-
8 ice at international points of origin;

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

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

14 (4) adopt new strategies and technologies for
15 dealing with intentional outbreaks of plant and ani-
16 mal disease arising from acts of terrorism or from
17 unintentional introduction, including—

18 (A) establishing cooperative agreements
19 among Veterinary Services of the Animal and
20 Plant Health Inspection Service, State animal
21 health commissions and regulatory agencies for
22 livestock and poultry health, and private veteri-
23 nary practitioners to enhance the preparedness
24 and ability of Veterinary Services and the com-
25 missions and agencies to respond to outbreaks
26 of such animal diseases; and

1 (B) strengthening planning and coordina-
2 tion with State and local agencies, including—

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

6 (ii) State agriculture departments;
7 and

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

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

12 (1) IN GENERAL.—To provide the agricultural
13 system of the United States with a new, enhanced
14 level of protection and biosecurity that does not exist
15 on the date of enactment of this Act, the Secretary
16 of Agriculture, in coordination with the Secretary of
17 Health and Human Services, shall implement a fully
18 secure surveillance and response system that utilizes,
19 or is capable of utilizing, field test devices capable
20 of detecting biological threats to animals and plants
21 and that electronically integrates the devices and the
22 tests on a real-time basis into a comprehensive sur-
23veillance, incident management, and emergency re-
24sponse system.

1 (2) EXPANSION OF SYSTEM.—The Secretary
2 shall expand the system implemented under para-
3 graph (1) as soon as practicable to include other
4 Federal agencies and the States where appropriate
5 and necessary to enhance the protection of the food
6 and agriculture system of the United States. To fa-
7 cilitate the expansion of the system, the Secretary
8 shall award grants to States.

9 (c) AUTOMATED RECORDKEEPING SYSTEM.—The
10 Administrator of the Animal and Plant Health Inspection
11 Service shall implement a central automated record-
12 keeping system to provide for the reliable tracking of the
13 status of animal and plant shipments, including those
14 shipments on hold at ports of entry and customs. The Sec-
15 retary shall ensure that such a system shall be fully acces-
16 sible to or fully integrated with the Food Safety Inspection
17 Service.

18 (d) AUTHORIZATION OF APPROPRIATIONS.—There is
19 authorized to be appropriated to carry out this section,
20 \$30,000,000 for fiscal year 2002, and such sums as may
21 be necessary for each subsequent fiscal year.

1 **SEC. 513. EXPANSION OF FOOD SAFETY INSPECTION SERV-**
2 **ICE ACTIVITIES.**

3 (a) IN GENERAL.—The Secretary of Agriculture shall
4 enhance and expand the capacity of the Food Safety In-
5 spection Service through the conduct of activities to—

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

9 (2) improve the capacity of the Service to in-
10 spect international meat and meat products, poultry
11 and poultry products, and egg products at points of
12 origin and at ports of entry;

13 (3) strengthen the ability of the Service to col-
14 laborate with relevant agencies within the Depart-
15 ment of Agriculture and with other entities in the
16 Federal Government, the States, and Indian tribes
17 through the sharing of information and technology;
18 and

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

21 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
22 authorized to be appropriated to carry out this section,
23 \$15,000,000 for fiscal year 2002, and such sums as may
24 be necessary for each subsequent fiscal year.

1 **SEC. 514. EXPANSION OF FOOD AND DRUG ADMINISTRA-**
2 **TION ACTIVITIES.**

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

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

9 (2) improve linkages between the Agency and
10 other regulatory agencies of the Federal Govern-
11 ment, the States, and Indian tribes with shared re-
12 sponsibilities.

13 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
14 authorized to be appropriated to carry out this section,
15 \$60,000,000 for fiscal year 2002, and such sums as may
16 be necessary for each subsequent fiscal year.

