

107TH CONGRESS  
1ST SESSION

# H. R. 3448

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

---

## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 11, 2001

Mr. TAUZIN (for himself, Mr. DINGELL, Mr. BILIRAKIS, Mr. BROWN of Ohio, Mr. BURR of North Carolina, Mr. PALLONE, Mr. GILLMOR, Ms. HARMAN, Mr. BARTON of Texas, Mr. WAXMAN, Mr. GREENWOOD, Mr. MARKEY, Mr. UPTON, Mr. TOWNS, Mr. SMITH of Texas, Mr. GORDON, Mr. BUYER, Mr. DEUTSCH, Mr. BRYANT, Mr. RUSH, Mr. GANSKE, Ms. ESHOO, Mr. RADANOVICH, Mr. STUPAK, Mr. TOM DAVIS of Virginia, Mr. ENGEL, Mr. SENSENBRENNER, Mr. SAWYER, Mr. SMITH of New Jersey, Ms. MCCARTHY of Missouri, Mr. WHITFIELD, Mr. STRICKLAND, Mr. CHAMBLISS, Ms. DEGETTE, Mr. LINDER, Mr. BARRETT of Wisconsin, Mr. FLETCHER, Mr. LUTHER, Mr. EHRlich, Mrs. CAPPS, Mrs. WILSON, Mr. JOHN, Mr. NORWOOD, Mr. CONYERS, Mrs. CUBIN, Ms. SLAUGHTER, Mr. BALDACCI, Mr. ANDREWS, Ms. PRYCE of Ohio, Mr. WATT of North Carolina, Mr. SUNUNU, Ms. ROYBAL-ALLARD, Mr. PLATTS, Mr. LARSON of Connecticut, Mr. GREEN of Wisconsin, Mr. SCHIFF, Mr. PICKERING, Mr. BALLENGER, Mr. TERRY, Mr. DIAZ-BALART, Mr. SAXTON, Mr. FOLEY, Mr. FRELINGHUYSEN, Mr. MCKEON, Mrs. BIGGERT, Mr. DEAL of Georgia, Mr. SCHROCK, Mr. SHIMKUS, Mr. WALDEN, Mr. VITTER, and Mr. CALLAHAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

## A BILL

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

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

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

4        (a) **SHORT TITLE.**—This Act may be cited as the  
 5 “Public Health Security and Bioterrorism Response Act  
 6 of 2001”.

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

Sec. 1. Short title; table of contents.

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

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

- Sec. 101. National preparedness and response.
- Sec. 102. Assistant Secretary for Emergency Preparedness; National Disaster  
 Medical System.
- Sec. 103. Improving ability of Centers for Disease Control and Prevention with  
 respect to bioterrorism and other public health emergencies; fa-  
 cilities.
- Sec. 104. Advisory committees and communications.
- Sec. 105. Education of health care personnel; training regarding pediatric  
 issues.
- Sec. 106. Grants regarding shortages of certain health professionals.
- Sec. 107. Emergency system for verification of credentials of health professions  
 volunteers.
- Sec. 108. Enhancing preparedness activities for bioterrorism and other public  
 health emergencies.
- Sec. 109. Improving State and local core public health capacities.
- Sec. 110. Antimicrobial resistance program.
- Sec. 111. Study regarding communications abilities of public health agencies.
- Sec. 112. Supplies and services in lieu of award funds.
- Sec. 113. Additional amendments.
- Sec. 114. Study regarding local emergency response methods.

Subtitle B—National Stockpile; Development of Priority Countermeasures

- Sec. 121. National stockpile.
- Sec. 122. Accelerated approval of priority countermeasures.
- Sec. 123. Use of animal trials in approval of certain drugs and biologics;  
 issuance of rule.
- Sec. 124. Security for countermeasure development and production.
- Sec. 125. Accelerated countermeasure research and development.
- Sec. 126. Evaluation of new and emerging technologies regarding bioterrorist  
 attack and other public health emergencies.

Sec. 127. Potassium iodide.

Subtitle C—Emergency Authorities; Additional Provisions

- Sec. 131. Expanded authority of Secretary of Health and Human Services to respond to public health emergencies.
- Sec. 132. Streamlining and clarifying communicable disease quarantine provisions.
- Sec. 133. Emergency waiver of Medicare, Medicaid, and SCHIP requirements.
- Sec. 134. Provision for expiration of public health emergencies.
- Sec. 135. Designated State public emergency announcement plan.
- Sec. 136. Expanded research by Secretary of Energy.
- Sec. 137. Agency for Toxic Substances and Disease Registry.
- Sec. 138. Expanded research on worker health and safety.
- Sec. 139. Technology opportunities program support.

Subtitle D—Authorization of Appropriations

Sec. 151. Authorization of Appropriations.

TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

Sec. 201. Regulation of certain biological agents and toxins.

TITLE III—AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

Subtitle A—Protection of Food Supply

- Sec. 301. Protection against intentional adulteration of food.
- Sec. 302. Administrative detention.
- Sec. 303. Permissive debarment regarding food importation.
- Sec. 304. Maintenance and inspection of records for foods.
- Sec. 305. Registration.
- Sec. 306. Prior notice of imported food shipments.
- Sec. 307. Authority to mark articles refused admission into United States.
- Sec. 308. Prohibition against port shopping for importation.
- Sec. 309. Notices to States regarding imported food.
- Sec. 310. Grants to States for inspections; response to notice regarding adulterated imported food.

Subtitle B—Protection of Drug Supply

- Sec. 311. Annual registration of foreign manufacturers; shipping information; drug and device listing.
- Sec. 312. Requirement of additional information regarding import components intended for use in export products.

TITLE IV—DRINKING WATER SECURITY AND SAFETY

Sec. 401. Amendment of the Safe Drinking Water Act.

1 **TITLE I—NATIONAL PREPARED-**  
2 **NESS FOR BIOTERRORISM**  
3 **AND OTHER PUBLIC HEALTH**  
4 **EMERGENCIES**

5 **Subtitle A—National Preparedness**  
6 **and Response Planning, Coordi-**  
7 **nating, and Reporting**

8 **SEC. 101. NATIONAL PREPAREDNESS AND RESPONSE.**

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

11 **“TITLE XXVIII—NATIONAL PRE-**  
12 **PAREDNESS FOR BIOTER-**  
13 **RORISM AND OTHER PUBLIC**  
14 **HEALTH EMERGENCIES**

15 **“Subtitle A—National Prepared-**  
16 **ness and Response Planning,**  
17 **Coordinating, and Reporting**

18 **“SEC. 2801. NATIONAL PREPAREDNESS PLAN.**

19 “(a) IN GENERAL.—

20 “(1) PREPAREDNESS AND RESPONSE REGARD-  
21 ING PUBLIC HEALTH EMERGENCIES.—The Secretary  
22 shall further develop and implement a coordinated  
23 strategy, building upon the core public health capa-  
24 bilities established pursuant to section 319A, for  
25 carrying out health-related activities to prepare for

1 and respond effectively to bioterrorism and other  
2 public health emergencies, including the preparation  
3 of a plan under this section. The Secretary shall pe-  
4 riodically thereafter review and as appropriate revise  
5 the plan.

6 “(2) CONSULTATION.—The Secretary shall  
7 carry out paragraph (1) in consultation with the  
8 Secretary of Defense, the Director of the Federal  
9 Emergency Management Agency, the Secretary of  
10 Veterans Affairs, the Attorney General, the Sec-  
11 retary of Agriculture, the Secretary of Energy, the  
12 Secretary of Labor, and the Administrator of the  
13 Environmental Protection Agency, and with other  
14 appropriate public and private entities.

15 “(3) NATIONAL APPROACH.—In carrying out  
16 paragraph (1), the Secretary shall collaborate with  
17 the States toward the goal of ensuring that the ac-  
18 tivities of the Secretary regarding bioterrorism and  
19 other public health emergencies are coordinated with  
20 activities of the States, including through local gov-  
21 ernments, such that there is a national plan for pre-  
22 paredness for and responding effectively to such  
23 emergencies.

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

1 marks and outcome measures for evaluating the  
2 progress of the Secretary and the States, including  
3 local governments, with respect to the plan under  
4 paragraph (1), including progress toward achieving  
5 the goals specified in subsection (b).

6 “(b) PREPAREDNESS GOALS.—The plan under sub-  
7 section (a) shall include provisions for achieving the fol-  
8 lowing goals with respect to preparedness for and respond-  
9 ing effectively to bioterrorism and other public health  
10 emergencies:

11 “(1) Providing effective assistance to State and  
12 local governments in the event of such an emer-  
13 gency.

14 “(2) Ensuring that State and local governments  
15 have adequate and appropriate capacity to detect  
16 and respond effectively to such emergencies, includ-  
17 ing capacities for the following:

18 “(A) Effective public health surveillance  
19 and reporting mechanisms at the State and  
20 local levels.

21 “(B) Adequate laboratory readiness.

22 “(C) Properly trained and equipped emer-  
23 gency response, public health, and medical per-  
24 sonnel.

1           “(D) Health and safety protection of work-  
2           ers involved in responding to such an emer-  
3           gency.

4           “(E) Public health agencies that are pre-  
5           pared to coordinate health services (including  
6           mental health services) during and after such  
7           emergencies.

8           “(F) Participation in communications net-  
9           works that can effectively disseminate relevant  
10          information in a timely and secure manner to  
11          appropriate public and private entities and to  
12          the public.

13          “(3) Developing and maintaining medical coun-  
14          termeasures (such as drugs, vaccines and other bio-  
15          logical products, and medical devices) against bio-  
16          logical agents that may be used in such emergencies.

17          “(4) Ensuring coordination and minimizing du-  
18          plication of Federal, State, and local planning, pre-  
19          paredness, and response activities, including among  
20          agencies during the investigation of a suspicious dis-  
21          ease outbreak.

22          “(5) Ensuring adequate readiness of hospitals  
23          and other health care facilities to respond effectively  
24          to such emergencies.

1           “(c) EVALUATION OF USING VA R&D CAPABILI-  
2 TIES.—The Secretary shall evaluate the feasibility of using  
3 the biomedical research and development capabilities of  
4 the Department of Veterans Affairs, in conjunction with  
5 that Department’s affiliations with health-professions uni-  
6 versities, as a means to assist the Secretary in achieving  
7 the goals specified in subsection (b).

8           “(d) REPORTS TO CONGRESS.—

9                 “(1) INITIAL REPORT TO CONGRESS.—Not later  
10 than one year after the date of the enactment of the  
11 Public Health Security and Bioterrorism Response  
12 Act of 2001, the Secretary shall submit to the Com-  
13 mittee on Energy and Commerce of the House of  
14 Representatives, and the Committee on Health, Edu-  
15 cation, Labor, and Pensions of the Senate, a report  
16 concerning progress with respect to the plan under  
17 subsection (a), including progress toward achieving  
18 the goals specified in subsection (b).

19                 “(2) BIENNIAL REPORTS.—Not later than 2  
20 years after the date on which the report under para-  
21 graph (1) is submitted, and biennially thereafter, the  
22 Secretary shall submit to each of the committees  
23 specified in such paragraph a report concerning the  
24 progress made with respect to the plan under sub-  
25 section (a), including the goals under subsection (b).



1           “(3) ADDITIONAL AUTHORITY.—Reports sub-  
2           mitted under paragraph (2) by the Secretary shall  
3           make recommendations concerning—

4                   “(A) any additional legislative authority  
5                   that the Secretary determines is necessary for  
6                   fully implementing the plan under subsection  
7                   (a), including meeting the goals under sub-  
8                   section (b); and

9                   “(B) any additional legislative authority  
10                  that the Secretary determines is necessary  
11                  under section 319 to protect the public health  
12                  in the event that a condition described in sec-  
13                  tion 319(a) occurs.

14          “(e) OTHER REPORTS.—Not later than one year  
15          after the date of the enactment of the Public Health Secu-  
16          rity and Bioterrorism Response Act of 2001, the Secretary  
17          shall submit to each of the committees specified in para-  
18          graph (1) a report concerning—

19                   “(1) the recommendations and findings of the  
20                   EPIC Advisory Committee under section  
21                   319F(c)(3);

22                   “(2) the characteristics that may render a rural  
23                   community uniquely vulnerable to a biological at-  
24                   tack, including distance, lack of emergency trans-  
25                   port, hospital or laboratory capacity, lack of integra-

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

3 “(3) the characteristics that may render areas  
4 or populations designated as medically underserved  
5 populations (as defined in section 330) uniquely vul-  
6 nerable to a biological attack, including significant  
7 numbers of low-income or uninsured individuals,  
8 lack of affordable and accessible health care services,  
9 insufficient public and primary health care re-  
10 sources, lack of integration of Federal or State pub-  
11 lic health networks, workforce deficits, or other rel-  
12 evant conditions; and

13 “(4) the recommendations of the Secretary with  
14 respect to additional legislative authority that the  
15 Secretary determines is necessary to effectively  
16 strengthen rural communities, or medically under-  
17 served populations (as defined in section 330).

18 “(f) RULE OF CONSTRUCTION.—This section may  
19 not be construed as expanding or limiting any of the au-  
20 thorities of the Secretary that, on the day before the date  
21 of the enactment of the Public Health Security and Bio-  
22 terrorism Response Act of 2001, were in effect with re-  
23 spect to preparing for and responding effectively to bioter-  
24 rorism and other public health emergencies.”.

1 **SEC. 102. ASSISTANT SECRETARY FOR EMERGENCY PRE-**  
2 **PAREDNESS; NATIONAL DISASTER MEDICAL**  
3 **SYSTEM.**

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

7 **“Subtitle B—Emergency**  
8 **Preparedness and Response**

9 **“SEC. 2811. COORDINATION OF PREPAREDNESS FOR AND**  
10 **RESPONSE TO BIOTERRORISM AND OTHER**  
11 **PUBLIC HEALTH EMERGENCIES.**

12 **“(a) ASSISTANT SECRETARY FOR EMERGENCY PRE-**  
13 **PAREDNESS.—**

14 **“(1) IN GENERAL.—**There is established within  
15 the Department of Health and Human Services the  
16 position of Assistant Secretary for Emergency Pre-  
17 paredness. The President, by and with the advice  
18 and consent of the Senate, shall appoint an indi-  
19 vidual to serve in such position. Such Assistant Sec-  
20 retary shall report to the Secretary.

21 **“(2) DUTIES.—**Subject to the authority of the  
22 Secretary, the Assistant Secretary for Emergency  
23 Preparedness shall carry out the following duties:

24 **“(A) Coordinate on behalf of the**  
25 **Secretary—**

1           “(i) all interagency interfaces between  
2           the Department of Health and Human  
3           Services (referred to in this paragraph as  
4           the ‘Department’) and other departments,  
5           agencies and offices of the United States,  
6           including the activities of the joint inter-  
7           departmental working groups under sub-  
8           sections (a) and (b) of section 319F; and

9           “(ii) all interfaces between the De-  
10          partment and State and local entities with  
11          responsibility for emergency preparedness.

12          “(B) Coordinate the operations of the Na-  
13          tional Disaster Medical System and any other  
14          emergency response activities within the De-  
15          partment of Health and Human Services that  
16          are related to bioterrorism or public health  
17          emergencies.

18          “(C) Coordinate the efforts of the Depart-  
19          ment to bolster State and local emergency pre-  
20          paredness for a bioterrorist attack or other pub-  
21          lic health emergency, and evaluate the progress  
22          of such entities in meeting the benchmarks and  
23          other outcome measures contained in the na-  
24          tional plan and in meeting the core public

1 health capabilities established pursuant to  
2 319A.

3 “(D) Coordinate the activities of the De-  
4 partment with respect to research and develop-  
5 ment of priority vaccines, other biological prod-  
6 ucts, drugs, and devices useful for detecting or  
7 responding to a bioterrorist attack or other  
8 public health emergency.

9 “(E) Coordinate the activities of the De-  
10 partment with respect to public education,  
11 awareness, and information relating to bioter-  
12 rorism or other public health emergencies, in-  
13 cluding the activities and recommendations of  
14 the EPIC Advisory Committee under section  
15 319F(e)(3).

16 “(F) Coordinate all other functions within  
17 the Department of Health and Human Services  
18 relating to emergency preparedness, including  
19 matters relating to bioterrorism and other pub-  
20 lic health emergencies that are addressed in the  
21 national plan under section 2801.

22 “(G) Any other duties determined appro-  
23 priate by the Secretary.

24 “(b) NATIONAL DISASTER MEDICAL SYSTEM.—

1           “(1) IN GENERAL.—The Secretary shall provide  
2           for the operation in accordance with this section of  
3           a system to be known as the National Disaster Med-  
4           ical System (in this section referred to as the ‘Na-  
5           tional System’). The Secretary shall designate the  
6           Assistant Secretary for Emergency Preparedness as  
7           the head of the National System, subject to the au-  
8           thority of the Secretary.

9           “(2) FEDERAL AND STATE COLLABORATIVE  
10          SYSTEM.—

11           “(A) IN GENERAL.—The National System  
12           shall be a coordinated effort by the Federal  
13           agencies specified in subparagraph (B), working  
14           in collaboration with the States and other ap-  
15           propriate public or private entities, to carry out  
16           the purposes described in paragraph (3).

17           “(B) PARTICIPATING FEDERAL AGEN-  
18           CIES.—The Federal agencies referred to in sub-  
19           paragraph (A) are the Department of Health  
20           and Human Services, the Federal Emergency  
21           Management Agency, the Department of De-  
22           fense, and the Department of Veterans Affairs.

