

In the Senate of the United States,

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

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

AMENDMENT:

Strike out all after the enacting clause and insert:

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

2 (a) *SHORT TITLE.*—*This Act may be cited as the “Bio-*
3 *terrorism Preparedness Act of 2001”.*

1 **(b) TABLE OF CONTENTS.**—*The table of contents of the*
 2 *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 seq.)*
 6 *is amended by adding at the end the following:*

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

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

6 *“Congress finds that the United States should further*
7 *develop and implement a coordinated strategy to prevent,*
8 *and if necessary, to respond to biological threats or attacks*
9 *upon the United States. Such strategy should include meas-*
10 *ures for—*

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

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

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

20 *“(4) enhancing the protection of the nation’s food*
21 *supply and protecting agriculture against biological*
22 *threats or attacks.”.*

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

4 **Subtitle A—Additional Authorities**

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

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

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

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

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

1 *goal of bioterrorism preparedness, including actions to*
2 *strengthen the preparedness of rural communities for a bio-*
3 *logical threat or attack.*

4 “(b) *BIENNIAL REPORTS.*—

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

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

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

22 “(B) *additional legislative authority that*
23 *the Secretary determines is necessary under sec-*
24 *tion 319 to protect the public health in the event*

1 *that a condition described in section 319(a) oc-*
2 *curs.*

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

6 “(1) *activities conducted under section 319F(b);*

7 “(2) *the characteristics that may render a rural*
8 *community uniquely vulnerable to a biological threat*
9 *or attack, including distance, lack of emergency trans-*
10 *port, hospital or laboratory capacity, lack of integra-*
11 *tion of Federal or State public health networks, work-*
12 *force deficits, or other relevant conditions;*

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

19 “(4) *the need for and benefits of a National Dis-*
20 *aster Response Medical Volunteer Service that would*
21 *be a private-sector, community-based rapid response*
22 *corps of medical volunteers.*

1 **“SEC. 2812. STRATEGIC NATIONAL PHARMACEUTICAL**
2 **STOCKPILE.**

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

11 “(b) *RULE OF CONSTRUCTION.*—*Nothing in subsection*
12 *(a) shall be construed to prohibit the Secretary from includ-*
13 *ing in the stockpile described in such subsection such vac-*
14 *cines, therapies, or medical supplies as may be necessary*
15 *to meet the needs of the United States in the event of a*
16 *nuclear, radiological, or chemical attack or other public*
17 *health emergency.*

18 “(c) *DEFINITION.*—*In this section, the term ‘stockpile’*
19 *means—*

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

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

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

3 “(1) *ensure that adequate procedures are followed*
4 *with respect to the stockpile maintained under sub-*
5 *section (a) for inventory management, accounting,*
6 *and for the physical security of such stockpile; and*

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

11 “(e) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
12 *authorized to be appropriated to carry out this section,*
13 *\$640,000,000 for fiscal year 2002, and such sums as may*
14 *be necessary for each of fiscal years 2003 through 2006.”.*

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

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

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

25 “(2) *in subsection (b)—*

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

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

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

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

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

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

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

22 “(4) *LOCAL DISCRETION.—Use of regional lab-*
23 *oratories, if established under paragraph (1), shall be*
24 *at the discretion of the public health agencies of the*
25 *States.*

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

3 “(A) *purchase or improve land or purchase*
4 *any building or other facility; or*

5 “(B) *construct, repair, or alter any building*
6 *or other facility.*

7 “(6) *SUPPLEMENT NOT SUPPLANT.*—*Funds ap-*
8 *propriated under this subsection shall be used to sup-*
9 *plement and not supplant other Federal, State, and*
10 *local public funds provided for activities under this*
11 *subsection.*

12 “(7) *AUTHORIZATION OF APPROPRIATIONS.*—
13 *There is authorized to be appropriated to carry out*
14 *this subsection, \$59,500,000 for fiscal year 2002, and*
15 *such sums as may be necessary for each of fiscal years*
16 *2003 through 2006.”.*

17 “(b) *EDUCATION AND TRAINING.*—*Section 319F(e) of*
18 *the Public Health Service Act (42 U.S.C. 247d6(e)) is*
19 *amended by adding at the end the following flush sentence:*
20 *“The education and training activities described in this*
21 *subsection may be carried out through Public Health Pre-*
22 *paredness Centers, Noble training facilities, the Emerging*
23 *Infections Program, and the Epidemic Intelligence Serv-*
24 *ice.”.*

1 ***Subtitle B—Coordination of Efforts***
2 ***and Responses***

3 ***SEC. 211. ASSISTANT SECRETARY FOR EMERGENCY PRE-***
4 ***PAREDNESS; NATIONAL DISASTER MEDICAL***
5 ***SYSTEM.***

6 *Title XXVIII of the Public Health Service Act, as*
7 *added by section 101, and amended by section 201, is fur-*
8 *ther amended by adding at the end the following:*

9 ***“SEC. 2813. ASSISTANT SECRETARY FOR EMERGENCY PRE-***
10 ***PAREDNESS.***

11 *“(a) APPOINTMENT OF ASSISTANT SECRETARY FOR*
12 *EMERGENCY PREPAREDNESS.—The President, with the ad-*
13 *vice and consent of the Senate, shall appoint an individual*
14 *to serve as the Assistant Secretary for Emergency Prepared-*
15 *ness who shall head the Office for Emergency Preparedness.*
16 *Such Assistant Secretary shall report to the Secretary.*

17 *“(b) DUTIES.—Subject to the authority of the Sec-*
18 *retary, the Assistant Secretary for Emergency Preparedness*
19 *shall—*

20 *“(1) serve as the principal adviser to the Sec-*
21 *retary on matters relating to emergency preparedness,*
22 *including preparing for and responding to biological*
23 *threats or attacks and for developing policy; and*

24 *“(2) coordinate all functions within the Depart-*
25 *ment of Health and Human Services relating to*

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

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

4 **“(a) NATIONAL DISASTER MEDICAL SYSTEM.—**

5 **“(1) IN GENERAL.—***There shall be operated a*
6 *system to be known as the National Disaster Medical*
7 *System (in this section referred to as the ‘National*
8 *System’) which shall be coordinated by the Secretary,*
9 *in collaboration with the Secretary of Defense, the*
10 *Secretary of Veterans Affairs, and the Director of the*
11 *Federal Emergency Management Agency.*

12 **“(2) FUNCTIONS.—***The National System shall*
13 *provide appropriate health services, health-related so-*
14 *cial services and, if necessary, auxiliary services (in-*
15 *cluding mortuary and veterinary services) to respond*
16 *to the needs of victims of a public health emergency*
17 *if the Secretary activates the System with respect to*
18 *the emergency. The National System shall carry out*
19 *such ongoing activities as may be necessary to pre-*
20 *pare for the provision of such services.*

21 **“(b) TEMPORARY DISASTER-RESPONSE PER-**
22 **SONNEL.—**

23 **“(1) IN GENERAL.—***For the purpose of assisting*
24 *the Office of Emergency Preparedness and the Na-*
25 *tional System in carrying out duties under this sec-*

1 *tion, the Secretary may in accordance with section*
2 *316.401 of title 5, Code of Federal Regulations (in-*
3 *cluding revisions to such section), and notwith-*
4 *standing the eligibility requirements set forth in*
5 *paragraphs (1) through (8) of section 316.402(b) of*
6 *such title (including revisions), make temporary ap-*
7 *pointments of individuals to intermittent positions to*
8 *serve as personnel of such Office or System.*

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

16 *“(3) LIABILITY.—For purposes of section 224(a)*
17 *and the remedies described in such section, an indi-*
18 *vidual appointed under paragraph (1) shall, while*
19 *acting within the scope of such appointment, be con-*
20 *sidered to be an employee of the Public Health Service*
21 *performing medical, surgical, dental, or related func-*
22 *tions. Participation in training programs carried out*
23 *by the Office of Emergency Preparedness or Federal*
24 *personnel of the National System shall be considered*
25 *within the scope of such an appointment (regardless*

1 *of whether the individual receives compensation for*
2 *such participation).*

3 “(c) *TEMPORARY DISASTER-RESPONSE APPOINTEE.*—
4 *For purposes of this section, the term ‘temporary disaster-*
5 *response appointee’ means an individual appointed by the*
6 *Secretary under subsection (b).*

7 “(d) *COMPENSATION FOR WORK INJURIES.*—*A tem-*
8 *porary disaster-response appointee, as designated by the*
9 *Secretary, shall be deemed an employee, and an injury sus-*
10 *tained by such an individual while actually serving or*
11 *while participating in a uncompensated training exercise*
12 *related to such service shall be deemed ‘in the performance*
13 *of duty’, for purposes of chapter 81 of title 5, United States*
14 *Code, pertaining to compensation for work injuries. In the*
15 *event of an injury to such a temporary disaster-response*
16 *appointee, the Secretary of Labor shall be responsible for*
17 *making determinations as to whether the claimants are en-*
18 *titled to compensation or other benefits in accordance with*
19 *chapter 81 of title 5, United States Code.*

20 “(e) *EMPLOYMENT AND REEMPLOYMENT RIGHTS.*—

21 “(1) *IN GENERAL.*—*A temporary disaster-re-*
22 *sponse appointee, as designated by the Secretary,*
23 *shall, when performing service as a temporary dis-*
24 *aster-response appointee or participating in an un-*
25 *compensated training exercise related to such service,*

1 *be deemed a person performing ‘service in the uni-*
2 *formed services’ for purposes of chapter 43 of title 38,*
3 *United States Code, pertaining to employment and*
4 *reemployment rights of members in the uniformed*
5 *services. All rights and obligations of such persons*
6 *and procedures for assistance, enforcement, and inves-*
7 *tigation shall be as provided for in chapter 43 of title*
8 *38, United States Code.*

9 “(2) *NOTICE OF ABSENCE FROM POSITION OF*
10 *EMPLOYMENT.—Preclusion of giving notice of service*
11 *by disaster response necessity shall be deemed pre-*
12 *clusion by ‘military necessity’ for purposes of section*
13 *4312(b) of title 38, United States Code, pertaining to*
14 *giving notice of absence from a position of employ-*
15 *ment. A determination of disaster response necessity*
16 *shall be made pursuant to regulations prescribed by*
17 *the Secretary, in consultation with the Secretary of*
18 *Defense, and shall not be subject to judicial review.*

19 “(f) *LIMITATION.—A temporary disaster-response ap-*
20 *pointee shall not be deemed an employee of the Public*
21 *Health Service or the Office of Emergency Preparedness for*
22 *purposes other than those specifically set forth in this sec-*
23 *tion.”.*

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

4 (a) *PROVISION OF DECLARATION TO CONGRESS.*—Sec-
5 tion 319(a) of the Public Health Service Act (42 U.S.C.
6 247d(a)) is amended by adding at the end the following:
7 “Not later than 48 hours after a declaration of a public
8 health emergency under this section, the Secretary shall pro-
9 vide a written declaration to Congress indicating that an
10 emergency under this section has been declared.”.

