

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

2 (a) **SHORT TITLE.**—This Act may be cited as the  
3 “Public Health Security and Bioterrorism Preparedness  
4 and Response Act of 2002”.

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

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

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

- Sec. 101. National preparedness and response.
- Sec. 102. Assistant Secretary for Public Health Emergency Preparedness; National Disaster Medical System.
- Sec. 103. Improving ability of Centers for Disease Control and Prevention.
- Sec. 104. Advisory committees and communications; study regarding communications abilities of public health agencies.
- 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 advance registration of health professions volunteers.
- Sec. 108. Working group.
- Sec. 109. Antimicrobial resistance.
- Sec. 110. Supplies and services in lieu of award funds.
- Sec. 111. Additional amendments.

Subtitle B—Strategic National Stockpile; Development of Priority  
Countermeasures

- Sec. 121. Strategic national stockpile.
- Sec. 122. Accelerated approval of priority countermeasures.
- Sec. 123. Issuance of rule on animal trials.
- 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—Improving State, Local, and Hospital Preparedness for and  
Response to Bioterrorism and Other Public Health Emergencies

- Sec. 131. Grants to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies.

Subtitle D—Emergency Authorities; Additional Provisions

- Sec. 141. Reporting deadlines.



- Sec. 142. Streamlining and clarifying communicable disease quarantine provisions.
- Sec. 143. Emergency waiver of Medicare, Medicaid, and SCHIP requirements.
- Sec. 144. Provision for expiration of public health emergencies.

Subtitle E—Additional Provisions

- Sec. 151. Designated State public emergency announcement plan.
- Sec. 152. Expanded research by Secretary of Energy.
- Sec. 153. Expanded research on worker health and safety.
- Sec. 154. Enhancement of emergency preparedness of Department of Veterans Affairs.
- Sec. 155. Reauthorization of existing program.
- Sec. 156. Sense of Congress.
- Sec. 157. General Accounting Office report.
- Sec. 158. Certain awards.
- Sec. 159. Public access defibrillation programs and public access defibrillation demonstration projects.

TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

Subtitle A—Department of Health and Human Services

- Sec. 201. Regulation of certain biological agents and toxins.
- Sec. 202. Implementation by Department of Health and Human Services.
- Sec. 203. Effective dates.
- Sec. 204. Conforming amendment.

Subtitle B—Department of Agriculture

- Sec. 211. Short title.
- Sec. 212. Regulation of certain biological agents and toxins.
- Sec. 213. Implementation by Department of Agriculture.

Subtitle C—Interagency Coordination Regarding Overlap Agents and Toxins

- Sec. 221. Interagency coordination.

Subtitle D—Criminal Penalties Regarding Certain Biological Agents and Toxins

- Sec. 231. Criminal penalties.

TITLE III—PROTECTING SAFETY AND SECURITY OF FOOD AND DRUG SUPPLY

Subtitle A—Protection of Food Supply

- Sec. 301. Food safety and security strategy.
- Sec. 302. Protection against adulteration of food.
- Sec. 303. Administrative detention.
- Sec. 304. Debarment for repeated or serious food import violations.
- Sec. 305. Registration of food facilities.
- Sec. 306. Maintenance and inspection of records for foods.
- Sec. 307. Prior notice of imported food shipments.
- Sec. 308. Authority to mark articles refused admission into United States.
- Sec. 309. Prohibition against port shopping.



- Sec. 310. Notices to States regarding imported food.
- Sec. 311. Grants to States for inspections.
- Sec. 312. Surveillance and information grants and authorities.
- Sec. 313. Surveillance of zoonotic diseases.
- Sec. 314. Authority to commission other Federal officials to conduct inspections.
- Sec. 315. Rule of construction.

Subtitle B—Protection of Drug Supply

- Sec. 321. Annual registration of foreign manufacturers; shipping information; drug and device listing.
- Sec. 322. Requirement of additional information regarding import components intended for use in export products.

Subtitle C—General Provisions Relating to Upgrade of Agricultural Security

- Sec. 331. Expansion of Animal and Plant Health Inspection Service activities.
- Sec. 332. Expansion of Food Safety Inspection Service activities.
- Sec. 333. Biosecurity upgrades at the Department of Agriculture.
- Sec. 334. Agricultural biosecurity.
- Sec. 335. Agricultural bioterrorism research and development.
- Sec. 336. Animal enterprise terrorism penalties.

TITLE IV—DRINKING WATER SECURITY AND SAFETY

- Sec. 401. Terrorist and other intentional acts.
- Sec. 402. Other Safe Drinking Water Act amendments.
- Sec. 403. Miscellaneous and technical amendments.

TITLE V—ADDITIONAL PROVISIONS

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- Sec. 501. Short title.
- Sec. 502. Findings.
- Sec. 503. Definitions.
- Sec. 504. Authority to assess and use drug fees.
- Sec. 505. Accountability and reports.
- Sec. 506. Reports of postmarketing studies.
- Sec. 507. Savings clause.
- Sec. 508. Effective date.
- Sec. 509. Sunset clause.

Subtitle B—Funding Provisions Regarding Food and Drug Administration

- Sec. 521. Office of Drug Safety.
- Sec. 522. Division of Drug Marketing, Advertising, and Communications.
- Sec. 523. Office of Generic Drugs.

Subtitle C—Additional Provisions

- Sec. 531. Transition to digital television.
- Sec. 532. 3-year delay in lock in procedures for Medicare+Choice plans; change in Medicare+Choice reporting deadlines and annual, coordinated election period for 2003, 2004, and 2005.



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

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

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

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

20 “(a) IN GENERAL.—

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



1 carrying out health-related activities to prepare for  
2 and respond effectively to bioterrorism and other  
3 public health emergencies, including the preparation  
4 of a plan under this section. The Secretary shall pe-  
5 riodically thereafter review and, as appropriate, re-  
6 vise the plan.

7 “(2) NATIONAL APPROACH.—In carrying out  
8 paragraph (1), the Secretary shall collaborate with  
9 the States toward the goal of ensuring that the ac-  
10 tivities of the Secretary regarding bioterrorism and  
11 other public health emergencies are coordinated with  
12 activities of the States, including local governments.

13 “(3) EVALUATION OF PROGRESS.—The plan  
14 under paragraph (1) shall provide for specific bench-  
15 marks and outcome measures for evaluating the  
16 progress of the Secretary and the States, including  
17 local governments, with respect to the plan under  
18 paragraph (1), including progress toward achieving  
19 the goals specified in subsection (b).

20 “(b) PREPAREDNESS GOALS.—The plan under sub-  
21 section (a) should include provisions in furtherance of the  
22 following:

23 “(1) Providing effective assistance to State and  
24 local governments in the event of bioterrorism or  
25 other public health emergency.



1           “(2) Ensuring that State and local governments  
2           have appropriate capacity to detect and respond ef-  
3           fectively to such emergencies, including capacities  
4           for the following:

5                   “(A) Effective public health surveillance  
6                   and reporting mechanisms at the State and  
7                   local levels.

8                   “(B) Appropriate laboratory readiness.

9                   “(C) Properly trained and equipped emer-  
10                  gency response, public health, and medical per-  
11                  sonnel.

12                  “(D) Health and safety protection of work-  
13                  ers responding to such an emergency.

14                  “(E) Public health agencies that are pre-  
15                  pared to coordinate health services (including  
16                  mental health services) during and after such  
17                  emergencies.

18                  “(F) Participation in communications net-  
19                  works that can effectively disseminate relevant  
20                  information in a timely and secure manner to  
21                  appropriate public and private entities and to  
22                  the public.

23           “(3) Developing and maintaining medical coun-  
24           termeasures (such as drugs, vaccines and other bio-  
25           logical products, medical devices, and other supplies)



1 against biological agents and toxins that may be in-  
2 volved in such emergencies.

3 “(4) Ensuring coordination and minimizing du-  
4 plication of Federal, State, and local planning, pre-  
5 paredness, and response activities, including during  
6 the investigation of a suspicious disease outbreak or  
7 other potential public health emergency.

8 “(5) Enhancing the readiness of hospitals and  
9 other health care facilities to respond effectively to  
10 such emergencies.

11 “(c) REPORTS TO CONGRESS.—

12 “(1) IN GENERAL.—Not later than one year  
13 after the date of the enactment of the Public Health  
14 Security and Bioterrorism Preparedness and Re-  
15 sponse Act of 2002, and biennially thereafter, the  
16 Secretary shall submit to the Committee on Energy  
17 and Commerce of the House of Representatives, and  
18 the Committee on Health, Education, Labor, and  
19 Pensions of the Senate, a report concerning progress  
20 with respect to the plan under subsection (a), includ-  
21 ing progress toward achieving the goals specified in  
22 subsection (b).

23 “(2) ADDITIONAL AUTHORITY.—Reports sub-  
24 mitted under paragraph (1) by the Secretary (other



1 than the first report) shall make recommendations  
2 concerning—

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

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

13 “(d) RULE OF CONSTRUCTION.—This section may  
14 not be construed as expanding or limiting any of the au-  
15 thorities of the Secretary that, on the day before the date  
16 of the enactment of the Public Health Security and Bio-  
17 terrorism Preparedness and Response Act of 2002, were  
18 in effect with respect to preparing for and responding ef-  
19 fectively to bioterrorism and other public health emer-  
20 gencies.”.

21 (b) OTHER REPORTS.—

22 (1) IN GENERAL.—Not later than one year  
23 after the date of the enactment of this Act, the Sec-  
24 retary of Health and Human Services (referred to in  
25 this subsection as the “Secretary”) shall submit to



1 the Committee on Energy and Commerce of the  
2 House of Representatives, and the Committee on  
3 Health, Education, Labor, and Pensions of the Sen-  
4 ate, a report concerning—

5 (A) the recommendations and findings of  
6 the National Advisory Committee on Children  
7 and Terrorism under section 319F(c)(2) of the  
8 Public Health Service Act;

9 (B) the recommendations and findings of  
10 the EPIC Advisory Committee under section  
11 319F(c)(3) of such Act;

12 (C) the characteristics that may render a  
13 rural community uniquely vulnerable to a bio-  
14 logical attack, including distance, lack of emer-  
15 gency transport, hospital or laboratory capacity,  
16 lack of integration of Federal or State public  
17 health networks, workforce deficits, or other rel-  
18 evant characteristics;

19 (D) the characteristics that may render  
20 areas or populations designated as medically  
21 underserved populations (as defined in section  
22 330 of such Act) uniquely vulnerable to a bio-  
23 logical attack, including significant numbers of  
24 low-income or uninsured individuals, lack of af-  
25 fordable and accessible health care services, in-



1 sufficient public and primary health care re-  
2 sources, lack of integration of Federal or State  
3 public health networks, workforce deficits, or  
4 other relevant characteristics;

5 (E) the recommendations of the Secretary  
6 with respect to additional legislative authority  
7 that the Secretary determines is necessary to  
8 effectively strengthen rural communities, or  
9 medically underserved populations (as defined  
10 in section 330 of such Act); and

11 (F) the need for and benefits of a National  
12 Disaster Response Medical Volunteer Service  
13 that would be a private-sector, community-  
14 based rapid response corps of medical volun-  
15 teers.

16 (2) STUDY REGARDING LOCAL EMERGENCY RE-  
17 SPONSE METHODS.—The Secretary shall conduct a  
18 study of effective methods for the provision of emer-  
19 gency response services through local governments  
20 (including through private response contractors and  
21 volunteers of such governments) in a consistent  
22 manner in response to acts of bioterrorism or other  
23 public health emergencies. Not later than 180 days  
24 after the date of the enactment of this Act, the Sec-  
25 retary shall submit to the Committee on Energy and



1 Commerce of the House of Representatives, and the  
2 Committee on Health, Education, Labor, and Pen-  
3 sions of the Senate, a report describing the findings  
4 of the study.

5 **SEC. 102. ASSISTANT SECRETARY FOR PUBLIC HEALTH**  
6 **EMERGENCY PREPAREDNESS; NATIONAL DIS-**  
7 **ASTER MEDICAL SYSTEM.**

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

11 **“Subtitle B—Emergency**  
12 **Preparedness and Response**

13 **“SEC. 2811. COORDINATION OF PREPAREDNESS FOR AND**  
14 **RESPONSE TO BIOTERRORISM AND OTHER**  
15 **PUBLIC HEALTH EMERGENCIES.**

16 “(a) ASSISTANT SECRETARY FOR PUBLIC HEALTH  
17 EMERGENCY PREPAREDNESS.—

18 “(1) IN GENERAL.—There is established within  
19 the Department of Health and Human Services the  
20 position of Assistant Secretary for Public Health  
21 Emergency Preparedness. The President shall ap-  
22 point an individual to serve in such position. Such  
23 Assistant Secretary shall report to the Secretary.

24 “(2) DUTIES.—Subject to the authority of the  
25 Secretary, the Assistant Secretary for Public Health



1       Emergency Preparedness shall carry out the fol-  
2       lowing duties with respect to bioterrorism and other  
3       public health emergencies:

4               “(A) Coordinate on behalf of the  
5       Secretary—

6               “(i) interagency interfaces between  
7       the Department of Health and Human  
8       Services (referred to in this paragraph as  
9       the ‘Department’) and other departments,  
10      agencies, and offices of the United States;  
11      and

12              “(ii) interfaces between the Depart-  
13      ment and State and local entities with re-  
14      sponsibility for emergency preparedness.

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

21              “(C) Coordinate the efforts of the Depart-  
22      ment to bolster State and local emergency pre-  
23      paredness for a bioterrorist attack or other pub-  
24      lic health emergency, and evaluate the progress  
25      of such entities in meeting the benchmarks and



1 other outcome measures contained in the na-  
2 tional plan and in meeting the core public  
3 health capabilities established pursuant to  
4 319A.

5 “(D) Any other duties determined appro-  
6 priate by the Secretary.

7 “(b) NATIONAL DISASTER MEDICAL SYSTEM.—

8 “(1) IN GENERAL.—The Secretary shall provide  
9 for the operation in accordance with this section of  
10 a system to be known as the National Disaster Med-  
11 ical System. The Secretary shall designate the As-  
12 sistant Secretary for Public Health Emergency Pre-  
13 paredness as the head of the National Disaster Med-  
14 ical System, subject to the authority of the Sec-  
15 retary.

16 “(2) FEDERAL AND STATE COLLABORATIVE  
17 SYSTEM.—

18 “(A) IN GENERAL.—The National Disaster  
19 Medical System shall be a coordinated effort by  
20 the Federal agencies specified in subparagraph  
21 (B), working in collaboration with the States  
22 and other appropriate public or private entities,  
23 to carry out the purposes described in para-  
24 graph (3).



1           “(B) PARTICIPATING FEDERAL AGEN-  
2           CIES.—The Federal agencies referred to in sub-  
3           paragraph (A) are the Department of Health  
4           and Human Services, the Federal Emergency  
5           Management Agency, the Department of De-  
6           fense, and the Department of Veterans Affairs.

7           “(3) PURPOSE OF SYSTEM.—

8           “(A) IN GENERAL.—The Secretary may  
9           activate the National Disaster Medical System  
10          to—

11           “(i) provide health services, health-re-  
12           lated social services, other appropriate  
13           human services, and appropriate auxiliary  
14           services to respond to the needs of victims  
15           of a public health emergency (whether or  
16           not determined to be a public health emer-  
17           gency under section 319); or

18           “(ii) be present at locations, and for  
19           limited periods of time, specified by the  
20           Secretary on the basis that the Secretary  
21           has determined that a location is at risk of  
22           a public health emergency during the time  
23           specified.

24           “(B) ONGOING ACTIVITIES.—The National  
25          Disaster Medical System shall carry out such



1 ongoing activities as may be necessary to pre-  
2 pare for the provision of services described in  
3 subparagraph (A) in the event that the Sec-  
4 retary activates the National Disaster Medical  
5 System for such purposes.

6 “(C) TEST FOR MOBILIZATION OF SYS-  
7 TEM.—During the one-year period beginning on  
8 the date of the enactment of the Public Health  
9 Security and Bioterrorism Preparedness and  
10 Response Act of 2002, the Secretary shall con-  
11 duct an exercise to test the capability and time-  
12 liness of the National Disaster Medical System  
13 to mobilize and otherwise respond effectively to  
14 a bioterrorist attack or other public health  
15 emergency that affects two or more geographic  
16 locations concurrently. Thereafter, the Sec-  
17 retary may periodically conduct such exercises  
18 regarding the National Disaster Medical Sys-  
19 tem as the Secretary determines to be appro-  
20 priate.

21 “(c) CRITERIA.—

22 “(1) IN GENERAL.—The Secretary shall estab-  
23 lish criteria for the operation of the National Dis-  
24 aster Medical System.



1           “(2) PARTICIPATION AGREEMENTS FOR NON-  
2 FEDERAL ENTITIES.—In carrying out paragraph (1),  
3 the Secretary shall establish criteria regarding the  
4 participation of States and private entities in the  
5 National Disaster Medical System, including criteria  
6 regarding agreements for such participation. The  
7 criteria shall include the following:

8           “(A) Provisions relating to the custody and  
9 use of Federal personal property by such enti-  
10 ties, which may in the discretion of the Sec-  
11 retary include authorizing the custody and use  
12 of such property to respond to emergency situa-  
13 tions for which the National Disaster Medical  
14 System has not been activated by the Secretary  
15 pursuant to subsection (b)(3)(A). Any such cus-  
16 tody and use of Federal personal property shall  
17 be on a reimbursable basis.

18           “(B) Provisions relating to circumstances  
19 in which an individual or entity has agreements  
20 with both the National Disaster Medical System  
21 and another entity regarding the provision of  
22 emergency services by the individual. Such pro-  
23 visions shall address the issue of priorities  
24 among the agreements involved.



1       “(d) INTERMITTENT DISASTER-RESPONSE PER-  
2 SONNEL.—

3               “(1) IN GENERAL.—For the purpose of assist-  
4 ing the National Disaster Medical System in car-  
5 rying out duties under this section, the Secretary  
6 may appoint individuals to serve as intermittent per-  
7 sonnel of such System in accordance with applicable  
8 civil service laws and regulations.

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



1       “(e) CERTAIN EMPLOYMENT ISSUES REGARDING  
2 INTERMITTENT APPOINTMENTS.—

3               “(1) INTERMITTENT DISASTER-RESPONSE AP-  
4       POINTEE.—For purposes of this subsection, the term  
5       ‘intermittent disaster-response appointee’ means an  
6       individual appointed by the Secretary under sub-  
7       section (d).

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



1 Code (regardless of whether the individuals receive  
2 compensation for such participation). In the event of  
3 an injury to such an intermittent disaster-response  
4 appointee, the Secretary of Labor shall be respon-  
5 sible for making determinations as to whether the  
6 claimant is entitled to compensation or other bene-  
7 fits in accordance with chapter 81 of title 5, United  
8 States Code.