17 **SEC. 515. BIOSECURITY UPGRADES AT THE DEPARTMENT**
18 **OF AGRICULTURE.**

19 There is authorized to be appropriated for fiscal year
20 2002, \$180,000,000 to enable the Agricultural Research
21 Service to conduct building upgrades to modernize existing
22 facilities, of which (1) \$100,000,000 is allocated for ren-
23 ovation, updating, and expansion of the Biosafety Level
24 3 laboratory and animal research facilities at the Plum
25 Island Animal Disease Center (Greenport, New York), and
26 of which (2) \$80,000,000 is allocated for the Agricultural

1 Research Service/Animal and Plant Health Inspection
 2 Service facility in Ames, Iowa. There is authorized to be
 3 appropriated such sums as may be necessary in fiscal
 4 years 2003 through 2006 for (1), (2) and the planning
 5 and design of an Agricultural Research Service biocontain-
 6 ment laboratory for poultry research in Athens, Georgia,
 7 and the planning, updating, and renovation of the Arthro-
 8 pod-Borne Animal Disease Laboratory in Laramie, Wyo-
 9 ming.

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

12 The Secretary of Health and Human Services shall
 13 take such actions to secure existing facilities of the De-
 14 partment of Health and Human Services where potential
 15 animal and plant pathogens are housed or researched.

16 **SEC. 517. AGRICULTURAL BIOSECURITY.**

17 (a) LAND GRANT ASSESSMENTS.—

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

23 (A) the security of all facilities where haz-
 24 ardous biological agents and toxins are stored
 25 or used for agricultural research purposes; and

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

4 (2) AVAILABILITY OF STANDARDS.—Not later
5 than 45 days after the establishment of security
6 standards under paragraph (1), the Secretary shall
7 make such standards available to land grant univer-
8 sities.

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

17 (b) NATIONAL HAZARDOUS AGENT INVENTORY.—
18 The Secretary shall carry out activities necessary to de-
19 velop a national inventory of hazardous biological agents
20 and toxins contained in agricultural research facilities.
21 Such activities shall include developing and distributing a
22 model inventory procedure, developing secure means of
23 transmitting inventory information, and conducting an-
24 nual inventory activities. The inventory shall be developed

1 in coordination with, or as a component of, similar sys-
2 tems in existence on the date of enactment of this Act.

3 (c) SCREENING PROTOCOL.—The Secretary shall es-
4 tablish a national protocol for the screening of individuals
5 who require access to agricultural research facilities in a
6 manner that provides for the protection of personal pri-
7 vacy.

8 (d) INDUSTRY-ON-FARM EDUCATION.—

9 (1) IN GENERAL.—The Secretary shall develop
10 and implement a program to provide education relat-
11 ing to farms, livestock confinement operations, and
12 livestock auction biosecurity to prevent the inten-
13 tional or accidental introduction of a foreign animal
14 disease and to attempt to discover the introduction
15 of such a disease before it can spread into an out-
16 break. Biosecurity for livestock includes animal
17 quarantine procedures, blood testing of new arrivals,
18 farm locations, control of human movement onto
19 farms and holding facilities, control of vermin, and
20 movement of vehicles onto farms.

21 (2) QUARANTINE AND TESTING.—The Sec-
22 retary shall develop and disseminate through edu-
23 cational programs animal quarantine and testing
24 guidelines to enable farmers and producers to better
25 monitor new arrivals. Any educational seminars and

1 training carried out by the Secretary under this
2 paragraph shall emphasize the economic benefits of
3 biosecurity and the profound negative impact of an
4 outbreak.

5 (3) CROP GUIDELINES.—The Secretary may de-
6 velop guidelines and educational materials relating
7 to biosecurity issues to be distributed to local crop
8 producers and facilities that handle, process, or
9 transport crops.

10 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
11 authorized to be appropriated to carry out this section,
12 \$20,000,000 for fiscal year 2002, and such sums as may
13 be necessary for each subsequent fiscal year, of which not
14 less than \$5,000,000 shall be made available in fiscal year
15 2002 for activities under subsection (a).