11 (b) *WAIVER OF REPORTING DEADLINES.*—Section 319
12 of the Public Health Service Act (42 U.S.C. 247d) is amend-
13 ed by adding at the end the following:

14 “(d) *WAIVER OF DATA SUBMITTAL AND REPORTING*
15 *DEADLINES.*—In any case in which the Secretary deter-
16 mines that, wholly or partially as a result of a public health
17 emergency that has been declared pursuant to subsection
18 (a), individuals or public or private entities are unable to
19 comply with deadlines for the submission to the Secretary
20 of data or reports required under any law administered by
21 the Secretary, the Secretary may, notwithstanding any
22 other provision of law, grant such extensions of such dead-
23 lines as the circumstances reasonably require, and may
24 waive any sanctions otherwise applicable to such failure to
25 comply.”.

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

5 “(e) *EMERGENCY DECLARATION PERIOD.*—A deter-
6 mination by the Secretary under subsection (a) that a pub-
7 lic health emergency exists shall remain in effect for not
8 longer than the 180-day period beginning on the date of
9 the determination. Such period may be extended by the Sec-
10 retary if—

11 “(1) the Secretary determines that such an exten-
12 sion is appropriate; and

13 “(2) the Secretary provides a written notifica-
14 tion to Congress within 48 hours of such extension.”.

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

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

20 “(a) *WORKING GROUP ON BIOTERRORISM.*—The Sec-
21 retary, in coordination with the Secretary of Defense, the
22 Director of the Federal Emergency Management Agency, the
23 Attorney General, the Secretary of Veterans Affairs, the Sec-
24 retary of Labor, and the Secretary of Agriculture, and with
25 other similar Federal officials as determined appropriate,

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

5 “(1) *prioritize countermeasures required to treat,*
6 *prevent, or identify exposure to a biological agent or*
7 *toxin pursuant to section 351A;*

8 “(2) *coordinate and facilitate the awarding of*
9 *grants, contracts, or cooperative agreements for the*
10 *development, manufacture, distribution, and purchase*
11 *of priority countermeasures;*

12 “(3) *coordinate research on pathogens likely to be*
13 *used in a biological threat or attack on the civilian*
14 *population;*

15 “(4) *develop shared standards for equipment to*
16 *detect and to protect against biological agents and*
17 *toxins;*

18 “(5) *coordinate the development, maintenance,*
19 *and procedures for the release of materials from the*
20 *Strategic National Pharmaceutical Stockpile;*

21 “(6) *assess the priorities for and enhance the*
22 *preparedness of public health institutions, providers*
23 *of medical care, and other emergency service per-*
24 *sonnel (including firefighters) to detect, diagnose, and*

1 *respond (including mental health response) to a bio-*
2 *logical threat or attack;*

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

10 *“(A) local firefighters, ambulance personnel,*
11 *police and public security officers, or other emer-*
12 *gency response personnel; and*

13 *“(B) hospitals, primary care facilities, and*
14 *public health agencies;*

15 *“(8) coordinate the development of strategies for*
16 *Federal, State, and local agencies to communicate in-*
17 *formation to the public regarding biological threats or*
18 *attacks;*

19 *“(9) develop methods to decontaminate facilities*
20 *contaminated as a result of a biological attack, in-*
21 *cluding appropriate protections for the safety of those*
22 *conducting such activities; and*

23 *“(10) ensure that the activities under this sub-*
24 *section address the needs of children and other vulner-*
25 *able populations.*

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

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

8 “(1) *NATIONAL TASK FORCE ON CHILDREN AND*
9 *TERRORISM.—*

10 “(A) *IN GENERAL.—The National Task*
11 *Force on Children and Terrorism, which shall be*
12 *composed of such Federal officials as may be ap-*
13 *propriate to address the special needs of children,*
14 *and child health experts on infectious disease, en-*
15 *vironmental health, toxicology, and other rel-*
16 *evant professional disciplines.*

17 “(B) *DUTIES.—The task force described in*
18 *subparagraph (A) shall provide recommenda-*
19 *tions to the Secretary regarding—*

20 “(i) *the preparedness of the health care*
21 *system to respond to bioterrorism as it re-*
22 *lates to children;*

23 “(ii) *needed changes to the health care*
24 *and emergency medical service systems and*
25 *emergency medical services protocols to meet*

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

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

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

8 “(A) *IN GENERAL.—The Emergency Public*
9 *Information and Communications (EPIC) Task*
10 *Force, which shall be composed of individuals*
11 *with expertise in public health, communications,*
12 *behavioral psychology, and other areas deter-*
13 *mined appropriate by the Secretary.*

14 “(B) *DUTIES.—The task force described in*
15 *subparagraph (A) shall make recommendations*
16 *and report to the Secretary on appropriate ways*
17 *to communicate information regarding biological*
18 *threats or attacks to the public, including public*
19 *service announcements or other appropriate*
20 *means to communicate in a manner that maxi-*
21 *mizes information and minimizes panic, and in-*
22 *cludes information relevant to children and other*
23 *vulnerable populations.*

24 “(3) *SUNSET.—Each Task Force established*
25 *under paragraphs (1) and (2) shall terminate on the*

1 1996; *CODIFICATION IN THE PUBLIC HEALTH SERVICE*
2 *ACT, WITH AMENDMENTS.*—

3 (1) *PUBLIC HEALTH SERVICE ACT.*—Subpart 1
4 *of part F of title III of the Public Health Service Act*
5 *(42 U.S.C. 262 et seq.) is amended by inserting after*
6 *section 351 the following:*

7 **“SEC. 351A. ENHANCED CONTROL OF BIOLOGICAL AGENTS**
8 **AND TOXINS.**

9 “(a) *REGULATORY CONTROL OF BIOLOGICAL AGENTS*
10 *AND TOXINS.*—

11 “(1) *LIST OF BIOLOGICAL AGENTS AND TOX-*
12 *INS.*—

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

18 “(B) *CRITERIA.*—*In determining whether to*
19 *include an agent or toxin on the list under sub-*
20 *paragraph (A), the Secretary shall—*

21 “(i) *consider—*

22 “(I) *the effect on human health of*
23 *exposure to the agent or toxin;*

24 “(II) *the degree of contagiousness*
25 *of the agent or toxin and the methods*

1 *by which the agent or toxin is trans-*
2 *ferred to humans;*

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

8 *“(IV) any other criteria, includ-*
9 *ing the needs of children and other vul-*
10 *nerable populations, that the Secretary*
11 *considers appropriate; and*

12 *“(ii) consult with appropriate Federal*
13 *departments and agencies, and scientific ex-*
14 *perts representing appropriate professional*
15 *groups, including those with pediatric ex-*
16 *pertise.*

17 *“(2) BIENNIAL REVIEW.—The Secretary shall re-*
18 *view and republish the list under paragraph (1) bien-*
19 *nially, or more often as needed, and shall, through*
20 *rulemaking, revise the list as necessary to incorporate*
21 *additions or deletions to ensure public health, safety,*
22 *and security.*

23 *“(3) EXEMPTIONS.—The Secretary may exempt*
24 *from the list under paragraph (1)—*

1 “(A) *attenuated or inactive biological*
2 *agents or toxins used in biomedical research or*
3 *for legitimate medical purposes; and*

4 “(B) *products that are cleared or approved*
5 *under the Federal Food, Drug, and Cosmetic Act*
6 *or under the Virus-Serum-Toxin Act, as amend-*
7 *ed in 1985 by the Food Safety and Security*
8 *Act.”;*

9 “(b) *REGULATION OF TRANSFERS OF LISTED BIO-*
10 *LOGICAL AGENTS AND TOXINS.—The Secretary shall by reg-*
11 *ulation provide for—*

12 “(1) *the establishment and enforcement of safety*
13 *procedures for the transfer of biological agents and*
14 *toxins listed pursuant to subsection (a)(1), including*
15 *measures to ensure—*

16 “(A) *proper training and appropriate skills*
17 *to handle such agents and toxins; and*

18 “(B) *proper laboratory facilities to contain*
19 *and dispose of such agents and toxins;*

20 “(2) *safeguards to prevent access to such agents*
21 *and toxins for use in domestic or international ter-*
22 *rorism or for any other criminal purpose;*

23 “(3) *the establishment of procedures to protect*
24 *the public safety in the event of a transfer or poten-*
25 *tial transfer of a biological agent or toxin in violation*

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

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

7 “(c) *POSSESSION AND USE OF LISTED BIOLOGICAL*
8 *AGENTS AND TOXINS.*—*The Secretary shall by regulation*
9 *provide for the establishment and enforcement of standards*
10 *and procedures governing the possession and use of biologi-*
11 *cal agents and toxins listed pursuant to subsection (a)(1)*
12 *in order to protect the public health and safety, including*
13 *the measures, safeguards, procedures, and availability of*
14 *such agents and toxins described in paragraphs (1) through*
15 *(4) of subsection (b), respectively.*

