

Calendar No. 255

107TH CONGRESS
1ST SESSION

S. 1765

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

DECEMBER 4, 2001

Mr. FRIST (for himself, Mr. KENNEDY, Mr. ALLEN, Mr. DASCHLE, Mr. BENNETT, Mr. AKAKA, Mr. BOND, Mr. BAUCUS, Mr. BROWNBACH, Mr. BAYH, Mr. BURNS, Mr. BIDEN, Mr. CAMPBELL, Mr. BINGAMAN, Mr. CHAFEE, Mr. BREAUX, Mr. COCHRAN, Mrs. CARNAHAN, Ms. COLLINS, Mr. CLELAND, Mr. CRAIG, Mrs. CLINTON, Mr. CRAPO, Mr. CORZINE, Mr. DEWINE, Mr. DODD, Mr. DOMENICI, Mr. DORGAN, Mr. GRASSLEY, Mr. DURBIN, Mr. HAGEL, Mr. EDWARDS, Mr. HUTCHINSON, Mrs. FEINSTEIN, Mrs. HUTCHISON, Mr. HARKIN, Mr. LUGAR, Mr. JEFFORDS, Mr. McCONNELL, Mr. JOHNSON, Mr. MURKOWSKI, Mr. KERRY, Mr. ROBERTS, Ms. LANDRIEU, Mr. SANTORUM, Mr. LEAHY, Ms. SNOWE, Mr. LIEBERMAN, Mr. SPECTER, Mrs. LINCOLN, Mr. STEVENS, Ms. MIKULSKI, Mr. THOMAS, Mr. MILLER, Mr. THOMPSON, Mrs. MURRAY, Mr. THURMOND, Mr. NELSON of Florida, Mr. VOINOVICH, Mr. REED, Mr. WARNER, Mr. REID, Mr. ROCKEFELLER, Mr. SARBANES, Mr. TORRICELLI, Mr. WELLSTONE, Mr. SCHUMER, Mr. DAYTON, Mr. HELMS, Mr. FITZGERALD, Mr. CONRAD, Mr. HATCH, Ms. STABENOW, Mr. INOUYE, Mr. LEVIN, and Mr. SESSIONS) introduced the following bill; which was read the first time

DECEMBER 5, 2001

Read the second time and placed on the calendar

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”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
 7 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**

Subtitle A—Additional Authorities

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:

7 **“TITLE XXVIII—STRENGTHENING**
8 **THE NATION’S PREPARED-**
9 **NESS FOR BIOTERRORISM**

10 **“SEC. 2801. CONGRESSIONAL FINDINGS ON BIOTERRORISM**
11 **PREPAREDNESS.**

12 “Congress finds that the United States should fur-
13 ther develop and implement a coordinated strategy to pre-
14 vent, and if necessary, to respond to biological threats or
15 attacks upon the United States. Such strategy should in-
16 clude measures for—

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

20 “(2) improving public health, hospital, labora-
21 tory, communications, and emergency response per-
22 sonnel preparedness and responsiveness at the State
23 and local levels;

1 “(3) rapidly developing and manufacturing
2 needed therapies, vaccines, and medical supplies;
3 and

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

7 **TITLE II—IMPROVING THE FED-
8 ERAL RESPONSE TO BIOTER-
9 RORISM**

10 **Subtitle A—Additional Authorities**

11 **SEC. 201. ADDITIONAL AUTHORITIES OF THE SECRETARY;**
12 **STRATEGIC NATIONAL PHARMACEUTICAL**
13 **STOCKPILE.**

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

17 **“Subtitle A—Improving the Federal
18 Response to Bioterrorism**

19 **“SEC. 2811. AUTHORITY OF THE SECRETARY RELATED TO
20 BIOTERRORISM PREPAREDNESS.**

21 “(a) PLAN.—To meet the objectives of this title (and
22 the amendments made by the Bioterrorism Preparedness
23 Act of 2001), and to help the United States fully prepare
24 for a biological threat or attack, the Secretary, consistent
25 with the recommendations and activities of the working

1 group established under section 319F(a), shall develop
2 and implement a coordinated plan to meet such objectives
3 that are within the jurisdiction of the Secretary. Such plan
4 shall include the development of specific criteria that will
5 enable measurements to be made of the progress made at
6 the national, State, and local levels toward achieving the
7 national goal of bioterrorism preparedness, including ac-
8 tions to strengthen the preparedness of rural communities
9 for a biological threat or attack.

10 “(b) BIENNIAL REPORTS.—

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

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

23 “(A) additional legislative authority that
24 the Secretary determines is necessary to meet
25 the objectives of this title (and the amendments

3 “(B) additional legislative authority that
4 the Secretary determines is necessary under
5 section 319 to protect the public health in the
6 event that a condition described in section
7 319(a) occurs.

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

11 “(1) activities conducted under section
12 319F(b);

13 “(2) the characteristics that may render a rural
14 community uniquely vulnerable to a biological threat
15 or attack, including distance, lack of emergency
16 transport, hospital or laboratory capacity, lack of in-
17 tegration of Federal or State public health networks,
18 workforce deficits, or other relevant conditions;

19 “(3) in any case in which the Secretary deter-
20 mines that additional legislative authority is nec-
21 essary to effectively strengthen the preparedness of
22 rural communities for responding to a biological
23 threat or attack, the recommendations of the Sec-
24 retary with respect to such legislative authority; and

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

5 **SEC. 2812. STRATEGIC NATIONAL PHARMACEUTICAL**
6 **STOCKPILE.**

7 “(a) IN GENERAL.—The Secretary, in coordination
8 with the Secretary of Veterans Affairs, shall maintain a
9 strategic stockpile of vaccines, therapies, and medical sup-
10 plies that are adequate, as determined by the Secretary,
11 to meet the health needs of the United States population,
12 including children and other vulnerable populations, for
13 use at the direction of the Secretary, in the event of a
14 biological threat or attack or other public health emer-
15 gency.

16 “(b) RULE OF CONSTRUCTION.—Nothing in sub-
17 section (a) shall be construed to prohibit the Secretary
18 from including in the stockpile described in such sub-
19 section such vaccines, therapies, or medical supplies as
20 may be necessary to meet the needs of the United States
21 in the event of a nuclear, radiological, or chemical attack
22 or other public health emergency.

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

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

3 “(2) a contractual agreement between the Sec-
4 retary and a vendor or vendors under which such
5 vendor or vendors agree to provide to the Secretary
6 such medical supplies as shall be described in the
7 contract at such time as shall be specified in the
8 contract.

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

11 “(1) ensure that adequate procedures are fol-
12 lowed with respect to the stockpile maintained under
13 subsection (a) for inventory management, account-
14 ing, and for the physical security of such stockpile;
15 and

16 “(2) in consultation with State and local offi-
17 cials, take into consideration the timing and location
18 of special events, including designated national secu-
19 rity events.

20 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
21 is authorized to be appropriated to carry out this section,
22 \$640,000,000 for fiscal year 2002, and such sums as may
23 be necessary for each of fiscal years 2003 through 2006.”.

1 **SEC. 202. IMPROVING THE ABILITY OF THE CENTERS FOR**
2 **DISEASE CONTROL AND PREVENTION TO RE-**
3 **SPOND EFFECTIVELY TO BIOTERRORISM.**

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

7 (1) in subsection (a), by inserting “, and ex-
8 panded, enhanced, and improved capabilities of the
9 Centers related to biological threats or attacks,”
10 after “modern facilities”;

11 (2) in subsection (b)—

12 (A) by inserting “, including preparing for
13 or responding to biological threats or attacks,”
14 after “public health activities”; and

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

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

18 “(c) IMPROVING PUBLIC HEALTH LABORATORY CA-
19 PACITY.—

20 “(1) IN GENERAL.—The Secretary shall provide
21 for the establishment of a coordinated network of
22 public health laboratories to assist with the detection
23 of and response to a biological threat or attack, that
24 may, at the discretion of the Secretary, include lab-
25 oratories that serve as regional reference labora-
26 tories.

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

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

8 “(4) LOCAL DISCRETION.—Use of regional lab-
9 oratories, if established under paragraph (1), shall
10 be at the discretion of the public health agencies of
11 the States.

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

15 “(A) purchase or improve land or purchase
16 any building or other facility; or
17 “(B) construct, repair, or alter any build-
18 ing or other facility.

19 “(6) SUPPLEMENT NOT SUPPLANT.—Funds ap-
20 propriated under this subsection shall be used to
21 supplement and not supplant other Federal, State,
22 and local public funds provided for activities under
23 this subsection.

24 “(7) AUTHORIZATION OF APPROPRIATIONS.—
25 There is authorized to be appropriated to carry out

1 this subsection, \$59,500,000 for fiscal year 2002,
2 and such sums as may be necessary for each of fis-
3 cal years 2003 through 2006.”.

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

8 “The education and training activities described in this
9 subsection may be carried out through Public Health Pre-
10 paredness Centers, Noble training facilities, the Emerging
11 Infections Program, and the Epidemic Intelligence Serv-
12 ice.”.

13 **Subtitle B—Coordination of Efforts
14 and Responses**

15 **SEC. 211. ASSISTANT SECRETARY FOR EMERGENCY PRE-
16 PAREDNESS; NATIONAL DISASTER MEDICAL
17 SYSTEM.**

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

21 **“SEC. 2813. ASSISTANT SECRETARY FOR EMERGENCY PRE-
22 PAREDNESS.**

23 “(a) APPOINTMENT OF ASSISTANT SECRETARY FOR
24 EMERGENCY PREPAREDNESS.—The President, with the
25 advice and consent of the Senate, shall appoint an indi-

1 vidual to serve as the Assistant Secretary for Emergency
2 Preparedness who shall head the Office for Emergency
3 Preparedness. Such Assistant Secretary shall report to the
4 Secretary.

5 “(b) DUTIES.—Subject to the authority of the Sec-
6 retary, the Assistant Secretary for Emergency Prepared-
7 ness shall—

8 “(1) serve as the principal adviser to the Sec-
9 retary on matters relating to emergency prepared-
10 ness, including preparing for and responding to bio-
11 logical threats or attacks and for developing policy;
12 and

13 “(2) coordinate all functions within the Depart-
14 ment of Health and Human Services relating to
15 emergency preparedness, including preparing for and
16 responding to biological threats or attacks.

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

18 “(a) NATIONAL DISASTER MEDICAL SYSTEM.—

19 “(1) IN GENERAL.—There shall be operated a
20 system to be known as the National Disaster Med-
21 ical System (in this section referred to as the ‘Na-
22 tional System’) which shall be coordinated by the
23 Secretary, in collaboration with the Secretary of De-
24 fense, the Secretary of Veterans Affairs, and the Di-

1 rector of the Federal Emergency Management Agen-
2 cy.