9 “(3) EMPLOYMENT AND REEMPLOYMENT  
10 RIGHTS.—

11 “(A) IN GENERAL.—Service as an inter-  
12 mittent disaster-response appointee when the  
13 Secretary activates the National Disaster Med-  
14 ical System or when the individual participates  
15 in a training program authorized by the Assist-  
16 ant Secretary for Public Health Emergency  
17 Preparedness or a comparable official of any  
18 Federal agency specified in subsection (b)(2)(B)  
19 shall be deemed ‘service in the uniformed serv-  
20 ices’ for purposes of chapter 43 of title 38,  
21 United States Code, pertaining to employment  
22 and reemployment rights of individuals who  
23 have performed service in the uniformed serv-  
24 ices (regardless of whether the individual re-  
25 ceives compensation for such participation). All



1 rights and obligations of such persons and pro-  
2 cedures for assistance, enforcement, and inves-  
3 tigation shall be as provided for in chapter 43  
4 of title 38, United States Code.

5 “(B) NOTICE OF ABSENCE FROM POSITION  
6 OF EMPLOYMENT.—Preclusion of giving notice  
7 of service by necessity of Service as an intermit-  
8 tent disaster-response appointee when the Sec-  
9 retary activates the National Disaster Medical  
10 System shall be deemed preclusion by ‘military  
11 necessity’ for purposes of section 4312(b) of  
12 title 38, United States Code, pertaining to giv-  
13 ing notice of absence from a position of employ-  
14 ment. A determination of such necessity shall  
15 be made by the Secretary, in consultation with  
16 the Secretary of Defense, and shall not be sub-  
17 ject to judicial review.

18 “(4) LIMITATION.—An intermittent disaster-re-  
19 sponse appointee shall not be deemed an employee of  
20 the Department of Health and Human Services for  
21 purposes other than those specifically set forth in  
22 this section.

23 “(f) RULE OF CONSTRUCTION REGARDING USE OF  
24 COMMISSIONED CORPS.—If the Secretary assigns commis-  
25 sioned officers of the Regular or Reserve Corps to serve

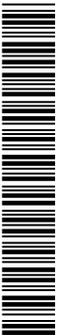


1 with the National Disaster Medical System, such assign-  
2 ments do not affect the terms and conditions of their ap-  
3 pointments as commissioned officers of the Regular or Re-  
4 serve Corps, respectively (including with respect to pay  
5 and allowances, retirement, benefits, rights, privileges, and  
6 immunities).

7 “(g) DEFINITION.—For purposes of this section, the  
8 term ‘auxiliary services’ includes mortuary services, veteri-  
9 nary services, and other services that are determined by  
10 the Secretary to be appropriate with respect to the needs  
11 referred to in subsection (b)(3)(A).

12 “(h) AUTHORIZATION OF APPROPRIATIONS.—For the  
13 purpose of providing for the Assistant Secretary for Public  
14 Health Emergency Preparedness and the operations of the  
15 National Disaster Medical System, other than purposes  
16 for which amounts in the Public Health Emergency Fund  
17 under section 319 are available, there are authorized to  
18 be appropriated such sums as may be necessary for each  
19 of the fiscal years 2002 through 2006.”.

20 (b) SENSE OF CONGRESS REGARDING RESOURCES  
21 OF NATIONAL DISASTER MEDICAL SYSTEM.—It is the  
22 sense of the Congress that the Secretary of Health and  
23 Human Services should provide sufficient resources to en-  
24 tities tasked to carry out the duties of the National Dis-  
25 aster Medical System for reimbursement of expenses, op-



1 erations, purchase and maintenance of equipment, train-  
2 ing, and other funds expended in furtherance of the Na-  
3 tional Disaster Medical System.

4 **SEC. 103. IMPROVING ABILITY OF CENTERS FOR DISEASE**  
5 **CONTROL AND PREVENTION.**

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

8 **“SEC. 319D. REVITALIZING THE CENTERS FOR DISEASE**  
9 **CONTROL AND PREVENTION.**

10 “(a) FACILITIES; CAPACITIES.—

11 “(1) FINDINGS.—Congress finds that the Cen-  
12 ters for Disease Control and Prevention has an es-  
13 sential role in defending against and combatting  
14 public health threats and requires secure and mod-  
15 ern facilities, and expanded and improved capabili-  
16 ties related to bioterrorism and other public health  
17 emergencies, sufficient to enable such Centers to  
18 conduct this important mission.

19 “(2) FACILITIES.—

20 “(A) IN GENERAL.—The Director of the  
21 Centers for Disease Control and Prevention  
22 may design, construct, and equip new facilities,  
23 renovate existing facilities (including labora-  
24 tories, laboratory support buildings, scientific  
25 communication facilities, transshipment com-



1           plexes, secured and isolated parking structures,  
2           office buildings, and other facilities and infra-  
3           structure), and upgrade security of such facili-  
4           ties, in order to better conduct the capacities  
5           described in section 319A, and for supporting  
6           public health activities.

7           “(B) MULTIYEAR CONTRACTING AUTHOR-  
8           ITY.—For any project of designing, con-  
9           structing, equipping, or renovating any facility  
10          under subparagraph (A), the Director of the  
11          Centers for Disease Control and Prevention  
12          may enter into a single contract or related con-  
13          tracts that collectively include the full scope of  
14          the project, and the solicitation and contract  
15          shall contain the clause ‘availability of funds’  
16          found at section 52.232–18 of title 48, Code of  
17          Federal Regulations.

18          “(3) IMPROVING THE CAPACITIES OF THE CEN-  
19          TERS FOR DISEASE CONTROL AND PREVENTION.—  
20          The Secretary, taking into account evaluations  
21          under section 319B(a), shall expand, enhance, and  
22          improve the capabilities of the Centers for Disease  
23          Control and Prevention relating to preparedness for  
24          and responding effectively to bioterrorism and other



1 public health emergencies. Activities that may be  
2 carried out under the preceding sentence include—

3 “(A) expanding or enhancing the training  
4 of personnel;

5 “(B) improving communications facilities  
6 and networks, including delivery of necessary  
7 information to rural areas;

8 “(C) improving capabilities for public  
9 health surveillance and reporting activities, tak-  
10 ing into account the integrated system or sys-  
11 tems of public health alert communications and  
12 surveillance networks under subsection (b); and

13 “(D) improving laboratory facilities related  
14 to bioterrorism and other public health emer-  
15 gencies, including increasing the security of  
16 such facilities.

17 “(b) NATIONAL COMMUNICATIONS AND SURVEIL-  
18 LANCE NETWORKS.—

19 “(1) IN GENERAL.—The Secretary, directly or  
20 through awards of grants, contracts, or cooperative  
21 agreements, shall provide for the establishment of an  
22 integrated system or systems of public health alert  
23 communications and surveillance networks between  
24 and among—



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

3           “(B) public and private health-related lab-  
4 oratories, hospitals, and other health care facili-  
5 ties; and

6           “(C) any other entities determined appro-  
7 priate by the Secretary.

8           “(2) REQUIREMENTS.—The Secretary shall en-  
9 sure that networks under paragraph (1) allow for  
10 the timely sharing and discussion, in a secure man-  
11 ner, of essential information concerning bioterrorism  
12 or another public health emergency, or recommended  
13 methods for responding to such an attack or emer-  
14 gency.

15           “(3) STANDARDS.—Not later than one year  
16 after the date of the enactment of the Public Health  
17 Security and Bioterrorism Preparedness and Re-  
18 sponse Act of 2002, the Secretary, in cooperation  
19 with health care providers and State and local public  
20 health officials, shall establish any additional tech-  
21 nical and reporting standards (including standards  
22 for interoperability) for networks under paragraph  
23 (1).

24           “(c) AUTHORIZATION OF APPROPRIATIONS.—

25           “(1) FACILITIES; CAPACITIES.—



1           “(A) FACILITIES.—For the purpose of car-  
2           rying out subsection (a)(2), there are author-  
3           ized to be appropriated \$300,000,000 for each  
4           of the fiscal years 2002 and 2003, and such  
5           sums as may be necessary for each of the fiscal  
6           years 2004 through 2006.

7           “(B) MISSION; IMPROVING CAPACITIES.—  
8           For the purposes of achieving the mission of  
9           the Centers for Disease Control and Prevention  
10          described in subsection (a)(1), for carrying out  
11          subsection (a)(3), for better conducting the ca-  
12          pacities described in section 319A, and for sup-  
13          porting public health activities, there are au-  
14          thorized to be appropriated such sums as may  
15          be necessary for each of the fiscal years 2002  
16          through 2006.

17          “(2) NATIONAL COMMUNICATIONS AND SUR-  
18          VEILLANCE NETWORKS.—For the purpose of car-  
19          rying out subsection (b), there are authorized to be  
20          appropriated such sums as may be necessary for  
21          each of the fiscal years 2002 through 2006.”.



1 **SEC. 104. ADVISORY COMMITTEES AND COMMUNICATIONS;**  
2 **STUDY REGARDING COMMUNICATIONS ABILI-**  
3 **TIES OF PUBLIC HEALTH AGENCIES.**

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

6 (1) by striking subsections (b) and (i);

7 (2) by redesignating subsections (c) through (h)  
8 as subsections (e) through (j), respectively; and

9 (3) by inserting after subsection (a) the fol-  
10 lowing subsections:

11 “(b) ADVICE TO THE FEDERAL GOVERNMENT.—

12 “(1) REQUIRED ADVISORY COMMITTEES.—In  
13 coordination with the working group under sub-  
14 section (a), the Secretary shall establish advisory  
15 committees in accordance with paragraphs (2) and  
16 (3) to provide expert recommendations to assist such  
17 working groups in carrying out their respective re-  
18 sponsibilities under subsections (a) and (b).

19 “(2) NATIONAL ADVISORY COMMITTEE ON  
20 CHILDREN AND TERRORISM.—

21 “(A) IN GENERAL.—For purposes of para-  
22 graph (1), the Secretary shall establish an advi-  
23 sory committee to be known as the National  
24 Advisory Committee on Children and Terrorism  
25 (referred to in this paragraph as the ‘Advisory  
26 Committee’).



1           “(B) DUTIES.—The Advisory Committee  
2 shall provide recommendations regarding—

3           “(i) the preparedness of the health  
4 care (including mental health care) system  
5 to respond to bioterrorism as it relates to  
6 children;

7           “(ii) needed changes to the health  
8 care and emergency medical service sys-  
9 tems and emergency medical services pro-  
10 tocols to meet the special needs of children;  
11 and

12           “(iii) changes, if necessary, to the na-  
13 tional stockpile under section 121 of the  
14 Public Health Security and Bioterrorism  
15 Preparedness and Response Act of 2002 to  
16 meet the emergency health security of chil-  
17 dren.

18           “(C) COMPOSITION.—The Advisory Com-  
19 mittee shall be composed of such Federal offi-  
20 cials as may be appropriate to address the spe-  
21 cial needs of the diverse population groups of  
22 children, and child health experts on infectious  
23 disease, environmental health, toxicology, and  
24 other relevant professional disciplines.



1           “(D) TERMINATION.—The Advisory Com-  
2           mittee terminates one year after the date of the  
3           enactment of the Public Health Security and  
4           Bioterrorism Preparedness and Response Act of  
5           2002.

6           “(3) EMERGENCY PUBLIC INFORMATION AND  
7           COMMUNICATIONS ADVISORY COMMITTEE.—

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

14          “(B) DUTIES.—The EPIC Advisory Com-  
15          mittee shall make recommendations to the Sec-  
16          retary and the working group under subsection  
17          (a) and report on appropriate ways to commu-  
18          nicate public health information regarding bio-  
19          terrorism and other public health emergencies  
20          to the public.

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



1           psychology, and other areas determined appro-  
2           priate by the Secretary.

3           “(D) DISSEMINATION.—The Secretary  
4           shall review the recommendations of the EPIC  
5           Advisory Committee and ensure that appro-  
6           priate information is disseminated to the public.

7           “(E) TERMINATION.—The EPIC Advisory  
8           Committee terminates one year after the date  
9           of the enactment of Public Health Security and  
10          Bioterrorism Preparedness and Response Act of  
11          2002.

12          “(c) STRATEGY FOR COMMUNICATION OF INFORMA-  
13          TION REGARDING BIOTERRORISM AND OTHER PUBLIC  
14          HEALTH EMERGENCIES.—In coordination with working  
15          group under subsection (a), the Secretary shall develop a  
16          strategy for effectively communicating information regard-  
17          ing bioterrorism and other public health emergencies, and  
18          shall develop means by which to communicate such infor-  
19          mation. The Secretary may carry out the preceding sen-  
20          tence directly or through grants, contracts, or cooperative  
21          agreements.

22          “(d) RECOMMENDATION OF CONGRESS REGARDING  
23          OFFICIAL FEDERAL INTERNET SITE ON BIOTER-  
24          RORISM.—It is the recommendation of Congress that there  
25          should be established an official Federal Internet site on



1 bioterrorism, either directly or through provision of a  
2 grant to an entity that has expertise in bioterrorism and  
3 the development of websites, that should include informa-  
4 tion relevant to diverse populations (including messages  
5 directed at the general public and such relevant groups  
6 as medical personnel, public safety workers, and agricul-  
7 tural workers) and links to appropriate State and local  
8 government sites.”.

9 (b) STUDY REGARDING COMMUNICATIONS ABILITIES  
10 OF PUBLIC HEALTH AGENCIES.—The Secretary of  
11 Health and Human Services, in consultation with the Fed-  
12 eral Communications Commission, the National Tele-  
13 communications and Information Administration, and  
14 other appropriate Federal agencies, shall conduct a study  
15 to determine whether local public health entities have the  
16 ability to maintain communications in the event of a bio-  
17 terrorist attack or other public health emergency. The  
18 study shall examine whether redundancies are required in  
19 the telecommunications system, particularly with respect  
20 to mobile communications, for public health entities to  
21 maintain systems operability and connectivity during such  
22 emergencies. The study shall also include recommenda-  
23 tions to industry and public health entities about how to  
24 implement such redundancies if necessary.



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(a)(2) of this Act, is amended  
5 to 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 of potential bioweapons and  
15 other agents that may create a public health  
16 emergency, and for the care of victims of such  
17 emergencies, recognizing the special needs of  
18 children and other vulnerable populations, to  
19 public health officials, medical professionals,  
20 emergency physicians and other emergency de-  
21 partment staff, laboratory personnel, and other  
22 personnel working in health care facilities (in-  
23 cluding poison control centers);

24 “(B) develop a core curriculum and mate-  
25 rials for community-wide planning by State and  
26 local governments, hospitals and other health



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

5 “(C) develop materials for proficiency test-  
6 ing of laboratory and other public health per-  
7 sonnel for the recognition and identification of  
8 potential bioweapons and other agents that may  
9 create a public health emergency; and

10 “(D) provide for dissemination and teach-  
11 ing of the materials described in subparagraphs  
12 (A) through (C) by appropriate means, which  
13 may include telemedicine, long-distance learn-  
14 ing, or other such means.

15 “(2) CERTAIN ENTITIES.—The entities through  
16 which education and training activities described in  
17 paragraph (1) may be carried out include Public  
18 Health Preparedness Centers, the Public Health  
19 Service’s Noble Training Center, the Emerging In-  
20 fections Program, the Epidemic Intelligence Service,  
21 the Public Health Leadership Institute, multi-State,  
22 multi-institutional consortia, other appropriate edu-  
23 cational entities, professional organizations and soci-  
24 eties, private accrediting organizations, and other



1 nonprofit institutions or entities meeting criteria es-  
2 tablished by the Secretary.

3 “(3) GRANTS AND CONTRACTS.—In carrying  
4 out paragraph (1), the Secretary may carry out ac-  
5 tivities directly and through the award of grants and  
6 contracts, and may enter into interagency coopera-  
7 tive agreements with other Federal agencies.

8 “(4) HEALTH-RELATED ASSISTANCE FOR  
9 EMERGENCY RESPONSE PERSONNEL TRAINING.—  
10 The Secretary, in consultation with the Attorney  
11 General and the Director of the Federal Emergency  
12 Management Agency, may provide technical assist-  
13 ance with respect to health-related aspects of emer-  
14 gency response personnel training carried out by the  
15 Department of Justice and the Federal Emergency  
16 Management Agency.”.

17 **SEC. 106. GRANTS REGARDING SHORTAGES OF CERTAIN**  
18 **HEALTH PROFESSIONALS.**

19 Part B of title III of the Public Health Service Act  
20 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
21 tion 319G the following section:



1 **“SEC. 319H. GRANTS REGARDING TRAINING AND EDU-**  
2 **CATION OF CERTAIN HEALTH PROFES-**  
3 **SIONALS.**

4 “(a) IN GENERAL.—The Secretary may make awards  
5 of grants and cooperative agreements to appropriate pub-  
6 lic and nonprofit private health or educational entities, in-  
7 cluding health professions schools and programs as de-  
8 fined in section 799B, for the purpose of providing low-  
9 interest loans, partial scholarships, partial fellowships, re-  
10 volving loan funds, or other cost-sharing forms of assist-  
11 ance for the education and training of individuals in any  
12 category of health professions for which there is a shortage  
13 that the Secretary determines should be alleviated in order  
14 to prepare for or respond effectively to bioterrorism and  
15 other public health emergencies.

16 “(b) AUTHORITY REGARDING NON-FEDERAL CON-  
17 TRIBUTIONS.—The Secretary may require as a condition  
18 of an award under subsection (a) that a grantee under  
19 such subsection provide non-Federal contributions toward  
20 the purpose described in such subsection.

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



1 **SEC. 107. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**  
2 **TION OF HEALTH PROFESSIONS VOLUN-**  
3 **TEERS.**

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

7 **“SEC. 319I. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**  
8 **TION OF HEALTH PROFESSIONS VOLUN-**  
9 **TEERS.**

10 “(a) IN GENERAL.—The Secretary shall, directly or  
11 through an award of a grant, contract, or cooperative  
12 agreement, establish and maintain a system for the ad-  
13 vance registration of health professionals for the purpose  
14 of verifying the credentials, licenses, accreditations, and  
15 hospital privileges of such professionals when, during pub-  
16 lic health emergencies, the professionals volunteer to pro-  
17 vide health services (referred to in this section as the ‘ver-  
18 ification system’). In carrying out the preceding sentence,  
19 the Secretary shall provide for an electronic database for  
20 the verification system.

21 “(b) CERTAIN CRITERIA.—The Secretary shall estab-  
22 lish provisions regarding the promptness and efficiency of  
23 the system in collecting, storing, updating, and dissemi-  
24 nating information on the credentials, licenses, accredita-  
25 tions, and hospital privileges of volunteers described in  
26 subsection (a).



1           “(c) OTHER ASSISTANCE.—The Secretary may make  
2 grants and provide technical assistance to States and  
3 other public or nonprofit private entities for activities re-  
4 lating to the verification system developed under sub-  
5 section (a).

6           “(d) COORDINATION AMONG STATES.—The Sec-  
7 retary may encourage each State to provide legal authority  
8 during a public health emergency for health professionals  
9 authorized in another State to provide certain health serv-  
10 ices to provide such health services in the State.

11          “(e) RULE OF CONSTRUCTION.—This section may  
12 not be construed as authorizing the Secretary to issue re-  
13 quirements regarding the provision by the States of cre-  
14 dentials, licenses, accreditations, or hospital privileges.

15          “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
16 purpose of carrying out this section, there are authorized  
17 to be appropriated \$2,000,000 for fiscal year 2002, and  
18 such sums as may be necessary for each of the fiscal years  
19 2003 through 2006.”.