23          “(3) PURPOSE OF SYSTEM.—

24           “(A) IN GENERAL.—The Secretary may  
25           activate the National System to—

1           “(i) provide health services, health-re-  
2           lated social services, other appropriate  
3           human services, and appropriate auxiliary  
4           services to respond to the needs of victims  
5           of a public health emergency (whether or  
6           not determined to be a public health emer-  
7           gency under section 319); or

8           “(ii) be present at locations, and for  
9           periods of time, specified by the Secretary  
10          on the basis that the Secretary has deter-  
11          mined that a location is at risk of a public  
12          health emergency during the time speci-  
13          fied.

14          “(B) ONGOING ACTIVITIES.—The National  
15          System shall carry out such ongoing activities  
16          as may be necessary to prepare for the provi-  
17          sion of services described in subparagraph (A)  
18          in the event that the Secretary activates the  
19          National System for such purposes.

20          “(C) TEST FOR MOBILIZATION OF SYS-  
21          TEM.—During the one-year period beginning on  
22          the date of the enactment of the Public Health  
23          Security and Bioterrorism Response Act of  
24          2001, the Secretary shall conduct an exercise to  
25          test the capability and timeliness of the Na-

1           tional System to mobilize and otherwise respond  
2           effectively to a bioterrorist attack or other pub-  
3           lic health emergency that affects two or more  
4           geographic locations concurrently. Thereafter,  
5           the Secretary may periodically conduct such ex-  
6           ercises regarding the National System as the  
7           Secretary determines to be appropriate.

8           “(c) CRITERIA.—

9           “(1) IN GENERAL.—The Secretary shall estab-  
10          lish criteria for the operation of the National Sys-  
11          tem.

12          “(2) EDUCATION AND TRAINING OF PER-  
13          SONNEL.—In carrying out paragraph (1), the Sec-  
14          retary shall establish criteria regarding the edu-  
15          cation and training of individuals who provide emer-  
16          gency services through the National System. In the  
17          case of permanent, full-time positions in the Depart-  
18          ment of Health and Human Services that involve  
19          significant supervisory roles within the National Sys-  
20          tem, the criteria shall require that individuals in  
21          such positions have completed appropriate education  
22          or training programs as determined by the Sec-  
23          retary.

24          “(3) PARTICIPATION AGREEMENTS FOR NON-  
25          FEDERAL ENTITIES.—In carrying out paragraph (1),



1 the Secretary shall establish criteria regarding the  
2 participation of States and private entities in the  
3 National System, including criteria regarding agree-  
4 ments for such participation. The criteria shall in-  
5 clude the following:

6 “(A) Provisions relating to the custody and  
7 use of Federal personal property by such enti-  
8 ties, which may in the discretion of the Sec-  
9 retary include authorizing the custody and use  
10 of such property on a reimbursable basis to re-  
11 spond to emergency situations for which the  
12 National System has not been activated by the  
13 Secretary pursuant to subsection (b)(3)(A).

14 “(B) Provisions relating to circumstances  
15 in which an individual or entity has agreements  
16 with both the National System and another en-  
17 tity regarding the provision of emergency serv-  
18 ices by the individual. Such provisions shall ad-  
19 dress the issue of priorities among the agree-  
20 ments involved.

21 “(d) INTERMITTENT DISASTER-RESPONSE PER-  
22 SONNEL.—

23 “(1) IN GENERAL.—For the purpose of assist-  
24 ing the National System in carrying out duties  
25 under this section, the Secretary may appoint indi-

1       viduals to serve as intermittent personnel of such  
2       System in accordance with applicable civil service  
3       laws and regulations.

4           “(2) LIABILITY.—For purposes of section  
5       224(a) and the remedies described in such section,  
6       an individual appointed under paragraph (1) shall,  
7       while acting within the scope of such appointment,  
8       be considered to be an employee of the Public  
9       Health Service performing medical, surgical, dental,  
10      or related functions. With respect to the participa-  
11      tion of individuals appointed under paragraph (1) in  
12      training programs authorized by the Assistant Sec-  
13      retary for Emergency Preparedness or a comparable  
14      official of any Federal agency specified in subsection  
15      (b)(2)(B), acts of individuals so appointed that are  
16      within the scope of such participation shall be con-  
17      sidered within the scope of the appointment under  
18      paragraph (1) (regardless of whether the individuals  
19      receive compensation for such participation).

20      “(e) CERTAIN EMPLOYMENT ISSUES REGARDING  
21      INTERMITTENT APPOINTMENTS.—

22           “(1) INTERMITTENT DISASTER-RESPONSE AP-  
23      POINTEE.—For purposes of this subsection, the term  
24      ‘intermittent disaster-response appointee’ means an

1 individual appointed by the Secretary under sub-  
2 section (d).

3 “(2) COMPENSATION FOR WORK INJURIES.—An  
4 intermittent disaster-response appointee shall, while  
5 acting in the scope of such appointment, be consid-  
6 ered to be an employee of the Public Health Service  
7 performing medical, surgical, dental, or related func-  
8 tions, and an injury sustained by such an individual  
9 shall be deemed ‘in the performance of duty’, for  
10 purposes of chapter 81 of title 5, United States  
11 Code, pertaining to compensation for work injuries.  
12 With respect to the participation of individuals ap-  
13 pointed under subsection (d) in training programs  
14 authorized by the Assistant Secretary for Emergency  
15 Preparedness or a comparable official of any Federal  
16 agency specified in subsection (b)(2)(B), injuries  
17 sustained by such an individual, while acting within  
18 the scope of such participation, also shall be deemed  
19 ‘in the performance of duty’ for purposes of chapter  
20 81 of title 5, United States Code (regardless of  
21 whether the individuals receive compensation for  
22 such participation). In the event of an injury to such  
23 an intermittent disaster-response appointee, the Sec-  
24 retary of Labor shall be responsible for making de-  
25 terminations as to whether the claimant is entitled

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

3 “(3) EMPLOYMENT AND REEMPLOYMENT  
4 RIGHTS.—

5 “(A) IN GENERAL.—Service as an inter-  
6 mittent disaster-response appointee when the  
7 Secretary activates the National System or  
8 when the individual participates in a training  
9 program authorized by the Assistant Secretary  
10 for Emergency Preparedness or a comparable  
11 official of any Federal agency specified in sub-  
12 section (b)(2)(B) shall be deemed ‘service in the  
13 uniformed services’ for purposes of chapter 43  
14 of title 38, United States Code, pertaining to  
15 employment and reemployment rights of indi-  
16 viduals who have performed service in the uni-  
17 formed services (regardless of whether the indi-  
18 vidual receives compensation for such participa-  
19 tion). All rights and obligations of such persons  
20 and procedures for assistance, enforcement, and  
21 investigation shall be as provided for in chapter  
22 43 of title 38, United States Code.

23 “(B) NOTICE OF ABSENCE FROM POSITION  
24 OF EMPLOYMENT.—Preclusion of giving notice  
25 of service by necessity of Service as an intermit-

1           tent disaster-response appointee when the Sec-  
2           retary activates the National System shall be  
3           deemed preclusion by ‘military necessity’ for  
4           purposes of section 4312(b) of title 38, United  
5           States Code, pertaining to giving notice of ab-  
6           sence from a position of employment. A deter-  
7           mination of such necessity shall be made by the  
8           Secretary, in consultation with the Secretary of  
9           Defense, and shall not be subject to judicial re-  
10          view.

11           “(4) LIMITATION.—An intermittent disaster-re-  
12          sponse appointee shall not be deemed an employee of  
13          the Department of Health and Human Services for  
14          purposes other than those specifically set forth in  
15          this section.

16           “(f) DEFINITION.—For purposes of this section, the  
17          term ‘auxiliary services’ includes mortuary services, veteri-  
18          nary services, and other services that are determined by  
19          the Secretary to be appropriate with respect to the needs  
20          referred to in subsection (b)(3)(A).

21           “(g) AUTHORIZATION OF APPROPRIATIONS.—For the  
22          purpose of providing for the Assistant Secretary for Emer-  
23          gency Preparedness and the operations of the National  
24          System, other than purposes for which amounts in the  
25          Public Health Emergency Fund under section 319 are

1 available, there are authorized to be appropriated such  
2 sums as may be necessary for each of the fiscal years 2002  
3 through 2006.”.

4 (b) SENSE OF CONGRESS REGARDING RESOURCES  
5 OF NATIONAL SYSTEM.—It is the sense of the Congress  
6 that the Secretary of Health and Human Services should  
7 provide sufficient resources to individuals and entities  
8 tasked to carry out the duties of the National Disaster  
9 Medical System for reimbursement of expenses, oper-  
10 ations, purchase and maintenance of equipment, training,  
11 and other funds expended in furtherance of such National  
12 System.

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

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

19 **“SEC. 319D. REVITALIZING THE CENTERS FOR DISEASE**  
20 **CONTROL AND PREVENTION.**

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

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

4 “(b) IMPROVING THE CAPACITIES OF THE CENTERS  
5 FOR DISEASE CONTROL AND PREVENTION.—

6 “(1) IN GENERAL.—The Secretary shall ex-  
7 pand, enhance, and improve the capabilities of the  
8 Centers for Disease Control and Prevention relating  
9 to preparedness for and responding effectively to  
10 bioterrorism and other public health emergencies.  
11 Activities that may be carried out under the pre-  
12 ceding sentence include—

13 “(A) expanding or enhancing the training  
14 of personnel;

15 “(B) improving communications facilities  
16 and networks;

17 “(C) improving capabilities for public  
18 health surveillance and reporting activities;

19 “(D) improving laboratory facilities related  
20 to bioterrorism, including increasing the secu-  
21 rity of such facilities; and

22 “(E) such other activities as the Secretary  
23 determines appropriate.

24 “(2) IMPROVING PUBLIC HEALTH LABORATORY  
25 CAPACITY.—

1           “(A) IN GENERAL.—The Secretary, di-  
2           rectly or through awards of grants, contracts,  
3           or cooperative agreements, shall provide for the  
4           establishment of a coordinated network of pub-  
5           lic health laboratories, that may, at the discre-  
6           tion of the Secretary, include laboratories that  
7           serve as regional reference laboratories.

8           “(B) PRIORITY.—In carrying out subpara-  
9           graph (A), the Secretary shall give priority to  
10          projects that include State or local government  
11          financial commitments, that seek to incorporate  
12          multiple public health and safety services or di-  
13          agnostic databases into an integrated public  
14          health or regional reference laboratory, and  
15          that cover geographic areas lacking advanced  
16          diagnostic and safety-level laboratory capabili-  
17          ties.

18          “(3) NATIONAL PUBLIC HEALTH COMMUNICA-  
19          TIONS AND SURVEILLANCE NETWORK.—

20                 “(A) IN GENERAL.—The Secretary, di-  
21                 rectly or through awards of grants, contracts,  
22                 or cooperative agreements, shall provide for the  
23                 establishment of integrated public health com-  
24                 munications and surveillance networks between  
25                 and among—



1                   “(i) Federal, State, and local public  
2                   health officials;

3                   “(ii) public and private health-related  
4                   laboratories, hospitals, and other health  
5                   care facilities; and

6                   “(iii) any other entities determined  
7                   appropriate by the Secretary.

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

15                  “(4) CONTINUITY OF EFFORT.—To the max-  
16                  imum extent practicable, the Secretary, in con-  
17                  ducting activities under paragraphs (1) through (3),  
18                  shall administer such activities in a manner that in-  
19                  tensifies, expands, or enhances activities being car-  
20                  ried out on the date of enactment of this subsection.

21                  “(c) FACILITIES.—

22                  “(1) IN GENERAL.—The Director of the Cen-  
23                  ters for Disease Control and Prevention may design,  
24                  construct, and equip new facilities, renovate existing  
25                  facilities (including laboratories, laboratory support

1 buildings, scientific communication facilities, trans-  
2 shipment complexes, secured and isolated parking  
3 structures, office buildings, and other facilities and  
4 infrastructure), and upgrade security of such facili-  
5 ties, in order to better conduct the capacities de-  
6 scribed in section 319A, and for supporting related  
7 public health activities.

8 “(2) MULTIYEAR CONTRACTING AUTHORITY.—

9 For any project of designing, constructing, equip-  
10 ping, or renovating any facility under paragraph (1),  
11 the Director of the Centers for Disease Control and  
12 Prevention may enter into a single contract or re-  
13 lated contracts that collectively include the full scope  
14 of the project, and the solicitation and contract shall  
15 contain the clause ‘availability of funds’ found at  
16 section 52.232–18 of title 48, Code of Federal Regu-  
17 lations.

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—

19 “(1) IN GENERAL.—For the purposes of achiev-  
20 ing the mission of the Centers for Disease Control  
21 and Prevention described in subsection (a), for car-  
22 rying out subsection (b), for better conducting the  
23 capacities described in section 319A, and for sup-  
24 porting related public health activities, there are au-  
25 thorized to be appropriated such sums as may be

1 necessary for each of the fiscal years 2002 through  
2 2006.

3 “(2) FACILITIES.—For the purpose of carrying  
4 out subsection (c), there are authorized to be appro-  
5 priated \$300,000,000 for each of the fiscal years  
6 2002 and 2003, and such sums as may be necessary  
7 for each of the fiscal years 2004 through 2006.”.

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

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

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

13 (2) by inserting after subsection (b) the fol-  
14 lowing subsections:

15 “(c) ADVICE TO THE FEDERAL GOVERNMENT.—

16 “(1) REQUIRED ADVISORY COMMITTEES.—In  
17 coordination with the working groups under sub-  
18 sections (a) and (b), the Secretary shall establish ad-  
19 visory committees in accordance with paragraphs (2)  
20 and (3) to provide expert recommendations to assist  
21 such working groups in carrying out their respective  
22 responsibilities under subsections (a) and (b).

23 “(2) NATIONAL ADVISORY COMMITTEE ON  
24 CHILDREN AND TERRORISM.—

1           “(A) IN GENERAL.—For purposes of para-  
2 graph (1), the Secretary shall establish an advi-  
3 sory committee to be known as the National  
4 Advisory Committee on Children and Terrorism  
5 (referred to in this paragraph as the ‘Advisory  
6 Committee’).

7           “(B) DUTIES.—The Advisory Committee  
8 shall provide recommendations regarding—

9           “(i) the preparedness of the health  
10 care (including mental health care) system  
11 to respond to bioterrorism as it relates to  
12 children;

13           “(ii) needed changes to the health  
14 care and emergency medical service sys-  
15 tems and emergency medical services pro-  
16 tocols to meet the special needs of children;  
17 and

18           “(iii) changes, if necessary, to the na-  
19 tional stockpile under section 121 of the  
20 Public Health Security and Bioterrorism  
21 Response Act of 2001 to meet the special  
22 needs of children.

23           “(C) COMPOSITION.—The Advisory Com-  
24 mittee shall be composed of such Federal offi-  
25 cials as may be appropriate to address the spe-

1           cial needs of the diverse population groups of  
2           children, and child health experts on infectious  
3           disease, environmental health, toxicology, and  
4           other relevant professional disciplines.

5           “(D) TERMINATION.—The Advisory Com-  
6           mittee terminates one year after the date of the  
7           enactment of the Public Health Security and  
8           Bioterrorism Response Act of 2001.

9           “(3) EMERGENCY PUBLIC INFORMATION AND  
10          COMMUNICATIONS ADVISORY COMMITTEE.—

11          “(A) IN GENERAL.—For purposes of para-  
12          graph (1), the Secretary shall establish an advi-  
13          sory committee to be known as the Emergency  
14          Public Information and Communications Advi-  
15          sory Committee (referred to in this paragraph  
16          as the ‘EPIC Advisory Committee’).

17          “(B) DUTIES.—The EPIC Advisory Com-  
18          mittee shall make recommendations and report  
19          on appropriate ways to communicate public-  
20          health information regarding biological attacks  
21          to the public.

22          “(C) COMPOSITION.—The EPIC Advisory  
23          Committee shall be composed of individuals rep-  
24          resenting a diverse group of experts in public  
25          health, communications, behavioral psychology,

1           and other areas determined appropriate by the  
2           Secretary.

3           “(D) DISSEMINATION.—The Secretary  
4           shall ensure that the recommendations of the  
5           EPIC Advisory Committee are widely dissemi-  
6           nated to the media, State and local govern-  
7           ments, poison control centers, and others as the  
8           Secretary determines appropriate.

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

13          “(d) STRATEGY FOR COMMUNICATION OF INFORMA-  
14          TION REGARDING BIOLOGICAL ATTACK.—In coordination  
15          with the joint interdepartmental working group under sub-  
16          section (b), the Secretary, acting through the Assistant  
17          Secretary for Emergency Preparedness, shall develop a  
18          strategy for effectively communicating information regard-  
19          ing a biological attack, and shall develop means by which  
20          to communicate such information. The Secretary may  
21          carry out the preceding sentence directly or through  
22          grants, contracts, or cooperative agreements.”.