16 **SEC. 518. BIOSECURITY OF FOOD MANUFACTURING, PROC-**
17 **ESSING, AND DISTRIBUTION.**

18 (a) IN GENERAL.—The Secretary of Health and
19 Human Services (referred to in this section as the “Sec-
20 retary”), in consultation with the Attorney General, may
21 award grants, contracts, or cooperative agreements to en-
22 able food manufacturers, food processors, food distribu-
23 tors, and other entities regulated by the Secretary for pur-
24 poses of ensuring the safety of food through the develop-
25 ment and implementation of educational programs to en-

1 sure the security of their facilities and modes of transpor-
 2 tation against potential bioterrorist attack.

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

7 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
 8 authorized to be appropriated to carry out this section,
 9 \$500,000 in fiscal year 2002, and such sums as may be
 10 necessary for each fiscal year.

11 **Subtitle B—Protection of the Food** 12 **Supply**

13 **SEC. 531. ADMINISTRATIVE DETENTION.**

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

17 “(h) ADMINISTRATIVE DETENTION OF FOODS.—

18 “(1) AUTHORITY.—Any officer or qualified em-
 19 ployee of the Food and Drug Administration may
 20 order the detention, in accordance with this sub-
 21 section, of any article of food that is found during
 22 an inspection, examination, or investigation under
 23 this Act conducted by such officer or qualified em-
 24 ployee, if the officer or qualified employee has cred-
 25 ible evidence or information indicating that the arti-

1 cle is in violation of this Act and presents a threat
 2 of serious adverse health consequences or death to
 3 humans or animals.

4 “(2) PERIOD OF DETENTION; APPROVAL BY
 5 SECRETARY OR SECRETARY’S DESIGNEE.—

6 “(A) DURATION.—An article of food may
 7 be detained under this subsection for a reason-
 8 able period, not to exceed 20 days, unless a
 9 greater period of time, not to exceed 30 days,
 10 is necessary to enable the Secretary to institute
 11 an action under subsection (a) or section 302.

12 “(B) SECRETARY’S APPROVAL.—Before an
 13 article of food may be ordered detained under
 14 this subsection, the Secretary or an officer or
 15 qualified employee designated by the Secretary
 16 must approve such order, after determining
 17 that the article presents a threat of serious ad-
 18 verse health consequences or death to humans
 19 or animals.

20 “(3) SECURITY OF DETAINED ARTICLE.—A de-
 21 tention order under this subsection with respect to
 22 an article of food may require that the article be la-
 23 beled or marked as detained, and may require that
 24 the article be removed to a secure facility. An article
 25 subject to a detention order under this subsection

1 shall not be moved by any person from the place at
2 which it is ordered detained until release by the Sec-
3 retary, or the expiration of the detention period ap-
4 plicable to such order, whichever occurs first.

5 “(4) APPEAL OF DETENTION ORDER.—Any per-
6 son who would be entitled to claim a detained article
7 if it were seized under subsection (a) may appeal to
8 the Secretary the detention order under this sub-
9 section. Within 15 days after such an appeal is filed,
10 the Secretary, after affording opportunity for an in-
11 formal hearing, shall by order confirm the detention
12 order or revoke it.

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

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

20 “(bb) The movement of an article of food in
21 violation of an order under section 304(h), or the re-
22 moval or alteration of any mark or label required by
23 the order in order to identify the article as de-
24 tained.”.

1 **SEC. 532. DEBARMENT FOR REPEATED OR SERIOUS FOOD**
2 **IMPORT VIOLATIONS.**

3 (a) DEBARMENT AUTHORITY.—

4 (1) PERMISSIVE DEBARMENT.—Section
5 306(b)(1) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 335a(b)(1)) is amended—

7 (A) by striking the period at the end of
8 subparagraph (B) and inserting “; or”; and

9 (B) by adding at the end the following:

10 “(C) a person from importing a food or of-
11 fering a food for import into the United States
12 if—

13 “(i) the person has been convicted of
14 a felony for conduct relating to the impor-
15 tation into the United States of any food;
16 or

17 “(ii) the person has engaged in a pat-
18 tern of importing or offering for import
19 adulterated food that presents a threat of
20 serious adverse health consequences or
21 death to humans or animals.”.