20 **SEC. 108. WORKING GROUP.**

21          Section 319F of the Public Health Service Act, as  
22 amended by section 104(a), is amended by striking sub-  
23 section (a) and inserting the following:

24          “(a) WORKING GROUP ON BIOTERRORISM AND  
25 OTHER PUBLIC HEALTH EMERGENCIES.—



1           “(1) IN GENERAL.—The Secretary, in coordina-  
2           tion with the Secretary of Agriculture, the Attorney  
3           General, the Director of Central Intelligence, the  
4           Secretary of Defense, the Secretary of Energy, the  
5           Administrator of the Environmental Protection  
6           Agency, the Director of the Federal Emergency  
7           Management Agency, the Secretary of Labor, the  
8           Secretary of Veterans Affairs, and with other similar  
9           Federal officials as determined appropriate, shall es-  
10          tablish a working group on the prevention, prepared-  
11          ness, and response to bioterrorism and other public  
12          health emergencies. Such joint working group, or  
13          subcommittees thereof, shall meet periodically for  
14          the purpose of consultation on, assisting in, and  
15          making recommendations on—

16                 “(A) responding to a bioterrorist attack,  
17                 including the provision of appropriate safety  
18                 and health training and protective measures for  
19                 medical, emergency service, and other personnel  
20                 responding to such attacks;

21                 “(B) prioritizing countermeasures required  
22                 to treat, prevent, or identify exposure to a bio-  
23                 logical agent or toxin pursuant to section 351A;

24                 “(C) facilitation of the awarding of grants,  
25                 contracts, or cooperative agreements for the de-



1           velopment, manufacture, distribution, supply-  
2           chain management, and purchase of priority  
3           countermeasures;

4           “(D) research on pathogens likely to be  
5           used in a biological threat or attack on the civil-  
6           ian population;

7           “(E) development of shared standards for  
8           equipment to detect and to protect against bio-  
9           logical agents and toxins;

10          “(F) assessment of the priorities for and  
11          enhancement of the preparedness of public  
12          health institutions, providers of medical care,  
13          and other emergency service personnel (includ-  
14          ing firefighters) to detect, diagnose, and re-  
15          spond (including mental health response) to a  
16          biological threat or attack;

17          “(G) in the recognition that medical and  
18          public health professionals are likely to provide  
19          much of the first response to such an attack,  
20          development and enhancement of the quality of  
21          joint planning and training programs that ad-  
22          dress the public health and medical con-  
23          sequences of a biological threat or attack on the  
24          civilian population between—



1                   “(i) local firefighters, ambulance per-  
2                   sonnel, police and public security officers,  
3                   or other emergency response personnel;  
4                   and

5                   “(ii) hospitals, primary care facilities,  
6                   and public health agencies;

7                   “(H) development of strategies for Fed-  
8                   eral, State, and local agencies to communicate  
9                   information to the public regarding biological  
10                  threats or attacks;

11                  “(I) ensuring that the activities under this  
12                  subsection address the health security needs of  
13                  children and other vulnerable populations;

14                  “(J) strategies for decontaminating facili-  
15                  ties contaminated as a result of a biological at-  
16                  tack, including appropriate protections for the  
17                  safety of workers conducting such activities;

18                  “(K) subject to compliance with other pro-  
19                  visions of Federal law, clarifying the respon-  
20                  sibilities among Federal officials for the inves-  
21                  tigation of suspicious outbreaks of disease and  
22                  other potential public health emergencies, and  
23                  for related revisions of the interagency plan  
24                  known as the Federal response plan; and



1           “(L) in consultation with the National  
2 Highway Traffic Safety Administration and the  
3 U.S. Fire Administration, ways to enhance co-  
4 ordination among Federal agencies involved  
5 with State, local, and community based emer-  
6 gency medical services, including issuing a re-  
7 port that—

8                   “(i) identifies needs of community-  
9 based emergency medical services; and

10                   “(ii) identifies ways to streamline and  
11 enhance the process through which Federal  
12 agencies support community-based emer-  
13 gency medical services.

14           “(2) CONSULTATION WITH EXPERTS.—In car-  
15 rying out subparagraphs (B) and (C) of paragraph  
16 (1), the working group under such paragraph shall  
17 consult with the pharmaceutical, biotechnology, and  
18 medical device industries, and other appropriate ex-  
19 perts.

20           “(3) USE OF SUBCOMMITTEES REGARDING  
21 CONSULTATION REQUIREMENTS.—With respect to a  
22 requirement under law that the working group under  
23 paragraph (1) be consulted on a matter, the working  
24 group may designate an appropriate subcommittee  
25 of the working group to engage in the consultation.



1           “(4) DISCRETION IN EXERCISE OF DUTIES.—  
2           Determinations made by the working group under  
3           paragraph (1) with respect to carrying out duties  
4           under such paragraph are matters committed to  
5           agency discretion for purposes of section 701(a) of  
6           title 5, Unites States Code.

7           “(5) RULE OF CONSTRUCTION.—This sub-  
8           section may not be construed as establishing new  
9           regulatory authority for any of the officials specified  
10          in paragraph (1), or as having any legal effect on  
11          any other provision of law, including the responsibil-  
12          ities and authorities of the Environmental Protection  
13          Agency.”.

14 **SEC. 109. ANTIMICROBIAL RESISTANCE.**

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

17                 (1) in subsection (b)—

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

23                         (B) by amending paragraph (4) to read as  
24                         follows:



1           “(4) the sequencing of the genomes, or other  
2           DNA analysis, or other comparative analysis, of pri-  
3           ority pathogens (as determined by the Director of  
4           the National Institutes of Health in consultation  
5           with the task force established under subsection (a)),  
6           in collaboration and coordination with the activities  
7           of the Department of Defense and the Joint Genome  
8           Institute of the Department of Energy; and”;

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

12          (3) in subsection (g), by striking “and such  
13          sums” and all that follows and inserting the fol-  
14          lowing: “\$25,000,000 for each of the fiscal years  
15          2002 and 2003, and such sums as may be necessary  
16          for each of the fiscal years 2004 through 2006.”.

17 **SEC. 110. SUPPLIES AND SERVICES IN LIEU OF AWARD**  
18 **FUNDS.**

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

22 **“SEC. 319J. SUPPLIES AND SERVICES IN LIEU OF AWARD**  
23 **FUNDS**

24          “(a) IN GENERAL.—Upon the request of a recipient  
25          of an award under any of sections 319 through 319I or



1 section 319K, the Secretary may, subject to subsection  
2 (b), provide supplies, equipment, and services for the pur-  
3 pose of aiding the recipient in carrying out the purposes  
4 for which the award is made and, for such purposes, may  
5 detail to the recipient any officer or employee of the De-  
6 partment of Health and Human Services.

7 “(b) CORRESPONDING REDUCTION IN PAYMENTS.—  
8 With respect to a request described in subsection (a), the  
9 Secretary shall reduce the amount of payments under the  
10 award involved by an amount equal to the costs of detail-  
11 ing personnel and the fair market value of any supplies,  
12 equipment, or services provided by the Secretary. The Sec-  
13 retary shall, for the payment of expenses incurred in com-  
14 plying with such request, expend the amounts withheld.”.

15 **SEC. 111. ADDITIONAL AMENDMENTS.**

16 Part B of title III of the Public Health Service Act  
17 (42 U.S.C. 243 et seq) is amended—

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

20 (2) in section 319B(a), in the first sentence, by  
21 striking “10 years” and inserting “five years”; and

22 (3) in section 391F(e)(2), as redesignated by  
23 section 104(a)(2) of this Act—

24 (A) by striking “or” after “clinic,”; and



1 (B) by inserting before the period fol-  
2 lowing: “, professional organization or society,  
3 school or program that trains medical labora-  
4 tory personnel, private accrediting organization,  
5 or other nonprofit private institution or entity  
6 meeting criteria established by the Secretary”.

7 **Subtitle B—Strategic National**  
8 **Stockpile; Development of Pri-**  
9 **ority Countermeasures**

10 **SEC. 121. STRATEGIC NATIONAL STOCKPILE.**

11 (a) STRATEGIC NATIONAL STOCKPILE.—

12 (1) IN GENERAL.—The Secretary of Health and  
13 Human Services (referred to in this section as the  
14 “Secretary”), in coordination with the Secretary of  
15 Veterans Affairs, shall maintain a stockpile or stock-  
16 piles of drugs, vaccines and other biological prod-  
17 ucts, medical devices, and other supplies in such  
18 numbers, types, and amounts as are determined by  
19 the Secretary to be appropriate and practicable, tak-  
20 ing into account other available sources, to provide  
21 for the emergency health security of the United  
22 States, including the emergency health security of  
23 children and other vulnerable populations, in the  
24 event of a bioterrorist attack or other public health  
25 emergency.



1           (2) PROCEDURES.—The Secretary, in managing  
2           the stockpile under paragraph (1), shall—

3                   (A) consult with the working group under  
4                   section 319F(a) of the Public Health Service  
5                   Act;

6                   (B) ensure that adequate procedures are  
7                   followed with respect to such stockpile for in-  
8                   ventory management and accounting, and for  
9                   the physical security of the stockpile;

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

13                  (D) review and revise, as appropriate, the  
14                  contents of the stockpile on a regular basis to  
15                  ensure that emerging threats, advanced tech-  
16                  nologies, and new countermeasures are ade-  
17                  quately considered;

18                  (E) devise plans for the effective and time-  
19                  ly supply-chain management of the stockpile, in  
20                  consultation with appropriate Federal, State  
21                  and local agencies, and the public and private  
22                  health care infrastructure; and

23                  (F) ensure the adequate physical security  
24                  of the stockpile.

25           (b) SMALLPOX VACCINE DEVELOPMENT.—



1           (1) IN GENERAL.—The Secretary shall award  
2           contracts, enter into cooperative agreements, or  
3           carry out such other activities as may reasonably be  
4           required in order to ensure that the stockpile under  
5           subsection (a) includes an amount of vaccine against  
6           smallpox as determined by the Secretary to be suffi-  
7           cient to meet the health security needs of the United  
8           States.

9           (2) RULE OF CONSTRUCTION.—Nothing in this  
10          section shall be construed to limit the private dis-  
11          tribution, purchase, or sale of vaccines from sources  
12          other than the stockpile described in subsection (a).

13          (c) DISCLOSURES.—No Federal agency shall disclose  
14          under section 552, United States Code, any information  
15          identifying the location at which materials in the stockpile  
16          under subsection (a) are stored.

17          (d) DEFINITION.—For purposes of subsection (a),  
18          the term “stockpile” includes—

19                (1) a physical accumulation (at one or more lo-  
20                cations) of the supplies described in subsection (a);  
21                or

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



1 (e) AUTHORIZATION OF APPROPRIATIONS.—

2 (1) STRATEGIC NATIONAL STOCKPILE.—For the  
3 purpose of carrying out subsection (a), there are au-  
4 thorized to be appropriated \$640,000,000 for fiscal  
5 year 2002, and such sums as may be necessary for  
6 each of fiscal years 2003 through 2006.

7 (2) SMALLPOX VACCINE DEVELOPMENT.—For  
8 the purpose of carrying out subsection (b), there are  
9 authorized to be appropriated \$509,000,000 for fis-  
10 cal year 2002, and such sums as may be necessary  
11 for each of fiscal years 2003 through 2006.

12 **SEC. 122. ACCELERATED APPROVAL OF PRIORITY COUN-**  
13 **TERMEASURES.**

14 (a) IN GENERAL.—The Secretary of Health and  
15 Human Services may designate a priority countermeasure  
16 as a fast-track product pursuant to section 506 of the  
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356)  
18 or as a device granted review priority pursuant to section  
19 515(d)(5) of such Act (21 U.S.C. 360e(d)(5)). Such a des-  
20 ignation may be made prior to the submission of—

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

23 (2) an application for the investigation of the  
24 drug under section 505(i) of such Act or section  
25 351(a)(3) of the Public Health Service Act.



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

3 (b) USE OF ANIMAL TRIALS.—A drug for which ap-  
4 proval is sought under section 505(b) of the Federal Food,  
5 Drug, and Cosmetic Act or section 351 of the Public  
6 Health Service Act on the basis of evidence of effectiveness  
7 that is derived from animal studies pursuant to section  
8 123 may be designated as a fast track product for pur-  
9 poses of this section.

10 (c) PRIORITY REVIEW OF DRUGS AND BIOLOGICAL  
11 PRODUCTS.—A priority countermeasure that is a drug or  
12 biological product shall be considered a priority drug or  
13 biological product for purposes of performance goals for  
14 priority drugs or biological products agreed to by the Com-  
15 missioner of Food and Drugs.

16 (d) DEFINITIONS.—For purposes of this title:

17 (1) The term “priority countermeasure” has the  
18 meaning given such term in section 319F(h)(4) of  
19 the Public Health Service Act.

20 (2) The term “priority drugs or biological prod-  
21 ucts” means a drug or biological product that is the  
22 subject of a drug or biologics application referred to  
23 in section 101(4) of the Food and Drug Administra-  
24 tion Modernization Act of 1997.



1 **SEC. 123. ISSUANCE OF RULE ON ANIMAL TRIALS.**

2 Not later than 90 days after the date of the enact-  
3 ment of this Act, the Secretary of Health and Human  
4 Services shall complete the process of rulemaking that was  
5 commenced under authority of section 505 of the Federal  
6 Food, Drug, and Cosmetic Act and section 351 of the  
7 Public Health Service Act with the issuance of the pro-  
8 posed rule entitled “New Drug and Biological Drug Prod-  
9 ucts; Evidence Needed to Demonstrate Efficacy of New  
10 Drugs for Use Against Lethal or Permanently Disabling  
11 Toxic Substances When Efficacy Studies in Humans Ethi-  
12 cally Cannot be Conducted” published in the Federal Reg-  
13 ister on October 5, 1999 (64 Fed. Reg. 53960), and shall  
14 promulgate a final rule.

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

17 Part B of title III of the Public Health Service Act,  
18 as amended by section 110 of this Act, is amended by in-  
19 serting after section 319J the following section:

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

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



1 duction, distribution, or storage of priority counter-  
2 measures (as defined in section 319F(h)(4)).

3 “(b) GUIDELINES.—The Secretary may develop  
4 guidelines to enable entities eligible to receive assistance  
5 under subsection (a) to secure their facilities against po-  
6 tential terrorist attack.”.

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

9 Section 319F(h) of the Public Health Service Act, as  
10 redesignated by section 104(a)(2) of this Act, is amended  
11 to read as follows:

12 “(h) ACCELERATED RESEARCH AND DEVELOPMENT  
13 ON PRIORITY PATHOGENS AND COUNTERMEASURES.—

14 “(1) IN GENERAL.—With respect to pathogens  
15 of potential use in a bioterrorist attack, and other  
16 agents that may cause a public health emergency,  
17 the Secretary, taking into consideration any rec-  
18 ommendations of the working group under sub-  
19 section (a), shall conduct, and award grants, con-  
20 tracts, or cooperative agreements for, research, in-  
21 vestigations, experiments, demonstrations, and stud-  
22 ies in the health sciences relating to—

23 “(A) the epidemiology and pathogenesis of  
24 such pathogens;



1           “(B) the sequencing of the genomes, or  
2           other DNA analysis, or other comparative anal-  
3           ysis, of priority pathogens (as determined by  
4           the Director of the National Institutes of  
5           Health in consultation with the working group  
6           established in subsection (a)), in collaboration  
7           and coordination with the activities of the De-  
8           partment of Defense and the Joint Genome In-  
9           stitute of the Department of Energy;

10           “(C) the development of priority counter-  
11           measures; and

12           “(D) other relevant areas of research;  
13           with consideration given to the needs of children and  
14           other vulnerable populations.

15           “(2) PRIORITY.—The Secretary shall give pri-  
16           ority under this section to the funding of research  
17           and other studies related to priority counter-  
18           measures.

19           “(3) ROLE OF DEPARTMENT OF VETERANS AF-  
20           FAIRS.—In carrying out paragraph (1), the Sec-  
21           retary shall consider using the biomedical research  
22           and development capabilities of the Department of  
23           Veterans Affairs, in conjunction with that Depart-  
24           ment’s affiliations with health-professions univer-  
25           sities. When advantageous to the Government in fur-



1 therance of the purposes of such paragraph, the Sec-  
2 retary may enter into cooperative agreements with  
3 the Secretary of Veterans Affairs to achieve such  
4 purposes.

5 “(4) PRIORITY COUNTERMEASURES.—For pur-  
6 poses of this section, the term ‘priority counter-  
7 measure’ means a drug, biological product, device,  
8 vaccine, vaccine adjuvant, antiviral, or diagnostic  
9 test that the Secretary determines to be—

10 “(A) a priority to treat, identify, or pre-  
11 vent infection by a biological agent or toxin list-  
12 ed pursuant to section 351A(a)(1), or harm  
13 from any other agent that may cause a public  
14 health emergency; or

15 “(B) a priority to diagnose conditions that  
16 may result in adverse health consequences or  
17 death and may be caused by the administering  
18 of a drug, biological product, device, vaccine,  
19 vaccine adjuvant, antiviral, or diagnostic test  
20 that is a priority under subparagraph (A).”.



1 **SEC. 126. EVALUATION OF NEW AND EMERGING TECH-**  
2 **NOLOGIES REGARDING BIOTERRORIST AT-**  
3 **TACK AND OTHER PUBLIC HEALTH EMER-**  
4 **GENCIES.**

5 (a) IN GENERAL.—The Secretary of Health and  
6 Human Services (referred to in this section as the “Sec-  
7 retary”) shall promptly carry out a program to periodi-  
8 cally evaluate new and emerging technologies that, in the  
9 determination of the Secretary, are designed to improve  
10 or enhance the ability of public health or safety officials  
11 to conduct public health surveillance activities relating to  
12 a bioterrorist attack or other public health emergency.

13 (b) CERTAIN ACTIVITIES.—In carrying out this sub-  
14 section, the Secretary shall, to the extent practicable—

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

18 (2) promptly issue a request, as necessary, for  
19 information from non-Federal public and private en-  
20 tities for ongoing activities in this area; and

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

23 (c) CONSULTATION AND EVALUATION.—In carrying  
24 out subsection (b)(3), the Secretary shall consult with the  
25 working group under section 319F(a) of the Public Health  
26 Service Act, as well as other appropriate public, nonprofit,



1 and private entities, to develop criteria for the evaluation  
2 of such technologies and to conduct such evaluations.

3 (d) REPORT.—Not later than 180 days after the date  
4 of the enactment of this Act, and periodically thereafter,  
5 the Secretary shall submit to the Committee on Energy  
6 and Commerce of the House of Representatives, and the  
7 Committee on Health, Education, Labor, and Pensions of  
8 the Senate, a report on the activities under this section.

9 **SEC. 127. POTASSIUM IODIDE.**

10 (a) IN GENERAL.—Through the national stockpile  
11 under section 121, the President, subject to subsections  
12 (b) and (c), shall make available to State and local govern-  
13 ments potassium iodide tablets for stockpiling and for dis-  
14 tribution as appropriate to public facilities, such as schools  
15 and hospitals, in quantities sufficient to provide adequate  
16 protection for the population within 20 miles of a nuclear  
17 power plant.