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

3 Section 319F(g) of the Public Health Service Act, as  
4 redesignated by section 104(1) of this Act, is amended to  
5 read as follows:

6 “(g) EDUCATION; TRAINING REGARDING PEDIATRIC  
7 ISSUES.—

8 “(1) MATERIALS; CORE CURRICULUM.—The  
9 Secretary, in collaboration with members of the  
10 working group described in subsection (b), and pro-  
11 fessional organizations and societies, shall—

12 “(A) develop materials for teaching the ele-  
13 ments of a core curriculum for the recognition  
14 and identification (including proficiency testing)  
15 of potential bioweapons and other agents that  
16 may create a public health emergency, and for  
17 the care of victims of such emergencies, recog-  
18 nizing the special needs of children and other  
19 vulnerable populations, to public health offi-  
20 cials, medical professionals, emergency physi-  
21 cians and other emergency department staff,  
22 laboratory personnel, and other personnel work-  
23 ing in health care facilities (including poison  
24 control centers);

25 “(B) develop a core curriculum and mate-  
26 rials for community-wide planning by State and

1 local governments, hospitals and other health  
2 care facilities, emergency response units, and  
3 appropriate public and private sector entities to  
4 respond to a bioterrorist attack or other public  
5 health emergency;

6 “(C) provide for dissemination and teach-  
7 ing of the materials described in subparagraphs  
8 (A) and (B) by all appropriate means, including  
9 telemedicine, long-distance learning, or other  
10 such means; and

11 “(D) to the extent practicable, establish  
12 and maintain an electronic database of individ-  
13 uals participating in training or education pro-  
14 grams carried out under this section, for the  
15 purpose of providing continuing education ma-  
16 terials and information to such participants.

17 “(2) GRANTS.—In carrying out paragraph (1),  
18 the Secretary may award grants to, or enter into co-  
19 operative agreements with, professional organiza-  
20 tions and societies, private accrediting organizations,  
21 or other nonprofit institutions or entities meeting  
22 criteria established by the Secretary, and may enter  
23 into interagency cooperative agreements with other  
24 Federal agencies.



1           “(3) HEALTH-RELATED ASSISTANCE FOR  
2           EMERGENCY RESPONSE PERSONNEL TRAINING.—  
3           The Secretary, in consultation with the Attorney  
4           General and the Director of the Federal Emergency  
5           Management Agency, may provide assistance with  
6           respect to health-related aspects of emergency re-  
7           sponse personnel training carried out by the Depart-  
8           ment of Justice and the Federal Emergency Man-  
9           agement Agency.”.

10 **SEC. 106. GRANTS REGARDING SHORTAGES OF CERTAIN**  
11 **HEALTH PROFESSIONALS.**

12           Part B of title III of the Public Health Service Act  
13 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
14 tion 319G the following section:

15 **“SEC. 319H. GRANTS REGARDING TRAINING AND EDU-**  
16 **CATION OF CERTAIN HEALTH PROFES-**  
17 **SIONALS.**

18           “(a) IN GENERAL.—The Secretary may make awards  
19 of grants and cooperative agreements to appropriate pub-  
20 lic and nonprofit private health or educational entities, in-  
21 cluding health professions schools and programs as de-  
22 fined in section 799B, for the purpose of providing low-  
23 interest loans, partial scholarships, partial fellowships, re-  
24 volving loan funds, or other cost-sharing forms of assist-  
25 ance for the education and training of individuals in any

1 category of health professions for which there is a shortage  
2 that the Secretary determines should be alleviated in order  
3 to prepare for or respond effectively to bioterrorism and  
4 other public health emergencies.

5 “(b) **AUTHORITY REGARDING NON-FEDERAL CON-**  
6 **TRIBUTIONS.**—The Secretary may require as a condition  
7 of an award under subsection (a) that a grantee under  
8 such subsection provide non-Federal contributions toward  
9 the purpose described in such subsection.

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

14 **SEC. 107. EMERGENCY SYSTEM FOR VERIFICATION OF CRE-**  
15 **DENTIALS OF HEALTH PROFESSIONS VOLUN-**  
16 **TEERS.**

17 Part B of title III of the Public Health Service Act,  
18 as amended by section 106 of this Act, is amended by in-  
19 serting after section 319H the following section:

20 **“SEC. 319I. EMERGENCY SYSTEM FOR VERIFICATION OF**  
21 **HEALTH PROFESSIONS VOLUNTEERS.**

22 “(a) **IN GENERAL.**—The Secretary shall, directly or  
23 through an award of a grant, contract, or cooperative  
24 agreement, establish and maintain a system for verifying  
25 the credentials, licenses, accreditations, and hospital privi-

1 leges of individuals, who during public health emergencies  
2 volunteer to serve as health professionals (referred to in  
3 this section as the ‘verification system’). In carrying out  
4 the preceding sentence, the Secretary shall provide for an  
5 electronic database for the verification system.

6       “(b) CERTAIN CRITERIA.—The Secretary shall estab-  
7 lish criteria regarding the verification system under sub-  
8 section (a), including provisions regarding the promptness  
9 and efficiency of the system in collecting, storing, updat-  
10 ing, and disseminating information on the credentials, li-  
11 censes, accreditations, and hospital privileges of volunteers  
12 described in subsection (a).

13       “(c) ADVANCE REGISTRATION OF VOLUNTEERS.—In  
14 order to facilitate the availability of health professionals  
15 during a public health emergency, the Secretary shall pro-  
16 vide for the advance registration with the system of health  
17 professionals who are willing to serve as volunteers de-  
18 scribed in subsection (a), and may carry out activities to  
19 encourage health professionals to register with the system.

20       “(d) OTHER ASSISTANCE.—The Secretary may make  
21 grants and provide technical assistance to States and  
22 other public or nonprofit private entities for activities re-  
23 lating to the verification system developed under sub-  
24 section (a).

1       “(e) COORDINATION AMONG STATES.—The Sec-  
2 retary shall encourage each State to provide legal author-  
3 ity during a public health emergency for health profes-  
4 sionals authorized in another State to provide certain  
5 health services to provide such health services in the State.

6       “(f) RULE OF CONSTRUCTION.—This section may  
7 not be construed as authorizing the Secretary to issue re-  
8 quirements regarding the provision by the States of cre-  
9 dentials, licenses, accreditations, or hospital privileges.

10       “(g) AUTHORIZATION OF APPROPRIATIONS.—For the  
11 purpose of carrying out this section, there are authorized  
12 to be appropriated \$2,000,000 for fiscal year 2002, and  
13 such sums as may be necessary for each of the fiscal years  
14 2003 through 2006.”.

15 **SEC. 108. ENHANCING PREPAREDNESS ACTIVITIES FOR**  
16 **BIOTERRORISM AND OTHER PUBLIC HEALTH**  
17 **EMERGENCIES.**

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

20               (1) by amending subsection (a) to read as fol-  
21 lows:

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

1 the Secretary of Veterans Affairs, the Secretary of Agri-  
2 culture, the Secretary of Energy, and the Administrator  
3 of the Environmental Protection Agency shall establish a  
4 joint interdepartmental working group on preparedness  
5 and readiness for the medical and public health effects of  
6 a bioterrorist attack on the civilian population. Such joint  
7 working group shall—

8           “(1) coordinate and prioritize research on, and  
9           the development of countermeasures against, patho-  
10          gens likely to be used in a bioterrorist attack on the  
11          civilian population;

12           “(2) facilitate the development, production, and  
13          regulatory review of priority countermeasures (as de-  
14          fined in subsection (h)(2)(C)) for a bioterrorist at-  
15          tack on the civilian population;

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

20           “(4) develop shared standards for equipment to  
21          detect and to protect against infection from patho-  
22          gens likely to be used in a bioterrorist attack on the  
23          civilian population; and

24           “(5) coordinate the development, maintenance,  
25          and procedures for the release and distribution of

1 strategic reserves of vaccines, drugs, and medical  
2 supplies which may be needed rapidly after a bioter-  
3 rorist attack upon the civilian population, including  
4 consideration of vulnerable populations (such as chil-  
5 dren, the elderly, and individuals with disabilities).”;

6 (2) in subsection (b)(1), by striking “The Sec-  
7 retary” and all that follows through “shall establish”  
8 and inserting the following: “The Secretary, in col-  
9 laboration with the Secretary of Defense, the Direc-  
10 tor of the Federal Emergency Management Agency,  
11 the Attorney General, the Secretary of Veterans Af-  
12 fairs, the Secretary of Agriculture, the Secretary of  
13 Labor, and the Administrator of the Environmental  
14 Protection Agency, shall establish”;

15 (3) in subsection (b)(2)—

16 (A) in subparagraph (A), by striking “re-  
17 spond to a bioterrorist attack; and” and insert-  
18 ing the following: “respond to a bioterrorist at-  
19 tack, including the provision of appropriate  
20 safety and health training and protective meas-  
21 ures for medical, emergency service, and other  
22 personnel responding to such attacks;”;

23 (B) in subparagraph (B), by striking the  
24 period and inserting “; and”; and

1 (C) by adding at the end the following sub-  
2 paragraph:

3 “(C) subject to compliance with other pro-  
4 visions of Federal law, clarify the responsibil-  
5 ities among Federal officials for the investiga-  
6 tion of suspicious outbreaks of disease, and re-  
7 vise the interagency plan known as the Federal  
8 response plan accordingly.”;

9 (4) in subsection (b)(3), by striking “Assistant  
10 Secretary for Health” and inserting “Assistant Sec-  
11 retary for Emergency Preparedness”; and

12 (5) in subsection (e) (as redesignated by section  
13 104(1) of this Act)—

14 (A) in paragraph (1), by striking “The  
15 Secretary” and all that follows and inserting  
16 the following: “In consultation with the working  
17 group established under subsection (b), the Sec-  
18 retary shall, based on criteria established by the  
19 Secretary, award grants to or enter into cooper-  
20 ative agreements with eligible entities to in-  
21 crease their capacity to detect, diagnose, and  
22 respond to acts of bioterrorism upon the civilian  
23 population.”;

24 (B) in paragraph (2)—

1 (i) by striking “or” after “clinic,”;

2 and

3 (ii) by inserting before the period the  
4 following: “, professional organizations and  
5 societies, schools or programs that train  
6 medical laboratory personnel, private ac-  
7 crediting organizations, or other nonprofit  
8 institutions or entities meeting criteria es-  
9 tablished by the Secretary”;

10 (C) in paragraph (3)—

11 (i) in the matter preceding subpara-  
12 graph (A), by striking “the priorities” and  
13 inserting “any priorities”; and

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

16 “(A) developing community-wide plans in-  
17 volving the public and private health care infra-  
18 structure to respond to bioterrorism or other  
19 public health emergencies, which are coordi-  
20 nated with the capacities of applicable national,  
21 State, and local health agencies;

22 “(B) training health care professionals and  
23 public health personnel to enhance the ability of  
24 such personnel to recognize the symptoms and  
25 epidemiological characteristics of exposure to a



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

3 “(C) addressing rapid and accurate identi-  
4 fication of potential bioweapons, or other agents  
5 that may cause a public health emergency;

6 “(D) coordinating medical care for individ-  
7 uals during public health emergencies, including  
8 bioterrorism;

9 “(E) conducting exercises to test the capa-  
10 bility and timeliness of public health emergency  
11 response activities;

12 “(F) facilitating and coordinating rapid  
13 communication of data generated from a bioter-  
14 rorist attack or public health emergency among  
15 national, State, and local health agencies, emer-  
16 gency response personnel, and health care pro-  
17 viders and facilities; and

18 “(G) purchasing or upgrading equipment,  
19 supplies, pharmaceuticals or other counter-  
20 measures to enhance preparedness for and re-  
21 sponse to bioterrorism or other public health  
22 emergencies, consistent with a plan described in  
23 subparagraph (A).”; and

24 (D) in paragraph (4)—

1 (i) in subparagraph (A), by striking  
2 “and” after the semicolon at the end;

3 (ii) in subparagraph (B), by striking  
4 the period at the end and inserting “;  
5 and”; and

6 (iii) by adding at the end the fol-  
7 lowing subparagraph:

8 “(C) coordinate grants under this sub-  
9 section with grants under 319C.”.

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

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

14 (1) in subsection (a), by striking “competitive”;  
15 and

16 (2) in subsection (c)—

17 (A) in paragraph (3), by striking “health  
18 care providers; and” and inserting “health care  
19 providers, including poison control centers;”;

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

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

24 “(4) purchase or upgrade equipment, supplies,  
25 pharmaceuticals or other countermeasures to en-

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

4 “(5) conduct exercises to test the capability and  
5 timeliness of public health emergency response ac-  
6 tivities;

7 “(6) within the meaning of part B of title XII,  
8 develop and implement the trauma care component  
9 of the State plan for the provision of emergency  
10 medical services; and”;

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

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

14 (1) in subsection (b)—

15 (A) by striking “shall conduct and sup-  
16 port” and inserting “shall directly or through  
17 awards of grants or cooperative agreements to  
18 public or private entities provide for the con-  
19 duct of”; and

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

22 “(4) the sequencing of the genomes, or other  
23 appropriate DNA analysis, or other necessary com-  
24 parative analysis, of priority pathogens (as deter-  
25 mined by the Director of the National Institutes of

1 Health in consultation with the task force estab-  
2 lished under subsection (a)), in collaboration and co-  
3 ordination with the activities of the Department of  
4 Defense and the Joint Genome Institute of the De-  
5 partment of Energy; and”;

6 (2) in subsection (e)(2), by inserting after “so-  
7 cieties,” the following: “schools or programs that  
8 train medical laboratory personnel,”; and

9 (3) in subsection (g), by striking “and such  
10 sums” and all that follows and inserting the fol-  
11 lowing: “\$25,000,000 for each of the fiscal years  
12 2002 and 2003, and such sums as may be necessary  
13 for each of the fiscal years 2004 through 2006.”.

14 **SEC. 111. STUDY REGARDING COMMUNICATIONS ABILITIES**  
15 **OF PUBLIC HEALTH AGENCIES.**

16 The Secretary of Health and Human Services, in con-  
17 sultation with the Federal Communications Commission,  
18 the National Telecommunications and Information Ad-  
19 ministration, and other appropriate Federal agencies,  
20 shall conduct a study to ensure that local public health  
21 entities have the ability to maintain communications in the  
22 event of a bioterrorist attack or other public health emer-  
23 gency. The study shall examine whether redundancies are  
24 required in the telecommunications system for public  
25 health entities to maintain systems operability and

1 connectivity during such emergencies. The study shall also  
2 include recommendations to industry and public health en-  
3 tities about how to implement such redundancies if nec-  
4 essary.

5 **SEC. 112. SUPPLIES AND SERVICES IN LIEU OF AWARD**  
6 **FUNDS.**

7 Part B of title III of the Public Health Service Act,  
8 as amended by section 107 of this Act, is amended by in-  
9 serting after section 319I the following section:

10 **“SEC. 319J. SUPPLIES AND SERVICES IN LIEU OF AWARD**  
11 **FUNDS.**

12 “(a) IN GENERAL.—Upon the request of a recipient  
13 of an award under any of sections 319 through 319I or  
14 section 319K, the Secretary may, subject to subsection  
15 (b), provide supplies, equipment, and services for the pur-  
16 pose of aiding the recipient in carrying out the purposes  
17 for which the award is made and, for such purposes, may  
18 detail to the recipient any officer or employee of the De-  
19 partment of Health and Human Services.

20 “(b) CORRESPONDING REDUCTION IN PAYMENTS.—  
21 With respect to a request described in subsection (a), the  
22 Secretary shall reduce the amount of payments under the  
23 award involved by an amount equal to the costs of detail-  
24 ing personnel and the fair market value of any supplies,  
25 equipment, or services provided by the Secretary. The Sec-

1 retary shall, for the payment of expenses incurred in com-  
2 plying with such request, expend the amounts withheld.”.

3 **SEC. 113. ADDITIONAL AMENDMENTS.**

4 Part B of title III of the Public Health Service Act  
5 (42 U.S.C. 243 et seq) is amended—

6 (1) in section 319A(a)(1), by striking “10  
7 years” and inserting “five years”; and

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

10 **SEC. 114. STUDY REGARDING LOCAL EMERGENCY RE-**  
11 **SPONSE METHODS.**

12 The Secretary of Health and Human Services shall  
13 conduct a study of best-practices methods for the provi-  
14 sion of emergency response services through local govern-  
15 ments (including through contractors and volunteers of  
16 such governments) in a consistent manner in response to  
17 acts of bioterrorism or other public health emergencies.  
18 Not later than 180 days after the date of the enactment  
19 of this Act, the Secretary shall submit to the Congress  
20 a report describing the findings of the study.

1 **Subtitle B—National Stockpile; De-**  
2 **velopment of Priority Counter-**  
3 **measures**

4 **SEC. 121. NATIONAL STOCKPILE.**

5 (a) IN GENERAL.—The Secretary of Health and  
6 Human Services (referred to in this section as the “Sec-  
7 retary”) shall maintain a stockpile or stockpiles of drugs,  
8 vaccines and other biological products, medical devices,  
9 and other supplies in such numbers, types, and amounts  
10 as are determined by the Secretary to be adequate to meet  
11 the health security needs of the United States, including  
12 consideration of vulnerable populations (such as children,  
13 the elderly, and individuals with disabilities), in the event  
14 of a bioterrorist attack or other public health emergency.

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

17 (1) consult with the Director of the Federal  
18 Emergency Management Agency, the Secretary of  
19 Defense, the Secretary of Veterans Affairs, the At-  
20 torney General, the Secretary of Energy, and the  
21 Administrator of the Environmental Protection  
22 Agency;

23 (2) ensure that adequate procedures are fol-  
24 lowed with respect to such stockpile for inventory

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

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

6 (4) review and revise, as appropriate, the con-  
7 tents of the stockpile on a regular basis to ensure  
8 that emerging threats, advanced technologies, and  
9 new countermeasures are adequately considered; and

10 (5) devise plans for the effective and timely dis-  
11 tribution of the stockpile, in consultation with appro-  
12 priate Federal, State and local agencies, and the  
13 public and private health care infrastructure.