3 “(2) FUNCTIONS.—The National System shall
4 provide appropriate health services, health-related
5 social services and, if necessary, auxiliary services
6 (including mortuary and veterinary services) to re-
7 spond to the needs of victims of a public health
8 emergency if the Secretary activates the System with
9 respect to the emergency. The National System shall
10 carry out such ongoing activities as may be nec-
11 essary to prepare for the provision of such services.

12 “(b) TEMPORARY DISASTER-RESPONSE PER-
13 SONNEL.—

14 “(1) IN GENERAL.—For the purpose of assist-
15 ing the Office of Emergency Preparedness and the
16 National System in carrying out duties under this
17 section, the Secretary may in accordance with sec-
18 tion 316.401 of title 5, Code of Federal Regulations
19 (including revisions to such section), and notwith-
20 standing the eligibility requirements set forth in
21 paragraphs (1) through (8) of section 316.402(b) of
22 such title (including revisions), make temporary ap-
23 pointments of individuals to intermittent positions to
24 serve as personnel of such Office or System.

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

8 “(3) LIABILITY.—For purposes of section 9 224(a) and the remedies described in such section, 10 an individual appointed under paragraph (1) shall, 11 while acting within the scope of such appointment, 12 be considered to be an employee of the Public 13 Health Service performing medical, surgical, dental, 14 or related functions. Participation in training programs carried out by the Office of Emergency Preparedness or Federal personnel of the National System shall be considered within the scope of such an 18 appointment (regardless of whether the individual 19 receives compensation for such participation).

20 “(c) TEMPORARY DISASTER-RESPONSE AP- 21 POINTEE.—For purposes of this section, the term ‘tem- 22 porary disaster-response appointee’ means an individual 23 appointed by the Secretary under subsection (b).

24 “(d) COMPENSATION FOR WORK INJURIES.—A tem- 25 porary disaster-response appointee, as designated by the

1 Secretary, shall be deemed an employee, and an injury
2 sustained by such an individual while actually serving or
3 while participating in a uncompensated training exercise
4 related to such service shall be deemed ‘in the performance
5 of duty’, for purposes of chapter 81 of title 5, United
6 States Code, pertaining to compensation for work injuries.
7 In the event of an injury to such a temporary disaster-
8 response appointee, the Secretary of Labor shall be re-
9 sponsible for making determinations as to whether the
10 claimants are entitled to compensation or other benefits
11 in accordance with chapter 81 of title 5, United States
12 Code.

13 “(e) EMPLOYMENT AND REEMPLOYMENT RIGHTS.—
14 “(1) IN GENERAL.—A temporary disaster-re-
15 sponse appointee, as designated by the Secretary,
16 shall, when performing service as a temporary dis-
17 aster-response appointee or participating in an un-
18 compensated training exercise related to such serv-
19 ice, be deemed a person performing ‘service in the
20 uniformed services’ for purposes of chapter 43 of
21 title 38, United States Code, pertaining to employ-
22 ment and reemployment rights of members in the
23 uniformed services. All rights and obligations of such
24 persons and procedures for assistance, enforcement,

1 and investigation shall be as provided for in chapter
2 43 of title 38, United States Code.

3 “(2) NOTICE OF ABSENCE FROM POSITION OF
4 EMPLOYMENT.—Preclusion of giving notice of serv-
5 ice by disaster response necessity shall be deemed
6 preclusion by ‘military necessity’ for purposes of sec-
7 tion 4312(b) of title 38, United States Code, per-
8 taining to giving notice of absence from a position
9 of employment. A determination of disaster response
10 necessity shall be made pursuant to regulations pre-
11 scribed by the Secretary, in consultation with the
12 Secretary of Defense, and shall not be subject to ju-
13 dicial review.

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

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

22 (a) PROVISION OF DECLARATION TO CONGRESS.—
23 Section 319(a) of the Public Health Service Act (42
24 U.S.C. 247d(a)) is amended by adding at the end the fol-
25 lowing: “Not later than 48 hours after a declaration of

1 a public health emergency under this section, the Sec-
2 retary shall provide a written declaration to Congress indi-
3 cating that an emergency under this section has been de-
4 clared.”.

5 (b) WAIVER OF REPORTING DEADLINES.—Section
6 319 of the Public Health Service Act (42 U.S.C. 247d)
7 is amended by adding at the end the following:

8 “(d) WAIVER OF DATA SUBMITTAL AND REPORTING
9 DEADLINES.—In any case in which the Secretary deter-
10 mines that, wholly or partially as a result of a public
11 health emergency that has been declared pursuant to sub-
12 section (a), individuals or public or private entities are un-
13 able to comply with deadlines for the submission to the
14 Secretary of data or reports required under any law ad-
15 ministered by the Secretary, the Secretary may, notwith-
16 standing any other provision of law, grant such extensions
17 of such deadlines as the circumstances reasonably require,
18 and may waive any sanctions otherwise applicable to such
19 failure to comply.”.

20 (c) EMERGENCY DECLARATION PERIOD.—Section
21 319 of the Public Health Service Act (42 U.S.C. 247d),
22 as amended by subsection (b), is further amended by add-
23 ing at the end the following:

24 (e) EMERGENCY DECLARATION PERIOD.—A deter-
25 mination by the Secretary under subsection (a) that a

1 public health emergency exists shall remain in effect for
2 not longer than the 180-day period beginning on the date
3 of the determination. Such period may be extended by the
4 Secretary if—

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

7 “(2) the Secretary provides a written notifica-
8 tion to Congress within 48 hours of such exten-
9 sion.”.

10 **SEC. 213. PUBLIC HEALTH PREPAREDNESS AND RESPONSE**

11 **TO A BIOTERRORIST ATTACK.**

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

15 “(a) WORKING GROUP ON BIOTERRORISM.—The
16 Secretary, in coordination with the Secretary of Defense,
17 the Director of the Federal Emergency Management
18 Agency, the Attorney General, the Secretary of Veterans
19 Affairs, the Secretary of Labor, and the Secretary of Agri-
20 culture, and with other similar Federal officials as deter-
21 mined appropriate, shall establish a joint interdepart-
22 mental working group on the prevention, preparedness,
23 and response to a biological threat or attack on the civilian
24 population. Such joint working group shall—

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

4 “(2) coordinate and facilitate the awarding of
5 grants, contracts, or cooperative agreements for the
6 development, manufacture, distribution, and pur-
7 chase of priority countermeasures;

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

11 “(4) develop shared standards for equipment to
12 detect and to protect against biological agents and
13 toxins;

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

17 “(6) assess the priorities for and enhance the
18 preparedness of public health institutions, providers
19 of medical care, and other emergency service per-
20 sonnel (including firefighters) to detect, diagnose,
21 and respond (including mental health response) to a
22 biological threat or attack;

23 “(7) in the recognition that medical and public
24 health professionals are likely to provide much of the
25 first response to such an attack, develop, coordinate,

1 enhance, and assure the quality of joint planning
2 and training programs that address the public
3 health and medical consequences of a biological
4 threat or attack on the civilian population between—

5 “(A) local firefighters, ambulance per-
6 sonnel, police and public security officers, or
7 other emergency response personnel; and

8 “(B) hospitals, primary care facilities, and
9 public health agencies;

10 “(8) coordinate the development of strategies
11 for Federal, State, and local agencies to commu-
12 nicate information to the public regarding biological
13 threats or attacks;

14 “(9) develop methods to decontaminate facilities
15 contaminated as a result of a biological attack, in-
16 cluding appropriate protections for the safety of
17 those conducting such activities; and

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

21 The working group shall carry out paragraphs (1) and (2)
22 in consultation with the pharmaceutical, biotechnology,
23 and medical device industries, and other appropriate ex-
24 perts.

1 “(b) ADVICE TO THE SECRETARY.—The Secretary
2 shall establish advisory committees to provide expert rec-
3 ommendations to the Secretary to assist the Secretary, in-
4 cluding the following:

5 “(1) NATIONAL TASK FORCE ON CHILDREN
6 AND TERRORISM.—

7 “(A) IN GENERAL.—The National Task
8 Force on Children and Terrorism, which shall
9 be composed of such Federal officials as may be
10 appropriate to address the special needs of chil-
11 dren, and child health experts on infectious dis-
12 ease, environmental health, toxicology, and
13 other relevant professional disciplines.

14 “(B) DUTIES.—The task force described in
15 subparagraph (A) shall provide recommenda-
16 tions to the Secretary regarding—

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

20 “(ii) needed changes to the health
21 care and emergency medical service sys-
22 tems and emergency medical services pro-
23 tocols to meet the special needs of children
24 with respect to a biological threat or at-
25 tack; and

1 “(iii) changes, if necessary, to the
2 Strategic National Pharmaceutical Stock-
3 pile, to meet the special needs of children.

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

6 “(A) IN GENERAL.—The Emergency Pub-
7 lic Information and Communications (EPIC)
8 Task Force, which shall be composed of individ-
9 uals with expertise in public health, communica-
10 tions, behavioral psychology, and other areas
11 determined appropriate by the Secretary.

12 “(B) DUTIES.—The task force described in
13 subparagraph (A) shall make recommendations
14 and report to the Secretary on appropriate
15 ways to communicate information regarding bi-
16 ological threats or attacks to the public, includ-
17 ing public service announcements or other ap-
18 propriate means to communicate in a manner
19 that maximizes information and minimizes
20 panic, and includes information relevant to chil-
21 dren and other vulnerable populations.

22 “(3) SUNSET.—Each Task Force established
23 under paragraphs (1) and (2) shall terminate on the
24 date that is 1 year after the date of enactment of
25 the Bioterrorism Preparedness Act of 2001.”.

1 **SEC. 214. THE OFFICIAL FEDERAL INTERNET SITE ON BIO-**2 **TERRORISM.**

3 It is the recommendation of Congress that there
4 should be established an official Federal Internet site on
5 bioterrorism, either directly or through provision of a
6 grant to an entity that has expertise in bioterrorism and
7 the development of websites, that should include informa-
8 tion relevant to diverse populations (including messages
9 directed at the general public and such relevant groups
10 as medical personnel, public safety workers, and agricul-
11 tural workers) and links to appropriate State and local
12 government sites.

13 **SEC. 215. TECHNICAL AMENDMENTS.**

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

16 (1) in subsection (a), by striking “competitive”;
17 and

18 (2) in subsection (f), by inserting
19 “\$420,000,000 for fiscal year 2002,” after “2001.”.