18 (b) STATE AND LOCAL PLANS.—

19 (1) IN GENERAL.—Subsection (a) applies with  
20 respect to a State or local government, subject to  
21 paragraph (2), if the government involved meets the  
22 following conditions:

23 (A) Such government submits to the Presi-  
24 dent a plan for the stockpiling of potassium io-  
25 dide tablets, and for the distribution and utili-



1 zation of potassium iodide tablets in the event  
2 of a nuclear incident.

3 (B) The plan is accompanied by certifi-  
4 cations by such government that the govern-  
5 ment has not already received sufficient quan-  
6 tities of potassium iodide tablets from the Fed-  
7 eral Government.

8 (2) LOCAL GOVERNMENTS.—Subsection (a) ap-  
9 plies with respect to a local government only if, in  
10 addition to the conditions described in paragraph  
11 (1), the following conditions are met:

12 (A) The State in which the locality in-  
13 volved is located—

14 (i) does not have a plan described in  
15 paragraph (1)(A); or

16 (ii) has a plan described in such para-  
17 graph, but the plan does not address popu-  
18 lations at a distance greater than 10 miles  
19 from the nuclear power plant involved.

20 (B) The local government has petitioned  
21 the State to modify the State plan to address  
22 such populations, not exceeding 20 miles from  
23 such plant, and 60 days have elapsed without  
24 the State modifying the State plan to address



1 populations at the full distance sought by the  
2 local government through the petition.

3 (C) The local government has submitted  
4 its local plan under paragraph (1)(A) to the  
5 State, and the State has approved the plan and  
6 certified that the plan is not inconsistent with  
7 the State emergency plan.

8 (c) GUIDELINES.—Not later than one year after the  
9 date of the enactment of this Act, the President, in con-  
10 sultation with individuals representing appropriate Fed-  
11 eral, State, and local agencies, shall establish guidelines  
12 for the stockpiling of potassium iodide tablets, and for the  
13 distribution and utilization of potassium iodide tablets in  
14 the event of a nuclear incident. Such tablets may not be  
15 made available under subsection (a) until such guidelines  
16 have been established.

17 (d) INFORMATION.—The President shall carry out ac-  
18 tivities to inform State and local governments of the pro-  
19 gram under this section.

20 (e) REPORTS.—

21 (1) PRESIDENT.—Not later than six months  
22 after the date on which the guidelines under sub-  
23 section (c) are issued, the President shall submit to  
24 the Congress a report—



1 (A) on whether potassium iodide tablets  
2 have been made available under subsection (a)  
3 or other Federal, State, or local programs, and  
4 the extent to which State and local governments  
5 have established stockpiles of such tablets; and

6 (B) the measures taken by the President  
7 to implement this section.

8 (2) NATIONAL ACADEMY OF SCIENCES.—

9 (A) IN GENERAL.—The President shall re-  
10 quest the National Academy of Sciences to  
11 enter into an agreement with the President  
12 under which the Academy conducts a study to  
13 determine what is the most effective and safe  
14 way to distribute and administer potassium io-  
15 dide tablets on a mass scale. If the Academy  
16 declines to conduct the study, the President  
17 shall enter into an agreement with another ap-  
18 propriate public or nonprofit private entity to  
19 conduct the study.

20 (B) REPORT.—The President shall ensure  
21 that, not later than six months after the date  
22 of the enactment of this Act, the study required  
23 in subparagraph (A) is completed and a report  
24 describing the findings made in the study is  
25 submitted to the Congress.



1 (f) APPLICABILITY.—Subsections (a) and (d) cease to  
2 apply as requirements if the President determines that  
3 there is an alternative and more effective prophylaxis or  
4 preventive measures for adverse thyroid conditions that  
5 may result from the release of radionuclides from nuclear  
6 power plants.

7 **Subtitle C—Improving State, Local,**  
8 **and Hospital Preparedness for**  
9 **and Response to Bioterrorism**  
10 **and Other Public Health Emer-**  
11 **gencies**

12 **SEC. 131. GRANTS TO IMPROVE STATE, LOCAL, AND HOS-**  
13 **PITAL PREPAREDNESS FOR AND RESPONSE**  
14 **TO BIOTERRORISM AND OTHER PUBLIC**  
15 **HEALTH EMERGENCIES.**

16 (a) IN GENERAL.—Part B of title III of the Public  
17 Health Service Act (42 U.S.C. 243 et seq.) is amended  
18 by inserting after section 319C the following sections:

19 **“SEC. 319C-1. GRANTS TO IMPROVE STATE, LOCAL, AND**  
20 **HOSPITAL PREPAREDNESS FOR AND RE-**  
21 **SPONSE TO BIOTERRORISM AND OTHER PUB-**  
22 **LIC HEALTH EMERGENCIES.**

23 “(a) IN GENERAL.—To enhance the security of the  
24 United States with respect to bioterrorism and other pub-  
25 lic health emergencies, the Secretary shall make awards



1 of grants or cooperative agreements to eligible entities to  
2 enable such entities to conduct the activities described in  
3 subsection (d).

4 “(b) ELIGIBLE ENTITIES.—

5 “(1) IN GENERAL.—To be eligible to receive an  
6 award under subsection (a), an entity shall—

7 “(A)(i) be a State; and

8 “(ii) prepare and submit to the Secretary  
9 an application at such time, and in such man-  
10 ner, and containing such information as the  
11 Secretary may require, including an assurance  
12 that the State—

13 “(I) has completed an evaluation  
14 under section 319B(a), or an evaluation  
15 that is substantially equivalent to an eval-  
16 uation described in such section (as deter-  
17 mined by the Secretary);

18 “(II) has prepared, or will (within 60  
19 days of receiving an award under this sec-  
20 tion) prepare, a Bioterrorism and Other  
21 Public Health Emergency Preparedness  
22 and Response Plan in accordance with sub-  
23 section (c);

24 “(III) has established a means by  
25 which to obtain public comment and input



1 on the plan prepared under subclause (II),  
2 and on the implementation of such plan,  
3 that shall include an advisory committee or  
4 other similar mechanism for obtaining  
5 comment from the public at large as well  
6 as from other State and local stakeholders;

7 “(IV) will use amounts received under  
8 the award in accordance with the plan pre-  
9 pared under subclause (II), including mak-  
10 ing expenditures to carry out the strategy  
11 contained in the plan; and

12 “(V) with respect to the plan prepared  
13 under subclause (II), will establish reason-  
14 able criteria to evaluate the effective per-  
15 formance of entities that receive funds  
16 under the award and include relevant  
17 benchmarks in the plan; or

18 “(B)(i) be a political subdivision of a State  
19 or a consortium of 2 or more such subdivisions;  
20 and

21 “(ii) prepare and submit to the Secretary  
22 an application at such time, and in such man-  
23 ner, and containing such information as the  
24 Secretary may require.



1           “(2) COORDINATION WITH STATEWIDE  
2 PLANS.—An award under subsection (a) to an eligi-  
3 ble entity described in paragraph (1)(B) may not be  
4 made unless the application of such entity is in co-  
5 ordination with, and consistent with, applicable  
6 Statewide plans described in subsection (d)(1).

7           “(c) BIOTERRORISM AND OTHER PUBLIC HEALTH  
8 EMERGENCY PREPAREDNESS AND RESPONSE PLAN.—  
9 Not later than 60 days after receiving amounts under an  
10 award under subsection (a), an eligible entity described  
11 in subsection (b)(1)(A) shall prepare and submit to the  
12 Secretary a Bioterrorism and Other Public Health Emer-  
13 gency Preparedness and Response Plan. Recognizing the  
14 assessment of public health needs conducted under section  
15 319B, such plan shall include a description of activities  
16 to be carried out by the entity to address the needs identi-  
17 fied in such assessment (or an equivalent assessment).

18           “(d) USE OF FUNDS.—An award under subsection  
19 (a) may be expended for activities that may include the  
20 following and similar activities:

21           “(1) To develop Statewide plans (including the  
22 development of the Bioterrorism and Other Public  
23 Health Emergency Preparedness and Response Plan  
24 required under subsection (c)), and community-wide  
25 plans for responding to bioterrorism and other pub-



1       lic health emergencies that are coordinated with the  
2       capacities of applicable national, State, and local  
3       health agencies and health care providers, including  
4       poison control centers.

5               “(2) To address deficiencies identified in the as-  
6       sessment conducted under section 319B.

7               “(3) To purchase or upgrade equipment (in-  
8       cluding stationary or mobile communications equip-  
9       ment), supplies, pharmaceuticals or other priority  
10      countermeasures to enhance preparedness for and  
11      response to bioterrorism or other public health emer-  
12      gencies, consistent with the plan described in sub-  
13      section (c).

14              “(4) To conduct exercises to test the capability  
15      and timeliness of public health emergency response  
16      activities.

17              “(5) To develop and implement the trauma care  
18      and burn center care components of the State plans  
19      for the provision of emergency medical services.

20              “(6) To improve training or workforce develop-  
21      ment to enhance public health laboratories.

22              “(7) To train public health and health care per-  
23      sonnel to enhance the ability of such personnel—

24                      “(A) to detect, provide accurate identifica-  
25      tion of, and recognize the symptoms and epide-



1 biological characteristics of exposure to a bio-  
2 logical agent that may cause a public health  
3 emergency; and

4 “(B) to provide treatment to individuals  
5 who are exposed to such an agent.

6 “(8) To develop, enhance, coordinate, or im-  
7 prove participation in systems by which disease de-  
8 tection and information about biological attacks and  
9 other public health emergencies can be rapidly com-  
10 municated among national, State, and local health  
11 agencies, emergency response personnel, and health  
12 care providers and facilities to detect and respond to  
13 a bioterrorist attack or other public health emer-  
14 gency, including activities to improve information  
15 technology and communications equipment available  
16 to health care and public health officials for use in  
17 responding to a biological threat or attack or other  
18 public health emergency.

19 “(9) To enhance communication to the public of  
20 information on bioterrorism and other public health  
21 emergencies, including through the use of 2-1-1 call  
22 centers.

23 “(10) To address the health security needs of  
24 children and other vulnerable populations with re-



1 spect to bioterrorism and other public health emer-  
2 gencies.

3 “(11) To provide training and develop, enhance,  
4 coordinate, or improve methods to enhance the safe-  
5 ty of workers and workplaces in the event of bioter-  
6 rorism.

7 “(12) To prepare and plan for contamination  
8 prevention efforts related to public health that may  
9 be implemented in the event of a bioterrorist attack,  
10 including training and planning to protect the health  
11 and safety of workers conducting the activities de-  
12 scribed in this paragraph.

13 “(13) To prepare a plan for triage and trans-  
14 port management in the event of bioterrorism or  
15 other public health emergencies.

16 “(14) To enhance the training of health care  
17 professionals to recognize and treat the mental  
18 health consequences of bioterrorism or other public  
19 health emergencies.

20 “(15) To enhance the training of health care  
21 professionals to assist in providing appropriate  
22 health care for large numbers of individuals exposed  
23 to a bioweapon.

24 “(16) To enhance training and planning to pro-  
25 tect the health and safety of personnel, including



1 health care professionals, involved in responding to  
2 a biological attack.

3 “(17) To improve surveillance, detection, and  
4 response activities to prepare for emergency re-  
5 sponse activities including biological threats or at-  
6 tacks, including training personnel in these and  
7 other necessary functions and including early warn-  
8 ing and surveillance networks that use advanced in-  
9 formation technology to provide early detection of bi-  
10 ological threats or attacks.

11 “(18) To develop, enhance, and coordinate or  
12 improve the ability of existing telemedicine programs  
13 to provide health care information and advice as  
14 part of the emergency public health response to bio-  
15 terrorism or other public health emergencies.

16 Nothing in this subsection may be construed as estab-  
17 lishing new regulatory authority or as modifying any exist-  
18 ing regulatory authority.

19 “(e) PRIORITIES IN USE OF GRANTS.—

20 “(1) IN GENERAL.—

21 “(A) PRIORITIES.—Except as provided in  
22 subparagraph (B), the Secretary shall, in car-  
23 rying out the activities described in this section,  
24 address the following hazards in the following  
25 priority:



1                   “(i) Bioterrorism or acute outbreaks  
2                   of infectious diseases.

3                   “(ii) Other public health threats and  
4                   emergencies.

5                   “(B) DETERMINATION OF THE SEC-  
6                   RETARY.—In the case of the hazard involved,  
7                   the degree of priority that would apply to the  
8                   hazard based on the categories specified in  
9                   clauses (i) and (ii) of subparagraph (A) may be  
10                  modified by the Secretary if the following condi-  
11                  tions are met:

12                  “(i) The Secretary determines that  
13                  the modification is appropriate on the  
14                  basis of the following factors:

15                  “(I) The extent to which eligible  
16                  entities are adequately prepared for  
17                  responding to hazards within the cat-  
18                  egory specified in clause (i) of sub-  
19                  paragraph (A).

20                  “(II) There has been a signifi-  
21                  cant change in the assessment of risks  
22                  to the public health posed by hazards  
23                  within the category specified in clause  
24                  (ii) of such subparagraph.



1                   “(ii) Prior to modifying the priority,  
2                   the Secretary notifies the appropriate com-  
3                   mittees of the Congress of the determina-  
4                   tion of the Secretary under clause (i) of  
5                   this subparagraph.

6                   “(2) AREAS OF EMPHASIS WITHIN CAT-  
7                   EGORIES.—The Secretary shall determine areas of  
8                   emphasis within the category of hazards specified in  
9                   clause (i) of paragraph (1)(A), and shall determine  
10                  areas of emphasis within the category of hazards  
11                  specified in clause (ii) of such paragraph, based on  
12                  an assessment of the risk and likely consequences of  
13                  such hazards and on an evaluation of Federal, State,  
14                  and local needs, and may also take into account the  
15                  extent to which receiving an award under subsection  
16                  (a) will develop capacities that can be used for pub-  
17                  lic health emergencies of varying types.

18                  “(f) CERTAIN ACTIVITIES.—In administering activi-  
19                  ties under section 319C(e)(4) or similar activities, the Sec-  
20                  retary shall, where appropriate, give priority to activities  
21                  that include State or local government financial commit-  
22                  ments, that seek to incorporate multiple public health and  
23                  safety services or diagnostic databases into an integrated  
24                  public health entity, and that cover geographic areas lack-  
25                  ing advanced diagnostic and laboratory capabilities.



1       “(g) COORDINATION WITH LOCAL MEDICAL RE-  
2 SPONSE SYSTEM.—An eligible entity and local Metropoli-  
3 tan Medical Response Systems shall, to the extent prac-  
4 ticable, ensure that activities carried out under an award  
5 under subsection (a) are coordinated with activities that  
6 are carried out by local Metropolitan Medical Response  
7 Systems.

8       “(h) COORDINATION OF FEDERAL ACTIVITIES.—In  
9 making awards under subsection (a), the Secretary shall—

10               “(1) annually notify the Director of the Federal  
11 Emergency Management Agency, the Director of the  
12 Office of Justice Programs, and the Director of the  
13 National Domestic Preparedness Office, as to the  
14 amount, activities covered under, and status of such  
15 awards; and

16               “(2) coordinate such awards with other activi-  
17 ties conducted or supported by the Secretary to en-  
18 hance preparedness for bioterrorism and other public  
19 health emergencies.

20       “(i) DEFINITION.—For purposes of this section, the  
21 term ‘eligible entity’ means an entity that meets the condi-  
22 tions described in subparagraph (A) or (B) of subsection  
23 (b)(1).

24       “(j) FUNDING.—

25               “(1) AUTHORIZATIONS OF APPROPRIATIONS.—



1 “(A) FISCAL YEAR 2003.—

2 “(i) AUTHORIZATIONS.—For the pur-  
3 pose of carrying out this section, there is  
4 authorized to be appropriated  
5 \$1,600,000,000 for fiscal year 2003, of  
6 which—

7 “(I) \$1,080,000,000 is author-  
8 ized to be appropriated for awards  
9 pursuant to paragraph (3) (subject to  
10 the authority of the Secretary to make  
11 awards pursuant to paragraphs (4)  
12 and (5)); and

13 “(II) \$520,000,000 is authorized  
14 to be appropriated—

15 “(aa) for awards under sub-  
16 section (a) to States,  
17 notwithstanding the eligibility con-  
18 ditions under subsection (b), for  
19 the purpose of enhancing the pre-  
20 paredness of hospitals (including  
21 children’s hospitals), clinics,  
22 health centers, and primary care  
23 facilities for bioterrorism and  
24 other public health emergencies;  
25 and



1                   “(bb) for Federal, State,  
2                   and local planning and adminis-  
3                   trative activities related to such  
4                   purpose.

5                   “(ii) CONTINGENT ADDITIONAL AU-  
6                   THORIZATION.—If a significant change in  
7                   circumstances warrants an increase in the  
8                   amount authorized to be appropriated  
9                   under clause (i) for fiscal year 2003, there  
10                  are authorized to be appropriated such  
11                  sums as may be necessary for such year  
12                  for carrying out this section, in addition to  
13                  the amount authorized in clause (i).

14                  “(B) OTHER FISCAL YEARS.—For the pur-  
15                  pose of carrying out this section, there are au-  
16                  thorized to be appropriated such sums as may  
17                  be necessary for each of the fiscal years 2004  
18                  through 2006.

19                  “(2) SUPPLEMENT NOT SUPPLANT.—Amounts  
20                  appropriated under paragraph (1) shall be used to  
21                  supplement and not supplant other State and local  
22                  public funds provided for activities under this sec-  
23                  tion.



1           “(3) STATE BIOTERRORISM AND OTHER PUBLIC  
2 HEALTH EMERGENCY PREPAREDNESS AND RE-  
3 SPONSE BLOCK GRANT FOR FISCAL YEAR 2003.—

4           “(A) IN GENERAL.—For fiscal year 2003,  
5 the Secretary shall, in an amount determined in  
6 accordance with subparagraphs (B) through  
7 (D), make an award under subsection (a) to  
8 each State, notwithstanding the eligibility con-  
9 ditions described in subsection (b), that submits  
10 to the Secretary an application for the award  
11 that meets the criteria of the Secretary for the  
12 receipt of such an award and that meets other  
13 implementation conditions established by the  
14 Secretary for such awards. No other awards  
15 may be made under subsection (a) for such fis-  
16 cal year, except as provided in paragraph  
17 (1)(A)(i)(II) and paragraphs (4) and (5).

18           “(B) BASE AMOUNT.—In determining the  
19 amount of an award pursuant to subparagraph  
20 (A) for a State, the Secretary shall first deter-  
21 mine an amount the Secretary considers appro-  
22 priate for the State (referred to in this para-  
23 graph as the ‘base amount’), except that such  
24 amount may not be greater than the minimum  
25 amount determined under subparagraph (D).



1           “(C) INCREASE ON BASIS OF POPU-  
2           LATION.—After determining the base amount  
3           for a State under subparagraph (B), the Sec-  
4           retary shall increase the base amount by an  
5           amount equal to the product of—

6                   “(i) the amount appropriated under  
7                   paragraph (1)(A)(i)(I) for the fiscal year,  
8                   less an amount equal to the sum of all  
9                   base amounts determined for the States  
10                  under subparagraph (B), and less the  
11                  amount, if any, reserved by the Secretary  
12                  under paragraphs (4) and (5); and

13                   “(ii) subject to paragraph (4)(C), the  
14                   percentage constituted by the ratio of an  
15                   amount equal to the population of the  
16                   State over an amount equal to the total  
17                   population of the States (as indicated by  
18                   the most recent data collected by the Bu-  
19                   reau of the Census).