14 (c) DEFINITION.—For purposes of subsection (a), the  
15 term “stockpile” includes—

16 (1) a physical accumulation (at one or more lo-  
17 cations) of the supplies described in subsection (a);  
18 or

19 (2) a contractual agreement between the Sec-  
20 retary and a vendor or vendors under which such  
21 vendor or vendors agree to provide to the Secretary  
22 supplies described in subsection (a).

23 (d) AUTHORIZATION OF APPROPRIATIONS.—For the  
24 purpose of carrying out this section, there are authorized  
25 to be appropriated \$1,155,000,000 for fiscal year 2002,



1 and such sums as may be necessary for each of fiscal years  
2 2003 through 2006.

3 **SEC. 122. ACCELERATED APPROVAL OF PRIORITY COUN-**  
4 **TERMEASURES.**

5 (a) IN GENERAL.—The Secretary of Health and  
6 Human Services may designate a priority countermeasure  
7 as a fast-track product pursuant to section 506 of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356).  
9 Such a designation may be made prior to the submission  
10 of—

- 11 (1) a request for designation by the sponsor; or  
12 (2) an application for the investigation of the  
13 drug under section 505(i) of such Act or section  
14 351(a)(3) of the Public Health Service Act. Nothing  
15 in this subsection shall be construed to prohibit a  
16 sponsor from declining such a designation.

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

22 (c) DEFINITION.—For purposes of this section, the  
23 term “priority countermeasure” means a drug or biologi-  
24 cal product that is a countermeasure to treat, identify, or  
25 prevent infection by a biological agent or toxin listed pur-

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

3 **SEC. 123. USE OF ANIMAL TRIALS IN APPROVAL OF CER-**  
4 **TAIN DRUGS AND BIOLOGICS; ISSUANCE OF**  
5 **RULE.**

6 Not later than 180 days after the date of the enact-  
7 ment of this Act, the Secretary of Health and Human  
8 Services shall complete the process of rulemaking that was  
9 commenced with the issuance of the proposed rule entitled  
10 “New Drug and Biological Drug Products; Evidence  
11 Needed to Demonstrate Efficacy of New Drugs for Use  
12 Against Lethal or Permanently Disabling Toxic Sub-  
13 stances When Efficacy Studies in Humans Ethically Can-  
14 not be Conducted” published in the Federal Register on  
15 October 5, 1999 (64 Fed. Reg. 53960).

16 **SEC. 124. SECURITY FOR COUNTERMEASURE DEVELOP-**  
17 **MENT AND PRODUCTION.**

18 Part B of title III of the Public Health Service Act,  
19 as amended by section 112 of this Act, is amended by in-  
20 serting after section 319J the following section:

21 **“SEC. 319K. SECURITY FOR COUNTERMEASURE DEVELOP-**  
22 **MENT AND PRODUCTION.**

23 “The Secretary, in consultation with the Attorney  
24 General and the Secretary of Defense, may provide tech-  
25 nical or other assistance to provide security to persons or

1 facilities that conduct development, production, distribu-  
2 tion, or storage of priority countermeasures (as defined  
3 in section 319F(h)(2)(C)).”.

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

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

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

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

12 “(1) IN GENERAL.—The Secretary”;

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

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

17 “(2) ACCELERATED COUNTERMEASURE RE-  
18 SEARCH AND DEVELOPMENT.—

19 “(A) IN GENERAL.—With respect to patho-  
20 gens of potential use in a bioterrorist attack,  
21 and other agents that may cause a public  
22 health emergency, the Secretary, taking into  
23 consideration any recommendations of the  
24 working group under subsection (a), shall con-  
25 duct, and award grants, contracts, or coopera-

1           tive agreements for, research, investigations, ex-  
2           periments, demonstrations, and studies in the  
3           health sciences relating to—

4                   “(i) the epidemiology and patho-  
5                   genesis of such pathogens;

6                   “(ii) the development of new vaccines  
7                   and therapeutics for use against such  
8                   pathogens and other agents;

9                   “(iii) the development of diagnostic  
10                  tests to detect such pathogens and other  
11                  agents; and

12                  “(iv) other relevant areas of research;  
13                  with consideration given to the needs of chil-  
14                  dren and other vulnerable populations.

15                  “(B) ROLE OF DEPARTMENT OF VET-  
16                  ERANS AFFAIRS.—In carrying out subpara-  
17                  graph (A), the Secretary shall consider using  
18                  the biomedical research and development capa-  
19                  bilities of the Department of Veterans Affairs,  
20                  in conjunction with that Department’s affili-  
21                  ations with health-professions universities.  
22                  When advantageous to the Government in fur-  
23                  therance of the purposes of such subparagraph,  
24                  the Secretary may enter into cooperative agree-

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

3           “(C) PRIORITY COUNTERMEASURES.—For  
4           purposes of this paragraph, the term ‘priority  
5           countermeasure’ means a countermeasure, in-  
6           cluding a drug, medical or other technological  
7           device, biological product, or diagnostic test, to  
8           treat, identify, or prevent infection by a biologi-  
9           cal agent or toxin listed pursuant to section  
10          351A(a)(1) or harm from any other agent that  
11          may cause a public health emergency.”.

12 **SEC. 126. EVALUATION OF NEW AND EMERGING TECH-**  
13 **NOLOGIES REGARDING BIOTERRORIST AT-**  
14 **TACK AND OTHER PUBLIC HEALTH EMER-**  
15 **GENCIES.**

16          (a) IN GENERAL.—The Secretary of Health and  
17 Human Services (referred to in this section as the “Sec-  
18 retary”) shall promptly carry out a program to evaluate  
19 new and emerging technologies that are designed to im-  
20 prove or enhance the ability of public health or safety offi-  
21 cials to detect, identify, diagnose, or conduct public health  
22 surveillance activities relating to a bioterrorist attack or  
23 other public health emergency.

24          (b) CERTAIN ACTIVITIES.—In carrying out this sub-  
25 section, the Secretary shall—

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

4           (2) promptly issue a request for information  
5           from non-Federal public and private entities for on-  
6           going activities in this area; and

7           (3) evaluate technologies identified under para-  
8           graphs (1) and (2) pursuant to subsection (c).

9           (c) CONSULTATION AND EVALUATION.—In carrying  
10          out subsection (b)(3), the Secretary shall consult with the  
11          joint interdepartmental working group under section  
12          319F(a) of the Public Health Service Act, as well as other  
13          appropriate public, nonprofit, and private entities, to de-  
14          velop criteria for the evaluation of such technologies and  
15          to conduct such evaluations.

16          (d) REPORT.—Not later than 180 days after the date  
17          of the enactment of this Act, the Secretary shall submit  
18          to the Committee on Energy and Commerce of the House  
19          of Representatives, and the Committee on Health, Edu-  
20          cation, Labor, and Pensions of the Senate, a report that  
21          provides a list of priority technologies whose development  
22          or deployment or both should be accelerated, and the esti-  
23          mated cost of doing so.

1 **SEC. 127. POTASSIUM IODIDE.**

2 (a) IN GENERAL.—Through the national stockpile  
3 under section 121, the Secretary of Health and Human  
4 Services (in this section referred to as the “Secretary”),  
5 subject to subsection (b), shall make available to State and  
6 local governments potassium iodide tablets for stockpiling  
7 and for distribution as appropriate to public facilities,  
8 such as schools and hospitals, that are within 20 miles  
9 of a nuclear power plant, in quantities sufficient to provide  
10 adequate protection for the populations within such miles.

11 (b) STATE AND LOCAL PLANS.—Subsection (a) ap-  
12 plies with respect to a State or local government if the  
13 government involved meets the following conditions:

14 (1) Such government submits to the Secretary,  
15 and to the Director of the Federal Emergency Man-  
16 agement Agency, a plan for the stockpiling of potas-  
17 sium iodide tablets, and for the distribution and uti-  
18 lization of potassium iodide tablets in the event of  
19 a nuclear incident.

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

22 (A) the government has not received suffi-  
23 cient quantities of potassium iodide tablets from  
24 the Nuclear Regulatory Commission; and

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

4 (c) GUIDELINES.—In consultation with the Director  
5 of the Federal Emergency Management Agency and with  
6 the Nuclear Regulatory Commission, the Secretary shall  
7 establish guidelines for the stockpiling of potassium iodide  
8 tablets, and for the distribution and utilization of potas-  
9 sium iodide tablets in the event of a nuclear incident.

10 (d) INFORMATION.—The Secretary shall carry out ac-  
11 tivities to inform State and local governments of the pro-  
12 gram under this section.

13 (e) REPORT.—Not later than six months after the  
14 date of the enactment of this Act, the Secretary shall sub-  
15 mit to the Congress a report—

16 (1) on whether potassium iodide tablets have  
17 been made available under subsection (a) and the ex-  
18 tent to which State and local governments have es-  
19 tablished stockpiles of such tablets; and

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

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



1 sult from the release of radionuclides from nuclear power  
2 plants.

3 **Subtitle C—Emergency Authorities;**  
4 **Additional Provisions**

5 **SEC. 131. EXPANDED AUTHORITY OF SECRETARY OF**  
6 **HEALTH AND HUMAN SERVICES TO RESPOND**  
7 **TO PUBLIC HEALTH EMERGENCIES.**

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

11 “(d) TRANSFERS OF FUNDS BETWEEN PROGRAMS  
12 AND ACCOUNTS.—

13 “(1) IN GENERAL.—At any time during a pub-  
14 lic health emergency declared by the Secretary under  
15 subsection (a), the Secretary may, subject to para-  
16 graph (2), transfer funds, to the extent authorized  
17 by law, between appropriations accounts adminis-  
18 tered by the Secretary under this Act, without re-  
19 gard to any waiting period imposed by any other  
20 provision of law, including any provision of an ap-  
21 propriations Act, except as provided in paragraphs  
22 (3) and (4).

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

1           “(A) The Secretary may not make a trans-  
2           fer under paragraph (1) in an amount exceed-  
3           ing a reasonable estimate by the Secretary of  
4           the amount necessary to respond to the emer-  
5           gency involved for a period of 60 days.

6           “(B) Subsequent transfers under para-  
7           graph (1) may be made by the Secretary, sub-  
8           ject to compliance with subparagraph (A).

9           “(3) NOTIFICATION.—Not later than 48 hours  
10          prior to making a transfer under paragraph (1), the  
11          Secretary shall submit a notice of the intent to make  
12          such transfer to the Committee on Appropriations of  
13          the House of Representatives, the Committee on En-  
14          ergy and Commerce of the House of Representa-  
15          tives, the Committee on Appropriations of the Sen-  
16          ate, and the Committee on Health, Education,  
17          Labor, and Pensions of the Senate.

18          “(4) SCOPE.—Paragraph (1) shall apply, not-  
19          withstanding any other provision of law including  
20          any provision of an appropriations Act and any Act  
21          enacted after the date of enactment of this sub-  
22          section, unless such provision specifically refers to  
23          and overrides this subsection.”.

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

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

3       “(e) DATA SUBMITTAL AND REPORTING DEAD-  
4 LINES.—In any case in which the Secretary determines  
5 that, wholly or partially as a result of a public health  
6 emergency that has been declared pursuant to subsection  
7 (a), individuals or public or private entities are unable to  
8 comply with deadlines for the submission to the Secretary  
9 of data or reports required under any law administered  
10 by the Secretary, the Secretary may, notwithstanding any  
11 other provision of law, grant such extensions of such dead-  
12 lines as the circumstances reasonably require, and may  
13 waive, wholly or partially, any sanctions otherwise applica-  
14 ble to such failure to comply. Before or promptly after  
15 granting such an extension or waiver, the Secretary shall  
16 notify the Congress of such action and publish in the Fed-  
17 eral Register a notice of the extension or waiver.”.

18 **SEC. 132. STREAMLINING AND CLARIFYING COMMU-**  
19 **NICABLE DISEASE QUARANTINE PROVISIONS.**

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

23           (1) EXECUTIVE ORDERS SPECIFYING DISEASES  
24       SUBJECT TO INDIVIDUAL DETENTIONS.—Section  
25       361(b) of the Public Health Act (42 U.S.C. 264(b))

1 is amended by striking “Executive orders of the  
2 President upon the recommendation of the National  
3 Advisory Health Council and the Surgeon General”  
4 and inserting “Executive orders of the President  
5 upon the recommendation of the Secretary, in con-  
6 sultation with the Surgeon General,”.

7 (2) REGULATIONS PROVIDING FOR APPREHEN-  
8 SION OF INDIVIDUALS.—Section 361(d) of the Pub-  
9 lic Health Act (42 U.S.C. 264(d)) is amended by  
10 striking “On recommendation of the National Advi-  
11 sory Health Council, regulations” and inserting  
12 “Regulations”.

13 (3) REGULATIONS PROVIDING FOR APPREHEN-  
14 SION OF INDIVIDUALS IN WARTIME.—Section 363 of  
15 the Public Health Act (42 U.S.C. 266) is amended  
16 by striking “the Surgeon General, on recommenda-  
17 tion of the National Advisory Health Council,” and  
18 inserting “the Secretary, in consultation with the  
19 Surgeon General,”.

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

22 (1) REGULATIONS PROVIDING FOR APPREHEN-  
23 SION OF INDIVIDUALS.—Section 361(d) of the Pub-  
24 lic Health Act (42 U.S.C. 264(d)), as amended by

1 subsection (a)(2), is further amended by inserting  
2 “or exposed to” after “to be infected with”.

3 (2) REGULATIONS PROVIDING FOR APPREHEN-  
4 SION OF INDIVIDUALS IN WARTIME.—Section 363 of  
5 the Public Health Act (42 U.S.C. 266), as amended  
6 by subsection (a)(3), is further amended by inserting  
7 “or exposed to” after “to be infected with”.

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

11 “(e) Nothing in this section or section 363, or the  
12 regulations promulgated under such sections, may be con-  
13 strued as superseding any provision under State law (in-  
14 cluding regulations and including provisions established by  
15 political subdivisions of States), except to the extent that  
16 such a provision conflicts with an exercise of Federal au-  
17 thority under this section or section 363.”.

18 **SEC. 133. EMERGENCY WAIVER OF MEDICARE, MEDICAID,**

19 **AND SCHIP REQUIREMENTS.**

20 (a) WAIVER AUTHORITY.—Title XI of the Social Se-  
21 curity Act (42 U.S.C. 1301 et seq.) is amended by insert-  
22 ing after section 1134 the following new section:

23 **“SEC. 1135. AUTHORITY TO WAIVE REQUIREMENTS DURING**

24 **NATIONAL EMERGENCIES.**

25 “(a) PURPOSE.—

1           “(1) IN GENERAL.—The purpose of this section  
2 is to enable the Secretary to ensure to the maximum  
3 extent feasible, in any emergency area and during an  
4 emergency period—

5           “(A) that sufficient health care items and  
6 services are available to meet the needs of indi-  
7 viduals in such area enrolled in the programs  
8 under titles XVIII, XIX, and XXI; and

9           “(B) that health care providers (as defined  
10 in subsection (g)) that furnish such items and  
11 services in good faith, but that are unable to  
12 comply with one or more requirements de-  
13 scribed in subsection (b), may be reimbursed  
14 for such items and services and exempted from  
15 sanctions for such noncompliance, absent any  
16 determination of fraud or abuse.

17           “(2) EMERGENCY AREA; EMERGENCY PE-  
18 RIOD.—For purposes of this section, an ‘emergency  
19 area’ is a geographical area in which, and an ‘emer-  
20 gency period’ is the period during which, there  
21 exists—

22           “(A) an emergency or disaster declared by  
23 the President pursuant to the National Emer-  
24 gencies Act or the Robert T. Stafford Disaster  
25 Relief and Emergency Assistance Act; and

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

4           “(b) SECRETARIAL AUTHORITY.—To the extent nec-  
5           essary to accomplish the purposes specified in subsection  
6           (a), the Secretary is authorized, subject to the provisions  
7           of this section, to temporarily waive or modify the applica-  
8           tion of, with respect to health care items and services fur-  
9           nished in any emergency area (or portion of such an area)  
10          during an emergency period, the requirements of titles  
11          XVIII, XIX, or XXI, or any regulation thereunder (and  
12          the requirements of this title, and regulations thereunder,  
13          insofar as they relate to such titles), pertaining to—

14           “(1) conditions of participation or other certifi-  
15          cation requirements for an individual health care  
16          provider or types of providers; program participation  
17          and similar requirements for an individual health  
18          care provider or types of providers; and pre-approval  
19          requirements;

20           “(2) requirements that physicians and other  
21          health care professionals be licensed in the State in  
22          which they provide such services, if they have equiv-  
23          alent licensing in another State;

24           “(3) sanctions under section 1867 (relating to  
25          examination and treatment for emergency medical

1 conditions and women in labor) for a transfer of an  
2 individual who has not been stabilized in violation of  
3 subsection (c) of such section if the transfer arises  
4 out of the circumstances of the emergency;

5 “(4) sanctions under section 1877(g) (relating  
6 to limitations on physician referral); and

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

10 “(c) AUTHORITY FOR RETROACTIVE WAIVER.—A  
11 waiver or modification of requirements pursuant to this  
12 section may, at the Secretary’s discretion, be made retro-  
13 active to the beginning of the emergency period or any  
14 subsequent date in such period specified by the Secretary.

15 “(d) NOTIFICATION OF CONGRESS.—The Secretary  
16 shall provide advance written notice to the Congress at  
17 least two days before exercising the authority under this  
18 section with respect to an emergency area. Such a notice  
19 shall include a description of the specific provisions that  
20 will be waived or modified, the health care providers to  
21 whom the waiver or modification will apply, the geographic  
22 area in which the waiver or modification will apply, and  
23 the period of time for which the waiver or modification  
24 will be in effect.