20 **SEC. 216. REGULATION OF BIOLOGICAL AGENTS AND TOX-
21 INS.**

22 (a) **BIOLOGICAL AGENTS PROVISIONS OF THE
23 ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT
24 OF 1996; CODIFICATION IN THE PUBLIC HEALTH SERV-
25 ICE ACT, WITH AMENDMENTS.—**

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

9 “(1) LIST OF BIOLOGICAL AGENTS AND TOX-
10 INS —

11 “(A) IN GENERAL.—The Secretary shall by
12 regulation establish and maintain a list of each
13 biological agent and each toxin that has the po-
14 tential to pose a severe threat to public health
15 and safety.

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

1 “(III) the availability and effec-
2 tiveness of pharmacotherapies and im-
3 munizations to treat and prevent any
4 illness resulting from infection by the
5 agent or toxin; and

6 “(IV) any other criteria, includ-
7 ing the needs of children and other
8 vulnerable populations, that the Sec-
9 retary considers appropriate; and

10 “(ii) consult with appropriate Federal
11 departments and agencies, and scientific
12 experts representing appropriate profes-
13 sional groups, including those with pedi-
14 atric expertise.

15 “(2) BIENNIAL REVIEW.—The Secretary shall
16 review and republish the list under paragraph (1) bi-
17 ennially, or more often as needed, and shall, through
18 rulemaking, revise the list as necessary to incor-
19 porate additions or deletions to ensure public health,
20 safety, and security.

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

23 “(A) attenuated or inactive biological
24 agents or toxins used in biomedical research or
25 for legitimate medical purposes; and

1 “(B) products that are cleared or approved
2 under the Federal Food, Drug, and Cosmetic
3 Act or under the Virus-Serum-Toxin Act, as
4 amended in 1985 by the Food Safety and Secu-
5 rity Act.”;

6 “(b) REGULATION OF TRANSFERS OF LISTED BIO-
7 LOGICAL AGENTS AND TOXINS.—The Secretary shall by
8 regulation provide for—

9 “(1) the establishment and enforcement of safe-
10 ty procedures for the transfer of biological agents
11 and toxins listed pursuant to subsection (a)(1), in-
12 cluding measures to ensure—

13 “(A) proper training and appropriate skills
14 to handle such agents and toxins; and

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

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

20 “(3) the establishment of procedures to protect
21 the public safety in the event of a transfer or poten-
22 tial transfer of a biological agent or toxin in viola-
23 tion of the safety procedures established under para-
24 graph (1) or the safeguards established under para-
25 graph (2); and

1 “(4) appropriate availability of biological agents
2 and toxins for research, education, and other legiti-
3 mate purposes.

4 “(c) POSSESSION AND USE OF LISTED BIOLOGICAL
5 AGENTS AND TOXINS.—The Secretary shall by regulation
6 provide for the establishment and enforcement of stand-
7 ards and procedures governing the possession and use of
8 biological agents and toxins listed pursuant to subsection
9 (a)(1) in order to protect the public health and safety, in-
10 cluding the measures, safeguards, procedures, and avail-
11 ability of such agents and toxins described in paragraphs
12 (1) through (4) of subsection (b), respectively.

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

24 “(e) INSPECTIONS.—The Secretary shall have the au-
25 thority to inspect persons subject to the regulations under

1 subsections (b) and (c) to ensure their compliance with
2 such regulations, including prohibitions on restricted per-
3 sons under subsection (g).

4 “(f) EXEMPTIONS.—

5 “(1) IN GENERAL.—The Secretary shall estab-
6 lish exemptions, including exemptions from the secu-
7 rity provisions, from the applicability of provisions
8 of—

9 “(A) the regulations issued under sub-
10 sections (b) and (c) when the Secretary deter-
11 mines that the exemptions, including exemp-
12 tions from the security requirements for the use
13 of attenuated or inactive biological agents or
14 toxins in biomedical research or for legitimate
15 medical purposes, are consistent with protecting
16 public health and safety; and

17 “(B) the regulations issued under sub-
18 section (c).

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) and (c).

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

3 “(i) CIVIL MONEY PENALTY.—Any person who vio-
4 lates a regulation under subsection (b) or (c) shall be sub-
5 ject to the United States for a civil money penalty in an
6 amount not exceeding \$250,000 in the case of an indi-
7 vidual and \$500,000 in the case of any other person. The
8 provisions of section 1128A of the Social Security Act
9 (other than subsections (a), (b), (h), and (i), the first sen-
10 tence of subsection (c), and paragraphs (1) and (2) of sub-
11 section (f) of such section) shall apply to civil money pen-
12 alties under this subsection in the same manner as such
13 provisions apply to a penalty or proceeding under section
14 1128A(a) of such Act. The Secretary may delegate author-
15 ity under this section in the same manner as provided in
16 section 1128A(j)(2) of such Act and such authority shall
17 include all powers described in section 6 of the Inspector
18 General Act of 1978 (5 U.S.C. App. 2)

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

22 (2) REGULATIONS.—

23 (A) DATE CERTAIN FOR PROMULGATION;
24 EFFECTIVE DATE REGARDING CRIMINAL AND
25 CIVIL PENALTIES.—Not later than 180 days

1 after the date of the enactment of this title, the
2 Secretary of Health and Human Services shall
3 promulgate an interim final rule for carrying
4 out section 351A(c) of the Public Health Serv-
5 ice Act, which amends the Antiterrorism and
6 Effective Death Penalty Act of 1996. Such in-
7 terim final rule will take effect 60 days after
8 the date on which such rule is promulgated, in-
9 cluding for purposes of—

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

14 (ii) section 351A(i) of the Public
15 Health Service Act (relating to civil pen-
16 alties).

17 (B) SUBMISSION OF REGISTRATION APPLI-
18 CATIONS.—A person required to register for
19 possession under the interim final rule promul-
20 gated under subparagraph (A) shall submit an
21 application for such registration not later than
22 60 days after the date on which such rule is
23 promulgated.

24 (3) CONFORMING AMENDMENT.—Subsections
25 (d), (e), (f), and (g) of section 511 of the

1 Antiterrorism and Effective Death Penalty Act of
2 1996 (42 U.S.C. 262 note) are repealed.

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

11 (b) SELECT AGENTS.—

12 (1) IN GENERAL.—Section 175 of title 18,
13 United States Code, as amended by the Uniting and
14 Strengthening America by Providing Appropriate
15 Tools Required to Intercept and Obstruct Terrorism
16 (USA PATRIOT ACT) Act of 2001 (Public Law
17 107-56), is amended—

18 (A) by redesignating subsections (b) and
19 (c) as subsections (c) and (d), respectively; and
20 (B) by inserting after subsection (a) the
21 following:

22 “(b) SELECT AGENTS.—

23 “(1) UNREGISTERED FOR POSSESSION.—Who-
24 ever knowingly possesses a biological agent or toxin
25 where such agent or toxin is a select agent for which

1 such person has not obtained a registration required
2 by regulation issued under section 351A(c) of the
3 Public Health Service Act shall be fined under this
4 title, or imprisoned for not more than 5 years, or
5 both.

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

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

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

18 “(1) The terms ‘biological agent’ and ‘toxin’
19 have the meanings given such terms in section 178,
20 except that, for purposes of subsections (b) and (c),
21 such terms do not encompass any biological agent or
22 toxin that is in its naturally occurring environment,
23 if the biological agent or toxin has not been cul-
24 tivated, cultured, collected, or otherwise extracted
25 from its natural source.

1 “(2) The term ‘for use as a weapon’ includes
2 the development, production, transfer, acquisition,
3 retention, or possession of any biological agent,
4 toxin, or delivery system, other than for prophylactic,
5 protective, or other peaceful purposes.

6 “(3) The term ‘select agent’ means a biological
7 agent or toxin, as defined in paragraph (1), that is
8 on the list that is in effect pursuant to section
9 511(d)(1) of the Antiterrorism and Effective Death
10 Penalty Act of 1996 (Public Law 104–132), or as
11 subsequently revised under section 351A(a) of the
12 Public Health Service Act.”.

13 (3) CONFORMING AMENDMENT.—

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

18 (B) Section 175(c) of title 18, United
19 States Code, (as redesignated by paragraph
20 (1)), is amended by striking the second sen-
21 tence.

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

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

3 (1) describes the extent to which there has been
4 compliance by governmental and private entities
5 with applicable regulations under section 351A of
6 the Public Health Service Act, including the extent
7 of compliance before the date of the enactment of
8 this Act, and including the extent of compliance with
9 regulations promulgated after such date of enact-
10 ment;

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

15 (3) describes the actions to date and future
16 plans of the Secretary for determining compliance
17 with regulations under such section 351A of the
18 Public Health Service Act and for taking appro-
19 priate enforcement actions; and

20 (4) provides any recommendations of the Sec-
21 retary for administrative or legislative initiatives re-
22 garding such section 351A of the Public Health
23 Service Act.

1 **TITLE III—IMPROVING STATE**
2 **AND LOCAL PREPAREDNESS**

3 **Subtitle A—Emergency Measures**
4 **to Improve State and Local Pre-**
5 **paredness**

6 **SEC. 301. STATE BIOTERRORISM PREPAREDNESS AND RE-**
7 **SPONSE BLOCK GRANT.**

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

11 “(c) STATE BIOTERRORISM PREPAREDNESS AND RE-
12 SPONSE BLOCK GRANTS.—

13 “(1) IN GENERAL.—The Secretary shall estab-
14 lish the State Bioterrorism Preparedness and Re-
15 sponse Block Grant Program (referred to in this
16 subsection as the ‘Program’) under which the Sec-
17 retary shall award grants to or enter into coopera-
18 tive agreements with States, the District of Colum-
19 bia, and territories (referred to in this section as ‘eli-
20 gible entities’) to enable such entities to prepare for
21 and respond to biological threats or attacks. The
22 Secretary shall ensure that activities conducted
23 under this section are coordinated with the activities
24 conducted under this section and section 319C.

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

8 “(A) not later than 180 days after the date
9 on which a grant or contract is received under
10 this subsection, prepare and submit to the Sec-
11 retary a Bioterrorism Preparedness and Re-
12 sponse Plan in accordance with subsection (c);

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

20 “(C) establish a means by which to obtain
21 public comment and input on the plan and plan
22 implementation that shall include an advisory
23 committee or other similar mechanism for ob-
24 taining input from the public at large as well as
25 other stakeholders;

1 “(D) use amounts received under para-
2 graph (1) in accordance with the plan sub-
3 mitted under paragraph (3), including making
4 expenditures to carry out the strategy contained
5 in the plan;

6 “(E) use amounts received under para-
7 graph (1) to supplement and not supplant fund-
8 ing at levels in existence prior to September 11,
9 2001 for public health capacities or bioter-
10 rorism preparedness; and

11 “(F) with respect to the plan under para-
12 graph (3), establish reasonable criteria to eval-
13 uate the effective performance of entities that re-
14 ceive funds under the grant or agreement and
15 shall include relevant benchmarks in the plan.