20           “(D) MINIMUM AMOUNT.—Subject to the  
21           amount appropriated under paragraph  
22           (1)(A)(i)(I), an award pursuant to subpara-  
23           graph (A) for a State shall be the greater of the  
24           base amount as increased under subparagraph  
25           (C), or the minimum amount under this sub-



1 paragraph. The minimum amount under this  
2 subparagraph is—

3 “(i) in the case of each of the several  
4 States, the District of Columbia, and the  
5 Commonwealth of Puerto Rico, an amount  
6 equal to the lesser of—

7 “(I) \$5,000,000; or

8 “(II) if the amount appropriated  
9 under paragraph (1)(A)(i)(I) is less  
10 than \$667,000,000, an amount equal  
11 to 0.75 percent of the amount appro-  
12 priated under such paragraph, less  
13 the amount, if any, reserved by the  
14 Secretary under paragraphs (4) and  
15 (5); or

16 “(ii) in the case of each of American  
17 Samoa, Guam, the Commonwealth of the  
18 Northern Mariana Islands, and the Virgin  
19 Islands, an amount determined by the Sec-  
20 retary to be appropriate, except that such  
21 amount may not exceed the amount deter-  
22 mined under clause (i).

23 “(4) CERTAIN POLITICAL SUBDIVISIONS.—

24 “(A) IN GENERAL.—For fiscal year 2003,  
25 the Secretary may, before making awards pur-



1 suant to paragraph (3) for such year, reserve  
2 from the amount appropriated under paragraph  
3 (1)(A)(i)(I) for the year an amount determined  
4 necessary by the Secretary to make awards  
5 under subsection (a) to political subdivisions  
6 that have a substantial number of residents,  
7 have a substantial local infrastructure for re-  
8 sponding to public health emergencies, and face  
9 a high degree of risk from bioterrorist attacks  
10 or other public health emergencies. Not more  
11 than three political subdivisions may receive  
12 awards pursuant to this subparagraph.

13 “(B) COORDINATION WITH STATEWIDE  
14 PLANS.—An award pursuant to subparagraph  
15 (A) may not be made unless the application of  
16 the political subdivision involved is in coordina-  
17 tion with, and consistent with, applicable State-  
18 wide plans described in subsection (c)(1).

19 “(C) RELATIONSHIP TO FORMULA  
20 GRANTS.—In the case of a State that will re-  
21 ceive an award pursuant to paragraph (3), and  
22 in which there is located a political subdivision  
23 that will receive an award pursuant to subpara-  
24 graph (A), the Secretary shall, in determining  
25 the amount under paragraph (3)(B) for the



1 State, subtract from the population of the State  
2 an amount equal to the population of such po-  
3 litical subdivision.

4 “(D) CONTINUITY OF FUNDING.—In deter-  
5 mining whether to make an award pursuant to  
6 subparagraph (A) to a political subdivision, the  
7 Secretary may consider, as a factor indicating  
8 that the award should be made, that the polit-  
9 ical subdivision received public health funding  
10 from the Secretary for fiscal year 2002.

11 “(5) SIGNIFICANT UNMET NEEDS; DEGREE OF  
12 RISK.—

13 “(A) IN GENERAL.—For fiscal year 2003,  
14 the Secretary may, before making awards pur-  
15 suant to paragraph (3) for such year, reserve  
16 from the amount appropriated under paragraph  
17 (1)(A)(i)(I) for the year an amount determined  
18 necessary by the Secretary to make awards  
19 under subsection (a) to eligible entities that—

20 “(i) have a significant need for funds  
21 to build capacity to identify, detect, mon-  
22 itor, and respond to a bioterrorist or other  
23 threat to the public health, which need will  
24 not be met by awards pursuant to para-  
25 graph (3); and



1                   “(ii) face a particularly high degree of  
2                   risk of such a threat.

3                   “(B) RECIPIENTS OF GRANTS.—Awards  
4                   pursuant to subparagraph (A) may be supple-  
5                   mental awards to States that receive awards  
6                   pursuant to paragraph (3), or may be awards  
7                   to eligible entities described in subsection  
8                   (b)(1)(B) within such States.

9                   “(C) FINDING WITH RESPECT TO DISTRICT  
10                  OF COLUMBIA.—The Secretary shall consider  
11                  the District of Columbia to have a significant  
12                  unmet need for purposes of subparagraph (A),  
13                  and to face a particularly high degree of risk  
14                  for such purposes, on the basis of the con-  
15                  centration of entities of national significance lo-  
16                  cated within the District.

17                  “(6) FUNDING OF LOCAL ENTITIES.—For fiscal  
18                  year 2003, the Secretary shall in making awards  
19                  under this section ensure that appropriate portions  
20                  of such awards are made available to political sub-  
21                  divisions, local departments of public health, hos-  
22                  pitals (including children’s hospitals), clinics, health  
23                  centers, or primary care facilities, or consortia of  
24                  such entities.



1 **“SEC. 319C-2. PARTNERSHIPS FOR COMMUNITY AND HOS-**  
2 **PITAL PREPAREDNESS.**

3 “(a) GRANTS.—The Secretary shall make awards of  
4 grants or cooperative agreements to eligible entities to en-  
5 able such entities to improve community and hospital pre-  
6 paredness for bioterrorism and other public health emer-  
7 gencies.

8 “(b) ELIGIBILITY.—To be eligible for an award under  
9 subsection (a), an entity shall—

10 “(1) be a partnership consisting of—

11 “(A) one or more hospitals (including chil-  
12 dren’s hospitals), clinics, health centers, or pri-  
13 mary care facilities; and

14 “(B)(i) one or more political subdivisions  
15 of States;

16 “(ii) one or more States; or

17 “(iii) one or more States and one or more  
18 political subdivisions of States; and

19 “(2) prepare, in consultation with the Chief Ex-  
20 ecutive Officer of the State, District, or territory in  
21 which the hospital, clinic, health center, or primary  
22 care facility described in paragraph (1)(A) is lo-  
23 cated, and submit to the Secretary, an application at  
24 such time, in such manner, and containing such in-  
25 formation as the Secretary may require.



1           “(c) REGIONAL COORDINATION.—In making awards  
2 under subsection (a), the Secretary shall give preference  
3 to eligible entities that submit applications that, in the de-  
4 termination of the Secretary, will—

5                   “(1) enhance coordination—

6                           “(A) among the entities described in sub-  
7 section (b)(1)(A); and

8                           “(B) between such entities and the entities  
9 described in subsection (b)(1)(B); and

10                   “(2) serve the needs of a defined geographic  
11 area.

12           “(d) CONSISTENCY OF PLANNED ACTIVITIES.—An  
13 entity described in subsection (b)(1) shall utilize amounts  
14 received under an award under subsection (a) in a manner  
15 that is coordinated and consistent, as determined by the  
16 Secretary, with an applicable State Bioterrorism and  
17 Other Public Health Emergency Preparedness and Re-  
18 sponse Plan.

19           “(e) USE OF FUNDS.—An award under subsection  
20 (a) may be expended for activities that may include the  
21 following and similar activities—

22                   “(1) planning and administration for such  
23 award;



1           “(2) preparing a plan for triage and transport  
2 management in the event of bioterrorism or other  
3 public health emergencies;

4           “(3) enhancing the training of health care pro-  
5 fessionals to improve the ability of such professionals  
6 to recognize the symptoms of exposure to a potential  
7 bioweapon, to make appropriate diagnosis, and to  
8 provide treatment to those individuals so exposed;

9           “(4) enhancing the training of health care pro-  
10 fessionals to recognize and treat the mental health  
11 consequences of bioterrorism or other public health  
12 emergencies;

13           “(5) enhancing the training of health care pro-  
14 fessionals to assist in providing appropriate health  
15 care for large numbers of individuals exposed to a  
16 bioweapon;

17           “(6) enhancing training and planning to protect  
18 the health and safety of personnel involved in re-  
19 sponding to a biological attack;

20           “(7) developing and implementing the trauma  
21 care and burn center care components of the State  
22 plans for the provision of emergency medical serv-  
23 ices; or

24           “(8) conducting such activities as are described  
25 in section 319C-1(d) that are appropriate for hos-



1       pitals (including children’s hospitals), clinics, health  
2       centers, or primary care facilities.

3       “(f) LIMITATION ON AWARDS.—A political subdivi-  
4       sion of a State shall not participate in more than one part-  
5       nership described in subsection (b)(1).

6       “(g) PRIORITIES IN USE OF GRANTS.—

7               “(1) IN GENERAL.—

8                       “(A) PRIORITIES.—Except as provided in  
9                       subparagraph (B), the Secretary shall, in car-  
10                      rying out the activities described in this section,  
11                      address the following hazards in the following  
12                      priority:

13                               “(i) Bioterrorism or acute outbreaks  
14                               of infectious diseases.

15                               “(ii) Other public health threats and  
16                               emergencies.

17                       “(B) DETERMINATION OF THE SEC-  
18                       RETARY.—In the case of the hazard involved,  
19                       the degree of priority that would apply to the  
20                       hazard based on the categories specified in  
21                       clauses (i) and (ii) of subparagraph (A) may be  
22                       modified by the Secretary if the following condi-  
23                       tions are met:



1                   “(i) The Secretary determines that  
2                   the modification is appropriate on the  
3                   basis of the following factors:

4                                 “(I) The extent to which eligible  
5                                 entities are adequately prepared for  
6                                 responding to hazards within the cat-  
7                                 egory specified in clause (i) of sub-  
8                                 paragraph (A).

9                                 “(II) There has been a signifi-  
10                                cant change in the assessment of risks  
11                                to the public health posed by hazards  
12                                within the category specified in clause  
13                                (ii) of such subparagraph.

14                               “(ii) Prior to modifying the priority,  
15                               the Secretary notifies the appropriate com-  
16                               mittees of the Congress of the determina-  
17                               tion of the Secretary under clause (i) of  
18                               this subparagraph.

19                               “(2) AREAS OF EMPHASIS WITHIN CAT-  
20                               EGORIES.—The Secretary shall determine areas of  
21                               emphasis within the category of hazards specified in  
22                               clause (i) of paragraph (1)(A), and shall determine  
23                               areas of emphasis within the category of hazards  
24                               specified in clause (ii) of such paragraph, based on  
25                               an assessment of the risk and likely consequences of



1 such hazards and on an evaluation of Federal, State,  
2 and local needs, and may also take into account the  
3 extent to which receiving an award under subsection  
4 (a) will develop capacities that can be used for pub-  
5 lic health emergencies of varying types.

6 “(h) COORDINATION WITH LOCAL MEDICAL RE-  
7 SPONSE SYSTEM.—An eligible entity and local Metropoli-  
8 tan Medical Response Systems shall, to the extent prac-  
9 ticable, ensure that activities carried out under an award  
10 under subsection (a) are coordinated with activities that  
11 are carried out by local Metropolitan Medical Response  
12 Systems.

13 “(i) AUTHORIZATION OF APPROPRIATIONS.—For the  
14 purpose of carrying out this section, there are authorized  
15 to be appropriated such sums as may be necessary for  
16 each of fiscal years 2004 through 2006.”.

17 (b) CERTAIN GRANTS.—Section 319C of the Public  
18 Health Service Act (42 U.S.C. 247d–3) is amended by  
19 striking subsection (f).

20 **Subtitle D—Emergency**  
21 **Authorities; Additional Provisions**

22 **SEC. 141. REPORTING DEADLINES.**

23 Section 319 of the Public Health Service Act (42  
24 U.S.C. 247d) is amended by adding at the end the fol-  
25 lowing:



1       “(d) DATA SUBMITTAL AND REPORTING DEAD-  
2 LINES.—In any case in which the Secretary determines  
3 that, wholly or partially as a result of a public health  
4 emergency that has been determined pursuant to sub-  
5 section (a), individuals or public or private entities are un-  
6 able to comply with deadlines for the submission to the  
7 Secretary of data or reports required under any law ad-  
8 ministered by the Secretary, the Secretary may, notwith-  
9 standing any other provision of law, grant such extensions  
10 of such deadlines as the circumstances reasonably require,  
11 and may waive, wholly or partially, any sanctions other-  
12 wise applicable to such failure to comply. Before or  
13 promptly after granting such an extension or waiver, the  
14 Secretary shall notify the Congress of such action and  
15 publish in the Federal Register a notice of the extension  
16 or waiver.”.

17 **SEC. 142. STREAMLINING AND CLARIFYING COMMU-**  
18 **NICABLE DISEASE QUARANTINE PROVISIONS.**

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

22           (1) EXECUTIVE ORDERS SPECIFYING DISEASES  
23 SUBJECT TO INDIVIDUAL DETENTIONS.—Section  
24 361(b) of the Public Health Act (42 U.S.C. 264(b))  
25 is amended by striking “Executive orders of the



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

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

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

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

21 (1) REGULATIONS PROVIDING FOR APPREHEN-  
22 SION OF INDIVIDUALS.—Section 361(d) of the Pub-  
23 lic Health Act (42 U.S.C. 264(d)), as amended by  
24 subsection (a)(2), is further amended—



1 (A) by striking “(1)” and “(2)” and in-  
2 serting “(A)” and “(B)”, respectively;

3 (B) by striking “(d)” and inserting  
4 “(d)(1)”;

5 (C) in paragraph (1) (as designated by  
6 subparagraph (B) of this paragraph), in the  
7 first sentence, by striking “in a communicable  
8 stage” each place such term appears and insert-  
9 ing “in a qualifying stage”; and

10 (D) by adding at the end the following  
11 paragraph:

12 “(2) For purposes of this subsection, the term ‘quali-  
13 fying stage’, with respect to a communicable disease,  
14 means that such disease—

15 “(A) is in a communicable stage; or

16 “(B) is in a precommunicable stage, if the dis-  
17 ease would be likely to cause a public health emer-  
18 gency if transmitted to other individuals.”.

19 (2) REGULATIONS PROVIDING FOR APPREHEN-  
20 SION OF INDIVIDUALS IN WARTIME.—Section 363 of  
21 the Public Health Act (42 U.S.C. 266), as amended  
22 by subsection (a)(3), is further amended by striking  
23 “in a communicable stage”



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

4 “(e) Nothing in this section or section 363, or the  
5 regulations promulgated under such sections, may be con-  
6 strued as superseding any provision under State law (in-  
7 cluding regulations and including provisions established by  
8 political subdivisions of States), except to the extent that  
9 such a provision conflicts with an exercise of Federal au-  
10 thority under this section or section 363.”.

11 **SEC. 143. EMERGENCY WAIVER OF MEDICARE, MEDICAID,**  
12 **AND SCHIP REQUIREMENTS.**

13 **SEC. 143. EMERGENCY WAIVER OF MEDICARE, MEDICAID,**  
14 **AND SCHIP REQUIREMENTS.**

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

18 “AUTHORITY TO WAIVE REQUIREMENTS DURING  
19 NATIONAL EMERGENCIES

20 “SEC. 1135. (a) PURPOSE.—The purpose of this sec-  
21 tion is to enable the Secretary to ensure to the maximum  
22 extent feasible, in any emergency area and during an  
23 emergency period (as defined in subsection (g)(1))—

24 “(1) that sufficient health care items and serv-  
25 ices are available to meet the needs of individuals in



1 such area enrolled in the programs under titles  
2 XVIII, XIX, and XXI; and

3 “(2) that health care providers (as defined in  
4 subsection (g)(2)) that furnish such items and serv-  
5 ices in good faith, but that are unable to comply  
6 with one or more requirements described in sub-  
7 section (b), may be reimbursed for such items and  
8 services and exempted from sanctions for such non-  
9 compliance, absent any determination of fraud or  
10 abuse.

11 “(b) SECRETARIAL AUTHORITY.—To the extent nec-  
12 essary to accomplish the purpose specified in subsection  
13 (a), the Secretary is authorized, subject to the provisions  
14 of this section, to temporarily waive or modify the applica-  
15 tion of, with respect to health care items and services fur-  
16 nished by a health care provider (or classes of health care  
17 providers) in any emergency area (or portion of such an  
18 area) during any portion of an emergency period, the re-  
19 quirements of titles XVIII, XIX, or XXI, or any regulation  
20 thereunder (and the requirements of this title other than  
21 this section, and regulations thereunder, insofar as they  
22 relate to such titles), pertaining to—

23 “(1)(A) conditions of participation or other cer-  
24 tification requirements for an individual health care  
25 provider or types of providers,



1           “(B) program participation and similar require-  
2           ments for an individual health care provider or types  
3           of providers, and

4           “(C) pre-approval requirements;

5           “(2) requirements that physicians and other  
6           health care professionals be licensed in the State in  
7           which they provide such services, if they have equiv-  
8           alent licensing in another State and are not affirma-  
9           tively excluded from practice in that State or in any  
10          State a part of which is included in the emergency  
11          area;

12          “(3) sanctions under section 1867 (relating to  
13          examination and treatment for emergency medical  
14          conditions and women in labor) for a transfer of an  
15          individual who has not been stabilized in violation of  
16          subsection (c) of such section if the transfer arises  
17          out of the circumstances of the emergency;

18          “(4) sanctions under section 1877(g) (relating  
19          to limitations on physician referral);

20          “(5) deadlines and timetables for performance  
21          of required activities, except that such deadlines and  
22          timetables may only be modified, not waived; and

23          “(6) limitations on payments under section  
24          1851(i) for health care items and services furnished  
25          to individuals enrolled in a Medicare+Choice plan by



1 health care professionals or facilities not included  
2 under such plan.

3 Insofar as the Secretary exercises authority under para-  
4 graph (6) with respect to individuals enrolled in a  
5 Medicare+Choice plan, to the extent possible given the  
6 circumstances, the Secretary shall reconcile payments  
7 made on behalf of such enrollees to ensure that the enroll-  
8 ees do not pay more than would be required had they re-  
9 ceived services from providers within the network of the  
10 plan and may reconcile payments to the organization of-  
11 fering the plan to ensure that such organization pays for  
12 services for which payment is included in the capitation  
13 payment it receives under part C of title XVIII.

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

19 “(d) CERTIFICATION TO CONGRESS.—The Secretary  
20 shall provide a certification and advance written notice to  
21 the Congress at least two days before exercising the au-  
22 thority under this section with respect to an emergency  
23 area. Such a certification and notice shall include—

24 “(1) a description of—



1           “(A) the specific provisions that will be  
2           waived or modified;

3           “(B) the health care providers to whom the  
4           waiver or modification will apply;

5           “(C) the geographic area in which the  
6           waiver or modification will apply; and

7           “(D) the period of time for which the waiv-  
8           er or modification will be in effect; and

9           “(2) a certification that the waiver or modifica-  
10          tion is necessary to carry out the purpose specified  
11          in subsection (a).

12          “(e) DURATION OF WAIVER.—

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

16                 “(A) the termination of the applicable dec-  
17          laration of emergency or disaster described in  
18          subsection (g)(1)(A);

19                 “(B) the termination of the applicable dec-  
20          laration of public health emergency described in  
21          subsection (g)(1)(B); or

22                 “(C) subject to paragraph (2), the termi-  
23          nation of a period of 60 days from the date the  
24          waiver or modification is first published (or, if



1 applicable, the date of extension of the waiver  
2 or modification under paragraph (2)).