25 “(e) DURATION OF WAIVER.—



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

4           “(A) the termination of the applicable dec-  
5 laration of emergency or disaster described in  
6 subsection (a)(2)(B);

7           “(B) the termination of the applicable dec-  
8 laration of public health emergency described in  
9 subsection (a)(2)(B); or

10           “(C) subject to paragraph (2), the termi-  
11 nation of a period of 90 days from the date the  
12 waiver or modification is first published (or, if  
13 applicable, the date of extension of the waiver  
14 or modification under paragraph (2)).

15           “(2) EXTENSION OF 90-DAY PERIODS.—The  
16 Secretary may, by notice, provide for an extension of  
17 a 90-day period described in paragraph (1)(C) (or  
18 an additional period provided under this paragraph)  
19 for additional period or periods (not to exceed, ex-  
20 cept as subsequently provided under this paragraph,  
21 90 days each), but any such extension shall not af-  
22 fect or prevent the termination of a waiver or modi-  
23 fication under subparagraph (A) or (B) of para-  
24 graph (1).

1       “(f) REPORT TO CONGRESS.—Within one year after  
2 the end of the emergency period in an emergency area in  
3 which the Secretary exercised the authority provided  
4 under this section, the Secretary shall report to the Con-  
5 gress regarding the approaches used to accomplish the  
6 purposes described in subsection (a), including an evalua-  
7 tion of the success of such approaches and recommenda-  
8 tions for improved approaches should the need for such  
9 emergency authority arise in the future.

10       “(g) HEALTH CARE PROVIDER DEFINED.—For pur-  
11 poses of this section, the term ‘health care provider’ means  
12 any entity that furnishes health care items or services, and  
13 includes a hospital or other provider of services, a physi-  
14 cian or other health care practitioner or professional, a  
15 health care facility, or a supplier of health care items or  
16 services.”.

17       (b) EFFECTIVE DATE.—The amendments made by  
18 subsection (a) shall be effective on and after September  
19 11, 2001.

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

22       Section 319(a) of the Public Health Service Act (42  
23 U.S.C. 247d(a)), is amended by adding at the end the fol-  
24 lowing new sentence: “Any such determination of a public  
25 health emergency terminates upon the Secretary declaring

1 that the emergency no longer exists, or upon the expira-  
2 tion of the 90-day period beginning on the date on which  
3 the determination is made by the Secretary, whichever oc-  
4 curs first. Determinations that terminate under the pre-  
5 ceding sentence may be renewed by the Secretary (on the  
6 basis of the same or additional facts), and the preceding  
7 sentence applies to each such renewal.”.

8 **SEC. 135. DESIGNATED STATE PUBLIC EMERGENCY AN-**  
9 **NOUNCEMENT PLAN.**

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

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

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

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

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

20 **SEC. 136. EXPANDED RESEARCH BY SECRETARY OF EN-**  
21 **ERGY.**

22 (a) IN GENERAL.—In coordination with the joint  
23 interdepartmental working group under section 319F(a)  
24 of the Public Health Service Act, the Secretary of Energy  
25 and the Administrator of the National Nuclear Security

1 Administration shall expand, enhance, and intensify re-  
2 search relevant to the rapid detection and identification  
3 of pathogens likely to be used in a bioterrorism attack or  
4 other agents that may cause a public health emergency.

5 (b) AUTHORIZATION OF APPROPRIATIONS.—There is  
6 authorized to be appropriated to carry out this section  
7 such sums as may be necessary for each of the fiscal years  
8 2002 through 2006.

9 **SEC. 137. AGENCY FOR TOXIC SUBSTANCE AND DISEASE**  
10 **REGISTRY.**

11 (a) IN GENERAL.—In planning for and responding  
12 to bioterrorism and other public health emergencies, in-  
13 cluding assisting State health departments, the Secretary  
14 of Health and Human Services (in this section referred  
15 to as the “Secretary”) shall take into account the role and  
16 expertise of the Agency for Toxic Substances and Disease  
17 Registry (in this section referred to as “ATSDR”).

18 (b) AUTHORIZATION OF APPROPRIATIONS.—For the  
19 purpose of providing resources (including increased per-  
20 sonnel, as appropriate) for ATSDR to use authorities  
21 under section 104(i) of the Comprehensive Environmental  
22 Response, Compensation, and Liability Act of 1980 to as-  
23 sist the Secretary in planning for or responding to bioter-  
24 rorism or other public health emergencies, there are au-  
25 thorized to be appropriated to the Secretary such sums

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

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

6 The Secretary, acting through the Director of the Na-  
7 tional Institute of Occupational Safety and Health, shall  
8 enhance and expand research as deemed appropriate on  
9 the health and safety of workers who are at risk for bioter-  
10 rorist threats or attacks in the workplace.

11 **SEC. 139. TECHNOLOGY OPPORTUNITIES PROGRAM SUP-**  
12 **PORT.**

13 For fiscal years 2003 and 2004, all of the informa-  
14 tion infrastructure grants provided by the National Tele-  
15 communications and Information Administration (under  
16 the program also known as the Technology Opportunities  
17 Program) shall be used to provide grants to health pro-  
18 viders to facilitate participation in the national public  
19 health communications and surveillance networks author-  
20 ized under section 319D(b)(3) of the Public Health Serv-  
21 ice Act.

1           **Subtitle D—Authorization of**  
2                           **Appropriations**

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

4           (a) IN GENERAL.—For the purpose of carrying out  
5 activities of the Department of Health and Human Serv-  
6 ices in accordance with the provisions referred to in sub-  
7 section (b), including making awards of grants, coopera-  
8 tive agreements, or contracts and providing other assist-  
9 ance to States and other public or private entities, there  
10 are authorized to be appropriated \$2,720,000,000 for fis-  
11 cal year 2002, and such sums as may be necessary for  
12 each of the fiscal years 2003 through 2006.

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

15                   (1) the provisions of this title;

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

18                   (3) title XXVIII of such Act; and

19                   (4) section 301 of such Act, to the extent that  
20 such section is used as the authority of the Sec-  
21 retary of Health and Human Services to carry out  
22 activities to supplement the activities carried out  
23 under the provisions referred to in paragraphs (1)  
24 through (3);

1 except that this section does not have any applicability  
2 with respect to the use of section 301 of such Act as au-  
3 thority for activities of the National Institutes of Health.

4 (c) FISCAL YEAR 2002.—

5 (1) IN GENERAL.—The aggregate amount of  
6 authorizations of appropriations under this title and  
7 under the Public Health Service Act for fiscal year  
8 2002 for the purpose described in subsection (a)  
9 does not exceed the amount specified for fiscal year  
10 2002 in such subsection, notwithstanding other au-  
11 thorizations of appropriations.

12 (2) ALLOCATIONS OF AUTHORIZATIONS.—Of  
13 the amount that is authorized to be appropriated  
14 under subsection (a) for fiscal year 2002, the fol-  
15 lowing authorizations of appropriations for such fis-  
16 cal year for the purpose described in such subsection  
17 apply:

18 (A) For making awards of grants, coopera-  
19 tive agreements, or contracts and providing  
20 other assistance to States and other public or  
21 private entities, \$1,000,000,000 is authorized,  
22 of which—

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

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

4           (iii) \$40,000,000 is authorized for  
5           grants or cooperative agreements under  
6           section 319H of the Public Health Service  
7           Act, as added by section 106 of this Act  
8           (relating to shortages of certain health pro-  
9           fessionals).

10           (B) For the national stockpile under sec-  
11           tion 121 of this Act, other than activities of the  
12           National Institutes of Health regarding small-  
13           pox vaccine, \$1,155,000,000 is authorized, of  
14           which \$509,000,000 is authorized for the acqui-  
15           sition of smallpox vaccine.

16           (C) For the Centers for Disease Control  
17           and Prevention, other than purposes to which  
18           the authorization established in subparagraph  
19           (A) applies, \$450,000,000, of which  
20           \$300,000,000 is authorized for facilities of such  
21           Centers for purposes described in section  
22           399D(c) of the Public Health Service Act.

23           (D) For activities on antimicrobial resist-  
24           ance under section 319E of such Act,  
25           \$25,000,000 is authorized.



1 **TITLE II—ENHANCING CON-**  
2 **TROLS ON DANGEROUS BIO-**  
3 **LOGICAL AGENTS AND TOX-**  
4 **INS**

5 **SEC. 201. REGULATION OF CERTAIN BIOLOGICAL AGENTS**  
6 **AND TOXINS.**

7 (a) BIOLOGICAL AGENTS PROVISIONS OF THE  
8 ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT  
9 OF 1996; CODIFICATION IN THE PUBLIC HEALTH SERV-  
10 ICE ACT, WITH AMENDMENTS.—

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

15 **“SEC. 351A. ENHANCED CONTROL OF DANGEROUS BIOLOGI-**  
16 **CAL AGENTS AND TOXINS.**

17 **“(a) REGULATORY CONTROL OF CERTAIN BIOLOGI-**  
18 **CAL AGENTS AND TOXINS.—**

19 **“(1) LIST OF BIOLOGICAL AGENTS AND TOX-**  
20 **INS.—**

21 **“(A) IN GENERAL.—**The Secretary shall by  
22 regulation establish and maintain a list of each  
23 biological agent and each toxin that has the po-  
24 tential to pose a severe threat to public health  
25 and safety.

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

4                   “(i) consider—

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

7                           “(II) the degree of contagious-  
8                           ness of the agent or toxin and the  
9                           methods by which the agent or toxin  
10                          is transferred to humans;

11                          “(III) the availability and effec-  
12                          tiveness of immunizations to prevent  
13                          and treatments for any illness result-  
14                          ing from infection by the agent or  
15                          toxin; and

16                          “(IV) any other criteria that the  
17                          Secretary considers appropriate; and

18                          “(ii) consult with scientific experts  
19                          representing appropriate professional  
20                          groups.

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

1       make such revisions as are appropriate to protect  
2       the public health and safety. In reviewing and revis-  
3       ing the list, the Secretary shall consider the needs  
4       of vulnerable populations, including children, and  
5       shall consult with appropriate Federal agencies and  
6       State and local public health officials.

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

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

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

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

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

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

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

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

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

15 “(d) REGISTRATION AND TRACEABILITY MECHA-  
16 NISMS; DATABASE.—Regulations under subsections (b)  
17 and (c) shall require registration of the possession, use,  
18 and transfer of biological agents and toxins listed pursu-  
19 ant to subsection (a)(1), and such registration shall in-  
20 clude (if available to the registered person) information  
21 regarding the characterization of such biological agents  
22 and toxins to facilitate their identification and traceability.  
23 The Secretary shall maintain a national database of the  
24 location of such agents and toxins, with information re-  
25 garding their characterizations.

1       “(e) INSPECTIONS.—The Secretary may conduct in-  
2       spections to ensure that persons subject to regulations  
3       under subsection (b) or (c) are in compliance with such  
4       regulations, including provisions regarding security and  
5       restrictions on access under subsection (g).

6       “(f) EXEMPTIONS.—The Secretary may establish ex-  
7       emptions from the applicability of provisions of regulations  
8       under subsection (b) or (c) if the Secretary determines  
9       that such exemptions are consistent with protecting the  
10      public health and safety. In the case of a clinical labora-  
11      tory that is in possession of a biological agent or toxin  
12      listed pursuant to subsection (a)(1), such an exemption  
13      may be provided only if such agent or toxin has been pre-  
14      sented for diagnosis, verification, or proficiency testing,  
15      and upon identification or verification of the agent or  
16      toxin, such laboratory—

17             “(1) promptly notifies the Secretary or other  
18             public health authorities when required under Fed-  
19             eral or State law; and

20             “(2) transfers or destroys the agent or toxin in  
21             accordance with such regulations.

22      “(g) SECURITY REQUIREMENTS FOR REGISTERED  
23      PERSONS.—

24             “(1) IN GENERAL.—In carrying out the provi-  
25             sions of subsections (b) and (c) that relate to safe-

1 guards, the Secretary, in consultation with the At-  
2 torney General, shall by regulation establish appro-  
3 priate security requirements for persons possessing,  
4 using, or transferring biological agents or toxins list-  
5 ed pursuant to subsection (a)(1), and ensure compli-  
6 ance with such requirements as a condition of reg-  
7 istration under subsection (b) or (c).

8 “(2) LIMITING ACCESS TO LISTED AGENTS AND  
9 TOXINS.—

10 “(A) IN GENERAL.—Regulations issued  
11 under subsections (b) and (c) shall include  
12 provisions—

13 “(i) to restrict access to biological  
14 agents and toxins listed pursuant to sub-  
15 section (a)(1) to only those individuals who  
16 have a legitimate need for access, as deter-  
17 mined according to the purposes for which  
18 the registration under such regulations is  
19 provided; and

20 “(ii) to ensure that individuals grant-  
21 ed such access are not—

22 “(I) restricted persons, as de-  
23 fined in section 175b of title 18,  
24 United States Code;

1                   “(II) named in a warrant issued  
2                   to a Federal or State law enforcement  
3                   agency for participation in any domes-  
4                   tic or international act of terrorism or  
5                   other act of violence;

6                   “(III) under investigation for in-  
7                   volvement with a domestic or inter-  
8                   national terrorist or criminal organi-  
9                   zation by any Federal law enforce-  
10                  ment or intelligence agency; or

11                  “(IV) suspected by any Federal  
12                  law enforcement or intelligence agency  
13                  of seeking to obtain covertly informa-  
14                  tion relating to biological agents or  
15                  toxins on behalf of the intelligence or  
16                  military operations of a foreign na-  
17                  tion.

18                  “(B) SCREENING PROTOCOL.—To carry  
19                  out subparagraph (A), the Secretary shall re-  
20                  quire that registered persons promptly submit  
21                  the names and other identifying information for  
22                  individuals described in subparagraph (A)(i) to  
23                  the Secretary and the Attorney General, with  
24                  which information the Attorney General shall  
25                  promptly use criminal, immigration, and na-

1           tional security databases available to the Fed-  
2           eral Government to identify whether such indi-  
3           viduals satisfy the conditions for access under  
4           subparagraph (A)(ii). The Secretary, in con-  
5           sultation with the Attorney General and other  
6           Federal agencies, shall periodically review and  
7           as appropriate revise the protocol for screening  
8           individuals for purposes of subparagraph (A),  
9           and may require by regulation additional  
10          screening measures if determined necessary to  
11          achieve the purposes of this section.

12          “(3) ASSISTANCE FOR CERTAIN ENTITIES.—  
13          The Secretary, in consultation with the Attorney  
14          General, may make awards of grants, contracts, or  
15          cooperative agreements to public and nonprofit pri-  
16          vate entities (other than Federal agencies), and may  
17          provide technical assistance to such entities, to im-  
18          prove security of the facilities of registered persons.

19          “(h) DISCLOSURE OF INFORMATION.—

20          “(1) IN GENERAL.—Any information in the  
21          possession of any Federal agency that identifies a  
22          person, or the geographic location of a person, who  
23          is registered pursuant to regulations under this sec-  
24          tion (including regulations promulgated before the  
25          effective date of this subsection), and any site-spe-



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

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

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

14 “(B) from making disclosures of such in-  
15 formation to any committee or subcommittee of  
16 the Congress with appropriate jurisdiction,  
17 upon request.

18 “(i) CIVIL MONEY PENALTY.—

19 “(1) IN GENERAL.—In addition to any other  
20 penalties that may apply under law, any person who  
21 violates any provision of regulations under sub-  
22 section (b) or (c) shall be subject to the United  
23 States for a civil money penalty in an amount not  
24 exceeding \$250,000 in the case of an individual and  
25 \$500,000 in the case of any other person.

1           “(2) APPLICABILITY OF CERTAIN PROVI-  
2           SIONS.—The provisions of section 1128A of the So-  
3           cial Security Act (other than subsections (a), (b),  
4           (h), and (i), the first sentence of subsection (c), and  
5           paragraphs (1) and (2) of subsection (f)) shall apply  
6           to a civil money penalty under paragraph (1) in the  
7           same manner as such provisions apply to a penalty  
8           or proceeding under section 1128A(a) of such Act.  
9           The Secretary may delegate authority under this  
10          subsection in the same manner as provided in sec-  
11          tion 1128A(j)(2) of the Social Security Act, and  
12          such authority shall include all powers as contained  
13          in section 6 of the Inspector General Act of 1978.

14          “(j) COORDINATION WITH REGULATIONS UNDER  
15          VIRUS-SERUM-TOXIN ACT.—

16                 “(1) IN GENERAL.—In establishing and enforce-  
17                 ing regulations under subsections (b) and (c), the  
18                 Secretary shall consult with the Secretary of Agri-  
19                 culture to ensure that such activities are coordi-  
20                 nated, to the greatest extent practicable, with regu-  
21                 lations governing certain biological agents and toxins  
22                 listed pursuant to subsection (a)(1) issued by the  
23                 Secretary of Agriculture under the Act commonly  
24                 known as the Virus-Serum-Toxin Act (the eighth  
25                 paragraph under the heading ‘Bureau of Animal In-

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

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

9 “(B) to minimize the administrative bur-  
10 den on persons subject to regulations under  
11 both this section and the VST Act;

12 “(C) to ensure the appropriate availability  
13 of such agents and toxins for legitimate agricul-  
14 tural or veterinary research, education, or other  
15 such purposes; and

16 “(D) to ensure the establishment of a na-  
17 tional database of such agents or toxins pursu-  
18 ant to subsection (d).