16 “(3) BIOTERRORISM PREPAREDNESS AND RE-
17 SPONSE PLAN.—Not later than 180 days after re-
18 ceiving amounts under this subsection, and 1 year
19 after such date, a State, the District of Columbia,
20 or a territory shall prepare and submit to the Sec-
21 retary a Bioterrorism Preparedness and Response
22 Plan for responding to biological threats or attacks.
23 Recognizing the assessment of public health capacity
24 conducted under section 319B, such plan shall
25 include—

1 “(A) a description of the program that the
2 eligible entity will adopt to achieve the core ca-
3 pacities developed under section 319A, includ-
4 ing measures that meet the needs of children
5 and other vulnerable populations;

6 “(B) a description (including amounts ex-
7 pended by the eligible entity for such purpose)
8 of the programs, projects, and activities that
9 the eligible entity will implement using amounts
10 received in order to detect and respond to bio-
11 logical threats or attacks, including the manner
12 in which the eligible entity will manage State
13 surveillance and response efforts and coordinate
14 such efforts with national efforts;

15 “(C) a description of the training initia-
16 tives that the eligible entity has carried out to
17 improve its ability to detect and respond to a
18 biological threat or attack, including training
19 and planning to protect the health and safety of
20 those conducting such detection and response
21 activities;

22 “(D) a description of the cleanup and con-
23 tamination prevention efforts that may be im-
24 plemented in the event of a biological threat or
25 attack;

1 “(E) a description of efforts to ensure that
2 hospitals and health care providers have ade-
3 quate capacity and plans in place to provide
4 health care items and services (including mental
5 health services and services to meet the needs
6 of children and other vulnerable populations
7 that may include the provision of telehealth
8 services) in the event of a biological threat or
9 attack; and

10 “(F) other information the Secretary may
11 by regulation require.

12 “Nothing in subparagraph (E) shall be con-
13 strued to require or recommend that States establish
14 or maintain stockpiles of vaccines, therapies, or
15 other medical supplies.

16 “(4) USE OF FUNDS.—

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

21 “(i) conduct the assessment under
22 section 319B to achieve the capacities de-
23 scribed in section 319A, if the assessment
24 has not previously been conducted;

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

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

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

9 “(i) improve surveillance, detection,
10 and response activities to prepare for
11 emergency response activities including bi-
12 logical threats or attacks, including train-
13 ing personnel in these and other necessary
14 functions;

15 “(ii) carry out activities to improve
16 communications and coordination efforts
17 within the eligible entity and between the
18 eligible entity and the Federal Govern-
19 ment, including activities to improve infor-
20 mation technology and communications
21 equipment available to health care and
22 public health officials for use in responding
23 to a biological threat or attack or other
24 public health emergency and including
25 early warning and surveillance networks

1 that use advanced information technology
2 to provide early detection of biological
3 threats or attacks;

4 “(iii) plan for triage and transport
5 management in the event of a biological
6 threat or attack;

7 “(iv) meet the special needs of chil-
8 dren and other vulnerable populations dur-
9 ing and after a biological threat or attack,
10 including the expansion of 2-1-1 call cen-
11 ters or other universal hotlines, or an al-
12 ternative communication plan to assist vic-
13 tims and their families in receiving timely
14 information;

15 “(v) improve the ability of hospitals
16 and other health care facilities to provide
17 effective health care (including mental
18 health care) during and after a biological
19 threat or attack, including the development
20 of model hospital preparedness plans by a
21 hospital accreditation organization or simi-
22 lar organizations; and

23 “(vi) enhance the safety of workplaces
24 in the event of a biological threat or at-
25 tack, except that nothing in this clause

1 shall be construed to create a new, or devi-
2 ate from an existing, authority to regulate,
3 modify, or otherwise effect safety and
4 health rules and standards.

5 “(C) PROHIBITED USES.—An eligible enti-
6 ty may not use amounts received under this
7 subsection to—

- 8 “(i) provide inpatient services;
- 9 “(ii) make cash payments to intended
10 recipients of health services;
- 11 “(iii) purchase or improve land or
12 purchase any building or other facility;
- 13 “(iv) construct, repair, or alter any
14 building or other facility; or
- 15 “(v) satisfy any requirement for the
16 expenditure of non-Federal funds as a con-
17 dition for the receipt of Federal funds.

18 “(5) AMOUNT OF GRANT.—

19 “(A) IN GENERAL.—Except as provided in
20 paragraph (2), the amount awarded to a State,
21 the District of Columbia, or a territory under
22 this subsection for a fiscal year shall be an
23 amount that bears the same ratio to the
24 amount appropriated under paragraph (9) for
25 such fiscal year (and remaining after amounts

1 are made available under subparagraphs (C)
2 and (D)) as the total population of the State,
3 District, or territory bears to the total popu-
4 lation of the United States.

5 “(B) EXCEPTIONS.—

6 “(i) MINIMUM AMOUNT WITH RE-
7 SPECT TO STATES.—Notwithstanding sub-
8 paragraph (A) and subject to the extent of
9 amounts made available under paragraph
10 (9), a State may not receive an award
11 under this subsection for a fiscal year in
12 an amount that is less than—

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

17 “(II) 0.75 percent of the total
18 amount appropriated under this sub-
19 section for any fiscal year in which
20 such total amount is less than
21 \$667,000,000.

22 “(ii) EXTRAORDINARY NEEDS.—

23 “(I) IN GENERAL.—Notwith-
24 standing subparagraph (A) and sub-
25 ject to the extent of amounts made

1 available under paragraph (9), the
2 Secretary may provide additional
3 funds to a State, District, or territory
4 under this subsection if the Secretary
5 determines that such State, District,
6 or territory has extraordinary needs
7 with respect to bioterrorism prepared-
8 ness.

19 “(C) RULE WITH RESPECT TO UNEX-
20 PENDED FUNDS.—To the extent that all the
21 funds appropriated under paragraph (9) for a
22 fiscal year and available in such fiscal year are
23 not otherwise paid to eligible entities because—
24 “(i) one or more eligible entities have
25 not submitted an application or public

1 health disaster plan in accordance with
2 paragraphs (2) and (3) for the fiscal year;

3 “(ii) one or more eligible entities have
4 notified the Secretary that they do not in-
5 tend to use the full amount awarded under
6 this subsection; or

7 “(iii) some eligible entity amounts are
8 offset or repaid;

9 such excess shall be provided to each of the re-
10 maining eligible entities in proportion to the
11 amount otherwise provided to such entities
12 under this paragraph for the fiscal year without
13 regard to this subparagraph.

14 “(D) AVAILABILITY OF FUNDS.—Any
15 amount paid to an eligible entity for a fiscal
16 year under this subsection and remaining unob-
17 ligated at the end of such year shall remain
18 available for the next fiscal year to such entity
19 for the purposes for which it was made.

20 “(6) INDIAN TRIBES.—

21 “(A) IN GENERAL.—If the Secretary—

22 “(i) receives a request from the gov-
23 erning body of an Indian tribe or tribal or-
24 ganization within any State that funds
25 under this subsection be provided directly

1 by the Secretary to such tribe or organiza-
2 tion; and

3 “(ii) determines that the members of
4 such tribe or tribal organization would be
5 better served by means of grants or agree-
6 ments made directly by the Secretary
7 under this subsection;

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

12 “(B) AMOUNT.—The Secretary shall re-
13 serve for the purpose of subparagraph (A) from
14 amounts that would otherwise be paid to such
15 State under paragraph (1) an amount equal to
16 the amount which bears the same ratio to the
17 amount awarded to the State for the fiscal year
18 involved as the population of the Indian tribe or
19 the individuals represented by the tribal organi-
20 zation bears to the total population of the
21 State.

22 “(C) GRANT.—The amount reserved by the
23 Secretary on the basis of a determination under
24 this paragraph shall be granted to the Indian
25 tribe or tribal organization serving the individ-

1 uals for whom such a determination has been
2 made.

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

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

15 “(7) WITHHOLDING.—

16 “(A) REQUIREMENTS.—

17 “(i) IN GENERAL.—The Secretary
18 shall, after adequate notice and an oppor-
19 tunity for a hearing conducted within the
20 affected eligible entity, withhold or recoup
21 funds from any such entity that does not
22 use amounts received under this subsection
23 in accordance with the requirements of this
24 subsection. The Secretary shall withhold or
25 recoup such funds until the Secretary finds

1 that the reason for the withholding or
2 recoupment has been removed and there is
3 reasonable assurance that it will not recur.

1 “(B) AVAILABILITY OF INFORMATION FOR
2 INSPECTION.—Each eligible entity, and other
3 entity which has received funds under this sec-
4 tion, shall make appropriate books, documents,
5 papers, and records available to the Secretary
6 or the Comptroller General of the United
7 States, or any of their duly authorized rep-
8 resentatives, for examination, copying, or me-
9 chanical reproduction on or off the premises of
10 the appropriate entity upon a reasonable re-
11 quest therefore.

12 “(C) LIMITATION ON REQUESTS FOR IN-
13 FORMATION.—

14 “(i) IN GENERAL.—In conducting any
15 investigation in an eligible entity, the Sec-
16 retary or the Comptroller General of the
17 United States may not make a request for
18 any information not readily available to
19 such eligible entity, or an entity which has
20 received funds under this subsection, or
21 make an unreasonable request for informa-
22 tion to be compiled, collected, or trans-
23 mitted in any form not readily available.

24 “(ii) JUDICIAL PROCEEDINGS.—
25 Clause (i) does not apply to the collection,

1 compilation, or transmittal of data in the
2 course of a judicial proceeding.

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

5 “(9) AUTHORIZATION OF APPROPRIATIONS.—
6 There is authorized to be appropriated to carry out
7 this subsection, \$667,000,000 for fiscal year 2002,
8 and such sums as may be necessary for fiscal year
9 2003, and no funds are authorized to be appro-
10 priated for subsequent fiscal years.”.