16 “(d) *REGISTRATION AND TRACEABILITY MECHA-*
17 *NISMS.*—*Regulations under subsections (b) and (c) shall re-*
18 *quire registration for the possession, use, and transfer of*
19 *biological agents and toxins listed pursuant to subsection*
20 *(a)(1), and such registration shall include (if available to*
21 *the registered person) information regarding the character-*
22 *ization of such biological agents and toxins to facilitate*
23 *their identification and traceability. The Secretary shall*
24 *maintain a national database of the location of such bio-*

1 *logical agents and toxins with information regarding their*
2 *characterizations.*

3 “(e) *INSPECTIONS.*—*The Secretary shall have the au-*
4 *thority to inspect persons subject to the regulations under*
5 *subsections (b) and (c) to ensure their compliance with such*
6 *regulations, including prohibitions on restricted persons*
7 *under subsection (g).*

8 “(f) *EXEMPTIONS.*—

9 “(1) *IN GENERAL.*—*The Secretary shall establish*
10 *exemptions, including exemptions from the security*
11 *provisions, from the applicability of provisions of—*

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

20 “(B) *the regulations issued under subsection*
21 *(c).*

22 “(2) *CLINICAL LABORATORIES.*—*The Secretary*
23 *shall exempt clinical laboratories and other persons*
24 *that possess, use, or transfer biological agents and tox-*
25 *ins listed pursuant to subsection (a)(1) from the ap-*

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

3 *“(A) such agents or toxins are presented for*
4 *diagnosis, verification, or proficiency testing;*

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

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

12 *“(g) SECURITY REQUIREMENTS FOR REGISTERED*
13 *PERSONS.—*

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

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

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

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

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

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

23 “(3) *CONSULTATION AND IMPLEMENTATION.—*
24 *Regulations under subsections (b) and (c) shall be de-*
25 *veloped in consultation with research-performing or-*

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

5 *“(h) DISCLOSURE OF INFORMATION.—*

6 *“(1) IN GENERAL.—Any information in the pos-*
7 *session of any Federal agency that identifies a person,*
8 *or the geographic location of a person, who is reg-*
9 *istered pursuant to regulations under this section (in-*
10 *cluding regulations promulgated before the effective*
11 *date of this subsection), or any site-specific informa-*
12 *tion relating to the type, quantity, or characterization*
13 *of a biological agent or toxin listed pursuant to sub-*
14 *section (a)(1) or the site-specific security mechanisms*
15 *in place to protect such agents and toxins, including*
16 *the national database required in subsection (d), shall*
17 *not be disclosed under section 552(a) of title 5, United*
18 *States Code.*

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

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

1 “(B) from making disclosures of such infor-
2 mation to any committee or subcommittee of the
3 Congress with appropriate jurisdiction, upon re-
4 quest.

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

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

24 (2) *REGULATIONS.*—

1 (A) *DATE CERTAIN FOR PROMULGATION;*
2 *EFFECTIVE DATE REGARDING CRIMINAL AND*
3 *CIVIL PENALTIES.*—*Not later than 180 days after*
4 *the date of the enactment of this title, the Sec-*
5 *retary of Health and Human Services shall pro-*
6 *mulgate an interim final rule for carrying out*
7 *section 351A(c) of the Public Health Service Act,*
8 *which amends the Antiterrorism and Effective*
9 *Death Penalty Act of 1996. Such interim final*
10 *rule will take effect 60 days after the date on*
11 *which such rule is promulgated, including for*
12 *purposes of—*

13 (i) *section 175(b) of title 18, United*
14 *States Code (relating to criminal penalties),*
15 *as added by subsection (b)(1)(B) of this sec-*
16 *tion; and*

17 (ii) *section 351A(i) of the Public*
18 *Health Service Act (relating to civil pen-*
19 *alties).*

20 (B) *SUBMISSION OF REGISTRATION APPLI-*
21 *CATIONS.*—*A person required to register for pos-*
22 *session under the interim final rule promulgated*
23 *under subparagraph (A) shall submit an appli-*
24 *cation for such registration not later than 60*

1 *days after the date on which such rule is promul-*
2 *gated.*

3 (3) *CONFORMING AMENDMENT.*—*Subsections (d),*
4 *(e), (f), and (g) of section 511 of the Antiterrorism*
5 *and Effective Death Penalty Act of 1996 (42 U.S.C.*
6 *262 note) are repealed.*

7 (4) *EFFECTIVE DATE.*—*Paragraph (1) shall take*
8 *effect as if incorporated in the Antiterrorism and Ef-*
9 *fective Death Penalty Act of 1996, and any regula-*
10 *tions, including the list under subsection (d)(1) of sec-*
11 *tion 511 of that Act, issued under section 511 of that*
12 *Act shall remain in effect as if issued under section*
13 *351A of the Public Health Service Act.*

14 (b) *SELECT AGENTS.*—

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

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

23 (B) *by inserting after subsection (a) the fol-*
24 *lowing:*

25 “(b) *SELECT AGENTS.*—

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

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

15 (2) *DEFINITIONS.*—Section 175 of title 18,
16 *United States Code, as amended by paragraph (1), is*
17 *further amended by striking subsection (d) and in-*
18 *serting the following:*

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

20 “(1) *The terms ‘biological agent’ and ‘toxin’ have*
21 *the meanings given such terms in section 178, except*
22 *that, for purposes of subsections (b) and (c), such*
23 *terms do not encompass any biological agent or toxin*
24 *that is in its naturally occurring environment, if the*
25 *biological agent or toxin has not been cultivated, cul-*

1 *tured, collected, or otherwise extracted from its nat-*
2 *ural source.*

3 “(2) *The term ‘for use as a weapon’ includes the*
4 *development, production, transfer, acquisition, reten-*
5 *tion, or possession of any biological agent, toxin, or*
6 *delivery system, other than for prophylactic, protec-*
7 *tive, or other peaceful purposes.*

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

15 (3) *CONFORMING AMENDMENT.—*

16 (A) *Section 175(a) of title 18, United States*
17 *Code, is amended in the second sentence by strik-*
18 *ing “under this section” and inserting “under*
19 *this subsection”.*

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

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

1 *other appropriate Federal agencies, shall submit to the Con-*
2 *gress a report that—*

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

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

14 *(3) describes the actions to date and future plans*
15 *of the Secretary for determining compliance with reg-*
16 *ulations under such section 351A of the Public Health*
17 *Service Act and for taking appropriate enforcement*
18 *actions; and*

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

1 **TITLE III—IMPROVING STATE**
2 **AND LOCAL PREPAREDNESS**
3 ***Subtitle A—Emergency Measures to***
4 ***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 Health
9 *Service Act (42 U.S.C. 247d–6) is amended by striking sub-*
10 *section (c) and inserting the following:*

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

13 “(1) *IN GENERAL.*—The Secretary shall establish
14 *the State Bioterrorism Preparedness and Response*
15 *Block Grant Program (referred to in this subsection*
16 *as the ‘Program’) under which the Secretary shall*
17 *award grants to or enter into cooperative agreements*
18 *with States, the District of Columbia, and territories*
19 *(referred to in this section as ‘eligible entities’) to en-*
20 *able such entities to prepare for and respond to bio-*
21 *logical threats or attacks. The Secretary shall ensure*
22 *that activities conducted under this section are co-*
23 *ordinated with the activities conducted under this sec-*
24 *tion and section 319C.*

1 “(2) *ELIGIBILITY.*—*To be eligible to receive*
2 *amounts under paragraph (1), a State, the District of*
3 *Columbia, or a territory shall prepare and submit to*
4 *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 date*
14 *on which a grant or contract is received under*
15 *this subsection, complete an assessment under*
16 *section 319B(a), or an assessment that is sub-*
17 *stantially equivalent as determined by the Sec-*
18 *retary unless such assessment has already been*
19 *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 paragraph
2 (1) in accordance with the plan submitted under
3 paragraph (3), including making expenditures to
4 carry out the strategy contained in the plan;

5 “(E) use amounts received under paragraph
6 (1) to supplement and not supplant funding at
7 levels in existence prior to September 11, 2001
8 for public health capacities or bioterrorism pre-
9 paredness; and

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

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

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

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

4 “(B) a description (including amounts ex-
5 *pende*d by the eligible entity for such purpose) of
6 *the programs, projects, and activities that the el-*
7 *igible entity will implement using amounts re-*
8 *ceived in order to detect and respond to biologi-*
9 *cal threats or attacks, including the manner in*
10 *which the eligible entity will manage State sur-*
11 *veillance and response efforts and coordinate*
12 *such efforts with national efforts;*

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

20 “(D) a description of the cleanup and con-
21 *tamination prevention efforts that may be imple-*
22 *mented in the event of a biological threat or at-*
23 *tack;*

24 “(E) a description of efforts to ensure that
25 *hospitals and health care providers have ade-*

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

7 *“(F) other information the Secretary may*
8 *by regulation require.*

9 *“Nothing in subparagraph (E) shall be construed*
10 *to require or recommend that States establish or*
11 *maintain stockpiles of vaccines, therapies, or other*
12 *medical supplies.*

13 *“(4) USE OF FUNDS.—*

14 *“(A) IN GENERAL.—In coordination with*
15 *the activities conducted under this section, an el-*
16 *igible entity shall use amounts received under*
17 *this section to—*

18 *“(i) conduct the assessment under sec-*
19 *tion 319B to achieve the capacities de-*
20 *scribed in section 319A, if the assessment*
21 *has not previously been conducted;*

22 *“(ii) achieve the public health capac-*
23 *ities developed under section 319A; and*