19 “(2) PERSONS REGULATED BY DEPARTMENT  
20 OF AGRICULTURE.—With respect to persons pos-  
21 sessed or using biological agents or toxins listed  
22 pursuant to subsection (a)(1) who, as of the date of  
23 enactment of the Public Health Security and Bioter-  
24 rorism Response Act of 2001, possess an unexpired,  
25 unrevoked, and unsuspended permit or license from

1 the Department of Agriculture for such possession  
2 or use, such persons may, for purposes of registra-  
3 tion under subsection (b) or (c), submit to the Sec-  
4 retary of Health and Human Services the same in-  
5 formation previously provided to the Secretary of  
6 Agriculture to obtain such permit or license, pro-  
7 vided that the information so submitted is accurate  
8 as of the time of submittal to the Secretary of  
9 Health and Human Services, and provided further  
10 that such Secretary may, after review of such sub-  
11 mission, request such additional information as the  
12 Secretary determines to be necessary to achieve the  
13 purposes of this section.

14 “(3) SAVINGS PROVISION.—Nothing in this sec-  
15 tion shall be construed as limiting any authority of  
16 the Secretary of Agriculture under the VST Act or  
17 any regulations issued thereunder.

18 “(k) DEFINITIONS.—For purposes of this section:

19 “(1) The terms ‘biological agent’ and ‘toxin’  
20 have the meanings given such terms in section 178  
21 of title 18, United States Code.

22 “(2) The term ‘registered person’ means a per-  
23 son registered under regulations under subsection  
24 (b) or (c).

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

5           (2) RELATION TO OTHER LAWS.—

6           (A) RULE OF CONSTRUCTION.—Regula-  
7 tions promulgated by the Secretary of Health  
8 and Human Services under section 511 of the  
9 Antiterrorism and Effective Death Penalty Act  
10 of 1996 are deemed to have been promulgated  
11 under section 351A of the Public Health Serv-  
12 ice Act, as added by paragraph (1) of this sub-  
13 section. Such regulations, including the list  
14 under subsection (d)(1) of such section 511,  
15 that were in effect on the day before the date  
16 of the enactment of this Act remain in effect  
17 until modified by the Secretary (including any  
18 revisions required under subsection (a)(2) of  
19 such section 351A).

20           (B) CONFORMING AMENDMENT.—Sub-  
21 sections (d), (e), (f), and (g) of section 511 of  
22 the Antiterrorism and Effective Death Penalty  
23 Act of 1996 (42 U.S.C. 262 note) are repealed.

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

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

4               (A) Not later than 30 days after the date  
5               of the enactment of this Act, the Secretary of  
6               Health and Human Services shall promulgate  
7               an interim final rule requiring all persons in  
8               possession of biological agents or toxins listed  
9               pursuant to subsection (a)(1) of such section  
10              (unless exempt under subsection (e) of such  
11              section) to provide notice to the Secretary of  
12              such possession, and to include in the notice  
13              such additional information as the Secretary  
14              may require for compliance with subsection (d)  
15              of such section or any other provision of such  
16              section, by not later than 30 days after the date  
17              on which such rule is promulgated. Such in-  
18              terim final rule takes effect on the date on  
19              which the rule is promulgated, except as fol-  
20              lows:

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

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

3           (ii) For purposes of subsection (i) of  
4           such section 351A (relating to civil pen-  
5           alties), the rule takes effect 60 days after  
6           the date on which the rule is promulgated.

7           (B) Not later than 120 days after the date  
8           of enactment of this Act, such Secretary shall  
9           promulgate an interim final rule for carrying  
10          out subsections (b) and (c) of such section  
11          351A. Such interim final rule takes effect 60  
12          days after the date on which the rule is promul-  
13          gated.

14          (4) EFFECTIVE DATE REGARDING DISCLOSURE  
15          OF INFORMATION.—Subsection (h) of section 351A  
16          of the Public Health Service Act, as added by para-  
17          graph (1) of this subsection, is deemed to have  
18          taken effect on the effective date of the  
19          Antiterrorism and Effective Death Penalty Act of  
20          1996.

21          (b) CRIMINAL PENALTIES REGARDING SELECT  
22          AGENTS.—

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

1 (A) by striking “(a)” and inserting  
2 “(a)(1)”;

3 (B) by transferring subsection (c) from the  
4 current placement of the subsection and insert-  
5 ing the subsection before subsection (b);

6 (C) by striking “(c)” and inserting “(2);

7 (D) by redesignating subsection (b) as sub-  
8 section (d); and

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

11 “(b) TRANSFER TO UNREGISTERED PERSON.—Who-  
12 ever knowingly transfers a select agent to a person without  
13 first verifying with the Secretary of Health and Human  
14 Services that the person has obtained a registration re-  
15 quired by regulations under subsection (b) or (c) of section  
16 351A of the Public Health Service Act shall be fined under  
17 this title, or imprisoned for not more than 5 years, or both.

18 “(c) UNREGISTERED FOR POSSESSION.—Whoever  
19 knowingly possesses a biological agent or toxin where such  
20 agent or toxin is a select agent for which such person has  
21 not obtained a registration required by regulations under  
22 section 351A(c) of the Public Health Service Act shall be  
23 fined under this title, or imprisoned for not more than  
24 5 years, or both.”.



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

3           (A) in section 175b (as added by section  
4 817 of Public Law 107–56 and amended by  
5 paragraph (1) of this subsection)—

6           (i) in subsection (d)(1), by striking  
7 “The term” and all that follows through  
8 “does not include” and inserting the fol-  
9 lowing: “The term ‘select agent’ means a  
10 biological agent or toxin to which sub-  
11 section (a) applies. Such term (including  
12 for purposes of subsection (a)) does not in-  
13 clude”; and

14           (ii) in the heading for the section, by  
15 striking “**Possession by restricted**  
16 **persons**” and inserting “**Select**  
17 **agents**”; and

18           (B) in the chapter analysis, in the item re-  
19 lating to section 175b, by striking “Possession  
20 by restricted persons.” and inserting “Select  
21 agents.”.

22           (3) TECHNICAL CORRECTIONS.—Chapter 10 of  
23 title 18, United States Code, as amended by section  
24 817 of Public Law 107–56 and paragraphs (1) and  
25 (2) of this subsection, is amended—

1 (A) in section 175—

2 (i) in subsection (a), in the second  
3 sentence, by striking “this section” and in-  
4 serting “this subsection”; and

5 (ii) in subsection (c), by striking “pro-  
6 tective” and all that follows and inserting  
7 “protective, bona fide research, or other  
8 peaceful purposes.”;

9 (B) in section 175b—

10 (i) in subsection (a)(1), by striking  
11 “described in subsection (b)” and all that  
12 follows and inserting the following: “shall  
13 ship or transport in or affecting interstate  
14 or foreign commerce, or possess in or af-  
15 fecting interstate or foreign commerce, any  
16 biological agent or toxin, or receive any bi-  
17 ological agent or toxin that has been  
18 shipped or transported in interstate or for-  
19 eign commerce, if the biological agent or  
20 toxin is listed as a select agent in Appen-  
21 dix A of part 72 of title 42, Code of Fed-  
22 eral Regulations, pursuant to section 351A  
23 of the Public Health Service Act, and is  
24 not exempted under subsection (h) of sec-  
25 tion 72.6, or Appendix A of part 72, of

1 title 42, Code of Federal Regulations.”;

2 and

3 (ii) in subsection (d)(3), by striking

4 “section 1010(a)(3)” and inserting “sec-

5 tion 101(a)(3)”;

6 (C) in section 176(a)(1)(A), by striking

7 “exists by reason of” and inserting “pertains

8 to”; and

9 (D) in section 178—

10 (i) in paragraph (1), by striking

11 “means any micro-organism” and all that

12 follows through “product, capable of” and

13 inserting the following: “means any micro-

14 organism (including, but not limited to,

15 bacteria, viruses, fungi, rickettsiae or pro-

16 tozoa), or infectious substance, or any nat-

17 urally occurring, bioengineered or syn-

18 thesized component of any such microorga-

19 nism or infectious substance, capable of”;

20 (ii) in paragraph (2), by striking

21 “means the toxic” and all that follows

22 through “including—” and inserting the

23 following: “means the toxic material or

24 product of plants, animals, microorganisms

25 (including, but not limited to, bacteria, vi-

1                   ruses, fungi, rickettsiae or protozoa), or in-  
2                   fectious substances, or a recombinant or  
3                   synthesized molecule, whatever their origin  
4                   and method of production, and includes—  
5                   ”; and

6                   (iii) in paragraph (4), by striking “re-  
7                   combinant molecule,” and all that follows  
8                   through “biotechnology,” and inserting  
9                   “recombinant or synthesized molecule.”

10                   (4) ADDITIONAL TECHNICAL CORRECTION.—

11                   Section 2332a of title 18, United States Code, is  
12                   amended—

13                   (A) in subsection (a), in the matter pre-  
14                   ceding paragraph (1), by striking “section  
15                   229F)” and all that follows through “section  
16                   178)—” and inserting “section 229F)—”; and

17                   (B) in subsection (c)(2)(C), by striking “a  
18                   disease organism” and inserting “a biological  
19                   agent, toxin, or vector (as those terms are de-  
20                   fined in section 178 of this title)”.

21                   (c) SECURITY UPGRADES AT THE DEPARTMENT OF  
22                   HEALTH AND HUMAN SERVICES.—For the purpose of en-  
23                   abling the Secretary of Health and Human Services to se-  
24                   cure existing facilities of the Department of Health and  
25                   Human Services where biological agents or toxins listed

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

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

11 (1) describes the extent to which there has been  
12 compliance by governmental and private entities  
13 with applicable regulations under section 351A of  
14 the Public Health Service Act (as added by sub-  
15 section (a) of this section), including the extent of  
16 compliance before the date of the enactment of this  
17 Act, and including the extent of compliance with  
18 regulations promulgated after such date of enact-  
19 ment;

20 (2) describes the actions to date and future  
21 plans of the Secretary for updating the list of bio-  
22 logical agents and toxins under such section 351A;

23 (3) describes the actions to date and future  
24 plans of the Secretary for determining compliance

1 with regulations under such section 351A and for  
2 taking appropriate enforcement actions; and

3 (4) provides any recommendations of the Sec-  
4 retary for administrative or legislative initiatives re-  
5 garding such section 351A.

6 **TITLE III—AMENDMENTS TO**  
7 **FEDERAL FOOD, DRUG, AND**  
8 **COSMETIC ACT**

9 **Subtitle A—Protection of Food**  
10 **Supply**

11 **SEC. 301. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
12 **TION OF FOOD.**

13 (a) INCREASING INSPECTIONS FOR DETECTION OF  
14 INTENTIONAL ADULTERATION OF FOOD.—Section 801 of  
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16 381) is amended by adding at the end the following sub-  
17 section:

18 “(h)(1) The Secretary shall give high priority to in-  
19 creasing the number of inspections under this section for  
20 the purpose of enabling the Secretary to inspect food of-  
21 fered for import at ports of entry into the United States,  
22 with the greatest priority given to inspections to detect  
23 the intentional adulteration of food.”.

24 (b) IMPROVEMENTS TO INFORMATION MANAGEMENT  
25 SYSTEMS.—Section 801(h) of the Federal Food, Drug,

1 and Cosmetic Act, as added by subsection (a) of this sec-  
2 tion, is amended by adding at the end the following para-  
3 graphs:

4       “(2) The Secretary shall give high priority to making  
5 necessary improvements to the information management  
6 systems of the Food and Drug Administration that con-  
7 tain information related to foods imported or offered for  
8 import into the United States for purposes of improving  
9 the ability of the Secretary to allocate resources, detect  
10 the intentional adulteration of food, and facilitate the im-  
11 portation of food that is in compliance with this Act.

12       “(3) The Secretary shall submit to the Committee on  
13 Energy and Commerce of the House of Representatives,  
14 and the Committee on Health, Education, Labor, and  
15 Pensions of the Senate, periodic reports describing the ac-  
16 tivities of the Secretary under paragraphs (1) and (2).”.

17       (c) TESTING FOR RAPID DETECTION OF INTEN-  
18 TIONAL ADULTERATION OF FOOD.—Section 801 of the  
19 Federal Food, Drug, and Cosmetic Act, as amended by  
20 subsection (a) of this section, is amended by adding at  
21 the end the following:

22       “(i)(1) For use in inspections of food under this sec-  
23 tion, the Secretary shall provide for research on the devel-  
24 opment of tests and sampling methodologies—

1           “(A) whose purpose is to test food in order  
2           to rapidly detect the adulteration of the food,  
3           with the greatest priority given to detect the in-  
4           tentional adulteration of food; and

5           “(B) whose results offer significant im-  
6           provements over the available technology in  
7           terms of accuracy, timing, or costs.

8           “(2) In providing for research under paragraph (1),  
9           the Secretary shall give priority to conducting research on  
10          the development of tests that are suitable for inspections  
11          of food at ports of entry into the United States.

12          “(3) In providing for research under paragraph (1),  
13          the Secretary shall as appropriate coordinate with the Di-  
14          rector of the Centers for Disease Control and Prevention,  
15          the Director of the National Institutes of Health, the Ad-  
16          ministrators of the Environmental Protection Agency, and  
17          the Secretary of Agriculture.

18          “(4) The Secretary shall annually submit to the Com-  
19          mittee on Energy and Commerce of the House of Rep-  
20          resentatives, and the Committee on Health, Education,  
21          Labor, and Pensions of the Senate, a report describing  
22          the progress made in research under paragraph (1), in-  
23          cluding progress regarding paragraph (2).”.

24          (d) ASSESSMENT OF THREAT OF INTENTIONAL  
25          ADULTERATION OF FOOD.—The Secretary of Health and



1 Human Services, acting through the Commissioner of  
2 Food and Drugs, shall ensure that, not later than six  
3 months after the date of the enactment of this Act—

4           (1) the assessment that (as of such date of en-  
5           actment) is being conducted on the threat of the in-  
6           tentional adulteration of food is completed; and

7           (2) a report describing the findings of the as-  
8           sessment is submitted to the Committee on Energy  
9           and Commerce of the House of Representatives and  
10          to the Committee on Health, Education, Labor, and  
11          Pensions of the Senate.

12          (e) **AUTHORIZATION OF APPROPRIATIONS.**—For the  
13          purpose of carrying out this section and the amendments  
14          made by this section, there are authorized to be appro-  
15          priated \$100,000,000 for fiscal year 2002, and such sums  
16          as may be necessary for each of the fiscal years 2003  
17          through 2006, in addition to other authorizations of ap-  
18          propriations that are available for such purpose.

19 **SEC. 302. ADMINISTRATIVE DETENTION.**

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

23               “(h) **ADMINISTRATIVE DETENTION OF FOODS.**—

24                       “(1) **DETENTION AUTHORITY.**—

1           “(A) IN GENERAL.—An officer or qualified  
2           employee of the Food and Drug Administration  
3           may order the detention, in accordance with  
4           this subsection, of any article of food that is  
5           found during an inspection, examination, or in-  
6           vestigation under this Act conducted by such  
7           officer or qualified employee, if the officer or  
8           qualified employee has credible evidence or in-  
9           formation indicating that such article presents  
10          a threat of serious adverse health consequences  
11          or death to humans or animals.

12          “(B) SECRETARY’S APPROVAL.—An article  
13          of food may be ordered detained under subpara-  
14          graph (A) only if the Secretary or an official  
15          designated by the Secretary approves the order.  
16          An official may not be so designated unless the  
17          official is the director of the district under this  
18          Act in which the article involved is located, or  
19          is an official senior to such director.

20          “(2) PERIOD OF DETENTION.—An article of  
21          food may be detained under paragraph (1) for a rea-  
22          sonable period, not to exceed 20 days, unless a  
23          greater period, not to exceed 30 days, is necessary,  
24          to enable the Secretary to institute an action under  
25          subsection (a) or section 302. The Secretary shall by

1 regulation provide for procedures for instituting such  
2 action on an expedited basis with respect to perish-  
3 able foods.

4 “(3) SECURITY OF DETAINED ARTICLE.—An  
5 order under paragraph (1) with respect to an article  
6 of food may require that such article be labeled or  
7 marked as detained, and may require that the article  
8 be removed to a secure facility. An article subject to  
9 such an order shall not be transferred by any person  
10 from the place at which the article is ordered de-  
11 tained, or from the place to which the article is so  
12 removed, as the case may be, until released by the  
13 Secretary or until the expiration of the detention pe-  
14 riod applicable under such order, whichever occurs  
15 first.

16 “(4) APPEAL OF DETENTION ORDER.—With re-  
17 spect to an article of food ordered detained under  
18 paragraph (1), any person who would be entitled to  
19 be a claimant for such article if the article were  
20 seized under subsection (a) may appeal the order to  
21 the Secretary. Within 72 hours after such an appeal  
22 is filed, the Secretary, after providing opportunity  
23 for an informal hearing, shall confirm or terminate  
24 the order involved, and such confirmation by the  
25 Secretary shall be considered a final agency action

1 for purposes of section 702 of title 5, United States  
2 Code. If during such 72-hour period the Secretary  
3 fails to provide such an opportunity, or to confirm  
4 or terminate such order, the order is deemed to be  
5 terminated.”.

6 (b) PROHIBITED ACT.—Section 301 of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
8 ed by adding at the end the following:

9 “(bb) The transfer of an article of food in violation  
10 of an order under section 304(h), or the removal or alter-  
11 ation of any mark or label required by the order to identify  
12 the article as detained.”.