11 (b) REAUTHORIZATION OF OTHER PROGRAMS.—Sec-
12 tion 319F(i) of the Public Health Service Act (42 U.S.C.
13 247d-6(i)) is amended to read as follows:

14 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated—

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

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

1 **Subtitle B—Improving Local Pre-**
2 **paredness and Response Capa-**
3 **bilities**

4 **SEC. 311. DESIGNATED BIOTERRORISM RESPONSE MED-**
5 **ICAL CENTERS.**

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

8 (1) by redesignating subsections (d) through (h)
9 and (i), as subsections (e) through (i) and (l), re-
10 spectively; and

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

13 “(d) DESIGNATED BIOTERRORISM RESPONSE MED-
14 ICAL CENTERS.—

15 “(1) GRANTS.—The Secretary shall award
16 project grants to eligible entities to enable such enti-
17 ties, in a manner consistent with applicable provi-
18 sions of the Bioterrorism Preparedness and Re-
19 sponse Plan, to improve local and bioterrorism re-
20 sponse medical center preparedness.

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

23 “(A) be a consortium that consists of at
24 least one entity from each of the following
25 categories—

1 “(i) a hospital including children’s
2 hospitals, clinic, health center, or primary
3 care facility;

4 “(ii) a political subdivision of a State;
5 and

6 “(iii) a department of public health;

7 “(B) prepare, in consultation with the
8 Chief Executive Officer of the State, District,
9 or territory in which the hospital, clinic, health
10 center, or primary care facility is located, and
11 submits to the Secretary, an application at such
12 time, in such manner, and containing such in-
13 formation as the Secretary may require;

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

18 “(D) provide assurances satisfactory to the
19 Secretary that such entity shall, upon the re-
20 quest of the Secretary or the Chief Executive
21 Officer of the State, District, or territory in
22 which the entity is located, during the emer-
23 gency period, serve the needs of the emergency
24 area, including providing adequate health care
25 capacity, serving as a regional resource in the

1 diagnosis, treatment, or care for persons, in-
2 cluding children and other vulnerable popu-
3 lations, exposed to a biological threat or attack,
4 and accepting the transfer of patients, where
5 appropriate.

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

9 “(A) the training of health care profes-
10 sionals to enhance the ability of such personnel
11 to recognize the symptoms of exposure to a po-
12 tential biological threat or attack and to provide
13 treatment to those so exposed;

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

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

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

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

4 “(F) other activities determined appro-
5 priate by the Secretary.

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

9 “(A) purchase or improve land or purchase
10 any building or other facility; or

11 “(B) construct, repair, or alter any build-
12 ing or facility.

13 “(6) TECHNICAL ASSISTANCE.—Not later than
14 180 days after the date of enactment of the Bioter-
15 rorism Preparedness Act of 2001, the Secretary
16 shall develop and publish technical guidelines relat-
17 ing to equipment, training, treatment, capacity, and
18 personnel, relevant to the status as a bioterrorism
19 response medical center and the Secretary may pro-
20 vide technical assistance to eligible entities, including
21 assistance to address the needs of children and other
22 vulnerable populations.”.

1 **SEC. 312. DESIGNATED STATE PUBLIC EMERGENCY AN-**2 **OUNCEMENT PLAN.**

3 Section 613(b) of the Robert T. Stafford Disaster Re-

4 lief and Emergency Assistance Act (42 U.S.C. 5196b(b))

5 is amended—

6 (1) in paragraph (5), by striking “and” at the

7 end;

8 (2) in paragraph (6), by striking the period and

9 inserting “; and”; and

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

11 “(7) include a plan for providing information to

12 the public in a coordinated manner.”.

13 **SEC. 313. TRAINING FOR PEDIATRIC ISSUES SURROUNDING**14 **BIOLOGICAL AGENTS USED IN WARFARE AND**15 **TERRORISM.**

16 Section 319F(f) of the Public Health Service Act (42

17 U.S.C. 247d-6(e)), as so redesignated by section 311, is

18 amended—

19 (1) in paragraph (1)—

20 (A) by inserting “(including mental health
21 care)” after “and care”; and

22 (B) by striking “and” at the end;

23 (2) in paragraph (2), by striking the period and

24 inserting “; and”; and

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

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

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

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

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

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

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

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

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

20 “(6) the activities of the working group de-
21 scribed in subsection (a) and the efforts made by
22 such group to carry out the activities described in
23 such subsection;

24 “(7) the activities and cost of the 2-1-1 call
25 centers and other universal hotlines; and

1 “(8) the activities and cost of the development
2 and improvement of public health laboratory capac-
3 ity.”.

4 **SEC. 315. ADDITIONAL RESEARCH.**

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

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

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

14 It is the sense of the Senate that—

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

19 (2) accelerating the crucial work done at uni-
20 versity centers and laboratories will contribute sig-
21 nificantly to the United States capacity to defend
22 against any biological threat or attack;

23 (3) maximizing the effectiveness of, and extend-
24 ing the mission of, established university programs
25 would be one appropriate use of the additional re-

1 sources provided for in the Bioterrorism Prepared-
2 ness Act of 2001; and

3 (4) Congress recognizes the importance of exist-
4 ing public and private university-based research,
5 training, public awareness, and safety related bio-
6 logical defense programs in the awarding of grants
7 and contracts made in accordance with this Act.

8 **TITLE IV—DEVELOPING NEW
9 COUNTERMEASURES
10 AGAINST BIOTERRORISM**

11 **SEC. 401. LIMITED ANTITRUST EXEMPTION.**

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

14 “(g) LIMITED ANTITRUST EXEMPTION.—

15 “(1) COUNTERMEASURES DEVELOPMENT MEET-
16 INGS.—

17 “(A) COUNTERMEASURES DEVELOPMENT
18 MEETINGS AND CONSULTATIONS.—The Sec-
19 retary may conduct meetings and consultations
20 with parties involved in the development of pri-
21 ority countermeasures for the purpose of the
22 development, manufacture, distribution, pur-
23 chase, or sale of priority countermeasures con-
24 sistent with the purposes of this title. The Sec-
25 retary shall give notice of such meetings and

1 consultations to the Attorney General and the
2 Chairperson of the Federal Trade Commission
3 (referred to in this subsection as the ‘Chair-
4 person’).

5 “(B) MEETING AND CONSULTATION CON-
6 DITIONS.—A meeting or consultation conducted
7 under subparagraph (A) shall—

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

10 “(ii) be open to parties involved in the
11 development, manufacture, distribution,
12 purchase, or sale of priority counter-
13 measures, as determined by the Secretary;

14 “(iii) be open to the Attorney General
15 and the Chairperson;

16 “(iv) be limited to discussions involv-
17 ing the development, manufacture, dis-
18 tribution, or sale of priority counter-
19 measures, consistent with the purposes of
20 this title; and

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

1 “(C) MINUTES.—The Secretary shall
2 maintain minutes of meetings and consultations
3 under this subsection, which shall not be dis-
4 closed under section 552 of title 5, United
5 States Code.

6 “(D) EXEMPTION.—The antitrust laws
7 shall not apply to meetings and consultations
8 under this paragraph, except that any agree-
9 ment or conduct that results from a meeting or
10 consultation and that does not receive an ex-
11 emption pursuant to this subsection shall be
12 subject to the antitrust laws.

13 “(2) WRITTEN AGREEMENTS.—The Secretary
14 shall file a written agreement regarding covered ac-
15 tivities, made pursuant to meetings or consultations
16 conducted under paragraph (1) and that is con-
17 sistent with this paragraph, with the Attorney Gen-
18 eral and the Chairperson for a determination of the
19 compliance of such agreement with antitrust laws.
20 In addition to the proposed agreement itself, any
21 such filing shall include—

22 “(A) an explanation of the intended pur-
23 pose of the agreement;

24 “(B) a specific statement of the substance
25 of the agreement;

1 “(C) a description of the methods that will
2 be utilized to achieve the objectives of the
3 agreement;

4 “(D) an explanation of the necessity of a
5 cooperative effort among the particular partici-
6 pating parties to achieve the objectives of the
7 agreement; and

8 “(E) any other relevant information deter-
9 mined necessary by the Secretary in consulta-
10 tion with the Attorney General and the Chair-
11 person.

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

16 “(A) be in compliance with the antitrust
17 laws, and so inform the Secretary and the par-
18 ticipating parties; or

19 “(B) violate the antitrust laws, in which
20 case, the filing shall be deemed to be a request
21 for an exemption from the antitrust laws, lim-
22 ited to the performance of the agreement con-
23 sistent with the purposes of this title.

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

1 “(A) IN GENERAL.—The Attorney General,
2 in consultation with the Chairperson, shall
3 grant, deny, grant in part and deny in part, or
4 propose modifications to a request for exemp-
5 tion from the antitrust laws under paragraph
6 (3) within 15 days of the receipt of such re-
7 quest.

8 “(B) EXTENSION.—The Attorney General
9 may extend the 15-day period referred to in
10 subparagraph (A) for an additional period of
11 not to exceed 10 days. Such additional period
12 may be further extended only by the United
13 States district court, upon an application by the
14 Attorney General after notice to the Secretary
15 and the parties involved.

16 “(C) DETERMINATION.—In granting an
17 exemption under this paragraph, the Attorney
18 General, in consultation with the Chairperson
19 and the Secretary—

20 (i) must find—

21 “(I) that the agreement involved
22 is necessary to ensure the availability
23 of priority countermeasures;

1 “(II) that the exemption from
2 the antitrust laws would promote the
3 public interest; and

4 “(III) that there is no substantial
5 competitive impact to areas not di-
6 rectly related to the purposes of the
7 agreement; and

8 “(ii) may consider any other factors
9 determined relevant by the Attorney Gen-
10 eral and the Chairperson.

11 “(5) LIMITATION ON AND RENEWAL OF EXEMP-
12 TIONS.—An exemption granted under paragraph (4)
13 shall be limited to covered activities, and shall expire
14 on the date that is 3 years after the date on which
15 the exemption becomes effective (and at 3 year in-
16 tervals thereafter, if renewed) unless the Attorney
17 General in consultation with the Chairperson deter-
18 mines that the exemption should be renewed (with
19 modifications, as appropriate) considering the fac-
20 tors described in paragraph (4).

21 “(6) LIMITATION ON PARTIES.—The use of any
22 information acquired under an exempted agreement
23 by the parties to such an agreement for any pur-
24 poses other than those specified in the antitrust ex-
25 emption granted by the Attorney General shall be

1 subject to the antitrust laws and any other applica-
2 ble laws.

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

6 “(8) REPORT.—Not later than 1 year after the
7 date of enactment of the Bioterrorism Preparedness
8 Act of 2001, and annually thereafter, the Attorney
9 General and the Chairperson shall report to Con-
10 gress on the use and continuing need for the exemp-
11 tion from the antitrust laws provided by this sub-
12 section.

13 “(9) SUNSET.—The authority of the Attorney
14 General to grant or renew a limited antitrust exemp-
15 tion under this subsection shall expire at the end of
16 the 6-year period that begins on the date of enact-
17 ment of the Bioterrorism Preparedness Act of 2001.