24 *“(iii) carry out the plan under para-*
25 *graph (3).*

1 “(B) *ADDITIONAL USES.*—*In addition to*
2 *the activities described in subparagraph (A), an*
3 *eligible entity may use amounts received under*
4 *this subsection to—*

5 “(i) *improve surveillance, detection,*
6 *and response activities to prepare for emer-*
7 *gency response activities including biologi-*
8 *cal threats or attacks, including training*
9 *personnel in these and other necessary func-*
10 *tions;*

11 “(ii) *carry out activities to improve*
12 *communications and coordination efforts*
13 *within the eligible entity and between the*
14 *eligible entity and the Federal Government,*
15 *including activities to improve information*
16 *technology and communications equipment*
17 *available to health care and public health*
18 *officials for use in responding to a biologi-*
19 *cal threat or attack or other public health*
20 *emergency and including early warning*
21 *and surveillance networks that use advanced*
22 *information technology to provide early de-*
23 *tection of biological threats or attacks;*

1 “(iii) plan for triage and transport
2 management in the event of a biological
3 threat or attack;

4 “(iv) meet the special needs of children
5 and other vulnerable populations during
6 and after a biological threat or attack, in-
7 cluding the expansion of 2-1-1 call centers
8 or other universal hotlines, or an alternative
9 communication plan to assist victims and
10 their families in receiving timely informa-
11 tion;

12 “(v) improve the ability of hospitals
13 and other health care facilities to provide ef-
14 fective health care (including mental health
15 care) during and after a biological threat or
16 attack, including the development of model
17 hospital preparedness plans by a hospital
18 accreditation organization or similar orga-
19 nizations; and

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

1 or otherwise effect safety and health rules
2 and standards.

3 “(C) *PROHIBITED USES.*—An eligible entity
4 may not use amounts received under this sub-
5 section to—

6 “(i) provide inpatient services;

7 “(ii) make cash payments to intended
8 recipients of health services;

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

11 “(iv) construct, repair, or alter any
12 building or other facility; or

13 “(v) satisfy any requirement for the ex-
14 penditure of non-Federal funds as a condi-
15 tion for the receipt of Federal funds.

16 “(5) *AMOUNT OF GRANT.*—

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

1 *ritory bears to the total population of the United*
2 *States.*

3 “(B) *EXCEPTIONS.*—

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

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

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

20 “(ii) *EXTRAORDINARY NEEDS.*—

21 “(I) *IN GENERAL.*—*Notwith-*
22 *standing subparagraph (A) and subject*
23 *to the extent of amounts made avail-*
24 *able under paragraph (9), the Sec-*
25 *retary may provide additional funds to*

1 *a State, District, or territory under*
2 *this subsection if the Secretary deter-*
3 *mines that such State, District, or ter-*
4 *ritory has extraordinary needs with re-*
5 *spect to bioterrorism preparedness.*

6 “(II) *FINDING WITH RESPECT TO*
7 *THE DISTRICT OF COLUMBIA.—As a re-*
8 *sult of the concentration of entities of*
9 *national significance located within*
10 *the District of Columbia, Congress*
11 *finds that the District of Columbia has*
12 *extraordinary needs with respect to*
13 *bioterrorism preparedness, and the*
14 *Secretary shall recognize such finding*
15 *for purposes of subclause (I).*

16 “(C) *RULE WITH RESPECT TO UNEXPENDED*
17 *FUNDS.—To the extent that all the funds appro-*
18 *priated under paragraph (9) for a fiscal year*
19 *and available in such fiscal year are not other-*
20 *wise paid to eligible entities because—*

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

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

5 “(iii) some eligible entity amounts are
6 offset or repaid;

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

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

18 “(6) INDIAN TRIBES.—

19 “(A) IN GENERAL.—If the Secretary—

20 “(i) receives a request from the gov-
21 erning body of an Indian tribe or tribal or-
22 ganization within any State that funds
23 under this subsection be provided directly
24 by the Secretary to such tribe or organiza-
25 tion; and

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

6 the Secretary shall reserve from amounts which
7 would otherwise be provided to such State under
8 this subsection for the fiscal year the amount de-
9 termined under subparagraph (B).

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

19 “(C) GRANT.—The amount reserved by the
20 Secretary on the basis of a determination under
21 this paragraph shall be granted to the Indian
22 tribe or tribal organization serving the individ-
23 uals for whom such a determination has been
24 made.

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

7 “(E) *DEFINITIONS.*—In this paragraph, the
8 terms ‘Indian tribe’ and ‘tribal organization’
9 have the same meaning given such terms in sec-
10 tion 4(b) and section 4(c) of the Indian Self-De-
11 termination and Education Assistance Act.

12 “(7) *WITHHOLDING.*—

13 “(A) *REQUIREMENTS.*—

14 “(i) *IN GENERAL.*—The Secretary
15 shall, after adequate notice and an oppor-
16 tunity for a hearing conducted within the
17 affected eligible entity, withhold or recoup
18 funds from any such entity that does not
19 use amounts received under this subsection
20 in accordance with the requirements of this
21 subsection. The Secretary shall withhold or
22 recoup such funds until the Secretary finds
23 that the reason for the withholding or
24 recoupment has been removed and there is
25 reasonable assurance that it will not recur.

1 “(ii) *INVESTIGATION.*—*The Secretary*
2 *may not institute proceedings to withhold*
3 *or recoup funds under clause (i) unless the*
4 *Secretary has conducted an investigation*
5 *concerning whether the eligible entity has*
6 *used grant or agreement amounts in accord-*
7 *ance with the requirements of this sub-*
8 *section. Investigations required by this*
9 *clause shall be conducted within the affected*
10 *entity by qualified investigators.*

11 “(iii) *RESPONSE TO COMPLAINTS.*—
12 *The Secretary shall respond in an expedi-*
13 *tious manner to complaints of a substantial*
14 *or serious nature that an eligible entity has*
15 *failed to use funds in accordance with the*
16 *requirements of this subsection.*

17 “(iv) *MINOR FAILURES.*—*The Sec-*
18 *retary may not withhold or recoup funds*
19 *under clause (i) from an eligible entity for*
20 *a minor failure to comply with the require-*
21 *ments of this subsection.*

22 “(B) *AVAILABILITY OF INFORMATION FOR*
23 *INSPECTION.*—*Each eligible entity, and other en-*
24 *tity which has received funds under this section,*
25 *shall make appropriate books, documents, pa-*

1 *pers, and records available to the Secretary or*
2 *the Comptroller General of the United States, or*
3 *any of their duly authorized representatives, for*
4 *examination, copying, or mechanical reproduc-*
5 *tion on or off the premises of the appropriate en-*
6 *tity upon a reasonable request therefore.*

7 “(C) *LIMITATION ON REQUESTS FOR INFOR-*
8 *MATION.—*

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

19 “(ii) *JUDICIAL PROCEEDINGS.—Clause*
20 *(i) does not apply to the collection, compila-*
21 *tion, or transmittal of data in the course of*
22 *a judicial proceeding.*

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

1 “(9) *AUTHORIZATION OF APPROPRIATIONS.*—
 2 *There is authorized to be appropriated to carry out*
 3 *this subsection, \$667,000,000 for fiscal year 2002, and*
 4 *such sums as may be necessary for fiscal year 2003,*
 5 *and no funds are authorized to be appropriated for*
 6 *subsequent fiscal years.”.*

7 **(b) *REAUTHORIZATION OF OTHER PROGRAMS.***—*Sec-*
 8 *tion 319F(i) of the Public Health Service Act (42 U.S.C.*
 9 *247d–6(i)) is amended to read as follows:*

10 “(i) *AUTHORIZATION OF APPROPRIATIONS.*—*There are*
 11 *authorized to be appropriated—*

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

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

18 ***Subtitle B—Improving Local Pre-***
 19 ***paredness and Response Capa-***
 20 ***bilities***

21 ***SEC. 311. DESIGNATED BIOTERRORISM RESPONSE MEDICAL***
 22 ***CENTERS.***

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

1 (1) *by redesignating subsections (d) through (h)*
2 *and (i), as subsections (e) through (i) and (l), respec-*
3 *tively; and*

4 (2) *by inserting after subsection (c), the fol-*
5 *lowing:*

6 “(d) *DESIGNATED BIOTERRORISM RESPONSE MED-*
7 *ICAL CENTERS.—*

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

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

16 “(A) *be a consortium that consists of at*
17 *least one entity from each of the following*
18 *categories—*

19 “(i) *a hospital including children’s*
20 *hospitals, clinic, health center, or primary*
21 *care facility;*

22 “(ii) *a political subdivision of a State;*
23 *and*

24 “(iii) *a department of public health;*

1 “(B) prepare, in consultation with the Chief
2 Executive Officer of the State, District, or terri-
3 tory in which the hospital, clinic, health center,
4 or primary care facility is located, and submits
5 to the Secretary, an application at such time, in
6 such manner, and containing such information
7 as the Secretary may require;

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

12 “(D) provide assurances satisfactory to the
13 Secretary that such entity shall, upon the request
14 of the Secretary or the Chief Executive Officer of
15 the State, District, or territory in which the enti-
16 ty is located, during the emergency period, serve
17 the needs of the emergency area, including pro-
18 viding adequate health care capacity, serving as
19 a regional resource in the diagnosis, treatment,
20 or care for persons, including children and other
21 vulnerable populations, exposed to a biological
22 threat or attack, and accepting the transfer of
23 patients, where appropriate.