3 “(2) EXTENSION OF 60-DAY PERIODS.—The  
4 Secretary may, by notice, provide for an extension of  
5 a 60-day period described in paragraph (1)(C) (or  
6 an additional period provided under this paragraph)  
7 for additional period or periods (not to exceed, ex-  
8 cept as subsequently provided under this paragraph,  
9 60 days each), but any such extension shall not af-  
10 fect or prevent the termination of a waiver or modi-  
11 fication under subparagraph (A) or (B) of para-  
12 graph (1).

13 “(f) REPORT TO CONGRESS.—Within one year after  
14 the end of the emergency period in an emergency area in  
15 which the Secretary exercised the authority provided  
16 under this section, the Secretary shall report to the Con-  
17 gress regarding the approaches used to accomplish the  
18 purposes described in subsection (a), including an evalua-  
19 tion of such approaches and recommendations for im-  
20 proved approaches should the need for such emergency au-  
21 thority arise in the future.

22 “(g) DEFINITIONS.—For purposes of this section:

23 “(1) EMERGENCY AREA; EMERGENCY PE-  
24 RIOD.—An ‘emergency area’ is a geographical area



1 in which, and an ‘emergency period’ is the period  
2 during which, there exists—

3 “(A) an emergency or disaster declared by  
4 the President pursuant to the National Emer-  
5 gencies Act or the Robert T. Stafford Disaster  
6 Relief and Emergency Assistance Act; and

7 “(B) a public health emergency declared  
8 by the Secretary pursuant to section 319 of the  
9 Public Health Service Act.

10 “(2) HEALTH CARE PROVIDER.—The term  
11 ‘health care provider’ means any entity that fur-  
12 nishes health care items or services, and includes a  
13 hospital or other provider of services, a physician or  
14 other health care practitioner or professional, a  
15 health care facility, or a supplier of health care  
16 items or services.”.

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

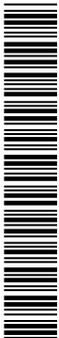
20 **SEC. 144. PROVISION FOR EXPIRATION OF PUBLIC HEALTH**  
21 **EMERGENCIES.**

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



1 upon the Secretary declaring that the emergency no longer  
2 exists, or upon the expiration of the 90-day period begin-  
3 ning on the date on which the determination is made by  
4 the Secretary, whichever occurs first. Determinations that  
5 terminate under the preceding sentence may be renewed  
6 by the Secretary (on the basis of the same or additional  
7 facts), and the preceding sentence applies to each such  
8 renewal. Not later than 48 hours after making a deter-  
9 mination under this subsection of a public health emer-  
10 gency (including a renewal), the Secretary shall submit to  
11 the Congress written notification of the determination.”.

12 (b) APPLICABILITY.—The amendment made by sub-  
13 section (a) applies to any public health emergency under  
14 section 319(a) of the Public Health Service Act, including  
15 any such emergency that was in effect as of the day before  
16 the date of the enactment of this Act. In the case of such  
17 an emergency that was in effect as of such day, the 90-  
18 day period described in such section with respect to the  
19 termination of the emergency is deemed to begin on such  
20 date of enactment.



1 **Subtitle E—Additional Provisions**

2 **SEC. 151. DESIGNATED STATE PUBLIC EMERGENCY AN-**  
3 **NOUNCEMENT PLAN.**

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

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

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

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

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

14 **SEC. 152. EXPANDED RESEARCH BY SECRETARY OF EN-**  
15 **ERGY.**

16 (a) DETECTION AND IDENTIFICATION RESEARCH.—

17 (1) IN GENERAL.—In conjunction with the  
18 working group under section 319F(a) of the Public  
19 Health Service Act, the Secretary of Energy and the  
20 Administrator of the National Nuclear Security Ad-  
21 ministration shall expand, enhance, and intensify re-  
22 search relevant to the rapid detection and identifica-  
23 tion of pathogens likely to be used in a bioterrorism  
24 attack or other agents that may cause a public  
25 health emergency.



1           (2) AUTHORIZED ACTIVITIES.—Activities car-  
2           ried out under paragraph (1) may include—

3                   (A) the improvement of methods for de-  
4                   tecting biological agents or toxins of potential  
5                   use in a biological attack and the testing of  
6                   such methods under variable conditions;

7                   (B) the improvement or pursuit of methods  
8                   for testing, verifying, and calibrating new detec-  
9                   tion and surveillance tools and techniques; and

10                   (C) carrying out other research activities  
11                   in relevant areas.

12           (3) REPORT.—Not later than 180 days after  
13           the date of the enactment of this Act, the Adminis-  
14           trator of the National Nuclear Security Administra-  
15           tion shall submit to the Committee on Energy and  
16           Natural Resources and the Committee on Armed  
17           Services of the Senate, and the Committee on En-  
18           ergy and Commerce and the Committee on Armed  
19           Services of the House of Representatives, a report  
20           setting forth the programs and projects that will be  
21           funded prior to the obligation of funds appropriated  
22           under subsection (b).

23           (b) AUTHORIZATION.—For the purpose of carrying  
24           out this section, there are authorized to be appropriated



1 such sums as may be necessary in each of fiscal years  
2 2002 through 2006.

3 **SEC. 153. EXPANDED RESEARCH ON WORKER HEALTH AND**  
4 **SAFETY.**

5 The Secretary of Health and Human Services (re-  
6 ferred to in this section as the “Secretary”), acting  
7 through the Director of the National Institute of Occupa-  
8 tional Safety and Health, shall enhance and expand re-  
9 search as deemed appropriate on the health and safety of  
10 workers who are at risk for bioterrorist threats or attacks  
11 in the workplace, including research on the health effects  
12 of measures taken to treat or protect such workers for  
13 diseases or disorders resulting from a bioterrorist threat  
14 or attack. Nothing in this section may be construed as  
15 establishing new regulatory authority for the Secretary or  
16 the Director to issue or modify any occupational safety  
17 and health rule or regulation.

18 **SEC. 154. ENHANCEMENT OF EMERGENCY PREPAREDNESS**  
19 **OF DEPARTMENT OF VETERANS AFFAIRS.**

20 (a) READINESS OF DEPARTMENT MEDICAL CEN-  
21 TER.—(1) The Secretary of Veterans Affairs shall take  
22 appropriate actions to enhance the readiness of Depart-  
23 ment of Veterans Affairs medical centers to protect the  
24 patients and staff of such centers from chemical or biologi-  
25 cal attack or otherwise to respond to such an attack and



1 so as to enable such centers to fulfil their obligations as  
2 part of the Federal response to public health emergencies.

3 (2) Actions under paragraph (1) shall include—

4 (A) the provision of decontamination equipment  
5 and personal protection equipment at Department  
6 medical centers; and

7 (B) the provision of training in the use of such  
8 equipment to staff of such centers.

9 (b) SECURITY AT DEPARTMENT MEDICAL AND RE-  
10 SEARCH FACILITIES.—(1) Not later than 180 days after  
11 the date of the enactment of this Act, the Secretary shall  
12 carry out an evaluation of the security needs at Depart-  
13 ment medical centers and research facilities. The evalua-  
14 tion shall address the following needs:

15 (A) Needs for the protection of patients and  
16 medical staff during emergencies, including a chem-  
17 ical or biological attack or other terrorist attack.

18 (B) Needs, if any, for screening personnel en-  
19 gaged in research relating to biological pathogens or  
20 agents, including work associated with such re-  
21 search.

22 (C) Needs for securing laboratories or other fa-  
23 cilities engaged in research relating to biological  
24 pathogens or agents.



1 (D) Any other needs the Secretary considers  
2 appropriate.

3 (2) The Secretary shall take appropriate actions to  
4 enhance the security of Department medical centers and  
5 research facilities, including staff and patients at such  
6 centers and facilities. In taking such actions, the Secretary  
7 shall take into account the results of the evaluation re-  
8 quired by paragraph (1).

9 (c) TRACKING OF PHARMACEUTICALS AND MEDICAL  
10 SUPPLIES AND EQUIPMENT.—The Secretary shall develop  
11 and maintain a centralized system for tracking the current  
12 location and availability of pharmaceuticals, medical sup-  
13 plies, and medical equipment throughout the Department  
14 health care system in order to permit the ready identifica-  
15 tion and utilization of such pharmaceuticals, supplies, and  
16 equipment for a variety of purposes, including response  
17 to a chemical or biological attack or other terrorist attack.

18 (d) TRAINING.—The Secretary shall ensure that the  
19 Department medical centers, in consultation with the ac-  
20 credited medical school affiliates of such medical centers,  
21 develop and implement curricula to train resident physi-  
22 cians and health care personnel in medical matters relat-  
23 ing to biological, chemical, or radiological attacks.

24 (e) PARTICIPATION IN NATIONAL DISASTER MED-  
25 ICAL SYSTEM.—(1) The Secretary shall, in consultation



1 with the Secretary of Defense, the Secretary of Health and  
2 Human Services, and the Director of the Federal Emer-  
3 gency Management Agency, establish and maintain a  
4 training program to facilitate the participation of the staff  
5 of Department medical centers, and of the community  
6 partners of such centers, in the National Disaster Medical  
7 System.

8 (2) The Secretary shall establish and maintain the  
9 training program under paragraph (1) in accordance with  
10 the recommendations of the working group under section  
11 319F(a) of the Public Health Service Act.

12 (f) MENTAL HEALTH COUNSELING.—(1) With re-  
13 spect to activities conducted by personnel serving at De-  
14 partment medical centers, the Secretary shall, in consulta-  
15 tion with the Secretary of Health and Human Services,  
16 the American Red Cross, and the working group under  
17 section 319F(a) of the Public Health Service Act, develop  
18 and maintain various strategies for providing mental  
19 health counseling and assistance, including counseling and  
20 assistance for post-traumatic stress disorder, to local and  
21 community emergency response providers, veterans, active  
22 duty military personnel, and individuals seeking care at  
23 Department medical centers following a bioterrorist attack  
24 or other public health emergency.



1 (2) The strategies under paragraph (1) shall include  
2 the following:

3 (A) Training and certification of providers of  
4 mental health counseling and assistance.

5 (B) Mechanisms for coordinating the provision  
6 of mental health counseling and assistance to emer-  
7 gency response providers referred to in that para-  
8 graph.

9 (g) AUTHORIZATION OF APPROPRIATIONS.—There is  
10 hereby authorized to be appropriated for the Department  
11 of Veterans Affairs amounts as follows:

12 (1) To carry out activities required by sub-  
13 section (a)—

14 (A) \$100,000,000 for fiscal year 2002; and

15 (B) such sums as may be necessary for  
16 each of fiscal years 2003 through 2006.

17 (2) To carry out activities required by sub-  
18 sections (b) through (f)—

19 (A) \$33,000,000 for fiscal year 2002; and

20 (B) such sums as may be necessary for  
21 each of fiscal years 2003 through 2006.

22 **SEC. 155. REAUTHORIZATION OF EXISTING PROGRAM.**

23 Section 582(f) of the Public Health Service Act (42  
24 U.S.C. 290hh-1(f)) is amended by striking “2002 and  
25 2003” and inserting “2003 through 2006”.



1 **SEC. 156. SENSE OF CONGRESS.**

2 It is the sense of the Congress that—

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

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

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

16 (4) the Secretary of Health and Human Serv-  
17 ices should, as appropriate, recognize the importance  
18 of existing public and private university-based re-  
19 search, training, public awareness, and safety related  
20 biological defense programs when the Secretary  
21 makes awards of grants and contracts in accordance  
22 with this Act and the amendments made by this Act.

23 **SEC. 157. GENERAL ACCOUNTING OFFICE REPORT.**

24 (a) IN GENERAL.—The Comptroller General shall  
25 submit to the Committee on Health, Education, Labor,  
26 and Pensions and the Committee on Appropriations of the



1 Senate, and to the Committee on Energy and Commerce  
2 and the Committee on Appropriations of the House of  
3 Representatives, a report that describes—

4 (1) Federal activities primarily related to re-  
5 search on, preparedness for, and the management of  
6 the public health and medical consequences of a bio-  
7 terrorist attack against the civilian population;

8 (2) the coordination of the activities described  
9 in paragraph (1);

10 (3) the effectiveness of such efforts in preparing  
11 national, State, and local authorities to address the  
12 public health and medical consequences of a poten-  
13 tial bioterrorist attack against the civilian popu-  
14 lation;

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

19 (5) the activities of the working group under  
20 subsection (a) and the efforts made by such group  
21 to carry out the activities described in such sub-  
22 section; and

23 (6) the ability of private sector contractors to  
24 enhance governmental responses to biological threats  
25 or attacks.



1 **SEC. 158. CERTAIN AWARDS.**

2 Section 319(a) of the Public Health Service Act (42  
3 U.S.C. 247d(a)) is amended in the matter after and below  
4 paragraph (2) by striking “grants and” and inserting  
5 “grants, providing awards for expenses, and”

6 **SEC. 159. PUBLIC ACCESS DEFIBRILLATION PROGRAMS**  
7 **AND PUBLIC ACCESS DEFIBRILLATION DEM-**  
8 **ONSTRATION PROJECTS.**

9 (a) **SHORT TITLE.**—This section may be cited as the  
10 “Community Access to Emergency Defibrillation Act of  
11 2002”.

12 (b) **FINDINGS.**—Congress makes the following find-  
13 ings:

14 (1) Over 220,000 Americans die each year from  
15 cardiac arrest. Every 2 minutes, an individual goes  
16 into cardiac arrest in the United States.

17 (2) The chance of successfully returning to a  
18 normal heart rhythm diminishes by 10 percent each  
19 minute following sudden cardiac arrest.

20 (3) Eighty percent of cardiac arrests are caused  
21 by ventricular fibrillation, for which defibrillation is  
22 the only effective treatment.

23 (4) Sixty percent of all cardiac arrests occur  
24 outside the hospital. The average national survival  
25 rate for out-of-hospital cardiac arrest is only 5 per-  
26 cent.



1 (5) Communities that have established and im-  
2 plemented public access defibrillation programs have  
3 achieved average survival rates for out-of-hospital  
4 cardiac arrest as high as 50 percent.

5 (6) According to the American Heart Associa-  
6 tion, wide use of defibrillators could save as many as  
7 50,000 lives nationally each year.

8 (7) Successful public access defibrillation pro-  
9 grams ensure that cardiac arrest victims have access  
10 to early 911 notification, early cardiopulmonary re-  
11 suscitation, early defibrillation, and early advanced  
12 care.

13 (c) PUBLIC ACCESS DEFIBRILLATION PROGRAMS  
14 AND PROJECTS.—Part B of title III of the Public Health  
15 Service Act (42 U.S.C. 243 et seq.), as amended by Public  
16 Law 106–310, is amended by adding after section 311 the  
17 following:

18 **“SEC. 312. PUBLIC ACCESS DEFIBRILLATION PROGRAMS.**

19 “(a) IN GENERAL.—The Secretary shall award  
20 grants to States, political subdivisions of States, Indian  
21 tribes, and tribal organizations to develop and implement  
22 public access defibrillation programs—

23 “(1) by training and equipping local emergency  
24 medical services personnel, including firefighters, po-  
25 lice officers, paramedics, emergency medical techni-



1 cians, and other first responders, to administer im-  
2 mediate care, including cardiopulmonary resuscita-  
3 tion and automated external defibrillation, to cardiac  
4 arrest victims;

5 “(2) by purchasing automated external  
6 defibrillators, placing the defibrillators in public  
7 places where cardiac arrests are likely to occur, and  
8 training personnel in such places to administer  
9 cardiopulmonary resuscitation and automated exter-  
10 nal defibrillation to cardiac arrest victims;

11 “(3) by setting procedures for proper mainte-  
12 nance and testing of such devices, according to the  
13 guidelines of the manufacturers of the devices;

14 “(4) by providing training to members of the  
15 public in cardiopulmonary resuscitation and auto-  
16 mated external defibrillation;

17 “(5) by integrating the emergency medical serv-  
18 ices system with the public access defibrillation pro-  
19 grams so that emergency medical services personnel,  
20 including dispatchers, are informed about the loca-  
21 tion of automated external defibrillators in their  
22 community; and

23 “(6) by encouraging private companies, includ-  
24 ing small businesses, to purchase automated external  
25 defibrillators and provide training for their employ-



1       ees to administer cardiopulmonary resuscitation and  
2       external automated defibrillation to cardiac arrest  
3       victims in their community.

4       “(b) PREFERENCE.—In awarding grants under sub-  
5       section (a), the Secretary shall give a preference to a  
6       State, political subdivision of a State, Indian tribe, or trib-  
7       al organization that—

8               “(1) has a particularly low local survival rate  
9               for cardiac arrests, or a particularly low local re-  
10              sponse rate for cardiac arrest victims; or

11             “(2) demonstrates in its application the great-  
12             est commitment to establishing and maintaining a  
13             public access defibrillation program.

14       “(c) USE OF FUNDS.—A State, political subdivision  
15       of a State, Indian tribe, or tribal organization that receives  
16       a grant under subsection (a) may use funds received  
17       through such grant to—

18             “(1) purchase automated external defibrillators  
19             that have been approved, or cleared for marketing,  
20             by the Food and Drug Administration;

21             “(2) provide automated external defibrillation  
22             and basic life support training in automated external  
23             defibrillator usage through nationally recognized  
24             courses;



1           “(3) provide information to community mem-  
2           bers about the public access defibrillation program  
3           to be funded with the grant;

4           “(4) provide information to the local emergency  
5           medical services system regarding the placement of  
6           automated external defibrillators in public places;

7           “(5) produce materials to encourage private  
8           companies, including small businesses, to purchase  
9           automated external defibrillators; and

10          “(6) further develop strategies to improve ac-  
11          cess to automated external defibrillators in public  
12          places.

13          “(d) APPLICATION.—

14                 “(1) IN GENERAL.—To be eligible to receive a  
15                 grant under subsection (a), a State, political subdivi-  
16                 sion of a State, Indian tribe, or tribal organization  
17                 shall prepare and submit an application to the Sec-  
18                 retary at such time, in such manner, and containing  
19                 such information as the Secretary may reasonably  
20                 require.

21                 “(2) CONTENTS.—An application submitted  
22                 under paragraph (1) shall—

23                         “(A) describe the comprehensive public ac-  
24                         cess defibrillation program to be funded with  
25                         the grant and demonstrate how such program



1 would make automated external defibrillation  
2 accessible and available to cardiac arrest vic-  
3 tims in the community;

4 “(B) contain procedures for implementing  
5 appropriate nationally recognized training  
6 courses in performing cardiopulmonary resus-  
7 citation and the use of automated external  
8 defibrillators;

9 “(C) contain procedures for ensuring direct  
10 involvement of a licensed medical professional  
11 and coordination with the local emergency med-  
12 ical services system in the oversight of training  
13 and notification of incidents of the use of the  
14 automated external defibrillators;

15 “(D) contain procedures for proper main-  
16 tenance and testing of the automated external  
17 defibrillators, according to the labeling of the  
18 manufacturer;

19 “(E) contain procedures for ensuring noti-  
20 fication of local emergency medical services sys-  
21 tem personnel, including dispatchers, of the lo-  
22 cation and type of devices used in the public ac-  
23 cess defibrillation program; and

24 “(F) provide for the collection of data re-  
25 garding the effectiveness of the public access





1       “(b) USE OF FUNDS.—A recipient of a grant under  
2 subsection (a) shall use the funds provided through the  
3 grant to—

4           “(1) purchase automated external defibrillators  
5 that have been approved, or cleared for marketing,  
6 by the Food and Drug Administration;

7           “(2) provide basic life training in automated ex-  
8 ternal defibrillator usage through nationally recog-  
9 nized courses;

10          “(3) provide information to community mem-  
11 bers about the public access defibrillation dem-  
12 onstration project to be funded with the grant;

13          “(4) provide information to the local emergency  
14 medical services system regarding the placement of  
15 automated external defibrillators in the unique set-  
16 tings; and

17          “(5) further develop strategies to improve ac-  
18 cess to automated external defibrillators in public  
19 places.