13 (c) TEMPORARY HOLDS AT PORTS OF ENTRY.—Sec-  
14 tion 801 of the Federal Food, Drug, and Cosmetic Act,  
15 as amended by section 301(c) of this Act, is amended by  
16 adding at the end the following:

17 “(j)(1) If an officer or qualified employee of the Food  
18 and Drug Administration has credible evidence or infor-  
19 mation indicating that an article of food presents a threat  
20 of serious adverse health consequences or death to humans  
21 or animals, and such officer or qualified employee is un-  
22 able to inspect, examine, or investigate such article upon  
23 the article being offered for import at a port of entry into  
24 the United States, the officer or qualified employee shall  
25 request the Secretary of Treasury to hold the food at the

1 port of entry for a reasonable period of time, not to exceed  
2 24 hours, for the purpose of enabling the Secretary to in-  
3 spect, examine, or investigate the article as appropriate.

4 “(2) The Secretary shall request the Secretary of  
5 Treasury to remove an article held pursuant to paragraph  
6 (1) to a secure facility, as appropriate. During the period  
7 of time that such article is so held, the article shall not  
8 be transferred by any person from the port of entry into  
9 the United States for the article, or from the secure facil-  
10 ity to which the article has been removed, as the case may  
11 be.

12 “(3) An officer or qualified employee of the Food and  
13 Drug Administration may make a request under para-  
14 graph (1) only if the Secretary or an official designated  
15 by the Secretary approves the request. An official may not  
16 be so designated unless the official is the director of the  
17 district under this Act in which the article involved is lo-  
18 cated, or is an official senior to such director.

19 “(4) With respect to an article of food for which a  
20 request under paragraph (1) is made, the Secretary,  
21 promptly after the request is made, shall notify the State  
22 in which the port of entry involved is located that the re-  
23 quest has been made, and as applicable, that such article  
24 is being held under this subsection.”.

1 **SEC. 303. PERMISSIVE DEBARMENT REGARDING FOOD IM-**  
2 **PORTATION.**

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

6 (1) in paragraph (1)—

7 (A) in subparagraph (A), by striking “or”  
8 after the comma at the end;

9 (B) in subparagraph (B), by striking the  
10 period at the end and inserting “, or”; and

11 (C) by adding at the end the following sub-  
12 paragraph:

13 “(C) a person from importing an article of  
14 food or offering such an article for import into  
15 the United States.”;

16 (2) in paragraph (2), in the matter preceding  
17 subparagraph (A), by inserting “subparagraph (A)  
18 or (B) of” before “paragraph (1)”;

19 (3) by redesignating paragraph (3) as para-  
20 graph (4); and

21 (4) by inserting after paragraph (2) the fol-  
22 lowing paragraph:

23 “(3) PERSONS SUBJECT TO PERMISSIVE DE-  
24 BARMENT; FOOD IMPORTATION.—A person is subject  
25 to debarment under paragraph (1)(C) if—

1           “(A) the person has been convicted of a  
2           felony for conduct relating to the importation  
3           into the United States of any article of food; or

4           “(B)(i) the person has repeatedly imported  
5           or offered for import adulterated articles of  
6           food; and

7           “(ii) the person knew, or should have  
8           known, that such articles were adulterated.”.

9           (b) CONFORMING AMENDMENTS.—Section 306 of the  
10          Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a)  
11          is amended—

12           (1) in subsection (a), in the heading for the  
13          subsection, by striking “MANDATORY DEBAR-  
14          MENT.—” and inserting “MANDATORY DEBARMENT;  
15          CERTAIN DRUG APPLICATIONS.—”;

16           (2) in subsection (b)—

17           (A) in the heading for the subsection, by  
18          striking “PERMISSIVE DEBARMENT.—” and in-  
19          serting “PERMISSIVE DEBARMENT; CERTAIN  
20          DRUG APPLICATIONS; FOOD IMPORTS.—”; and

21           (B) in paragraph (2), in the heading for  
22          the paragraph, by striking “PERMISSIVE DE-  
23          BARMENT.—” and inserting “PERMISSIVE DE-  
24          BARMENT; CERTAIN DRUG APPLICATIONS.—”;

1           (3) in subsection (c)(2)(A)(iii), by striking  
2           “subsection (b)(2)” and inserting “paragraph (2) or  
3           (3) of subsection (b)”;

4           (4) in subsection (d)(3)—

5                 (A) in subparagraph (A)(i), by striking “or  
6                 (b)(2)(A)” and inserting “or paragraph (2)(A)  
7                 or (3) of subsection (b)”;

8                 (B) in subparagraph (A)(ii)(II), by insert-  
9                 ing “in applicable cases,” before “sufficient au-  
10                 dits”; and

11                 (C) in subparagraph (B), in each of  
12                 clauses (i) and (ii), by inserting “or subsection  
13                 (b)(3)” after “subsection (b)(2)(B)”.

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

17                 (1) in the first sentence—

18                         (A) by striking “and” after “subsection  
19                         (b)(2)”;

20                         (B) by inserting “, and subsection (b)(3)”  
21                         after “subsection (b)(2)(B)”;

22                 (2) in the second sentence, by inserting “, sub-  
23                 section (b)(3),” after “subsection (b)(2)(B)”.

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



1 302(b) of this Act, is amended by adding at the end the  
2 following:

3 “(cc) The importing or offering for import into the  
4 United States of an article of food by, with the assistance  
5 of, or at the direction of, a person debarred under section  
6 306(b)(1)(C).”.

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

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

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

13 “(a) RECORDS INSPECTION.—If the Secretary has  
14 credible evidence or information indicating that an article  
15 of food presents a threat of serious adverse health con-  
16 sequences or death to humans or animals, each person (ex-  
17 cluding farms and restaurants) who manufactures, proc-  
18 esses, packs, distributes, receives, holds, or imports such  
19 article shall, at the request of an officer or employee duly  
20 designated by the Secretary, permit such officer or em-  
21 ployee, upon presentation of appropriate credentials and  
22 a written notice to such person, at reasonable times and  
23 within reasonable limits and in a reasonable manner, to  
24 have access to and copy all records relating to such article  
25 that are needed to assist the Secretary in investigating

1 such credible evidence or information. The requirement  
2 under the preceding sentence applies to all records relating  
3 to the manufacture, processing, packing, distribution, re-  
4 ceipt, holding, or importation of such article maintained  
5 by or on behalf of such person in any format (including  
6 paper and electronic formats) and at any location.

7       “(b) REGULATIONS CONCERNING RECORD-  
8 KEEPING.—The Secretary, in consultation and coordina-  
9 tion, as appropriate, with other Federal departments and  
10 agencies with responsibilities for regulating food safety,  
11 may by regulation establish requirements regarding the  
12 maintenance of records by persons (excluding farms and  
13 restaurants) who manufacture, process, pack, transport,  
14 distribute, receive, hold, or import food, as may be nec-  
15 essary to trace the source and chain of distribution of food  
16 and its packaging in order to address credible threats of  
17 serious adverse health consequences or death to humans  
18 or animals. The Secretary shall take into account the size  
19 of a business in promulgating regulations under this sec-  
20 tion.

21       “(c) PROTECTION OF SENSITIVE INFORMATION.—  
22 The Secretary shall take appropriate measures to ensure  
23 that there are in effect effective procedures to prevent the  
24 unauthorized disclosure of any trade secret or confidential

1 information that is obtained by the Secretary pursuant to  
2 this section.

3 “(d) LIMITATIONS.—This section shall not be  
4 construed—

5 “(1) to limit the authority of the Secretary to  
6 inspect records or to require maintenance of records  
7 under any other provision of this Act;

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

16 “(3) to have any legal effect on section 552 of  
17 title 5, United States Code, or section 1905 of title  
18 18, United States Code; or

19 “(4) to extend to recipes for food, financial  
20 data, pricing data, personnel data, research data, or  
21 sales data (other than shipment data regarding  
22 sales).”.

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

1           (1) in paragraph (1), by inserting after the first  
2 sentence the following new sentence: “In the case of  
3 any person (excluding farms and restaurants) who  
4 manufactures, processes, packs, transports, distrib-  
5 utes, holds, or imports foods, the inspection shall ex-  
6 tend to all records and other information described  
7 in section 414 when the Secretary has credible evi-  
8 dence or information indicating that an article of  
9 food presents a threat of serious adverse health con-  
10 sequences or death to humans or animals, subject to  
11 the limitations established in section 414(d).”; and

12           (2) in paragraph (2), in the matter preceding  
13 subparagraph (A), by striking “second sentence”  
14 and inserting “third sentence”.

15       (c) PROHIBITED ACT.—Section 301(e) of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is  
17 amended—

18           (1) by striking “by section 412, 504, or 703”  
19 and inserting “by section 412, 414, 504, 703, or  
20 704(a)”; and

21           (2) by striking “under section 412” and insert-  
22 ing “under section 412, 414(b)”.

23 **SEC. 305. REGISTRATION.**

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

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

3 **“SEC. 415. REGISTRATION.**

4 “(a) REGISTRATION.—

5 “(1) IN GENERAL.—Any facility (excluding  
6 farms) engaged in manufacturing, processing, pack-  
7 ing, or holding food for consumption in the United  
8 States shall be registered with the Secretary. To be  
9 registered—

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

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

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

1 category (as identified under section 170.3 of title  
2 21, Code of Federal Regulations, or successor regu-  
3 lations) of any food manufactured, processed,  
4 packed, or held at such facility. The registrant shall  
5 notify the Secretary in a timely manner of changes  
6 to such information.

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

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

18 “(b) EXEMPTION.—The Secretary shall by regulation  
19 exempt types of retail establishments from the require-  
20 ments of subsection (a) only if the Secretary determines  
21 that the registration of such facilities is not needed for  
22 effective enforcement of this chapter and any regulations  
23 issued under this chapter.

24 “(c) FACILITY.—For purposes of this section, the  
25 term ‘facility’ includes any factory, warehouse, or estab-

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

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

9 (b) PROHIBITED ACTS.—

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

14 “(dd) The failure to register in accordance with sec-  
15 tion 415.”

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

19 “(t) If it is manufactured, processed, packed, or held  
20 in a facility that is not registered in accordance with sec-  
21 tion 415.”

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

1 (d) NOTICE.—Not later than 60 days after the date  
2 of the enactment of this Act, the Secretary of Health and  
3 Human Services, after consultation with appropriate State  
4 and local officials, shall take sufficient measures to notify  
5 entities that manufacture, process, pack, or hold food for  
6 consumption in the United States of the requirement pur-  
7 suant to this section that facilities be registered with the  
8 Secretary. The Secretary shall develop guidance, as need-  
9 ed, to identify facilities required to register under this sec-  
10 tion.

11 (e) ELECTRONIC FILING.—For the purpose of reduc-  
12 ing paperwork and reporting burdens, the Secretary of  
13 Health and Human Services may provide for, and encour-  
14 age the use of, electronic methods of submitting to the  
15 Secretary registrations required pursuant to this section.  
16 In providing for the electronic submission of such registra-  
17 tions, the Secretary shall ensure adequate authentication  
18 protocols are used to enable identification of the registrant  
19 and validation of the data as appropriate.

20 (f) SAVINGS CLAUSE.—This section may not be con-  
21 strued as authorizing the Secretary of Health and Human  
22 Services to impose any requirements with respect to a food  
23 to the extent that it is within the exclusive jurisdiction  
24 of the Secretary of Agriculture pursuant to the Federal  
25 Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry



1 Products Inspection Act (21 U.S.C. 451 et seq.), or the  
2 Egg Products Inspection Act (21 U.S.C. 1031 et seq).

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

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

8 “(k)(1) In the case of an article of food that is being  
9 imported or offered for import into the United States, the  
10 Secretary, after consultation with the Secretary of the  
11 Treasury, shall by regulation require, for the purpose of  
12 enabling such article to be inspected at ports of entry into  
13 the United States, the submission to the Secretary of a  
14 notice providing the identity of each of the following: The  
15 article; the manufacturer and shipper of the article, and  
16 if known within the specified period of time that notice  
17 is required to be provided, the grower of the article; the  
18 country from which the article originates; the country  
19 from which the article is shipped; and the anticipated port  
20 of entry for the article. An article of food imported or of-  
21 fered for import without submission of such notice in ac-  
22 cordance with regulations under this paragraph shall be  
23 refused admission into the United States. Nothing in this  
24 section may be construed as a limitation on the port of  
25 entry for an article of food.

1       “(2)(A) Regulations under paragraph (1) shall re-  
2       quire that a notice under such paragraph be provided by  
3       a specified period of time, not fewer than 24 hours, in  
4       advance of the time of the importation of the article of  
5       food involved or the offering of the food for import, except  
6       that the advance period so required may not exceed 72  
7       hours.

8       “(B)(i) If an article of food is being imported or of-  
9       fered for import into the United States and a notice under  
10      paragraph (1) is not provided in advance in accordance  
11      with subparagraph (A), such article shall be held at the  
12      port of entry for the article, and may not be delivered to  
13      the importer, owner, or consignee of the article, until such  
14      notice is submitted to the Secretary, and the Secretary  
15      examines the notice and determines that the notice is in  
16      accordance with regulations under paragraph (1). The  
17      preceding sentence may not be construed as authorizing  
18      such delivery pursuant to the execution of a bond, pending  
19      such a determination by the Secretary.

20      “(ii) In carrying out clause (i) with respect to an arti-  
21      cle of food, the Secretary shall determine whether there  
22      is in the possession of the Secretary any credible evidence  
23      or information indicating that such article presents a  
24      threat of serious adverse health consequences or death to  
25      humans or animals.

1 “(3)(A) This subsection may not be construed as lim-  
2 iting the authority of the Secretary to obtain information  
3 under any other provision of this Act.

4 “(B) This subsection may not be construed as au-  
5 thorizing the Secretary to impose any requirements with  
6 respect to a food to the extent that it is within the exclu-  
7 sive jurisdiction of the Secretary of Agriculture pursuant  
8 to the Federal Meat Inspection Act (21 U.S.C. 601 et  
9 seq.), the Poultry Products Inspection Act (21 U.S.C. 451  
10 et seq.), or the Egg Products Inspection Act (21 U.S.C.  
11 1031 et seq).”.

12 (b) PROHIBITED ACT.—Section 301 of the Federal  
13 Food, Drug, and Cosmetic Act, as amended by section  
14 305(b)(1) of this Act, is amended by adding at the end  
15 the following:

16 “(ee) The importing or offering for import into the  
17 United States of an article of food in violation of regula-  
18 tions under section 801(k).”.

19 **SEC. 307. AUTHORITY TO MARK ARTICLES REFUSED ADMIS-**  
20 **SION INTO UNITED STATES.**

21 (a) IN GENERAL.—Section 801 of the Federal Food,  
22 Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended  
23 by section 306(a) of this Act, is amended by adding at  
24 the end the following:

1       “(l)(1) If a food has been refused admission under  
2 subsection (a), other than such a food that is required to  
3 be destroyed, and the Secretary determines that the food  
4 presents a threat of serious adverse health consequences  
5 or death to humans or animals, the Secretary may require  
6 the owner or consignee of the food to affix to the container  
7 of the food a label that clearly and conspicuously bears  
8 the statement: ‘UNITED STATES: REFUSED  
9 ENTRY’.

10       “(2) All expenses in connection with affixing a label  
11 under paragraph (1) shall be paid by the owner or con-  
12 signee of the food involved, and in default of such pay-  
13 ment, shall constitute a lien against future importations  
14 made by such owner or consignee.

15       “(3) A requirement under paragraph (1) remains in  
16 effect until the Secretary determines that the food involved  
17 has been brought into compliance with this Act.”.

18       (b) MISBRANDED FOODS.—Section 403 of the Fed-  
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 343), as  
20 amended by section 305(b)(2) of this Act, is amended by  
21 adding at the end the following:

22       “(u) If it fails to bear a label required by the Sec-  
23 retary under section 801(l)(1) (relating to food refused ad-  
24 mission into the United States).”.

1 (c) RULE OF CONSTRUCTION.—With respect to arti-  
 2 cles of food that are imported or offered for import into  
 3 the United States, nothing in this section shall be con-  
 4 strued to limit the authority of the Secretary of Health  
 5 and Human Services or the Secretary of the Treasury to  
 6 require the marking of refused articles of food under any  
 7 other provision of law.

8 **SEC. 308. PROHIBITION AGAINST PORT SHOPPING FOR IM-**  
 9 **PORTATION.**

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

13 “(h) If it is an article of food imported or offered  
 14 for import into the United States and such article has pre-  
 15 viously been refused admission under section 801(a), un-  
 16 less the person reoffering the article affirmatively estab-  
 17 lishes, at the expense of the owner or consignee of the  
 18 article, that the article is not adulterated, as determined  
 19 by the Secretary.”.

20 **SEC. 309. NOTICES TO STATES REGARDING IMPORTED**  
 21 **FOOD.**

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

1 **“SEC. 908. NOTICES TO STATES REGARDING IMPORTED**  
2 **FOOD.**

3 “(a) IN GENERAL.—If the Secretary has credible evi-  
4 dence or information indicating that a shipment of im-  
5 ported food or portion thereof presents a threat of serious  
6 adverse health consequences or death to humans or ani-  
7 mals, the Secretary shall provide notice regarding such  
8 threat to the States in which the food is held or will be  
9 held, and to the States in which the manufacturer, packer,  
10 or distributor of the food is located, to the extent that  
11 the Secretary has knowledge of which States are so in-  
12 volved. In providing the notice to a State, the Secretary  
13 shall request the State to take such action as the State  
14 considers appropriate, if any, to protect the public health  
15 regarding the food involved.