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

4 “(A) *the training of health care profes-*
5 *sionals to enhance the ability of such personnel*
6 *to recognize the symptoms of exposure to a po-*
7 *tential biological threat or attack and to provide*
8 *treatment to those so exposed;*

9 “(B) *the training of health care profes-*
10 *sionals to recognize and treat the mental health*
11 *consequences of a biological threat or attack;*

12 “(C) *increasing the capacity of such entity*
13 *to provide appropriate health care for large*
14 *numbers of individuals exposed to a biological*
15 *threat or attack;*

16 “(D) *the purchase of reserves of vaccines,*
17 *therapies, and other medical supplies to be used*
18 *until materials from the Strategic National*
19 *Pharmaceutical Stockpile arrive;*

20 “(E) *training and planning to protect the*
21 *health and safety of personnel involved in re-*
22 *sponding to a biological threat or attack; or*

23 “(F) *other activities determined appropriate*
24 *by the Secretary.*

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

3 “(A) *purchase or improve land or purchase*
4 *any building or other facility; or*

5 “(B) *construct, repair, or alter any building*
6 *or facility.*

7 “(6) *TECHNICAL ASSISTANCE.*—*Not later than*
8 *180 days after the date of enactment of the Bioterrorism Preparedness Act of 2001, the Secretary shall*
9 *develop and publish technical guidelines relating to*
10 *equipment, training, treatment, capacity, and per-*
11 *sonnel, relevant to the status as a bioterrorism re-*
12 *sponse medical center and the Secretary may provide*
13 *technical assistance to eligible entities, including as-*
14 *sistance to address the needs of children and other*
15 *vulnerable populations.”.*

17 **SEC. 312. DESIGNATED STATE PUBLIC EMERGENCY AN-**
18 **NOUNCEMENT PLAN.**

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

22 (1) *in paragraph (5), by striking “and” at the*
23 *end;*

24 (2) *in paragraph (6), by striking the period and*
25 *inserting “; and”; and*

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

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

4 **SEC. 313. TRAINING FOR PEDIATRIC ISSUES SURROUNDING**
5 **BIOLOGICAL AGENTS USED IN WARFARE AND**
6 **TERRORISM.**

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

10 (1) in paragraph (1)—

11 (A) by inserting “(including mental health
12 care)” after “and care”; and

13 (B) by striking “and” at the end;

14 (2) in paragraph (2), by striking the period and
15 inserting “; and”; and

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

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

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

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

1 (1) *by striking “Not later than 180 days after*
2 *the date of the enactment of this section, the” and in-*
3 *serting “The”;*

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

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

8 (4) *by adding at the end the following:*

9 *“(5) the activities and cost of the Civil Support*
10 *Teams of the National Guard in responding to bio-*
11 *logical threats or attacks against the civilian popu-*
12 *lation;*

13 *“(6) the activities of the working group described*
14 *in subsection (a) and the efforts made by such group*
15 *to carry out the activities described in such sub-*
16 *section;*

17 *“(7) the activities and cost of the 2–1–1 call cen-*
18 *ters and other universal hotlines; and*

19 *“(8) the activities and cost of the development*
20 *and improvement of public health laboratory capac-*
21 *ity.”.*

22 **SEC. 315. ADDITIONAL RESEARCH.**

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

1 “(h) *RESEARCH RELATING TO BIOLOGICAL THREATS*
2 *OR ATTACKS IN THE WORKPLACE.*—*The Director shall en-*
3 *hance and expand research as deemed appropriate by the*
4 *Director on the health and safety of workers who are at*
5 *risk for biological threats or attacks in the workplace.*”.

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

7 *It is the sense of the Senate that—*

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

12 (2) *accelerating the crucial work done at univer-*
13 *sity centers and laboratories will contribute signifi-*
14 *cantly to the United States capacity to defend against*
15 *any biological threat or attack;*

16 (3) *maximizing the effectiveness of, and extend-*
17 *ing the mission of, established university programs*
18 *would be one appropriate use of the additional re-*
19 *sources provided for in the Bioterrorism Preparedness*
20 *Act of 2001; and*

21 (4) *Congress recognizes the importance of exist-*
22 *ing public and private university-based research,*
23 *training, public awareness, and safety related biologi-*
24 *cal defense programs in the awarding of grants and*
25 *contracts made in accordance with this Act.*

1 **TITLE IV—DEVELOPING NEW**
2 **COUNTERMEASURES AGAINST**
3 **BIOTERRORISM**

4 **SEC. 401. LIMITED ANTITRUST EXEMPTION.**

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

7 “(g) *LIMITED ANTITRUST EXEMPTION.*—

8 “(1) *COUNTERMEASURES DEVELOPMENT MEET-*
9 *INGS.*—

10 “(A) *COUNTERMEASURES DEVELOPMENT*
11 *MEETINGS AND CONSULTATIONS.*—*The Secretary*
12 *may conduct meetings and consultations with*
13 *parties involved in the development of priority*
14 *countermeasures for the purpose of the develop-*
15 *ment, manufacture, distribution, purchase, or*
16 *sale of priority countermeasures consistent with*
17 *the purposes of this title. The Secretary shall*
18 *give notice of such meetings and consultations to*
19 *the Attorney General and the Chairperson of the*
20 *Federal Trade Commission (referred to in this*
21 *subsection as the ‘Chairperson’).*

22 “(B) *MEETING AND CONSULTATION CONDI-*
23 *TIONS.*—*A meeting or consultation conducted*
24 *under subparagraph (A) shall—*

1 “(i) be chaired or, in the case of a con-
2 sultation, facilitated by the Secretary;

3 “(ii) be open to parties involved in the
4 development, manufacture, distribution,
5 purchase, or sale of priority counter-
6 measures, as determined by the Secretary;

7 “(iii) be open to the Attorney General
8 and the Chairperson;

9 “(iv) be limited to discussions involv-
10 ing the development, manufacture, distribu-
11 tion, or sale of priority countermeasures,
12 consistent with the purposes of this title;
13 and

14 “(v) be conducted in such manner as to
15 ensure that national security, confidential,
16 and proprietary information is not dis-
17 closed outside the meeting or consultation.

18 “(C) MINUTES.—The Secretary shall main-
19 tain minutes of meetings and consultations
20 under this subsection, which shall not be dis-
21 closed under section 552 of title 5, United States
22 Code.

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

1 *conduct that results from a meeting or consulta-*
2 *tion and that does not receive an exemption pur-*
3 *suant to this subsection shall be subject to the*
4 *antitrust laws.*

5 “(2) *WRITTEN AGREEMENTS.*—*The Secretary*
6 *shall file a written agreement regarding covered ac-*
7 *tivities, made pursuant to meetings or consultations*
8 *conducted under paragraph (1) and that is consistent*
9 *with this paragraph, with the Attorney General and*
10 *the Chairperson for a determination of the compliance*
11 *of such agreement with antitrust laws. In addition to*
12 *the proposed agreement itself, any such filing shall*
13 *include—*

14 “(A) *an explanation of the intended purpose*
15 *of the agreement;*

16 “(B) *a specific statement of the substance of*
17 *the agreement;*

18 “(C) *a description of the methods that will*
19 *be utilized to achieve the objectives of the agree-*
20 *ment;*

21 “(D) *an explanation of the necessity of a co-*
22 *operative effort among the particular partici-*
23 *parting parties to achieve the objectives of the*
24 *agreement; and*

1 “(E) any other relevant information deter-
2 mined necessary by the Secretary in consultation
3 with the Attorney General and the Chairperson.

4 “(3) DETERMINATION.—The Attorney General,
5 in consultation with the Chairperson, shall determine
6 whether an agreement regarding covered activities re-
7 ferred to in paragraph (2) would likely—

8 “(A) be in compliance with the antitrust
9 laws, and so inform the Secretary and the par-
10 ticipating parties; or

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

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

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

23 “(B) EXTENSION.—The Attorney General
24 may extend the 15-day period referred to in sub-
25 paragraph (A) for an additional period of not to

1 *exceed 10 days. Such additional period may be*
2 *further extended only by the United States dis-*
3 *trict court, upon an application by the Attorney*
4 *General after notice to the Secretary and the*
5 *parties involved.*

6 “(C) *DETERMINATION.*—*In granting an ex-*
7 *emption under this paragraph, the Attorney*
8 *General, in consultation with the Chairperson*
9 *and the Secretary—*

10 *(i) must find—*

11 *“(I) that the agreement involved*
12 *is necessary to ensure the availability*
13 *of priority countermeasures;*

14 *“(II) that the exemption from the*
15 *antitrust laws would promote the pub-*
16 *lic interest; and*

17 *“(III) that there is no substantial*
18 *competitive impact to areas not di-*
19 *rectly related to the purposes of the*
20 *agreement; and*

21 *“(ii) may consider any other factors*
22 *determined relevant by the Attorney General*
23 *and the Chairperson.*

24 “(5) *LIMITATION ON AND RENEWAL OF EXEMP-*
25 *TIONS.*—*An exemption granted under paragraph (4)*

1 *shall be limited to covered activities, and shall expire*
2 *on the date that is 3 years after the date on which*
3 *the exemption becomes effective (and at 3 year inter-*
4 *vals thereafter, if renewed) unless the Attorney Gen-*
5 *eral in consultation with the Chairperson determines*
6 *that the exemption should be renewed (with modifica-*
7 *tions, as appropriate) considering the factors de-*
8 *scribed in paragraph (4).*

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

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

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

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

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

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

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

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

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

19 *“(2) COVERED ACTIVITIES.—*

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

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

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

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

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

20 “(v) *the testing in connection with the*
21 *production of a product, process, or services*
22 *necessary to the development of priority*
23 *countermeasures;*

24 “(vi) *the collection, exchange, and*
25 *analysis of research or production informa-*

1 *tion necessary to the development of pri-*
2 *ority countermeasures; or*

3 *“(vii) any combination of the purposes*
4 *described in clauses (i) through (vi);*

5 *and such term may include the establishment*
6 *and operation of facilities for the conduct of cov-*
7 *ered activities described in clauses (i) through*
8 *(vi), the conduct of such covered activities on a*
9 *protracted and proprietary basis, and the proc-*
10 *essing of applications for patents and the grant-*
11 *ing of licenses for the results of such covered ac-*
12 *tivities.*