20       “(c) APPLICATION.—

21           “(1) IN GENERAL.—To be eligible to receive a  
22 grant under subsection (a), a political subdivision of  
23 a State, Indian tribe, or tribal organization shall  
24 prepare and submit an application to the Secretary  
25 at such time, in such manner, and containing such



1 information as the Secretary may reasonably re-  
2 quire.

3 “(2) CONTENTS.—An application submitted  
4 under paragraph (1) may—

5 “(A) describe the innovative, comprehen-  
6 sive, community-based public access  
7 defibrillation demonstration project to be fund-  
8 ed with the grant;

9 “(B) explain how such public access  
10 defibrillation demonstration project represents  
11 innovation in providing public access to auto-  
12 mated external defibrillation; and

13 “(C) provide for the collection of data re-  
14 garding the effectiveness of the demonstration  
15 project to be funded with the grant in—

16 “(i) providing emergency  
17 cardiopulmonary resuscitation and auto-  
18 mated external defibrillation to cardiac ar-  
19 rest victims in the setting served by the  
20 demonstration project; and

21 “(ii) affecting the cardiac arrest sur-  
22 vival rate in the setting served by the dem-  
23 onstration project.

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



1 \$5,000,000 for each of fiscal years 2002 through 2006.  
2 Not more than 10 percent of amounts received under a  
3 grant awarded under this section may be used for adminis-  
4 trative expenses.”.

5 **TITLE II—ENHANCING CON-**  
6 **TROLS ON DANGEROUS BIO-**  
7 **LOGICAL AGENTS AND TOX-**  
8 **INS**

9 **Subtitle A—Department of Health**  
10 **and Human Services**

11 **SEC. 201. REGULATION OF CERTAIN BIOLOGICAL AGENTS**  
12 **AND TOXINS.**

13 (a) BIOLOGICAL AGENTS PROVISIONS OF THE  
14 ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT  
15 OF 1996; CODIFICATION IN THE PUBLIC HEALTH SERV-  
16 ICE ACT, WITH AMENDMENTS.—Subpart 1 of part F of  
17 title III of the Public Health Service Act (42 U.S.C. 262  
18 et seq.) is amended by inserting after section 351 the fol-  
19 lowing:

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

22 “(a) REGULATORY CONTROL OF CERTAIN BIOLOGI-  
23 CAL AGENTS AND TOXINS.—

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



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

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

9                   “(i) consider—

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

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

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

21                           “(IV) any other criteria, includ-  
22 ing the needs of children and other  
23 vulnerable populations, that the Sec-  
24 retary considers appropriate; and



1                   “(ii) consult with appropriate Federal  
2                   departments and agencies and with sci-  
3                   entific experts representing appropriate  
4                   professional groups, including groups with  
5                   pediatric expertise.

6                   “(2) BIENNIAL REVIEW.—The Secretary shall  
7                   review and republish the list under paragraph (1) bi-  
8                   ennially, or more often as needed, and shall by regu-  
9                   lation revise the list as necessary in accordance with  
10                  such paragraph.

11                  “(b) REGULATION OF TRANSFERS OF LISTED  
12                  AGENTS AND TOXINS.—The Secretary shall by regulation  
13                  provide for—

14                  “(1) the establishment and enforcement of safe-  
15                  ty procedures for the transfer of listed agents and  
16                  toxins, including measures to ensure—

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

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

21                  “(2) the establishment and enforcement of safe-  
22                  guard and security measures to prevent access to  
23                  such agents and toxins for use in domestic or inter-  
24                  national terrorism or for any other criminal purpose;



1           “(3) the establishment of procedures to protect  
2           the public safety in the event of a transfer or poten-  
3           tial transfer of such an agent or toxin in violation  
4           of the safety procedures established under paragraph  
5           (1) or the safeguard and security measures estab-  
6           lished under paragraph (2); and

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

10          “(c) POSSESSION AND USE OF LISTED AGENTS AND  
11          TOXINS.—The Secretary shall by regulation provide for  
12          the establishment and enforcement of standards and pro-  
13          cedures governing the possession and use of listed agents  
14          and toxins, including the provisions described in para-  
15          graphs (1) through (4) of subsection (b), in order to pro-  
16          tect the public health and safety.

17          “(d) REGISTRATION; IDENTIFICATION; DATABASE.—

18                 “(1) REGISTRATION.—Regulations under sub-  
19                 sections (b) and (c) shall require registration with  
20                 the Secretary of the possession, use, and transfer of  
21                 listed agents and toxins, and shall include provisions  
22                 to ensure that persons seeking to register under  
23                 such regulations have a lawful purpose to possess,  
24                 use, or transfer such agents and toxins, including  
25                 provisions in accordance with subsection (e)(6).



1           “(2) IDENTIFICATION; DATABASE.—Regulations  
2           under subsections (b) and (c) shall require that reg-  
3           istration include (if available to the person reg-  
4           istering) information regarding the characterization  
5           of listed agents and toxins to facilitate their identi-  
6           fication, including their source. The Secretary shall  
7           maintain a national database that includes the  
8           names and locations of registered persons, the listed  
9           agents and toxins such persons are possessing,  
10          using, or transferring, and information regarding  
11          the characterization of such agents and toxins.

12          “(e) SAFEGUARD AND SECURITY REQUIREMENTS  
13          FOR REGISTERED PERSONS.—

14               “(1) IN GENERAL.—Regulations under sub-  
15               sections (b) and (c) shall include appropriate safe-  
16               guard and security requirements for persons pos-  
17               sessing, using, or transferring a listed agent or toxin  
18               commensurate with the risk such agent or toxin  
19               poses to public health and safety (including the risk  
20               of use in domestic or international terrorism). The  
21               Secretary shall establish such requirements in con-  
22               sultation with the Attorney General, and shall en-  
23               sure compliance with such requirements as part of  
24               the registration system under such regulations.



1           “(2) LIMITING ACCESS TO LISTED AGENTS AND  
2           TOXINS.—Requirements under paragraph (1) shall  
3           include provisions to ensure that registered  
4           persons—

5                   “(A) provide access to listed agents and  
6                   toxins to only those individuals whom the reg-  
7                   istered person involved determines have a legiti-  
8                   mate need to handle or use such agents and  
9                   toxins;

10                   “(B) submit the names and other identi-  
11                   fying information for such individuals to the  
12                   Secretary and the Attorney General, promptly  
13                   after first determining that the individuals need  
14                   access under subparagraph (A), and periodically  
15                   thereafter while the individuals have such ac-  
16                   cess, not less frequently than once every five  
17                   years;

18                   “(C) deny access to such agents and toxins  
19                   by individuals whom the Attorney General has  
20                   identified as restricted persons; and

21                   “(D) limit or deny access to such agents  
22                   and toxins by individuals whom the Attorney  
23                   General has identified as within any category  
24                   under paragraph (3)(B)(ii), if limiting or deny-  
25                   ing such access by the individuals involved is



1 determined appropriate by the Secretary, in  
2 consultation with the Attorney General.

3 “(3) SUBMITTED NAMES; USE OF DATABASES  
4 BY ATTORNEY GENERAL.—

5 “(A) IN GENERAL.—Upon the receipt of  
6 names and other identifying information under  
7 paragraph (2)(B), the Attorney General shall,  
8 for the sole purpose of identifying whether the  
9 individuals involved are within any of the cat-  
10 egories specified in subparagraph (B), promptly  
11 use criminal, immigration, national security,  
12 and other electronic databases that are avail-  
13 able to the Federal Government and are appro-  
14 priate for such purpose.

15 “(B) CERTAIN INDIVIDUALS.—For pur-  
16 poses of subparagraph (A), the categories speci-  
17 fied in this subparagraph regarding an indi-  
18 vidual are that—

19 “(i) the individual is a restricted per-  
20 son; or

21 “(ii) the individual is reasonably sus-  
22 pected by any Federal law enforcement or  
23 intelligence agency of—



1                   “(I) committing a crime set forth  
2                   in section 2332b(g)(5) of title 18,  
3                   United States Code;

4                   “(II) knowing involvement with  
5                   an organization that engages in do-  
6                   mestic or international terrorism (as  
7                   defined in section 2331 of such title  
8                   18) or with any other organization  
9                   that engages in intentional crimes of  
10                  violence; or

11                  “(III) being an agent of a foreign  
12                  power (as defined in section 1801 of  
13                  title 50, United States Code).

14                  “(C) NOTIFICATION BY ATTORNEY GEN-  
15                  ERAL REGARDING SUBMITTED NAMES.—After  
16                  the receipt of a name and other identifying in-  
17                  formation under paragraph (2)(B), the Attor-  
18                  ney General shall promptly notify the Secretary  
19                  whether the individual is within any of the cat-  
20                  egories specified in subparagraph (B).

21                  “(4) NOTIFICATIONS BY SECRETARY.—The Sec-  
22                  retary, after receiving notice under paragraph (3)  
23                  regarding an individual, shall promptly notify the  
24                  registered person involved of whether the individual  
25                  is granted or denied access under paragraph (2). If



1 the individual is denied such access, the Secretary  
2 shall promptly notify the individual of the denial.

3 “(5) EXPEDITED REVIEW.—Regulations under  
4 subsections (b) and (c) shall provide for a procedure  
5 through which, upon request to the Secretary by a  
6 registered person who submits names and other  
7 identifying information under paragraph (2)(B) and  
8 who demonstrates good cause, the Secretary may, as  
9 determined appropriate by the Secretary—

10 “(A) request the Attorney General to expedite  
11 the process of identification under paragraph  
12 (3)(A) and notification of the Secretary  
13 under paragraph (3)(C); and

14 “(B) expedite the notification of the registered  
15 person by the Secretary under paragraph  
16 (4).

17 “(6) PROCESS REGARDING PERSONS SEEKING  
18 TO REGISTER.—

19 “(A) INDIVIDUALS.—Regulations under  
20 subsections (b) and (c) shall provide that an individual  
21 who seeks to register under either of  
22 such subsections is subject to the same processes  
23 described in paragraphs (2) through (4)  
24 as apply to names and other identifying information  
25 submitted to the Attorney General



1 under paragraph (2)(B). Paragraph (5) does  
2 not apply for purposes of this subparagraph.

3 “(B) OTHER PERSONS.—Regulations  
4 under subsections (b) and (c) shall provide that,  
5 in determining whether to deny or revoke reg-  
6 istration by a person other than an individual,  
7 the Secretary shall submit the name of such  
8 person to the Attorney General, who shall use  
9 criminal, immigration, national security, and  
10 other electronic databases available to the Fed-  
11 eral Government, as appropriate for the pur-  
12 pose of promptly notifying the Secretary wheth-  
13 er the person, or, where relevant, the individual  
14 who owns or controls such person, is a re-  
15 stricted person or is reasonably suspected by  
16 any Federal law enforcement or intelligence  
17 agency of being within any category specified in  
18 paragraph (3)(B)(ii) (as applied to persons, in-  
19 cluding individuals). Such regulations shall pro-  
20 vide that a person who seeks to register under  
21 either of such subsections is subject to the same  
22 processes described in paragraphs (2) and (4)  
23 as apply to names and other identifying infor-  
24 mation submitted to the Attorney General  
25 under paragraph (2)(B). Paragraph (5) does



1 not apply for purposes of this subparagraph.  
2 The Secretary may exempt Federal, State, or  
3 local governmental agencies from the require-  
4 ments of this subparagraph.

5 “(7) REVIEW.—

6 “(A) ADMINISTRATIVE REVIEW.—

7 “(i) IN GENERAL.—Regulations under  
8 subsections (b) and (c) shall provide for an  
9 opportunity for a review by the  
10 Secretary—

11 “(I) when requested by the indi-  
12 vidual involved, of a determination  
13 under paragraph (2) to deny the indi-  
14 vidual access to listed agents and tox-  
15 ins; and

16 “(II) when requested by the per-  
17 son involved, of a determination under  
18 paragraph (6) to deny or revoke reg-  
19 istration for such person.

20 “(ii) EX PARTE REVIEW.—During a  
21 review under clause (i), the Secretary may  
22 consider information relevant to the review  
23 ex parte to the extent that disclosure of  
24 the information could compromise national



1 security or an investigation by any law en-  
2 forcement agency.

3 “(iii) FINAL AGENCY ACTION.—The  
4 decision of the Secretary in a review under  
5 clause (i) constitutes final agency action  
6 for purposes of section 702 of title 5,  
7 United States Code.

8 “(B) CERTAIN PROCEDURES.—

9 “(i) SUBMISSION OF EX PARTE MATE-  
10 RIALS IN JUDICIAL PROCEEDINGS.—When  
11 reviewing a decision of the Secretary under  
12 subparagraph (A), and upon request made  
13 ex parte and in writing by the United  
14 States, a court, upon a sufficient showing,  
15 may review and consider ex parte docu-  
16 ments containing information the disclo-  
17 sure of which could compromise national  
18 security or an investigation by any law en-  
19 forcement agency. If the court determines  
20 that portions of the documents considered  
21 ex parte should be disclosed to the person  
22 involved to allow a response, the court  
23 shall authorize the United States to delete  
24 from such documents specified items of in-  
25 formation the disclosure of which could



1           compromise national security or an inves-  
2           tigation by any law enforcement agency, or  
3           to substitute a summary of the information  
4           to which the person may respond. Any  
5           order by the court authorizing the disclo-  
6           sure of information that the United States  
7           believes could compromise national security  
8           or an investigation by any law enforcement  
9           agency shall be subject to the processes set  
10          forth in subparagraphs (A) and (B)(i) of  
11          section 2339B(f)(5) of title 18, United  
12          States Code (relating to interlocutory ap-  
13          peal and expedited consideration).

14                   “(ii) DISCLOSURE OF INFORMA-  
15                   TION.—In a review under subparagraph  
16                   (A), and in any judicial proceeding con-  
17                   ducted pursuant to such review, neither  
18                   the Secretary nor the Attorney General  
19                   may be required to disclose to the public  
20                   any information that under subsection (h)  
21                   shall not be disclosed under section 552 of  
22                   title 5, United States Code.

23                   “(8) NOTIFICATIONS REGARDING THEFT OR  
24                   LOSS OF AGENTS.—Requirements under paragraph  
25                   (1) shall include the prompt notification of the Sec-



1       retary, and appropriate Federal, State, and local law  
2       enforcement agencies, of the theft or loss of listed  
3       agents and toxins.

4               “(9) TECHNICAL ASSISTANCE FOR REGISTERED  
5       PERSONS.—The Secretary, in consultation with the  
6       Attorney General, may provide technical assistance  
7       to registered persons to improve security of the fa-  
8       cilities of such persons.

9               “(f) INSPECTIONS.—The Secretary shall have the au-  
10      thority to inspect persons subject to regulations under  
11      subsection (b) or (c) to ensure their compliance with such  
12      regulations, including prohibitions on restricted persons  
13      and other provisions of subsection (e).

14              “(g) EXEMPTIONS.—

15                      “(1) CLINICAL OR DIAGNOSTIC LABORA-  
16      TORIES.—Regulations under subsections (b) and (c)  
17      shall exempt clinical or diagnostic laboratories and  
18      other persons who possess, use, or transfer listed  
19      agents or toxins that are contained in specimens  
20      presented for diagnosis, verification, or proficiency  
21      testing, provided that—

22                              “(A) the identification of such agents or  
23                              toxins is reported to the Secretary, and when  
24                              required under Federal, State, or local law, to  
25                              other appropriate authorities; and



1           “(B) such agents or toxins are transferred  
2 or destroyed in a manner set forth by the Sec-  
3 retary by regulation.

4           “(2) PRODUCTS.—

5           “(A) IN GENERAL.—Regulations under  
6 subsections (b) and (c) shall exempt products  
7 that are, bear, or contain listed agents or toxins  
8 and are cleared, approved, licensed, or reg-  
9 istered under any of the Acts specified in sub-  
10 paragraph (B), unless the Secretary by order  
11 determines that applying additional regulation  
12 under subsection (b) or (c) to a specific product  
13 is necessary to protect public health and safety.

14           “(B) RELEVANT LAWS.—For purposes of  
15 subparagraph (A), the Acts specified in this  
16 subparagraph are the following:

17           “(i) The Federal Food, Drug, and  
18 Cosmetic Act.

19           “(ii) Section 351 of this Act.

20           “(iii) The Act commonly known as the  
21 Virus-Serum-Toxin Act (the eighth para-  
22 graph under the heading ‘Bureau of Ani-  
23 mal Industry’ in the Act of March 4, 1913;  
24 21 U.S.C. 151-159).



1           “(iv) The Federal Insecticide, Fun-  
2           gicide, and Rodenticide Act.

3           “(C) INVESTIGATIONAL USE.—

4           “(i) IN GENERAL.—The Secretary  
5           may exempt an investigational product  
6           that is, bears, or contains a listed agent or  
7           toxin from the applicability of provisions of  
8           regulations under subsection (b) or (c)  
9           when such product is being used in an in-  
10          vestigation authorized under any Federal  
11          Act and the Secretary determines that ap-  
12          plying additional regulation under sub-  
13          section (b) or (c) to such product is not  
14          necessary to protect public health and safe-  
15          ty.

16          “(ii) CERTAIN PROCESSES.—Regula-  
17          tions under subsections (b) and (c) shall  
18          set forth the procedures for applying for  
19          an exemption under clause (i). In the case  
20          of investigational products authorized  
21          under any of the Acts specified in subpara-  
22          graph (B), the Secretary shall make a de-  
23          termination regarding a request for an ex-  
24          emption not later than 14 days after the  
25          first date on which both of the following



1 conditions have been met by the person re-  
2 questing the exemption:

3 “(I) The person has submitted to  
4 the Secretary an application for the  
5 exemption meeting the requirements  
6 established by the Secretary.

7 “(II) The person has notified the  
8 Secretary that the investigation has  
9 been authorized under such an Act.

10 “(3) PUBLIC HEALTH EMERGENCIES.—The  
11 Secretary may temporarily exempt a person from the  
12 applicability of the requirements of this section, in  
13 whole or in part, if the Secretary determines that  
14 such exemption is necessary to provide for the timely  
15 participation of the person in a response to a domes-  
16 tic or foreign public health emergency (whether de-  
17 termined under section 319(a) or otherwise) that in-  
18 volves a listed agent or toxin. With respect to the  
19 emergency involved, such exemption for a person  
20 may not exceed 30 days, except that the Secretary,  
21 after review of whether such exemption remains nec-  
22 essary, may provide one extension of an additional  
23 30 days.