22 (2) CONFORMING AMENDMENT.—Section
23 306(b)(2) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 335a(b)(2)) is amended—

1 (A) in the paragraph heading, by inserting
 2 “RELATING TO DRUG APPLICATIONS” after
 3 “DEBARMENT”; and

4 (B) in the matter preceding subparagraph
 5 (A), by striking “paragraph (1)” and inserting
 6 “subparagraphs (A) and (B) of paragraph (1)”.

7 (3) DEBARMENT PERIOD.—Section
 8 306(c)(2)(A)(iii) of the Federal Food, Drug, and
 9 Cosmetic Act (21 U.S.C. 335a(c)(2)(A)(iii)) is
 10 amended by striking “subsection (b)(2)” and insert-
 11 ing “subsection (b)(1)(C) or (b)(2)”.

12 (4) TERMINATION OF DEBARMENT.—Section
 13 306(d)(3) of the Federal Food, Drug, and Cosmetic
 14 Act (21 U.S.C. 335a(d)(3)) is amended—

15 (A) in subparagraph (A)(i), by striking “or
 16 (b)(2)(A)” and inserting “, or (b)(2)(A), or
 17 (b)(1)(C)”;

18 (B) in subparagraph (A)(ii)(II), by insert-
 19 ing “in applicable cases,” before “sufficient au-
 20 dits”; and

21 (C) in subparagraph (B), in each of
 22 clauses (i) and (ii), by inserting “or (b)(1)(C)”
 23 after “(b)(2)(B)”.

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

4 (A) in the first sentence, by inserting “and
 5 subsection (b)(1)(C)” after “subsection
 6 (b)(2)(B)”; and

7 (B) in the second sentence, by striking
 8 “and subsections (f) and (g) of this section”
 9 and inserting “subsections (f) and (g), and sub-
 10 section (b)(1)(C)”.

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

14 “(h) If it is an article of food imported or offered
 15 for import into the United States by, with the assistance
 16 of, or at the direction of, a person debarred under section
 17 306(b)(1)(C).”.

18 **SEC. 533. MAINTENANCE AND INSPECTION OF RECORDS**
 19 **FOR FOODS.**

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

23 **“SEC. 414. MAINTENANCE AND INSPECTION OF RECORDS.**

24 “(a) IN GENERAL.—If the Secretary has reason to
 25 believe that an article of food is adulterated or misbranded

1 under this Act and presents a threat of serious adverse
2 health consequences or death to humans or animals, each
3 person (excluding restaurants and farms) that manufac-
4 tures, processes, packs, distributes, receives, holds, or im-
5 ports such food shall, at the request of an officer or em-
6 ployee duly designated by the Secretary, permit such offi-
7 cer or employee, upon presentation of appropriate creden-
8 tials and a written notice to such person, at reasonable
9 times and within reasonable limits and in a reasonable
10 manner, to have access to and to copy all records relating
11 to such food that may assist the Secretary to determine
12 the cause and scope of the violation. This requirement ap-
13 plies to all records relating to such manufacture, proc-
14 essing, packing, distribution, receipt, holding, or importa-
15 tion of such food maintained by or on behalf of such per-
16 son in any format (including paper and electronic formats)
17 and at any location.

18 “(b) REGULATIONS CONCERNING RECORD-
19 KEEPING.—The Secretary shall promulgate regulations re-
20 garding the maintenance and retention of records for in-
21 spection for not longer than 2 years by persons (excluding
22 restaurants and farms) that manufacture, process, pack,
23 transport, distribute, receive, hold, or import food, as may
24 be needed to allow the Secretary—

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

5 “(2) to determine whether food manufactured,
6 processed, packed, or held by the person may be
7 adulterated or misbranded to the extent that it pre-
8 sents a threat of serious adverse health consequences
9 or death to humans or animals under this Act.

10 The Secretary may impose reduced requirements under
11 such regulations for small businesses with 50 or fewer em-
12 ployees.