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

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

22 *“(ii) Entering into any agreement or*
23 *engaging in any other conduct—*

24 *“(I) to restrict or require the sale,*
25 *licensing, or sharing of inventions, de-*

1 *velopments, products, processes, or*
2 *services not developed through, pro-*
3 *duced by, or distributed or sold*
4 *through such covered activities; or*

5 *“(II) to restrict or require partici-*
6 *pation by any person who is a party*
7 *to such covered activities in other re-*
8 *search and development activities, that*
9 *is not reasonably necessary to prevent*
10 *the misappropriation of proprietary*
11 *information contributed by any person*
12 *who is a party to such covered activi-*
13 *ties or of the results of such covered ac-*
14 *tivities.*

15 *“(iii) Entering into any agreement or*
16 *engaging in any other conduct allocating a*
17 *market with a competitor that is not ex-*
18 *pressly exempted from the antitrust laws by*
19 *a determination under subsection (i)(4).*

20 *“(iv) Exchanging information among*
21 *competitors relating to production (other*
22 *than production by such covered activities)*
23 *of a product, process, or service if such in-*
24 *formation is not reasonably necessary to*

1 *carry out the purpose of such covered activi-*
2 *ties.*

3 “(v) *Entering into any agreement or*
4 *engaging in any other conduct restricting,*
5 *requiring, or otherwise involving the pro-*
6 *duction of a product, process, or service that*
7 *is not so expressly exempted from the anti-*
8 *trust laws by a determination under sub-*
9 *section (i)(4).*

10 “(vi) *Except as otherwise provided in*
11 *this subsection, entering into any agreement*
12 *or engaging in any other conduct to restrict*
13 *or require participation by any person who*
14 *is a party to such activities, in any unilat-*
15 *eral or joint activity that is not reasonably*
16 *necessary to carry out the purpose of such*
17 *covered activities.*

18 “(3) *DEVELOPMENT.*—*The term ‘development’*
19 *includes the identification of suitable compounds or*
20 *biological materials, the conduct of preclinical and*
21 *clinical studies, the preparation of an application for*
22 *marketing approval, and any other actions related to*
23 *preparation of a countermeasure.*

1 *other such vaccines determined by the Secretary to be suffi-*
2 *cient to meet the needs of the population of the United*
3 *States.*

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

8 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
9 *authorized to be appropriated to carry out this section,*
10 *\$509,000,000 for fiscal year 2002, and such sums as may*
11 *be necessary for each of fiscal years 2003 through 2006.*

12 **“SEC. 2842. CONTRACT AUTHORITY FOR PRIORITY COUN-**
13 **TERMEASURES.**

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

18 “(1) *ensuring the development of priority coun-*
19 *termeasures that are necessary to prepare for a bioter-*
20 *rorist attack or other significant disease emergency;*

21 “(2) *securing the manufacture, distribution, and*
22 *adequate supply of such countermeasures, including*
23 *through the development of novel production methods*
24 *for such countermeasures;*

1 “(3) *maintaining the Strategic National Phar-*
2 *maceutical Stockpile under section 2812; and*

3 “(4) *carrying out such other activities deter-*
4 *mined appropriate by the Secretary to achieve the*
5 *purposes of this title.*

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

15 “(1) *involve one or more aspects of the develop-*
16 *ment, manufacture, purchase, or distribution of one*
17 *or more uses of one or more countermeasures; and*

18 “(2) *set forth guaranteed minimum quantities of*
19 *products and negotiated unit prices.*

20 **“SEC. 2843. SECURITY FOR COUNTERMEASURE DEVELOP-**
21 **MENT AND PRODUCTION.**

22 “(a) *IN GENERAL.—The Secretary, in consultation*
23 *with the Attorney General and the Secretary of Defense,*
24 *may provide technical or other assistance, to provide secu-*
25 *rity to persons or facilities that conduct development, pro-*

1 duction, distribution, or storage of priority counter-
2 measures.

3 “(b) *BEST PRACTICES.*—The Secretary shall develop
4 guidelines and best practices to enable entities eligible to
5 receive assistance under this section to secure their facilities
6 against potential terrorist attack.”.

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

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

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

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

15 (3) by inserting after paragraph (3), the fol-
16 lowing:

17 “(4) the sequencing of the genomes of priority
18 pathogens as determined appropriate by the Director
19 of the National Institutes of Health, in consultation
20 with the working group established in subsection (a);
21 and”.

1 **SEC. 404. ACCELERATED COUNTERMEASURE RESEARCH**
2 **AND DEVELOPMENT.**

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

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

9 *(2) by striking “The Secretary” and inserting*
10 *the following:*

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

12 *(3) by adding at the end the following:*

13 *“(2) ACCELERATED COUNTERMEASURE RE-*
14 *SEARCH AND DEVELOPMENT.—*

15 *“(A) IN GENERAL.—The Secretary shall*
16 *conduct, and award grants, contracts, or cooper-*
17 *ative agreements for, research, investigations, ex-*
18 *periments, demonstrations, and studies in the*
19 *health sciences relating to—*

20 *“(i) the epidemiology and pathogenesis*
21 *of biological agents or toxins of potential*
22 *use in a bioterrorist attack;*

23 *“(ii) the development of new vaccines*
24 *and therapeutics for use against biological*
25 *agents or toxins of potential use in a bioter-*
26 *rorist attack;*

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

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

7 “(B) *PRIORITY*.—The Secretary shall give
8 priority under this paragraph to the funding of
9 research and other studies related to priority
10 countermeasures.”.

11 **SEC. 405. ACCELERATED APPROVAL OF PRIORITY COUN-**
12 **TERMEASURES.**

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

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

22 (2) an application for the investigation of the
23 drug under section 505(i) of such Act or section
24 351(a)(3) of the Public Health Service Act.

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

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

9 **(c) PRIORITY REVIEW.**—

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

15 **(2) DEFINITION.**—*In this subsection the term*
16 *“priority drugs or biological products” means a drug*
17 *or biological product that is the subject of a drug ap-*
18 *plication referred to in section 101(4) of the Food and*
19 *Drug Administration Modernization Act of 1997.*

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

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

1 *Efficacy of New Drugs for Use Against Lethal or Perma-*
2 *nently Disabling Toxic Substances When Efficacy Studies*
3 *in Humans Ethically Cannot be Conducted” as published*
4 *in the Federal Register on October 5, 1999 (64 Fed. Reg.).*

5 **SEC. 407. MISCELLANEOUS PROVISIONS.**

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

9 **“Subtitle C—Miscellaneous**
10 **Provisions**

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

12 *“A State or local government, or other entity to which*
13 *a grant, contract, or cooperative agreement is awarded*
14 *under this title, may not use amounts received under the*
15 *grant, contract, or cooperative agreement to supplant ex-*
16 *penditures by the entity for activities provided for under*
17 *this title, but shall use such amounts only to supplement*
18 *such expenditures at a level at least equal to the level of*
19 *such expenditures for fiscal year 2001 (excluding those ad-*
20 *ditional, extraordinary expenditures that may have been*
21 *made after September 10, 2001).”.*

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

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

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

7 (a) *IN GENERAL.*—*The President’s Council on Food*
8 *Safety (as established by Executive Order 13100), the Sec-*
9 *retary of Commerce, and the Secretary of Transportation,*
10 *shall, in consultation with the food industry and consumer*
11 *and producer groups, and the States, develop a crisis com-*
12 *munications and education strategy with respect to bioter-*
13 *rorist threats to the food supply. Such strategy shall address*
14 *threat assessments, response and notification procedures,*
15 *and risks communications to the public.*

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

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

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

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

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

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

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

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

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

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

6 (ii) State agriculture departments; and

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

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

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

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

1 *an Agricultural Research Service biocontainment labora-*
2 *tory for poultry research in Athens, Georgia, and the plan-*
3 *ning, updating, and renovation of the Arthropod-Borne*
4 *Animal Disease Laboratory in Laramie, Wyoming.*

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

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

12 **SEC. 517. AGRICULTURAL BIOSECURITY.**

13 *(a) LAND GRANT ASSESSMENTS.—*

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

19 *(A) the security of all facilities where haz-*
20 *ardous biological agents and toxins are stored or*
21 *used for agricultural research purposes; and*

22 *(B) communication networks that transmit*
23 *information about hazardous biological agents*
24 *and toxins.*

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

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

14 (b) *NATIONAL HAZARDOUS AGENT INVENTORY.*—The
15 Secretary shall carry out activities necessary to develop a
16 national inventory of hazardous biological agents and tox-
17 ins contained in agricultural research facilities. Such ac-
18 tivities shall include developing and distributing a model
19 inventory procedure, developing secure means of transmit-
20 ting inventory information, and conducting annual inven-
21 tory activities. The inventory shall be developed in coordi-
22 nation with, or as a component of, similar systems in exist-
23 ence on the date of enactment of this Act.