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

20 “(1) ANTITRUST LAWS.—The term ‘antitrust
21 laws’—

22 “(A) has the meaning given such term in
23 subsection (a) of the first section of the Clayton
24 Act (15 U.S.C. 12(a)), except that such term
25 includes the Act of June 19, 1936 (15 U.S.C.

1 13 et seq.) commonly known as the Robinson-
2 Patman Act), and section 5 of the Federal
3 Trade Commission Act (15 U.S.C. 45) to the
4 extent such section 5 applies to unfair methods
5 of competition; and

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

8 “(2) COVERED ACTIVITIES.—

9 “(A) IN GENERAL.—Except as provided in
10 subparagraph (B), the term ‘covered activities’
11 means any group of activities or conduct, in-
12 cluding attempting to make, making, or per-
13 forming a contract or agreement or engaging in
14 other conduct, for the purpose of—

15 “(i) theoretical analysis, experimen-
16 tation, or the systematic study of phe-
17 nomena or observable facts necessary to
18 the development of priority counter-
19 measures;

20 “(ii) the development or testing of
21 basic engineering techniques necessary to
22 the development of priority counter-
23 measures;

24 “(iii) the extension of investigative
25 findings or theory of a scientific or tech-

1 nical nature into practical application for
2 experimental and demonstration purposes,
3 including the experimental production and
4 testing of models, prototypes, equipment,
5 materials, and processes necessary to the
6 development of priority countermeasures;

20 and such term may include the establishment
21 and operation of facilities for the conduct of
22 covered activities described in clauses (i)
23 through (vi), the conduct of such covered activi-
24 ties on a protracted and proprietary basis, and
25 the processing of applications for patents and

1 the granting of licenses for the results of such
2 covered activities.

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

6 “(i) Exchanging information among
7 competitors relating to costs, sales, profit-
8 ability, prices, marketing, or distribution of
9 any product, process, or service if such in-
10 formation is not reasonably necessary to
11 carry out the purposes of covered activi-
12 ties.

13 “(ii) Entering into any agreement or
14 engaging in any other conduct—

15 “(I) to restrict or require the
16 sale, licensing, or sharing of inven-
17 tions, developments, products, proc-
18 esses, or services not developed
19 through, produced by, or distributed
20 or sold through such covered activi-
21 ties; or

22 “(II) to restrict or require par-
23 ticipation by any person who is a
24 party to such covered activities in
25 other research and development activi-

ties, that is not reasonably necessary to prevent the misappropriation of proprietary information contributed by any person who is a party to such covered activities or of the results of such covered activities.

1 “(vi) Except as otherwise provided in
2 this subsection, entering into any agree-
3 ment or engaging in any other conduct to
4 restrict or require participation by any per-
5 son who is a party to such activities, in
6 any unilateral or joint activity that is not
7 reasonably necessary to carry out the pur-
8 pose of such covered activities.

9 “(3) DEVELOPMENT.—The term ‘development’
10 includes the identification of suitable compounds or
11 biological materials, the conduct of preclinical and
12 clinical studies, the preparation of an application for
13 marketing approval, and any other actions related to
14 preparation of a countermeasure.

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

18 “(5) PRIORITY COUNTERMEASURE.—The term
19 ‘priority countermeasure’ means a countermeasure,
20 including a drug, medical device, biological product,
21 or diagnostic test to treat, identify, or prevent infec-
22 tion by a biological agent or toxin on the list devel-
23 oped under section 351A(a)(1) and prioritized under
24 subsection (a)(1).”.

1 **SEC. 402. DEVELOPING NEW COUNTERMEASURES AGAINST**
2 **BIOTERRORISM.**

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

6 **“Subtitle B—Developing New**
7 **Countermeasures Against Bio-**
8 **terrorism**

9 **“SEC. 2841. SMALLPOX VACCINE AND OTHER VACCINE DE-**
10 **VELOPMENT.**

11 “(a) IN GENERAL.—The Secretary shall award con-
12 tracts, enter into cooperative agreements, or carry out
13 such other activities as may reasonably be required in
14 order to ensure that the stockpile described in section
15 2812 shall include the number of doses of vaccine against
16 smallpox and other such vaccines determined by the Sec-
17 retary to be sufficient to meet the needs of the population
18 of the United States.

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

23 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
24 is authorized to be appropriated to carry out this section,
25 \$509,000,000 for fiscal year 2002, and such sums as may
26 be necessary for each of fiscal years 2003 through 2006.

1 **“SEC. 2842. CONTRACT AUTHORITY FOR PRIORITY COUN-**2 **TERMEASURES.**

3 “(a) IN GENERAL.—The Secretary shall, to the ex-
4 tent the Secretary determines necessary to achieve the
5 purposes of this title, enter into long-term contracts and
6 comparable grants or cooperative agreements, for the pur-
7 pose of—

8 “(1) ensuring the development of priority coun-
9 termeasures that are necessary to prepare for a bio-
10 terrorist attack or other significant disease emer-
11 gency;

12 “(2) securing the manufacture, distribution,
13 and adequate supply of such countermeasures, in-
14 cluding through the development of novel production
15 methods for such countermeasures;

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

18 “(4) carrying out such other activities deter-
19 mined appropriate by the Secretary to achieve the
20 purposes of this title.

21 “(b) TERMS OF CONTRACTS.—Notwithstanding any
22 other provision of law, the Secretary may enter into a con-
23 tract or cooperative agreement under subsection (a) prior
24 to the development, approval, or clearance of the counter-
25 measure that is the subject of the contract. The contract
26 or cooperative agreement may provide for its termination

1 for the convenience of the Federal Government if the con-
2 tractor does not develop the countermeasure involved.
3 Such a contract or cooperative agreement may—

4 “(1) involve one or more aspects of the develop-
5 ment, manufacture, purchase, or distribution of one
6 or more uses of one or more countermeasures; and
7 “(2) set forth guaranteed minimum quantities
8 of products and negotiated unit prices.

9 **“SEC. 2843. SECURITY FOR COUNTERMEASURE DEVELOP-
10 MENT AND PRODUCTION.**

11 “(a) IN GENERAL.—The Secretary, in consultation
12 with the Attorney General and the Secretary of Defense,
13 may provide technical or other assistance, to provide secu-
14 rity to persons or facilities that conduct development, pro-
15 duction, distribution, or storage of priority counter-
16 measures.

17 “(b) BEST PRACTICES.—The Secretary shall develop
18 guidelines and best practices to enable entities eligible to
19 receive assistance under this section to secure their facili-
20 ties against potential terrorist attack.”.

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

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

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

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

5 (3) by inserting after paragraph (3), the fol-
6 lowing:

7 “(4) the sequencing of the genomes of priority
8 pathogens as determined appropriate by the Director
9 of the National Institutes of Health, in consultation
10 with the working group established in subsection (a);
11 and”.

12 SEC. 404. ACCELERATED COUNTERMEASURE RESEARCH
13 AND DEVELOPMENT.

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

17 (1) by redesignating paragraphs (1) through
18 (5), as subparagraphs (A) through (E), respectively
19 and indenting appropriately:

20 (2) by striking “The Secretary” and inserting
21 the following:

22 "(1) IN GENEBAI.—The Secretary": and

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

24 “(2) ACCELERATED COUNTERMEASURE RE-
25 SEARCH AND DEVELOPMENT —

1 “(A) IN GENERAL.—The Secretary shall
2 conduct, and award grants, contracts, or coop-
3 erative agreements for, research, investigations,
4 experiments, demonstrations, and studies in the
5 health sciences relating to—

6 “(i) the epidemiology and patho-
7 genesis of biological agents or toxins of po-
8 tential use in a bioterrorist attack;

9 “(ii) the development of new vaccines
10 and therapeutics for use against biological
11 agents or toxins of potential use in a bio-
12 terrorist attack;

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

16 “(iv) other relevant areas of research;
17 with consideration given to the needs of chil-
18 dren and other vulnerable populations.

19 “(B) PRIORITY.—The Secretary shall give
20 priority under this paragraph to the funding of
21 research and other studies related to priority
22 countermeasures.”.

1 **SEC. 405. ACCELERATED APPROVAL OF PRIORITY COUN-**2 **TERMEASURES.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services may designate a priority countermeasure
5 as a fast-track product pursuant to section 506 of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356)
7 or as a device granted priority review pursuant to section
8 515(d)(5) of such Act (21 U.S.C. 366e(d)(5)). Such a des-
9 ignation may be made prior to the submission of—

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

12 (2) an application for the investigation of the
13 drug under section 505(i) of such Act or section
14 351(a)(3) of the Public Health Service Act.

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

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

24 (c) PRIORITY REVIEW.—

25 (1) IN GENERAL.—A priority countermeasure
26 that is a drug or biological product shall be subject

1 to the performance goals established by the Commis-
2 sioner of Food and Drugs for priority drugs or bio-
3 logical products.

4 (2) DEFINITION.—In this subsection the term
5 “priority drugs or biological products” means a drug
6 or biological product that is the subject of a drug
7 application referred to in section 101(4) of the Food
8 and Drug Administration Modernization Act of
9 1997.

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

12 Not later than 30 days after the date of enactment
13 of this Act, the Secretary of Health and Human Services
14 shall issue a final rule for the proposal entitled “New
15 Drug and Biological Drug Products; Evidence Needed to
16 Demonstrate Efficacy of New Drugs for Use Against Le-
17 thal or Permanently Disabling Toxic Substances When Ef-
18 ficacy Studies in Humans Ethically Cannot be Conducted”
19 as published in the Federal Register on October 5, 1999
20 (64 Fed. Reg.).

21 **SEC. 407. MISCELLANEOUS PROVISIONS.**

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

1 **“Subtitle C—Miscellaneous**
2 **Provisions**

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

4 “A State or local government, or other entity to
5 which a grant, contract, or cooperative agreement is
6 awarded under this title, may not use amounts received
7 under the grant, contract, or cooperative agreement to
8 supplant expenditures by the entity for activities provided
9 for under this title, but shall use such amounts only to
10 supplement such expenditures at a level at least equal to
11 the level of such expenditures for fiscal year 2001 (exclud-
12 ing those additional, extraordinary expenditures that may
13 have been made after September 10, 2001).”.

14 **TITLE V—PROTECTING THE**
15 **SAFETY AND SECURITY OF**
16 **THE FOOD SUPPLY**

17 **Subtitle A—General Provisions to**
18 **Expand and Upgrade Security**

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

20 (a) IN GENERAL.—The President’s Council on Food
21 Safety (as established by Executive Order 13100), the
22 Secretary of Commerce, and the Secretary of Transpor-
23 tation, shall, in consultation with the food industry and
24 consumer and producer groups, and the States, develop
25 a crisis communications and education strategy with re-

1 spect to bioterrorist threats to the food supply. Such strat-
2 egy shall address threat assessments, response and notifi-
3 cation procedures, and risks communications to the public.