13 “(c) LIMITATIONS.—Nothing in this section shall be
14 construed—

15 “(1) to limit the authority of the Secretary to
16 inspect records or to require maintenance of records
17 under any other provision of or regulations issued
18 under this Act;

19 “(2) to authorize the Secretary to impose any
20 requirements with respect to a food to the extent
21 that it is within the exclusive jurisdiction of the Sec-
22 retary of Agriculture pursuant to the Federal Meat
23 Inspection Act (21 U.S.C. 601 et seq.), the Poultry
24 Products Inspection Act (21 U.S.C. 451 et seq.), or

1 the Egg Products Inspection Act (21 U.S.C. 1031 et
2 seq.);

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

6 “(4) to alter, amend, or affect in any way the
7 disclosure or nondisclosure under section 552 of title
8 5, United States Code, of information copied or col-
9 lected under this section, or its treatment under sec-
10 tion 1905 of title 18, United States Code.”.

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

14 (1) in paragraph (1), by adding after the first
15 sentence the following: “In the case of any person
16 (excluding restaurants and farms) that manufac-
17 tures, processes, packs, transports, distributes, re-
18 ceives, holds, or imports foods, the inspection shall
19 extend to all records and other information described
20 in section 414(a), or required to be maintained pur-
21 suant to section 414(b).”; and

22 (2) in paragraph (2), in the matter preceding
23 subparagraph (A), by striking “second sentence”
24 and inserting “third sentence”.

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

4 (1) in subsection (e)—

5 (A) by striking “by section 412, 504, or
 6 703” and inserting “by section 412, 414, 504,
 7 703, or 704(a)”; and

8 (B) by striking “under section 412” and
 9 inserting “under section 412, 414(b)”; and

10 (2) in section (j), by inserting “414,” after
 11 “412,”.

12 (d) EXPEDITED RULEMAKING.—Not later than 18
 13 months after the date of enactment of this Act, the Sec-
 14 retary shall promulgate proposed and final regulations es-
 15 tablishing recordkeeping requirements under subsection
 16 414(b)(1) of the Federal Food, Drug, and Cosmetic Act.

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

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

23 **“SEC. 415. REGISTRATION OF FOOD MANUFACTURING,**
 24 **PROCESSING, AND HANDLING FACILITIES.**

25 “(a) REGISTRATION.—

1 “(1) IN GENERAL.—Any facility engaged in
2 manufacturing, processing, or handling food for con-
3 sumption in the United States shall be registered
4 with the Secretary. To be registered—

5 “(A) for a domestic facility, the owner, op-
6 erator, or agent in charge of the facility shall
7 submit a registration to the Secretary; and

8 “(B) for a foreign facility, the owner, oper-
9 ator, or agent in charge of the facility shall sub-
10 mit a registration to the Secretary and shall in-
11 clude with the registration the name of the
12 United States agent for the facility.

13 “(2) REGISTRATION.—An entity (referred to in
14 this section as the ‘registrant’) shall submit a reg-
15 istration under paragraph (1) to the Secretary con-
16 taining information necessary to notify the Secretary
17 of the name and address of each facility at which,
18 and all trade names under which, the registrant con-
19 ducts business and, when determined necessary by
20 the Secretary through guidance, the general food
21 category (as identified under section 170.3 of title
22 21, Code of Federal Regulations) of any food manu-
23 factured, processed, or handled at such facility. The
24 registrant shall notify the Secretary in a timely man-
25 ner of changes to such information.

1 “(3) PROCEDURE.—Upon receipt of a com-
2 pleted registration described in paragraph (1), the
3 Secretary shall notify the registrant of the receipt of
4 such registration and assign a registration number
5 to each registered facility.

6 “(4) LIST.—The Secretary shall compile and
7 maintain an up-to-date list of facilities that are reg-
8 istered under this section. Such list and other infor-
9 mation required to be submitted under this sub-
10 section shall not be subject to the disclosure require-
11 ments of section 552 of title 5, United States Code.

12 “(b) EXEMPTION AUTHORITY.—The Secretary may
13 by regulation exempt types of retail establishments or
14 farms from the requirements of subsection (a) if the Sec-
15 retary determines that the registration of such facilities
16 is not needed for effective enforcement of chapter IV and
17 any regulations issued under such chapter.