24 (c) *SCREENING PROTOCOL.*—The Secretary shall es-
25 tablish a national protocol for the screening of individuals

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

3 *(d) INDUSTRY-ON-FARM EDUCATION.—*

4 *(1) IN GENERAL.—The Secretary shall develop*
5 *and implement a program to provide education relat-*
6 *ing to farms, livestock confinement operations, and*
7 *livestock auction biosecurity to prevent the intentional*
8 *or accidental introduction of a foreign animal disease*
9 *and to attempt to discover the introduction of such a*
10 *disease before it can spread into an outbreak. Biosecu-*
11 *rity for livestock includes animal quarantine proce-*
12 *dures, blood testing of new arrivals, farm locations,*
13 *control of human movement onto farms and holding*
14 *facilities, control of vermin, and movement of vehicles*
15 *onto farms.*

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

24 *(3) CROP GUIDELINES.—The Secretary may de-*
25 *velop guidelines and educational materials relating to*

1 *biosecurity issues to be distributed to local crop pro-*
2 *ducers and facilities that handle, process, or transport*
3 *crops.*

4 *(e) AUTHORIZATION OF APPROPRIATIONS.—There is*
5 *authorized to be appropriated to carry out this section,*
6 *\$20,000,000 for fiscal year 2002, and such sums as may*
7 *be necessary for each subsequent fiscal year, of which not*
8 *less than \$5,000,000 shall be made available in fiscal year*
9 *2002 for activities under subsection (a).*

10 **SEC. 518. BIOSECURITY OF FOOD MANUFACTURING, PROC-**
11 **ESSING, AND DISTRIBUTION.**

12 *(a) IN GENERAL.—The Secretary of Health and*
13 *Human Services (referred to in this section as the “Sec-*
14 *retary”), in consultation with the Attorney General, may*
15 *award grants, contracts, or cooperative agreements to en-*
16 *able food manufacturers, food processors, food distributors,*
17 *and other entities regulated by the Secretary to ensure the*
18 *safety of food through the development and implementation*
19 *of educational programs to ensure the security of their fa-*
20 *cilities and modes of transportation against potential bio-*
21 *terrorist attack.*

22 *(b) BEST PRACTICES.—The Secretary may develop*
23 *best practices to enable entities eligible for funding under*
24 *this section to secure their facilities and modes of transpor-*
25 *tation against potential bioterrorist attacks.*

1 “(A) *DURATION.*—*An article of food may be*
2 *detained under this subsection for a reasonable*
3 *period, not to exceed 20 days, unless a greater*
4 *period of time, not to exceed 30 days, is nec-*
5 *essary to enable the Secretary to institute an ac-*
6 *tion under subsection (a) or section 302.*

7 “(B) *SECRETARY’S APPROVAL.*—*Before an*
8 *article of food may be ordered detained under*
9 *this subsection, the Secretary or an officer or*
10 *qualified employee designated by the Secretary*
11 *must approve such order, after determining that*
12 *the article presents a threat of serious adverse*
13 *health consequences or death to humans or ani-*
14 *mals.*

15 “(3) *SECURITY OF DETAINED ARTICLE.*—*A de-*
16 *tention order under this subsection with respect to an*
17 *article of food may require that the article be labeled*
18 *or marked as detained, and may require that the arti-*
19 *cle be removed to a secure facility. An article subject*
20 *to a detention order under this subsection shall not be*
21 *moved by any person from the place at which it is*
22 *ordered detained until released by the Secretary, or*
23 *the expiration of the detention period applicable to*
24 *such order, whichever occurs first.*

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

9 “(5) *PERISHABLE FOODS.*—The Secretary shall
 10 provide in regulation or in guidance for procedures
 11 for instituting and appealing on an expedited basis
 12 administrative detention of perishable foods.”.

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

16 “(bb) The movement of an article of food in vio-
 17 lation of an order under section 304(h), or the re-
 18 moval or alteration of any mark or label required by
 19 the order in order to identify the article as detained.”.

20 **SEC. 532. DEBARMENT FOR REPEATED OR SERIOUS FOOD**
 21 **IMPORT VIOLATIONS.**

22 (a) *DEBARMENT AUTHORITY.*—

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

1 (A) by striking the period at the end of sub-
2 paragraph (B) and inserting “; or”; and

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

4 “(C) a person from importing a food or of-
5 fering a food for import into the United States
6 if—

7 “(i) the person has been convicted of a
8 felony for conduct relating to the importa-
9 tion into the United States of any food; or

10 “(ii) the person has engaged in a pat-
11 tern of importing or offering for import
12 adulterated food that presents a threat of se-
13 rious adverse health consequences or death
14 to humans or animals.”.

15 (2) CONFORMING AMENDMENT.—Section
16 306(b)(2) of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 335a(b)(2)) is amended—

18 (A) in the paragraph heading, by inserting
19 “RELATING TO DRUG APPLICATIONS” after “DE-
20 BARMENT”; and

21 (B) in the matter preceding subparagraph
22 (A), by striking “paragraph (1)” and inserting
23 “subparagraphs (A) and (B) of paragraph (1)”.

24 (3) DEBARMENT PERIOD.—Section
25 306(c)(2)(A)(iii) of the Federal Food, Drug, and Cos-

1 *metic Act (21 U.S.C. 335a(c)(2)(A)(iii)) is amended*
2 *by striking “subsection (b)(2)” and inserting “sub-*
3 *section (b)(1)(C) or (b)(2)”.*

4 (4) *TERMINATION OF DEBARMENT.—Section*
5 *306(d)(3) of the Federal Food, Drug, and Cosmetic*
6 *Act (21 U.S.C. 335a(d)(3)) is amended—*

7 (A) *in subparagraph (A)(i), by striking “or*
8 *(b)(2)(A)” and inserting “, or (b)(2)(A), or*
9 *(b)(1)(C)”;*

10 (B) *in subparagraph (A)(ii)(II), by insert-*
11 *ing “in applicable cases,” before “sufficient au-*
12 *ditions”; and*

13 (C) *in subparagraph (B), in each of clauses*
14 *(i) and (ii), by inserting “or (b)(1)(C)” after*
15 *“(b)(2)(B)”.*

16 (5) *EFFECTIVE DATES.—Section 306(l)(2) of the*
17 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
18 *335a(l)(2)) is amended—*

19 (A) *in the first sentence, by inserting “and*
20 *subsection (b)(1)(C)” after “subsection*
21 *(b)(2)(B)”;* and

22 (B) *in the second sentence, by striking “and*
23 *subsections (f) and (g) of this section” and in-*
24 *serting “subsections (f) and (g), and subsection*
25 *(b)(1)(C)”.*

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

4 “(h) *If it is an article of food imported or offered for*
5 *import into the United States by, with the assistance of,*
6 *or at the direction of, a person debarred under section*
7 *306(b)(1)(C).”.*

8 **SEC. 533. MAINTENANCE AND INSPECTION OF RECORDS**
9 **FOR FOODS.**

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

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

14 “(a) *IN GENERAL.*—*If the Secretary has reason to be-*
15 *lieve that an article of food is adulterated or misbranded*
16 *under this Act and presents a threat of serious adverse*
17 *health consequences or death to humans or animals, each*
18 *person (excluding restaurants and farms) that manufac-*
19 *tures, processes, packs, distributes, receives, holds, or im-*
20 *ports such food shall, at the request of an officer or employee*
21 *duly designated by the Secretary, permit such officer or em-*
22 *ployee, upon presentation of appropriate credentials and a*
23 *written notice to such person, at reasonable times and with-*
24 *in reasonable limits and in a reasonable manner, to have*
25 *access to and to copy all records relating to such food that*

1 *may assist the Secretary to determine the cause and scope*
2 *of the violation. This requirement applies to all records re-*
3 *lating to such manufacture, processing, packing, distribu-*
4 *tion, receipt, holding, or importation of such food main-*
5 *tained by or on behalf of such person in any format (includ-*
6 *ing paper and electronic formats) and at any location.*

7 “(b) *REGULATIONS CONCERNING RECORDKEEPING.—*
8 *The Secretary shall promulgate regulations regarding the*
9 *maintenance and retention of records for inspection for not*
10 *longer than 2 years by persons (excluding restaurants and*
11 *farms) that manufacture, process, pack, transport, dis-*
12 *tribute, receive, hold, or import food, as may be needed to*
13 *allow the Secretary—*

14 “(1) *to promptly trace the source and chain of*
15 *distribution of food and its packaging to address*
16 *threats of serious adverse health consequences or death*
17 *to humans or animals; or*

18 “(2) *to determine whether food manufactured,*
19 *processed, packed, or held by the person may be adul-*
20 *terated or misbranded to the extent that it presents a*
21 *threat of serious adverse health consequences or death*
22 *to humans or animals under this Act.*

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

1 “(c) *LIMITATIONS.*—*Nothing in this section shall be*
2 *construed—*

3 “(1) *to limit the authority of the Secretary to in-*
4 *spect records or to require maintenance of records*
5 *under any other provision of or regulations issued*
6 *under this Act;*

7 “(2) *to authorize the Secretary to impose any re-*
8 *quirements with respect to a food to the extent that*
9 *it is within the exclusive jurisdiction of the Secretary*
10 *of Agriculture pursuant to the Federal Meat Inspec-*
11 *tion Act (21 U.S.C. 601 et seq.), the Poultry Products*
12 *Inspection Act (21 U.S.C. 451 et seq.), or the Egg*
13 *Products Inspection Act (21 U.S.C. 1031 et seq.);*

14 “(3) *to extend to recipes for food, financial data,*
15 *sales data other than shipment data, pricing data,*
16 *personnel data, or research data; or*

17 “(4) *to alter, amend, or affect in any way the*
18 *disclosure or nondisclosure under section 552 of title*
19 *5, United States Code, of information copied or col-*
20 *lected under this section, or its treatment under sec-*
21 *tion 1905 of title 18, United States Code.”.*

22 “(b) *FACTORY INSPECTION.*—*Section 704(a) of the Fed-*
23 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is*
24 *amended—*

1 (1) *in paragraph (1), by adding after the first*
2 *sentence the following: “In the case of any person (ex-*
3 *cluding restaurants and farms) that manufactures,*
4 *processes, packs, transports, distributes, receives,*
5 *holds, or imports foods, the inspection shall extend to*
6 *all records and other information described in section*
7 *414(a), or required to be maintained pursuant to sec-*
8 *tion 414(b).”;* and

9 (2) *in paragraph (2), in the matter preceding*
10 *subparagraph (A), by striking “second sentence” and*
11 *inserting “third sentence”.*

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

15 (1) *in subsection (e)—*

16 (A) *by striking “by section 412, 504, or*
17 *703” and inserting “by section 412, 414, 504,*
18 *703, or 704(a)”;* and

19 (B) *by striking “under section 412” and in-*
20 *serting “under section 412, 414(b)”;* and