4 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
5 authorized to be appropriated, \$500,000 for fiscal year
6 2002, and such sums as may be necessary in each subse-
7 quent fiscal year to implement the strategy developed
8 under subsection (a) in cooperation with the Secretary of
9 Agriculture, the Secretary of Health and Human Services,
10 and the Administrator of the Environmental Protection
11 Agency.

12 **SEC. 512. EXPANSION OF ANIMAL AND PLANT HEALTH IN-**
13 **SPECTION SERVICE ACTIVITIES.**

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

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

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

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

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

5 (A) establishing cooperative agreements
6 among Veterinary Services of the Animal and
7 Plant Health Inspection Service, State animal
8 health commissions and regulatory agencies for
9 livestock and poultry health, and private veteri-
10 nary practitioners to enhance the preparedness
11 and ability of Veterinary Services and the com-
12 missions and agencies to respond to outbreaks
13 of such animal diseases; and

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

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

19 (ii) State agriculture departments;
20 and

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

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

22 (c) AUTOMATED RECORDKEEPING SYSTEM.—The
23 Administrator of the Animal and Plant Health Inspection
24 Service shall implement a central automated record-
25 keeping system to provide for the reliable tracking of the

1 status of animal and plant shipments, including those
2 shipments on hold at ports of entry and customs. The Sec-
3 retary shall ensure that such a system shall be fully acces-
4 sible to or fully integrated with the Food Safety Inspection
5 Service.

6 (d) AUTHORIZATION OF APPROPRIATIONS.—There is
7 authorized to be appropriated to carry out this section,
8 \$30,000,000 for fiscal year 2002, and such sums as may
9 be necessary for each subsequent fiscal year.

10 **SEC. 513. EXPANSION OF FOOD SAFETY INSPECTION SERV-
11 ICE ACTIVITIES.**

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

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

18 (2) improve the capacity of the Service to in-
19 spect international meat and meat products, poultry
20 and poultry products, and egg products at points of
21 origin and at ports of entry;

22 (3) strengthen the ability of the Service to col-
23 laborate with relevant agencies within the Depart-
24 ment of Agriculture and with other entities in the
25 Federal Government, the States, and Indian tribes

1 through the sharing of information and technology;
2 and

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

5 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
6 authorized to be appropriated to carry out this section,
7 \$15,000,000 for fiscal year 2002, and such sums as may
8 be necessary for each subsequent fiscal year.

9 **SEC. 514. EXPANSION OF FOOD AND DRUG ADMINIS-
10 TATION ACTIVITIES.**

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

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

17 (2) improve linkages between the Agency and
18 other regulatory agencies of the Federal Govern-
19 ment, the States, and Indian tribes with shared re-
20 sponsibilities.

21 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
22 authorized to be appropriated to carry out this section,
23 \$59,000,000 for fiscal year 2002, and such sums as may
24 be necessary for each subsequent fiscal year.

1 **SEC. 515. BIOSECURITY UPGRADES AT THE DEPARTMENT**2 **OF AGRICULTURE.**

3 There is authorized to be appropriated for fiscal year
4 2002, \$180,000,000 to enable the Agricultural Research
5 Service to conduct building upgrades to modernize existing
6 facilities, of which (1) \$100,000,000 is allocated for ren-
7 ovation, updating, and expansion of the Biosafety Level
8 3 laboratory and animal research facilities at the Plum
9 Island Animal Disease Center (Greenport, New York), and
10 of which (2) \$80,000,000 is allocated for the Agricultural
11 Research Service/Animal and Plant Health Inspection
12 Service facility in Ames, Iowa. There is authorized to be
13 appropriated such sums as may be necessary in fiscal
14 years 2003 through 2006 for (1), (2) and the planning
15 and design of an Agricultural Research Service biocontain-
16 ment laboratory for poultry research in Athens, Georgia,
17 and the planning, updating, and renovation of the Arthro-
18 pod-Borne Animal Disease Laboratory in Laramie, Wyo-
19 ming.

20 **SEC. 516. BIOSECURITY UPGRADES AT THE DEPARTMENT**21 **OF HEALTH AND HUMAN SERVICES.**

22 The Secretary of Health and Human Services shall
23 take such actions as may be necessary to secure existing
24 facilities of the Department of Health and Human Serv-
25 ices where potential animal and plant pathogens are
26 housed or researched.

1 **SEC. 517. AGRICULTURAL BIOSECURITY.**

2 (a) LAND GRANT ASSESSMENTS.—

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

8 (A) the security of all facilities where haz-
9 ardous biological agents and toxins are stored
10 or used for agricultural research purposes; and
11 (B) communication networks that transmit
12 information about hazardous biological agents
13 and toxins.

14 (2) AVAILABILITY OF STANDARDS.—Not later
15 than 45 days after the establishment of security
16 standards under paragraph (1), the Secretary shall
17 make such standards available to land grant univer-
18 sities.

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

1 (b) NATIONAL HAZARDOUS AGENT INVENTORY.—

2 The Secretary shall carry out activities necessary to de-
3 velop a national inventory of hazardous biological agents
4 and toxins contained in agricultural research facilities.
5 Such activities shall include developing and distributing a
6 model inventory procedure, developing secure means of
7 transmitting inventory information, and conducting an-
8 nual inventory activities. The inventory shall be developed
9 in coordination with, or as a component of, similar sys-
10 tems in existence on the date of enactment of this Act.

11 (c) SCREENING PROTOCOL.—The Secretary shall es-
12 tablish a national protocol for the screening of individuals
13 who require access to agricultural research facilities in a
14 manner that provides for the protection of personal pri-
15 vacy.

16 (d) INDUSTRY-ON-FARM EDUCATION.—

17 (1) IN GENERAL.—The Secretary shall develop
18 and implement a program to provide education relat-
19 ing to farms, livestock confinement operations, and
20 livestock auction biosecurity to prevent the inten-
21 tional or accidental introduction of a foreign animal
22 disease and to attempt to discover the introduction
23 of such a disease before it can spread into an out-
24 break. Biosecurity for livestock includes animal
25 quarantine procedures, blood testing of new arrivals,

1 farm locations, control of human movement onto
2 farms and holding facilities, control of vermin, and
3 movement of vehicles onto farms.

4 (2) QUARANTINE AND TESTING.—The Sec-
5 retary shall develop and disseminate through edu-
6 cational programs animal quarantine and testing
7 guidelines to enable farmers and producers to better
8 monitor new arrivals. Any educational seminars and
9 training carried out by the Secretary under this
10 paragraph shall emphasize the economic benefits of
11 biosecurity and the profound negative impact of an
12 outbreak.

13 (3) CROP GUIDELINES.—The Secretary may de-
14 velop guidelines and educational materials relating
15 to biosecurity issues to be distributed to local crop
16 producers and facilities that handle, process, or
17 transport crops.

18 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
19 authorized to be appropriated to carry out this section,
20 \$20,000,000 for fiscal year 2002, and such sums as may
21 be necessary for each subsequent fiscal year, of which not
22 less than \$5,000,000 shall be made available in fiscal year
23 2002 for activities under subsection (a).

1 **SEC. 518. BIOSECURITY OF FOOD MANUFACTURING, PROC-**2 **ESSING, AND DISTRIBUTION.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services (referred to in this section as the “Sec-
5 retary”), in consultation with the Attorney General, may
6 award grants, contracts, or cooperative agreements to en-
7 able food manufacturers, food processors, food distribu-
8 tors, and other entities regulated by the Secretary to en-
9 sure the safety of food through the development and im-
10 plementation of educational programs to ensure the secu-
11 rity of their facilities and modes of transportation against
12 potential bioterrorist attack.

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

17 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
18 authorized to be appropriated to carry out this section,
19 \$500,000 in fiscal year 2002, and such sums as may be
20 necessary for each fiscal year thereafter.

21 **Subtitle B—Protection of the Food
22 Supply**

23 **SEC. 531. ADMINISTRATIVE DETENTION.**

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

1 “(h) ADMINISTRATIVE DETENTION OF FOODS.—

2 “(1) AUTHORITY.—Any officer or qualified em-
3 ployee of the Food and Drug Administration may
4 order the detention, in accordance with this sub-
5 section, of any article of food that is found during
6 an inspection, examination, or investigation under
7 this Act conducted by such officer or qualified em-
8 ployee, if the officer or qualified employee has cred-
9 ible evidence or information indicating that the arti-
10 cle is in violation of this Act and presents a threat
11 of serious adverse health consequences or death to
12 humans or animals.

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

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

21 “(B) SECRETARY'S APPROVAL.—Before an
22 article of food may be ordered detained under
23 this subsection, the Secretary or an officer or
24 qualified employee designated by the Secretary
25 must approve such order, after determining

1 that the article presents a threat of serious ad-
2 verse health consequences or death to humans
3 or animals.

4 “(3) SECURITY OF DETAINED ARTICLE.—A de-
5 tention order under this subsection with respect to
6 an article of food may require that the article be la-
7 beled or marked as detained, and may require that
8 the article be removed to a secure facility. An article
9 subject to a detention order under this subsection
10 shall not be moved by any person from the place at
11 which it is ordered detained until released by the
12 Secretary, or the expiration of the detention period
13 applicable to such order, whichever occurs first.

14 “(4) APPEAL OF DETENTION ORDER.—Any per-
15 son who would be entitled to claim a detained article
16 if it were seized under subsection (a) may appeal to
17 the Secretary the detention order under this sub-
18 section. Within 15 days after such an appeal is filed,
19 the Secretary, after affording opportunity for an in-
20 formal hearing, shall by order confirm the detention
21 order or revoke it.

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

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

4 “(bb) The movement of an article of food in
5 violation of an order under section 304(h), or the re-
6 moval or alteration of any mark or label required by
7 the order in order to identify the article as de-
8 tained.”.

9 **SEC. 532. DEBARMENT FOR REPEATED OR SERIOUS FOOD**

10 **IMPORT VIOLATIONS.**

11 (a) DEBARMENT AUTHORITY.—

12 (1) PERMISSIVE DEBARMENT.—Section
13 306(b)(1) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 335a(b)(1)) is amended—

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

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

18 “(C) a person from importing a food or of-
19 fering a food for import into the United States
20 if—

21 “(i) the person has been convicted of
22 a felony for conduct relating to the impor-
23 tation into the United States of any food;

24 or

1 “(ii) the person has engaged in a pat-
2 tern of importing or offering for import
3 adulterated food that presents a threat of
4 serious adverse health consequences or
5 death to humans or animals.”.