18 “(c) FACILITY.—In this section, the term ‘facility’ in-
19 cludes any factory, warehouse, or establishment (including
20 a factory, warehouse, or establishment of an importer),
21 that manufactures, handles, or processes food. Such term
22 does not include restaurants.

23 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
24 tion shall be construed to authorize the Secretary to re-
25 quire an application, review, or licensing process.”.

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

4 “(t) If it is a food from a facility for which registra-
 5 tion has not been submitted to the Secretary under section
 6 415(a).”.

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

10 **SEC. 535. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.**

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

15 “(j) PRIOR NOTICE OF IMPORTED FOOD SHIP-
 16 MENTS.—

17 “(1) IN GENERAL.—At least 4 hours before a
 18 food is imported or offered for importation into the
 19 United States, the producer, manufacturer, or ship-
 20 per of the food shall provide documentation to the
 21 Secretary of the Treasury and the Secretary of
 22 Health and Human Services that—

23 “(A) identifies—

24 “(i) the food;

1 “(ii) the countries of origin of the
2 food; and

3 “(iii) the quantity to be imported; and

4 “(B) includes such other information as
5 the Secretary may require by regulation.

6 “(2) REFUSAL OF ADMISSION.—If documenta-
7 tion is not provided as required by paragraph (1) at
8 least 4 hours before the food is imported or offered
9 for importation, the food may be refused admission.

10 “(3) LIMITATION.—Nothing in this subsection
11 shall be construed to authorize the Secretary to im-
12 pose any requirements with respect to a food to the
13 extent that it is within the exclusive jurisdiction of
14 the Secretary of Agriculture pursuant to the Federal
15 Meat Inspection Act (21 U.S.C. 601 et seq.), the
16 Poultry Products Inspection Act (21 U.S.C. 451 et
17 seq.), or the Egg Products Inspection Act (21
18 U.S.C. 1031 et seq.).”.

19 (b) PROHIBITION OF KNOWINGLY MAKING FALSE
20 STATEMENTS.—Section 301 of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 331), as amended by section
22 531(b), is further amended by inserting after subsection
23 (bb) the following:

24 “(cc) Knowingly making a false statement in docu-
25 mentation required under section 801(j).”.

1 **SEC. 536. AUTHORITY TO MARK REFUSED ARTICLES.**

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

6 “(u) If—

7 “(1) it has been refused admission under sec-
8 tion 801(a);

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

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

13 “(4) it presents a threat of serious adverse
14 health consequences or death to humans or ani-
15 mals.”.

16 (b) REQUIREMENT.—Section 801(a) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
18 amended by adding at the end the following: “The Sec-
19 retary of Health and Human Services may require the
20 owner or consignee of a food that has been refused admis-
21 sion under this section, and has not been required to be
22 destroyed, to affix to the packaging of the food a label
23 or labeling that—

24 “(1) clearly and conspicuously bears the state-
25 ment: ‘United States: Refused Entry’;

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

3 “(3) has been provided at the expense of the
4 owner or consignee of the food.”.

5 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
6 tion shall be construed to limit the authority of the Sec-
7 retary of Health and Human Services or the Secretary of
8 the Treasury to require the marketing of refused articles
9 under any other provision of law.

10 **SEC. 537. AUTHORITY TO COMMISSION OTHER FEDERAL**
11 **OFFICIALS TO CONDUCT INSPECTIONS.**

12 Section 702(a) of the Federal Food, Drug and Cos-
13 metic Act (21 U.S.C. 372(a)) is amended in the first
14 sentence—

15 (1) by inserting “qualified” before “employees”;
16 and

17 (2) by inserting “or of other Federal Depart-
18 ments or agencies, notwithstanding any other provi-
19 sion of law restricting the use of a Department’s or
20 agency’s officers, employees, or funds,” after “offi-
21 cers and employees of the Department”.