21 (2) *in section (j), by inserting “414,” after*
22 *“412,”.*

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

1 *lishing recordkeeping requirements under subsection*
 2 *414(b)(1) of the Federal Food, Drug, and Cosmetic Act.*

3 **SEC. 534. REGISTRATION OF FOOD MANUFACTURING, PROC-**
 4 **ESSING, AND HANDLING FACILITIES.**

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

9 **“SEC. 415. REGISTRATION OF FOOD MANUFACTURING,**
 10 **PROCESSING, AND HANDLING FACILITIES.**

11 *“(a) REGISTRATION.—*

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

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

19 *“(B) for a foreign facility, the owner, oper-*
 20 *ator, or agent in charge of the facility shall sub-*
 21 *mit a registration to the Secretary and shall in-*
 22 *clude with the registration the name of the*
 23 *United States agent for the facility.*

24 *“(2) REGISTRATION.—An entity (referred to in*
 25 *this section as the ‘registrant’) shall submit a reg-*

1 *istration under paragraph (1) to the Secretary con-*
2 *taining information necessary to notify the Secretary*
3 *of the name and address of each facility at which,*
4 *and all trade names under which, the registrant con-*
5 *ducts business and, when determined necessary by the*
6 *Secretary through guidance, the general food category*
7 *(as identified under section 170.3 of title 21, Code of*
8 *Federal Regulations) of any food manufactured, proc-*
9 *essed, or handled at such facility. The registrant shall*
10 *notify the Secretary in a timely manner of changes*
11 *to such information.*

12 *“(3) PROCEDURE.—Upon receipt of a completed*
13 *registration described in paragraph (1), the Secretary*
14 *shall notify the registrant of the receipt of such reg-*
15 *istration and assign a registration number to each*
16 *registered facility.*

17 *“(4) LIST.—The Secretary shall compile and*
18 *maintain an up-to-date list of facilities that are reg-*
19 *istered under this section. Such list and other infor-*
20 *mation required to be submitted under this subsection*
21 *shall not be subject to the disclosure requirements of*
22 *section 552 of title 5, United States Code.*

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

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

4 “(c) *FACILITY*.—*In this section, the term ‘facility’ in-*
5 *cludes any factory, warehouse, or establishment (including*
6 *a factory, warehouse, or establishment of an importer), that*
7 *manufactures, handles, or processes food. Such term does*
8 *not include restaurants.*

9 “(d) *RULE OF CONSTRUCTION*.—*Nothing in this sec-*
10 *tion shall be construed to authorize the Secretary to require*
11 *an application, review, or licensing process.”.*

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

15 “(t) *If it is a food from a facility for which registration*
16 *has not been submitted to the Secretary under section*
17 *415(a).”.*

18 (c) *EFFECTIVE DATE*.—*The amendment made by sub-*
19 *section (b) shall take effect 180 days after the date of enact-*
20 *ment of this Act.*

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

22 (a) *PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS*.—
23 *Section 801 of the Federal Food, Drug, and Cosmetic Act*
24 *(21 U.S.C. 381) is amended by adding at the end the fol-*
25 *lowing:*

1 “(j) *PRIOR NOTICE OF IMPORTED FOOD SHIP-*
2 *MENTS.—*

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

9 “(A) *identifies—*

10 “(i) *the food;*

11 “(ii) *the countries of origin of the food;*

12 *and*

13 “(iii) *the quantity to be imported; and*

14 “(B) *includes such other information as the*
15 *Secretary of Health and Human Services may*
16 *require by regulation.*

17 “(2) *REFUSAL OF ADMISSION.—If documentation*
18 *is not provided as required by paragraph (1) at least*
19 *4 hours before the food is imported or offered for im-*
20 *portation, the food may be refused admission.*

21 “(3) *LIMITATION.—Nothing in this subsection*
22 *shall be construed to authorize the Secretary to im-*
23 *pose any requirements with respect to a food to the*
24 *extent that it is within the exclusive jurisdiction of*
25 *the Secretary of Agriculture pursuant to the Federal*

1 *Meat Inspection Act (21 U.S.C. 601 et seq.), the Poul-*
2 *try Products Inspection Act (21 U.S.C. 451 et seq.),*
3 *or the Egg Products Inspection Act (21 U.S.C. 1031*
4 *et seq.).”.*

5 **(b) PROHIBITION OF KNOWINGLY MAKING FALSE**
6 **STATEMENTS.**—*Section 301 of the Federal Food, Drug, and*
7 *Cosmetic Act (21 U.S.C. 331), as amended by section*
8 *531(b), is further amended by inserting after subsection (bb)*
9 *the following:*

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

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

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

17 “*(u) If—*

18 “*(1) it has been refused admission under section*
19 *801(a);*

20 “*(2) it has not been required to be destroyed*
21 *under section 801(a);*

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

24 “*(4) it presents a threat of serious adverse health*
25 *consequences or death to humans or animals.”.*

1 (b) *REQUIREMENT.*—Section 801(a) of the Federal
2 *Food, Drug, and Cosmetic Act* (21 U.S.C. 381(a)) is amend-
3 *ed by adding at the end the following: “The Secretary of*
4 *Health and Human Services may require the owner or con-*
5 *signee of a food that has been refused admission under this*
6 *section, and has not been required to be destroyed, to affix*
7 *to the packaging of the food a label or labeling that—*

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

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

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

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

19 **SEC. 537. AUTHORITY TO COMMISSION OTHER FEDERAL OF-**
20 **FICIALS TO CONDUCT INSPECTIONS.**

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

23 (1) *by inserting “qualified” before “employees”;*
24 *and*

1 (2) by inserting “or of other Federal Depart-
2 ments or agencies, notwithstanding any other provi-
3 sion of law restricting the use of a Department’s or
4 agency’s officers, employees, or funds,” after “officers
5 and qualified employees of the Department”.

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

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

10 “(i) If it is an article of food imported or offered for
11 import into the United States and the article of food has
12 previously been refused admission under section 801(a), un-
13 less the person reoffering the article affirmatively estab-
14 lishes, at the expense of the owner or consignee of the article,
15 that the article complies with the applicable requirements
16 of this Act, as determined by the Secretary.”.

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

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

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

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

1 *The funds provided under such grants shall only be avail-*
2 *able for the costs of conducting such examinations, inspec-*
3 *tions, investigations, and related activities.*

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

8 **SEC. 540. RULE OF CONSTRUCTION.**

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

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

14 *(2) limit the authority of the Secretary of Agri-*
15 *culture with respect to such products.*

16 ***Subtitle C—Research and Training***
17 ***to Enhance Food Safety and Se-***
18 ***curity***

19 **SEC. 541. SURVEILLANCE AND INFORMATION GRANTS AND**
20 **AUTHORITIES.**

21 *Part B of title III of the Public Health Service Act*
22 *(42 U.S.C. 243 et seq.) is amended by inserting after section*
23 *317P the following:*

1 **“SEC. 317Q. FOOD SAFETY GRANTS.**

2 “(a) *IN GENERAL.*—*The Secretary may award food*
3 *safety grants to States to expand the number of States par-*
4 *ticipating in Pulsenet, the Foodborne Diseases Active Sur-*
5 *veillance Network, and other networks to enhance Federal,*
6 *State, and local food safety efforts.*

7 “(b) *USE OF FUNDS.*—*Funds awarded under this sec-*
8 *tion shall be used by States to assist such States in meeting*
9 *the costs of establishing and maintaining the food safety*
10 *surveillance, technical and laboratory capacity needed to*
11 *participate in Pulsenet, Foodborne Diseases Active Surveil-*
12 *lance Network, and other networks to enhance Federal,*
13 *State, and local food safety efforts.*

14 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
15 *authorized to be appropriated to carry out this section,*
16 *\$19,500,000 for fiscal year 2002, and such sums as may*
17 *be necessary for each of fiscal years 2003 through 2006.*

18 **“SEC. 317R. SURVEILLANCE OF ANIMAL AND HUMAN**
19 **HEALTH.**

20 “*The Secretary, through the Commissioner of the Food*
21 *and Drug Administration and the Director of the Centers*
22 *for Disease Control and Prevention, and the Secretary of*
23 *Agriculture shall develop and implement a plan for coordi-*
24 *nating the surveillance for zoonotic disease and human dis-*
25 *ease.*”.

1 **SEC. 542. AGRICULTURAL BIOTERRORISM RESEARCH AND**
2 **DEVELOPMENT.**

3 (a) *IN GENERAL.*—*The Secretary of Agriculture, to the*
4 *maximum extent practicable, shall utilize existing authori-*
5 *ties to expand Agricultural Research Service, and Coopera-*
6 *tive State Research Education and Extension Service, pro-*
7 *grams to protect the food supply of the United States by*
8 *conducting activities to—*

9 (1) *enhance the capability of the Service to re-*
10 *spond immediately to the needs of Federal regulatory*
11 *agencies involved in protecting the food and agricul-*
12 *tural system;*

13 (2) *continue existing partnerships with institu-*
14 *tions of higher education (including partnerships*
15 *with 3 institutions of higher education that are na-*
16 *tional centers for countermeasures against agricul-*
17 *tural bioterrorism and 7 additional institutions with*
18 *existing programs related to bioterrorism) to help*
19 *form stable, long-term programs of research, develop-*
20 *ment, and evaluation of options to enhance the bio-*
21 *security of United States agriculture;*

22 (3) *strengthen linkages with the intelligence com-*
23 *munity to better identify research needs and evaluate*
24 *acquired materials;*

1 (4) *expand Service involvement with inter-*
2 *national organizations dealing with plant and ani-*
3 *mal disease control; and*

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

6 (b) *AUTHORIZATION OF APPROPRIATIONS.—There is*
7 *authorized to be appropriated to carry out this section,*
8 *\$190,000,000 for fiscal year 2002, and such sums as may*
9 *be necessary for each subsequent fiscal year.*

Attest:

Secretary.

107TH CONGRESS
1ST SESSION

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AMENDMENT