6 (2) CONFORMING AMENDMENT.—Section
7 306(b)(2) of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 335a(b)(2)) is amended—

9 (A) in the paragraph heading, by inserting
10 “RELATING TO DRUG APPLICATIONS” after
11 “DEBARMENT”; and

12 (B) in the matter preceding subparagraph
13 (A), by striking “paragraph (1)” and inserting
14 “subparagraphs (A) and (B) of paragraph (1)”.

15 (3) DEBARMENT PERIOD.—Section
16 306(c)(2)(A)(iii) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 335a(c)(2)(A)(iii)) is
18 amended by striking “subsection (b)(2)” and insert-
19 ing “subsection (b)(1)(C) or (b)(2)”.

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

23 (A) in subparagraph (A)(i), by striking “or
24 (b)(2)(A)” and inserting “, or (b)(2)(A), or
25 (b)(1)(C);

1 (B) in subparagraph (A)(ii)(II), by insert-
2 ing “in applicable cases,” before “sufficient au-
3 dits”; and

4 (C) in subparagraph (B), in each of
5 clauses (i) and (ii), by inserting “or (b)(1)(C)”
6 after “(b)(2)(B)”.

10 (A) in the first sentence, by inserting “and
11 subsection (b)(1)(C)” after “subsection
12 (b)(2)(B)”;

13 (B) in the second sentence, by striking
14 “and subsections (f) and (g) of this section”
15 and inserting “subsection (f) and (g), and sub-
16 section (b)(1)(C)”.

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

20 "(h) If it is an article of food imported or offered
21 for import into the United States by, with the assistance
22 of, or at the direction of, a person debarred under section
23 306(b)(1)(C).".

1 **SEC. 533. MAINTENANCE AND INSPECTION OF RECORDS**2 **FOR FOODS.**

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

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

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

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

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

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

17 The Secretary may impose reduced requirements under
18 such regulations for small businesses with 50 or fewer em-
19 ployees.

20 “(c) LIMITATIONS.—Nothing in this section shall be
21 construed—

22 “(1) to limit the authority of the Secretary to
23 inspect records or to require maintenance of records
24 under any other provision of or regulations issued
25 under this Act;

1 “(2) to authorize the Secretary to impose any
2 requirements with respect to a food to the extent
3 that it is within the exclusive jurisdiction of the Sec-
4 retary of Agriculture pursuant to the Federal Meat
5 Inspection Act (21 U.S.C. 601 et seq.), the Poultry
6 Products Inspection Act (21 U.S.C. 451 et seq.), or
7 the Egg Products Inspection Act (21 U.S.C. 1031 et
8 seq.);

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

12 “(4) to alter, amend, or affect in any way the
13 disclosure or nondisclosure under section 552 of title
14 5, United States Code, of information copied or col-
15 lected under this section, or its treatment under sec-
16 tion 1905 of title 18, United States Code.”.

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

20 (1) in paragraph (1), by adding after the first
21 sentence the following: “In the case of any person
22 (excluding restaurants and farms) that manufac-
23 tures, processes, packs, transports, distributes, re-
24 ceives, holds, or imports foods, the inspection shall
25 extend to all records and other information described

1 in section 414(a), or required to be maintained pur-
2 suant to section 414(b)."; and

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

9 (1) in subsection (e)—

10 (A) by striking “by section 412, 504, or
11 703” and inserting “by section 412, 414, 504,
12 703, or 704(a)”;

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

17 (d) EXPEDITED RULEMAKING.—Not later than 18
18 months after the date of enactment of this Act, the Sec-
19 retary shall promulgate proposed and final regulations es-
20 tablishing recordkeeping requirements under subsection
21 414(b)(1) of the Federal Food, Drug, and Cosmetic Act.

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

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

1 amended by section 533, is further amended by adding
2 at the end the following:

3 **SEC. 415. REGISTRATION OF FOOD MANUFACTURING,
4 PROCESSING, AND HANDLING FACILITIES.**

5 **“(a) REGISTRATION.—**

6 **“(1) IN GENERAL.—**Any facility engaged in
7 manufacturing, processing, or handling food for con-
8 sumption in the United States shall be registered
9 with the Secretary. To be registered—

10 **“(A) for a domestic facility, the owner, op-**
11 **erator, or agent in charge of the facility shall**
12 **submit a registration to the Secretary; and**

13 **“(B) for a foreign facility, the owner, oper-**
14 **ator, or agent in charge of the facility shall sub-**
15 **mit a registration to the Secretary and shall in-**
16 **clude with the registration the name of the**
17 **United States agent for the facility.**

18 **“(2) REGISTRATION.—**An entity (referred to in
19 this section as the ‘registrant’) shall submit a reg-
20 stration under paragraph (1) to the Secretary con-
21 taining information necessary to notify the Secretary
22 of the name and address of each facility at which,
23 and all trade names under which, the registrant con-
24 ducts business and, when determined necessary by
25 the Secretary through guidance, the general food

1 category (as identified under section 170.3 of title
2 21, Code of Federal Regulations) of any food manu-
3 factured, processed, or handled at such facility. The
4 registrant shall notify the Secretary in a timely man-
5 ner of changes to such information.

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

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

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

23 “(c) FACILITY.—In this section, the term ‘facility’ in-
24 cludes any factory, warehouse, or establishment (including
25 a factory, warehouse, or establishment of an importer),

1 that manufactures, handles, or processes food. Such term
2 does not include restaurants.

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

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

9 “(t) If it is a food from a facility for which regis-
10 tration has not been submitted to the Secretary under section
11 415(a).”.

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

15 SEC. 535. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

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

20 “(j) PRIOR NOTICE OF IMPORTED FOOD SHIP-
21 MENTS.—

22 “(1) IN GENERAL.—At least 4 hours before a
23 food is imported or offered for importation into the
24 United States, the producer, manufacturer, or ship-
25 per of the food shall provide documentation to the

1 Secretary of the Treasury and the Secretary of
2 Health and Human Services that—

3 “(A) identifies—

4 “(i) the food;

5 “(ii) the countries of origin of the
6 food; and

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

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

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

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

24 (b) PROHIBITION OF KNOWINGLY MAKING FALSE
25 STATEMENTS.—Section 301 of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 331), as amended by section
2 531(b), is further amended by inserting after subsection
3 (bb) the following:

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

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

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

11 “(u) If—

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

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

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

18 “(4) it presents a threat of serious adverse
19 health consequences or death to humans or ani-
20 mals.”.

21 (b) REQUIREMENT.—Section 801(a) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
23 amended by adding at the end the following: “The Sec-
24 retary of Health and Human Services may require the
25 owner or consignee of a food that has been refused admis-

1 sion under this section, and has not been required to be
2 destroyed, to affix to the packaging of the food a label
3 or labeling that—

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

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

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

10 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
11 tion shall be construed to limit the authority of the Sec-
12 retary of Health and Human Services or the Secretary of
13 the Treasury to require the marking of refused articles
14 under any other provision of law.

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

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

20 (1) by inserting “qualified” before “employees”;
21 and

22 (2) by inserting “or of other Federal Depart-
23 ments or agencies, notwithstanding any other provi-
24 sion of law restricting the use of a Department’s or

1 agency's officers, employees, or funds," after "offi-
2 cers and qualified employees of the Department".

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

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

7 "(i) If it is an article of food imported or offered for
8 import into the United States and the article of food has
9 previously been refused admission under section 801(a),
10 unless the person reoffering the article affirmatively estab-
11 lishes, at the expense of the owner or consignee of the
12 article, that the article complies with the applicable re-
13 quirements of this Act, as determined by the Secretary.".

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

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

18 **"SEC. 910. GRANTS TO STATES FOR INSPECTIONS.**

19 "(a) IN GENERAL.—The Secretary is authorized to
20 make grants to States, territories, and Federally recog-
21 nized Indian tribes that undertake examinations, inspec-
22 tions, and investigations, and related activities under sec-
23 tion 702. The funds provided under such grants shall only
24 be available for the costs of conducting such examinations,
25 inspections, investigations, and related activities.

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

5 **SEC. 540. RULE OF CONSTRUCTION.**

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

8 (1) provide the Food and Drug Administration
9 with additional authority related to the regulation of
10 meat, poultry, and egg products; or
11 (2) limit the authority of the Secretary of Agri-
12 culture with respect to such products.

13 **Subtitle C—Research and Training
to Enhance Food Safety and Se-
curity**

16 **SEC. 541. SURVEILLANCE AND INFORMATION GRANTS AND
17 AUTHORITIES.**

18 Part B of title III of the Public Health Service Act
19 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
20 tion 317P the following:

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

22 “(a) IN GENERAL.—The Secretary may award food
23 safety grants to States to expand the number of States
24 participating in Pulsenet, the Foodborne Diseases Active

1 Surveillance Network, and other networks to enhance Fed-
2 eral, State, and local food safety efforts.

3 “(b) USE OF FUNDS.—Funds awarded under this
4 section shall be used by States to assist such States in
5 meeting the costs of establishing and maintaining the food
6 safety surveillance, technical and laboratory capacity need-
7 ed to participate in Pulsenet, Foodborne Diseases Active
8 Surveillance Network, and other networks to enhance Fed-
9 eral, State, and local food safety efforts.

10 "(c) AUTHORIZATION OF APPROPRIATIONS.—There
11 is authorized to be appropriated to carry out this section,
12 \$19,500,000 for fiscal year 2002, and such sums as may
13 be necessary for each of fiscal years 2003 through 2006.

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

16 “The Secretary, through the Commissioner of the
17 Food and Drug Administration and the Director of the
18 Centers for Disease Control and Prevention, and the Sec-
19 retary of Agriculture shall develop and implement a plan
20 for coordinating the surveillance for zoonotic disease and
21 human disease.”.

22 SEC. 542. AGRICULTURAL BIOTERRORISM RESEARCH AND
23 DEVELOPMENT.

24 (a) IN GENERAL.—The Secretary of Agriculture, to
25 the maximum extent practicable, shall utilize existing au-

1 thorities to expand Agricultural Research Service, and Co-
2 operative State Research Education and Extension Serv-
3 ice, programs to protect the food supply of the United
4 States by conducting activities to—

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

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

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

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

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

1 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this section,
3 \$190,000,000 for fiscal year 2002, and such sums as may
4 be necessary for each subsequent fiscal year.

Calendar No. 255

107TH CONGRESS
1ST SESSION **S. 1765**

A BILL

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

DECEMBER 5, 2001

Read the second time and placed on the calendar