22 **SEC. 538. PROHIBITION AGAINST PORT SHOPPING.**

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

1 “(i) If it is an article of food imported or offered for
 2 import into the United States and the article of food has
 3 previously been refused admission under section 801(a),
 4 unless the person reoffering the article affirmatively estab-
 5 lishes, at the expense of the owner or consignee of the
 6 article, that the article complies with the applicable re-
 7 quirements of this Act, as determined by the Secretary.”.

8 **SEC. 539. GRANTS TO STATES FOR INSPECTIONS.**

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

12 **“SEC. 910. GRANTS TO STATES FOR INSPECTIONS.**

13 “(a) IN GENERAL.—The Secretary is authorized to
 14 make grants to States, territories, and Federally recog-
 15 nized Indian tribes that undertake to examinations, in-
 16 spections, and investigations, and related activities under
 17 section 702, the funds provided under such grants to be
 18 available only for the costs of conducting such examina-
 19 tions, inspections, investigations, and related activities.

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

1 **SEC. 540. RULE OF CONSTRUCTION.**

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

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

7 (2) limit the authority of the Secretary of Agri-
8 culture with respect to such products.

9 **Subtitle C—Research and Training**
10 **to Enhance Food Safety and Se-**
11 **curity**

12 **SEC. 541. SURVEILLANCE AND INFORMATION GRANTS AND**
13 **AUTHORITIES.**

14 Part B of title III of the Public Health Service Act
15 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
16 tion 317P the following:

17 **“SEC. 317Q. FOOD SAFETY GRANTS.**

18 “(a) IN GENERAL.—The Secretary may award food
19 safety grants to States to expand the number of States
20 participating in Pulsenet, the Foodborne Diseases Active
21 Surveillance Network, and other networks to enhance Fed-
22 eral, State, and local food safety efforts.

23 “(b) USE OF FUNDS.—Funds awarded under this
24 section shall be used by States to assist such States in
25 meeting the costs of establishing and maintaining the food
26 safety surveillance, technical and laboratory capacity need-

1 ed to participate in PulseNet, Foodborne Diseases Active
 2 Surveillance Network, and other networks to enhance Fed-
 3 eral, State, and local food safety efforts.

4 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
 5 is authorized to be appropriated to carry out this section,
 6 such sums as may be necessary for each fiscal year.

7 **“SEC. 317R. SURVEILLANCE OF ANIMAL AND HUMAN**
 8 **HEALTH.**

9 “(a) IN GENERAL.—The Secretary, through the
 10 Commissioner of the Food and Drug Administration and
 11 the Director of the Centers for Disease Control and Pre-
 12 vention, and the Secretary of Agriculture shall develop and
 13 implement a plan for coordinating the surveillance for
 14 zoonotic disease and human disease.

15 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
 16 is authorized to be appropriated to carry out this section,
 17 \$19,500,000 for fiscal year 2002, and such sums as may
 18 be necessary for each subsequent fiscal year.”.

19 **SEC. 542. AGRICULTURAL BIOTERRORISM RESEARCH AND**
 20 **DEVELOPMENT.**

21 (a) IN GENERAL.—The Secretary of Agriculture, to
 22 the maximum extent practicable, shall utilize existing au-
 23 thorities to expand Agricultural Research Service, and Co-
 24 operative State Research Education and Extension Serv-

1 ice, programs to protect the food supply of the United
2 States by conducting activities to—

3 (1) enhance the capability of the Service to re-
4 spond immediately to the needs of Federal regu-
5 latory agencies involved in protecting the food and
6 agricultural system;

7 (2) continue existing partnerships with institu-
8 tions of higher education (including partnerships
9 with 3 institutions of higher education that are na-
10 tional centers for countermeasures against agricul-
11 tural bioterrorism and 7 additional institutions with
12 existing programs related to bioterrorism) to help
13 form stable, long-term programs of research, devel-
14 opment, and evaluation of options to enhance the
15 biosecurity of United States agriculture;

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

19 (4) expand Service involvement with inter-
20 national organizations dealing with plant and animal
21 disease control; and

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

24 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
25 authorized to be appropriated to carry out this section,

- 1 \$190,000,000 for fiscal year 2002, and such sums as may
- 2 be necessary for each subsequent fiscal year.