16 “(b) RULE OF CONSTRUCTION.—Subsection (a) may  
17 not be construed as limiting the authority of the Secretary  
18 with respect to adulterated food under any other provision  
19 of this Act.”.

20 **SEC. 310. GRANTS TO STATES FOR INSPECTIONS; RE-**  
21 **SPONSE TO NOTICE REGARDING ADULTER-**  
22 **ATED IMPORTED FOOD.**

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

1 **“SEC. 909. GRANTS TO STATES REGARDING FOOD INSPEC-**  
2 **TIONS.**

3 “(a) IN GENERAL.—The Secretary may make grants  
4 to States and Territories for the purpose of conducting  
5 with respect to food examinations, inspections, investiga-  
6 tions, and related activities under section 702 through in-  
7 dividuals who, under subsection (a) of such section, are  
8 duly commissioned by the Secretary as officers of the De-  
9 partment.

10 “(b) NOTICES REGARDING ADULTERATED IM-  
11 PORTED FOOD.—The Secretary may make grants to the  
12 States for the purpose of assisting the States with the  
13 costs of taking appropriate action to protect the public  
14 health in response to notices under section 908, including  
15 planning and otherwise preparing to take such action.

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

20 **Subtitle B—Protection of Drug**  
21 **Supply**

22 **SEC. 311. ANNUAL REGISTRATION OF FOREIGN MANUFAC-**  
23 **TURERS; SHIPPING INFORMATION; DRUG**  
24 **AND DEVICE LISTING.**

25 (a) ANNUAL REGISTRATION; LISTING.—

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

4           (A) in subsection (i)(1)—

5           (i) by striking “Any establishment”  
6 and inserting “On or before December 31  
7 of each year, any establishment”;

8           (ii) by striking “establishment and the  
9 name” and inserting “establishment, the  
10 name”; and

11           (iii) by inserting before the period the  
12 following: “, the name of each importer of  
13 such drug or device in the United States  
14 that is known to the establishment, and  
15 the name of each carrier used by the estab-  
16 lishment in transporting such drug or de-  
17 vice to the United States for purposes of  
18 importation”; and

19           (B) in subsection (j)(1), in the first sen-  
20 tence, by striking “or (d)” and inserting “(d),  
21 or (i)”.

22           (2) MISBRANDING.—Section 502(o) of the Fed-  
23 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
24 352(o)) is amended by striking “in any State”.



1 (b) IMPORTATION; STATEMENT REGARDING REG-  
2 ISTRATION OF MANUFACTURER.—

3 (1) IN GENERAL.—Section 801 of the Federal  
4 Food, Drug, and Cosmetic Act, as amended by sec-  
5 tion 307(a) of this Act, is amended by adding at the  
6 end the following subsection:

7 “(m) A drug or device that is imported or offered  
8 for import into the United States may be refused admis-  
9 sion if the importer of the drug or device does not, at the  
10 time of offering the drug or device for import, submit to  
11 the Secretary a statement that identifies the registration  
12 under section 510(i) of each establishment that with re-  
13 spect to such drug or device is required under such section  
14 to register with the Secretary.”.

15 (2) PROHIBITED ACT.—Section 301 of the Fed-  
16 eral Food, Drug, and Cosmetic Act, as amended by  
17 section 306(b) of this Act, is amended by adding at  
18 the end the following:

19 “(ff) The importing or offering for import into the  
20 United States of a drug or device with respect to which  
21 there is a failure to comply with an order of the Secretary  
22 to submit to the Secretary a statement under section  
23 801(m).”.

24 (c) EFFECTIVE DATE.—The amendments made by  
25 this section take effect upon the expiration of the 180-

1 day period beginning on the date of the enactment of this  
2 Act.

3 **SEC. 312. REQUIREMENT OF ADDITIONAL INFORMATION**  
4 **REGARDING IMPORT COMPONENTS IN-**  
5 **TENDED FOR USE IN EXPORT PRODUCTS.**

6 (a) IN GENERAL.—Section 801(d)(3) of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)(3)) is  
8 amended to read as follows:

9 “(3)(A) Subject to subparagraph (B), no component  
10 of a drug, no component part or accessory of a device,  
11 or other article of device requiring further processing,  
12 which is ready or suitable for use for health-related pur-  
13 poses, and no article of a food additive, color additive, or  
14 dietary supplement, including a product in bulk form,  
15 shall be excluded from importation into the United States  
16 under subsection (a) if each of the following conditions  
17 is met:

18 “(i) The importer of such article of a drug or  
19 device or importer of such article of a food additive,  
20 color additive, or dietary supplement submits to the  
21 Secretary, at the time of initial importation, a state-  
22 ment in accordance with the following:

23 “(I) Such statement provides that such ar-  
24 ticle is intended to be further processed by the  
25 initial owner or consignee, or incorporated by

1 the initial owner or consignee, into a drug, bio-  
2 logical product, device, food, food additive, color  
3 additive, or dietary supplement that will be ex-  
4 ported by the initial owner or consignee from  
5 the United States in accordance with subsection  
6 (e) or section 802, or with section 351(h) of the  
7 Public Health Service Act.

8 “(II) The statement identifies the manu-  
9 facturer of such article and each processor,  
10 packer, distributor, carrier, or other entity that  
11 had possession of the article in the chain of  
12 possession of the article from the manufacturer  
13 to such importer of the article.

14 “(ii) If such article is known to be, or to con-  
15 tain or bear, any chemical substance or biological  
16 substance, the statement under clause (i) is accom-  
17 panied by such certificates of analysis as are nec-  
18 essary to identify each such substance.

19 “(iii) At the time of initial importation and be-  
20 fore the delivery of such article to the importer or  
21 the initial owner or consignee, such owner or con-  
22 signee executes a good and sufficient bond providing  
23 for the payment of such liquidated damages in the  
24 event of default as may be required pursuant to reg-  
25 ulations of the Secretary of the Treasury.

1           “(iv) Such article is used and exported by the  
2           initial owner or consignee in accordance with the in-  
3           tent described under clause (i)(I), except for any  
4           portions of the article that are destroyed.

5           “(v) The initial owner or consignee maintains  
6           records on the use or destruction of such article or  
7           portions thereof, as the case may be, and submits to  
8           the Secretary any such records requested by the Sec-  
9           retary.

10           “(vi) Upon request of the Secretary, the initial  
11           owner or consignee submits a report that provides  
12           an accounting of the exportation or destruction of  
13           such article or portions thereof, and the manner in  
14           which such owner or consignee complied with the re-  
15           quirements of this subparagraph.

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

22           “(C) This section may not be construed as affecting  
23           the responsibility of the Secretary to ensure that articles  
24           imported into the United States under authority of sub-

1 paragraph (A) meet each of the conditions established in  
2 such subparagraph for importation.”.

3 (b) PROHIBITED ACT.—Section 301(w) of the Fed-  
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(w))  
5 is amended to read as follows:

6 “(w) The making of a knowingly false statement in  
7 any statement, certificate of analysis, record, or report re-  
8 quired or requested under section 801(d)(3); the failure  
9 to submit a certificate of analysis as required under such  
10 section; the failure to maintain records or to submit  
11 records or reports as required by such section; the release  
12 into interstate commerce of any article or portion thereof  
13 imported into the United States under such section or any  
14 finished product made from such article or portion, except  
15 for export in accordance with section 801(e) or 802, or  
16 with section 351(h) of the Public Health Service Act; or  
17 the failure to so export or to destroy such an article or  
18 portions thereof, or such a finished product.”.

19 (c) EFFECTIVE DATE.—The amendments made by  
20 this section take effect upon the expiration of the 90-day  
21 period beginning on the date of the enactment of this Act.

1           **TITLE IV—DRINKING WATER**  
2                   **SECURITY AND SAFETY**

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

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

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

9   **“SEC. 1433. TERRORIST AND OTHER INTENTIONAL ACTS.**

10           “(a) **VULNERABILITY ASSESSMENTS.**—(1) Each  
11 community water system serving a population of greater  
12 than 3,300 persons shall conduct an assessment of the vul-  
13 nerability of its system to a terrorist attack or other inten-  
14 tional acts intended to substantially disrupt the ability of  
15 the system to provide a safe and reliable supply of drink-  
16 ing water. The vulnerability assessment shall include, but  
17 not be limited to, a review of pipes and constructed con-  
18 veyances, physical barriers, water collection, pretreatment,  
19 treatment, storage and distribution facilities, electronic,  
20 computer or other automated systems which are utilized  
21 by the public water system, the use, storage, or handling  
22 of various chemicals, and the operation and maintenance  
23 of such system. The Administrator, not later than March  
24 1, 2002, after consultation with appropriate departments  
25 and agencies of the Federal Government and with State

1 and local governments, shall provide baseline information  
2 to community water systems required to conduct vulner-  
3 ability assessments regarding which kinds of terrorist at-  
4 tacks or other intentional acts are the probable threats  
5 to—

6           “(A) substantially disrupt the ability of the sys-  
7 tem to provide a safe and reliable supply of drinking  
8 water; or

9           “(B) otherwise present significant public health  
10 concerns.

11       “(2) Each community water system referred to in  
12 paragraph (1) shall certify to the Administrator that the  
13 system has conducted an assessment complying with para-  
14 graph (1) prior to:

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

17           “(B) June 30, 2003, in the case of systems  
18 serving a population of 50,000 or more but less than  
19 100,000.

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

23       “(b) EMERGENCY RESPONSE PLAN.—Each commu-  
24 nity water system serving a population greater than 3,300  
25 shall prepare or revise, where necessary, an emergency re-

1 sponse plan that incorporates the results of vulnerability  
2 assessments that have been completed. Each such commu-  
3 nity water system shall certify to the Administrator, as  
4 soon as reasonably possible after the enactment of this  
5 section, but not later than 6 months after the completion  
6 of the vulnerability assessment under subsection (a), that  
7 the system has completed such plan. The emergency re-  
8 sponse plan shall include, but not be limited to, plans, pro-  
9 cedures, and identification of equipment that can be imple-  
10 mented or utilized in the event of a terrorist or other in-  
11 tentional attack on the public water system. The emer-  
12 gency response plan shall also include actions, procedures,  
13 and identification of equipment which can obviate or sig-  
14 nificantly lessen the impact of terrorist attacks or other  
15 intentional actions on the public health and the safety and  
16 supply of drinking water provided to communities and in-  
17 dividuals. Community water systems shall, to the extent  
18 possible, coordinate with existing Local Emergency Plan-  
19 ning Committees established under the Emergency Plan-  
20 ning and Community Right-to-Know Act (42 U.S.C.  
21 11001, et seq.) when preparing or revising an emergency  
22 response plan under this subsection.

23       “(c) GUIDANCE TO SMALL PUBLIC WATER SYS-  
24 TEMS.—The Administrator shall provide guidance to com-  
25 munity water systems serving a population of less than



1 3,300 persons on how to conduct vulnerability assess-  
2 ments, prepare emergency response plans, and address  
3 threats from terrorist attacks or other intentional actions  
4 designed to disrupt the provision of safe drinking water  
5 or significantly affect the public health or significantly af-  
6 fect the safety or supply of drinking water provided to  
7 communities and individuals.

8 “(d) FUNDING.—There are authorized to be appro-  
9 priated to carry out this section not more than  
10 \$120,000,000 for the fiscal year 2002 and such sums as  
11 may be necessary for fiscal year 2003 and fiscal year  
12 2004. The Administrator, in coordination with State and  
13 local governments, may provide financial assistance to  
14 community water systems for purposes of compliance with  
15 the requirements of subsections (a) and (b) and to commu-  
16 nity water systems for expenses and contracts designed  
17 to address basic security enhancements of critical impor-  
18 tance and significant threats to public health and the sup-  
19 ply of drinking water as determined by a vulnerability as-  
20 sessment under subsection (a).

21 **“SEC. 1434. CONTAMINANT PREVENTION, DETECTION AND**  
22 **RESPONSE.**

23 “(a) IN GENERAL.—The Administrator, in consulta-  
24 tion with the Centers for Disease Control and, after con-  
25 sultation with appropriate departments and agencies of

1 the Federal Government and with State and local govern-  
2 ments, shall review (or enter into contracts or cooperative  
3 agreements to provide for a review of) current and future  
4 methods to prevent, detect and respond to the intentional  
5 introduction of chemical, biological or radiological con-  
6 taminants into community water systems and source  
7 water for community water systems, including each of the  
8 following:

9           “(1) Methods, means and equipment designed  
10       to monitor and detect chemical, biological, and radi-  
11       ological contaminants and reduce the likelihood that  
12       such contaminants can be successfully introduced  
13       into water supplies intended to be used for drinking  
14       water.

15           “(2) Methods and means to provide sufficient  
16       notice to operators of public water systems, and in-  
17       dividuals served by such systems, of the introduction  
18       of chemical, biological or radiological contaminants  
19       and the possible effect of such introduction on public  
20       health and the safety and supply of drinking water.

21           “(3) Procedures and equipment necessary to  
22       prevent the flow of contaminated drinking water to  
23       individuals served by public water systems.

24           “(4) Methods, means, and equipment which  
25       could negate or mitigate deleterious effects on public

1 health and the safety and supply caused by the in-  
2 troduction of contaminants into water intended to be  
3 used for drinking water, including an examination of  
4 the effectiveness of various drinking water tech-  
5 nologies in removing, inactivating, or neutralizing bi-  
6 ological, chemical, and radiological contaminants.

7 “(5) Biomedical research into the short-term  
8 and long-term impact on public health of various  
9 chemical, biological and radiological contaminants  
10 that may be introduced into public water systems  
11 through terrorist or other intentional acts.

12 “(b) FUNDING.—For the authorization of appropria-  
13 tions to carry out this section, see section 1435(c).

14 **“SEC. 1435. SUPPLY DISRUPTION PREVENTION, DETECTION**  
15 **AND RESPONSE.**

16 “(a) DISRUPTION OF SUPPLY OR SAFETY.—The Ad-  
17 ministrator, in coordination with the appropriate depart-  
18 ments and agencies of the Federal Government, shall re-  
19 view (or enter into contracts or cooperative agreements to  
20 provide for a review of) methods and means by which ter-  
21 rorists or other individuals or groups could disrupt the  
22 supply of safe drinking water or take other actions against  
23 water collection, pretreatment, treatment, storage and dis-  
24 tribution facilities which could render such water signifi-

1 cantly less safe for human consumption, including each  
2 of the following:

3           “(1) Methods and means by which pipes and  
4           other constructed conveyances utilized in public  
5           water systems could be destroyed or otherwise pre-  
6           vented from providing adequate supplies of drinking  
7           water meeting applicable public health standards.

8           “(2) Methods and means by which collection,  
9           pretreatment, treatment, storage and distribution fa-  
10          cilities utilized or used in connection with public  
11          water systems and collection and pretreatment stor-  
12          age facilities used in connection with public water  
13          systems could be destroyed or otherwise prevented  
14          from providing adequate supplies of drinking water  
15          meeting applicable public health standards.

16          “(3) Methods and means by which pipes, con-  
17          structed conveyances, collection, pretreatment, treat-  
18          ment, storage and distribution systems that are uti-  
19          lized in connection with public water systems could  
20          be altered or affected so as to be subject to cross-  
21          contamination of drinking water supplies.

22          “(4) Methods and means by which pipes, con-  
23          structed conveyances, collection, pretreatment, treat-  
24          ment, storage and distribution systems that are uti-  
25          lized in connection with public water systems could

1 be reasonably protected from terrorist attacks or  
2 other acts intended to disrupt the supply or affect  
3 the safety of drinking water.

4 “(b) ALTERNATIVE SOURCES.—the review under this  
5 section shall also include a review of the methods and  
6 means by which alternative supplies of drinking water  
7 could be provided in the event of the destruction, impair-  
8 ment or contamination of public water systems.

9 “(c) FUNDING.—There are authorized to be appro-  
10 priated to carry out this section and section 1434 not  
11 more than \$15,000,000 for the fiscal year 2002 and such  
12 sums as may be necessary for fiscal year 2003 and fiscal  
13 year 2004.”.

14 (2) Section 1414(i)(1) is amended by inserting  
15 “1433” after “1417”.

16 (3) Section 1431 is amended by inserting in the  
17 first sentence after “drinking water” the following:  
18 “, or that there is a threatened or potential terrorist  
19 attack (or other intentional act designed to disrupt  
20 the provision of safe drinking water or to impact ad-  
21 versely the safety of drinking water supplied to com-  
22 munities and individuals), which”.

23 (4) Section 1432 is amended as follows:

24 (A) By striking “5 years” in subsection (a)  
25 and inserting “20 years”.

1 (B) By striking “3 years” in subsection (b)  
2 and inserting “10 years”.

3 (C) By striking “\$50,000” in subsection  
4 (c) and inserting “\$1,000,000”.

5 (D) By striking “\$20,000” in subsection  
6 (c) and inserting “\$100,000”.

7 (5) Section 1442 is amended as follows:

8 (A) By striking “this subparagraph” in  
9 subsection (b) and inserting “this subsection”.

10 (B) By amending subsection (d) to read as  
11 follows:

12 “(d) There are authorized to be appropriated to carry  
13 out subsection (b) not more than \$35,000,000 for the fis-  
14 cal year 2002 and such sums as may be necessary for each  
15 fiscal year thereafter.”.

○