24 “(4) AGRICULTURAL EMERGENCIES.—Upon re-  
25 quest of the Secretary of Agriculture, after the



1       granting by such Secretary of an exemption under  
2       section 212(g)(1)(D) of the Agricultural Bioter-  
3       rorism Protection Act of 2002 pursuant to a finding  
4       that there is an agricultural emergency, the Sec-  
5       retary of Health and Human Services may tempo-  
6       rarily exempt a person from the applicability of the  
7       requirements of this section, in whole or in part, to  
8       provide for the timely participation of the person in  
9       a response to the agricultural emergency. With re-  
10      spect to the emergency involved, the exemption  
11      under this paragraph for a person may not exceed  
12      30 days, except that upon request of the Secretary  
13      of Agriculture, the Secretary of Health and Human  
14      Services may, after review of whether such exemp-  
15      tion remains necessary, provide one extension of an  
16      additional 30 days.

17      “(h) DISCLOSURE OF INFORMATION.—

18             “(1) NONDISCLOSURE OF CERTAIN INFORMA-  
19      TION.—No Federal agency specified in paragraph  
20      (2) shall disclose under section 552 of title 5, United  
21      States Code, any of the following:

22             “(A) Any registration or transfer docu-  
23      mentation submitted under subsections (b) and  
24      (c) for the possession, use, or transfer of a list-  
25      ed agent or toxin; or information derived there-



1 from to the extent that it identifies the listed  
2 agent or toxin possessed, used, or transferred  
3 by a specific registered person or discloses the  
4 identity or location of a specific registered per-  
5 son.

6 “(B) The national database developed pur-  
7 suant to subsection (d), or any other compila-  
8 tion of the registration or transfer information  
9 submitted under subsections (b) and (c) to the  
10 extent that such compilation discloses site-spe-  
11 cific registration or transfer information.

12 “(C) Any portion of a record that discloses  
13 the site-specific or transfer-specific safeguard  
14 and security measures used by a registered per-  
15 son to prevent unauthorized access to listed  
16 agents and toxins.

17 “(D) Any notification of a release of a list-  
18 ed agent or toxin submitted under subsections  
19 (b) and (c), or any notification of theft or loss  
20 submitted under such subsections.

21 “(E) Any portion of an evaluation or re-  
22 port of an inspection of a specific registered  
23 person conducted under subsection (f) that  
24 identifies the listed agent or toxin possessed by  
25 a specific registered person or that discloses the



1 identity or location of a specific registered per-  
2 son if the agency determines that public disclo-  
3 sure of the information would endanger public  
4 health or safety.

5 “(2) COVERED AGENCIES.—For purposes of  
6 paragraph (1) only, the Federal agencies specified in  
7 this paragraph are the following:

8 “(A) The Department of Health and  
9 Human Services, the Department of Justice,  
10 the Department of Agriculture, and the Depart-  
11 ment of Transportation.

12 “(B) Any Federal agency to which infor-  
13 mation specified in paragraph (1) is transferred  
14 by any agency specified in subparagraph (A) of  
15 this paragraph.

16 “(C) Any Federal agency that is a reg-  
17 istered person, or has a sub-agency component  
18 that is a registered person.

19 “(D) Any Federal agency that awards  
20 grants or enters into contracts or cooperative  
21 agreements involving listed agents and toxins to  
22 or with a registered person, and to which infor-  
23 mation specified in paragraph (1) is transferred  
24 by any such registered person.



1           “(3) OTHER EXEMPTIONS.—This subsection  
2           may not be construed as altering the application of  
3           any exemptions to public disclosure under section  
4           552 of title 5, United States Code, except as to sub-  
5           section 552(b)(3) of such title, to any of the infor-  
6           mation specified in paragraph (1).

7           “(4) RULE OF CONSTRUCTION.—Except as spe-  
8           cifically provided in paragraph (1), this subsection  
9           may not be construed as altering the authority of  
10          any Federal agency to withhold under section 552 of  
11          title 5, United States Code, or the obligation of any  
12          Federal agency to disclose under section 552 of title  
13          5, United States Code, any information, including  
14          information relating to—

15               “(A) listed agents and toxins, or individ-  
16               uals seeking access to such agents and toxins;

17               “(B) registered persons, or persons seeking  
18               to register their possession, use, or transfer of  
19               such agents and toxins;

20               “(C) general safeguard and security poli-  
21               cies and requirements under regulations under  
22               subsections (b) and (c); or

23               “(D) summary or statistical information  
24               concerning registrations, registrants, denials or  
25               revocations of registrations, listed agents and



1 toxins, inspection evaluations and reports, or in-  
2 dividuals seeking access to such agents and tox-  
3 ins.

4 “(5) DISCLOSURES TO CONGRESS; OTHER DIS-  
5 CLOSURES.—This subsection may not be construed  
6 as providing any authority—

7 “(A) to withhold information from the  
8 Congress or any committee or subcommittee  
9 thereof; or

10 “(B) to withhold information from any  
11 person under any other Federal law or treaty.

12 “(i) CIVIL MONEY PENALTY.—

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

20 “(2) APPLICABILITY OF CERTAIN PROVI-  
21 SIONS.—The provisions of section 1128A of the So-  
22 cial Security Act (other than subsections (a), (b),  
23 (h), and (i), the first sentence of subsection (c), and  
24 paragraphs (1) and (2) of subsection (f)) shall apply  
25 to a civil money penalty under paragraph (1) in the



1 same manner as such provisions apply to a penalty  
2 or proceeding under section 1128A(a) of such Act.  
3 The Secretary may delegate authority under this  
4 subsection in the same manner as provided in sec-  
5 tion 1128A(j)(2) of the Social Security Act, and  
6 such authority shall include all powers as contained  
7 in section 6 of the Inspector General Act of 1978 (5  
8 U.S.C. App.).

9 “(j) NOTIFICATION IN EVENT OF RELEASE.—Regu-  
10 lations under subsections (b) and (c) shall require the  
11 prompt notification of the Secretary by a registered person  
12 whenever a release, meeting criteria established by the  
13 Secretary, of a listed agent or toxin has occurred outside  
14 of the biocontainment area of a facility of the registered  
15 person. Upon receipt of such notification and a finding  
16 by the Secretary that the release poses a threat to public  
17 health or safety, the Secretary shall take appropriate ac-  
18 tion to notify relevant State and local public health au-  
19 thorities, other relevant Federal authorities, and, if nec-  
20 essary, other appropriate persons (including the public).  
21 If the released listed agent or toxin is an overlap agent  
22 or toxin (as defined in subsection (l)), the Secretary shall  
23 promptly notify the Secretary of Agriculture upon notifica-  
24 tion by the registered person.



1       “(k) REPORTS.—The Secretary shall report to the  
2 Congress annually on the number and nature of notifica-  
3 tions received under subsection (e)(8) (relating to theft or  
4 loss) and subsection (j) (relating to releases).

5       “(l) DEFINITIONS.—For purposes of this section:

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

9           “(2) The term ‘listed agents and toxins’ means  
10 biological agents and toxins listed pursuant to sub-  
11 section (a)(1).

12           “(3) The term ‘listed agents or toxins’ means  
13 biological agents or toxins listed pursuant to sub-  
14 section (a)(1).

15           “(4) The term ‘overlap agents and toxins’  
16 means biological agents and toxins that—

17           “(A) are listed pursuant to subsection  
18 (a)(1); and

19           “(B) are listed pursuant to section  
20 212(a)(1) of the Agricultural Bioterrorism Pro-  
21 tection Act of 2002.

22           “(5) The term ‘overlap agent or toxin’ means a  
23 biological agent or toxin that—

24           “(A) is listed pursuant to subsection  
25 (a)(1); and



1           “(B) is listed pursuant to section  
2           212(a)(1) of the Agricultural Bioterrorism Pro-  
3           tection Act of 2002.

4           “(6) The term ‘person’ includes Federal, State,  
5           and local governmental entities.

6           “(7) The term ‘registered person’ means a per-  
7           son registered under regulations under subsection  
8           (b) or (c).

9           “(8) The term ‘restricted person’ has the mean-  
10          ing given such term in section 175b of title 18,  
11          United States Code.

12          “(m) AUTHORIZATION OF APPROPRIATIONS.—For  
13          the purpose of carrying out this section, there are author-  
14          ized to be appropriated such sums as may be necessary  
15          for each of the fiscal years 2002 through 2007.”.

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

21                (1) describes the extent to which there has been  
22                compliance by governmental and private entities  
23                with applicable regulations under section 351A of  
24                the Public Health Service Act (as added by sub-  
25                section (a) of this section), including the extent of



1 compliance before the date of the enactment of this  
2 Act, and including the extent of compliance with  
3 regulations promulgated after such date of enact-  
4 ment;

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

8 (3) describes the actions to date and future  
9 plans of the Secretary for determining compliance  
10 with regulations under such section 351A and for  
11 taking appropriate enforcement actions;

12 (4) evaluates the impact of such section 351A  
13 on research on biological agents and toxins listed  
14 pursuant to such section; and

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

18 **SEC. 202. IMPLEMENTATION BY DEPARTMENT OF HEALTH**

19 **AND HUMAN SERVICES.**

20 (a) **DATE CERTAIN FOR NOTICE OF POSSESSION.—**

21 Not later than 90 days after the date of the enactment  
22 of this Act, all persons (unless exempt under subsection  
23 (g) of section 351A of the Public Health Service Act, as  
24 added by section 201 of this Act) in possession of biologi-  
25 cal agents or toxins listed under such section 351A of the



1 Public Health Service Act shall notify the Secretary of  
2 Health and Human Services of such possession. Not later  
3 than 30 days after such date of enactment, the Secretary  
4 shall provide written guidance on how such notice is to  
5 be provided to the Secretary.

6 (b) DATE CERTAIN FOR PROMULGATION; EFFECTIVE  
7 DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—  
8 Not later than 180 days after the date of the enactment  
9 of this Act, the Secretary of Health and Human Services  
10 shall promulgate an interim final rule for carrying out sec-  
11 tion 351A of the Public Health Service Act, subject to sub-  
12 section (c). Such interim final rule shall take effect 60  
13 days after the date on which such rule is promulgated,  
14 including for purposes of—

15 (1) section 175b(c) of title 18, United States  
16 Code (relating to criminal penalties), as added by  
17 section 231(a)(5) of this Act; and

18 (2) section 351A(i) of the Public Health Service  
19 Act (relating to civil penalties).

20 (c) TRANSITIONAL PROVISION REGARDING CURRENT  
21 RESEARCH AND EDUCATION.—The interim final rule  
22 under subsection (b) shall include time frames for the ap-  
23 plicability of the rule that minimize disruption of research  
24 or educational projects that involve biological agents and  
25 toxins listed pursuant to section 351A(a)(1) of the Public



1 Health Service Act and that were underway as of the ef-  
2 fective date of such rule.

3 **SEC. 203. EFFECTIVE DATES.**

4 (a) IN GENERAL.—Regulations promulgated by the  
5 Secretary of Health and Human Services under section  
6 511 of the Antiterrorism and Effective Death Penalty Act  
7 of 1996 are deemed to have been promulgated under sec-  
8 tion 351A of the Public Health Service Act, as added by  
9 section 201 of this Act. Such regulations, including the  
10 list under subsection (d)(1) of such section 511, that were  
11 in effect on the day before the date of the enactment of  
12 this Act remain in effect until modified by the Secretary  
13 in accordance with such section 351A and with section  
14 202 of this Act.

15 (b) EFFECTIVE DATE REGARDING DISCLOSURE OF  
16 INFORMATION.—Subsection (h) of section 351A of the  
17 Public Health Service Act, as added by section 201 of this  
18 Act, is deemed to have taken effect on the effective date  
19 of the Antiterrorism and Effective Death Penalty Act of  
20 1996.

21 **SEC. 204. CONFORMING AMENDMENT.**

22 Subsections (d), (e), (f), and (g) of section 511 of  
23 the Antiterrorism and Effective Death Penalty Act of  
24 1996 (42 U.S.C. 262 note) are repealed.



1                   **Subtitle B—Department of**  
2                   **Agriculture**

3 **SEC. 211. SHORT TITLE.**

4           This subtitle may be cited as the “Agricultural Bio-  
5 terrorism Protection Act of 2002”.

6 **SEC. 212. REGULATION OF CERTAIN BIOLOGICAL AGENTS**  
7                   **AND TOXINS.**

8           (a) **REGULATORY CONTROL OF CERTAIN BIOLOGICAL**  
9 **AGENTS AND TOXINS.—**

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

12                           (A) **IN GENERAL.—**The Secretary of Agri-  
13 culture shall by regulation establish and main-  
14 tain a list of each biological agent and each  
15 toxin that the Secretary determines has the po-  
16 tential to pose a severe threat to animal or  
17 plant health, or to animal or plant products.

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

21                                   (i) consider—

22   (I) the effect of exposure to the  
23 agent or toxin on animal or plant  
24 health, and on the production and



1 marketability of animal or plant prod-  
2 ucts;

3 (II) the pathogenicity of the  
4 agent or the toxicity of the toxin and  
5 the methods by which the agent or  
6 toxin is transferred to animals or  
7 plants;

8 (III) the availability and effec-  
9 tiveness of pharmacotherapies and  
10 prophylaxis to treat and prevent any  
11 illness caused by the agent or toxin;  
12 and

13 (IV) any other criteria that the  
14 Secretary considers appropriate to  
15 protect animal or plant health, or ani-  
16 mal or plant products; and

17 (ii) consult with appropriate Federal  
18 departments and agencies and with sci-  
19 entific experts representing appropriate  
20 professional groups.

21 (2) BIENNIAL REVIEW.—The Secretary shall re-  
22 view and republish the list under paragraph (1) bi-  
23 ennially, or more often as needed, and shall by regu-  
24 lation revise the list as necessary in accordance with  
25 such paragraph.



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

4 (1) the establishment and enforcement of safety  
5 procedures for the transfer of listed agents and tox-  
6 ins, including measures to ensure—

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

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

11 (2) the establishment and enforcement of safe-  
12 guard and security measures to prevent access to  
13 such agents and toxins for use in domestic or inter-  
14 national terrorism or for any other criminal purpose;

15 (3) the establishment of procedures to protect  
16 animal and plant health, and animal and plant prod-  
17 ucts, in the event of a transfer or potential transfer  
18 of such an agent or toxin in violation of the safety  
19 procedures established under paragraph (1) or the  
20 safeguard and security measures established under  
21 paragraph (2); and

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



1 (c) POSSESSION AND USE OF LISTED AGENTS AND  
2 TOXINS.—The Secretary shall by regulation provide for  
3 the establishment and enforcement of standards and pro-  
4 cedures governing the possession and use of listed agents  
5 and toxins, including the provisions described in para-  
6 graphs (1) through (4) of subsection (b), in order to pro-  
7 tect animal and plant health, and animal and plant prod-  
8 ucts.

9 (d) REGISTRATION; IDENTIFICATION; DATABASE.—

10 (1) REGISTRATION.—Regulations under sub-  
11 sections (b) and (c) shall require registration with  
12 the Secretary of the possession, use, and transfer of  
13 listed agents and toxins, and shall include provisions  
14 to ensure that persons seeking to register under  
15 such regulations have a lawful purpose to possess,  
16 use, or transfer such agents and toxins, including  
17 provisions in accordance with subsection (e)(6).

18 (2) IDENTIFICATION; DATABASE.—Regulations  
19 under subsections (b) and (c) shall require that reg-  
20 istration include (if available to the person reg-  
21 istering) information regarding the characterization  
22 of listed agents and toxins to facilitate their identi-  
23 fication, including their source. The Secretary shall  
24 maintain a national database that includes the  
25 names and locations of registered persons, the listed



1 agents and toxins such persons are possessing,  
2 using, or transferring, and information regarding  
3 the characterization of such agents and toxins.

4 (e) SAFEGUARD AND SECURITY REQUIREMENTS FOR  
5 REGISTERED PERSONS.—

6 (1) IN GENERAL.—Regulations under sub-  
7 sections (b) and (c) shall include appropriate safe-  
8 guard and security requirements for persons pos-  
9 sessed, using, or transferring a listed agent or toxin  
10 commensurate with the risk such agent or toxin  
11 poses to animal and plant health, and animal and  
12 plant products (including the risk of use in domestic  
13 or international terrorism). The Secretary shall es-  
14 tablish such requirements in consultation with the  
15 Attorney General, and shall ensure compliance with  
16 such requirements as part of the registration system  
17 under such regulations.

18 (2) LIMITING ACCESS TO LISTED AGENTS AND  
19 TOXINS.—Requirements under paragraph (1) shall  
20 include provisions to ensure that registered  
21 persons—

22 (A) provide access to listed agents and tox-  
23 ins to only those individuals whom the reg-  
24 istered person involved determines have a legiti-



1           mate need to handle or use such agents and  
2           toxins;

3                   (B) submit the names and other identi-  
4           fying information for such individuals to the  
5           Secretary and the Attorney General, promptly  
6           after first determining that the individuals need  
7           access under subparagraph (A), and periodically  
8           thereafter while the individuals have such ac-  
9           cess, not less frequently than once every five  
10          years; and

11                   (C)(i) in the case of listed agents and tox-  
12          ins that are not overlap agents and toxins (as  
13          defined in subsection (g)(1)(A)(ii)), limit or  
14          deny access to such agents and toxins by indi-  
15          viduals whom the Attorney General has identi-  
16          fied as within any category under paragraph  
17          (3)(B), if limiting or denying such access by the  
18          individuals involved is determined appropriate  
19          by the Secretary, in consultation with the At-  
20          torney General; and

21                   (ii) in the case of listed agents and toxins  
22          that are overlap agents—

23                           (I) deny access to such agents  
24                           and toxins by individuals whom the  
25                           Attorney General has identified as



1 within any category referred to in  
2 paragraph (3)(B)(i); and

3 (II) limit or deny access to such  
4 agents and toxins by individuals whom  
5 the Attorney General has identified as  
6 within any category under paragraph  
7 (3)(B)(ii), if limiting or denying such  
8 access by the individuals involved is  
9 determined appropriate by the Sec-  
10 retary, in consultation with the Attor-  
11 ney General.

12 (3) SUBMITTED NAMES; USE OF DATABASES BY  
13 ATTORNEY GENERAL.—

14 (A) IN GENERAL.—Upon the receipt of  
15 names and other identifying information under  
16 paragraph (2)(B), the Attorney General shall,  
17 for the sole purpose of identifying whether the  
18 individuals involved are within any of the cat-  
19 egories specified in subparagraph (B), promptly  
20 use criminal, immigration, national security,  
21 and other electronic databases that are avail-  
22 able to the Federal Government and are appro-  
23 priate for such purpose.

24 (B) CERTAIN INDIVIDUALS.—For purposes  
25 of subparagraph (A), the categories specified in



1           this subparagraph regarding an individual are  
2           that—

3                   (i) the individual is within any of the  
4                   categories described in section 175b(d)(1)  
5                   of title 18, United States Code (relating to  
6                   restricted persons); or

7                   (ii) the individual is reasonably sus-  
8                   pected by any Federal law enforcement or  
9                   intelligence agency of—

10                           (I) committing a crime set forth  
11                           in section 2332b(g)(5) of title 18,  
12                           United States Code;

13                           (II) knowing involvement with an  
14                           organization that engages in domestic  
15                           or international terrorism (as defined  
16                           in section 2331 of such title 18) or  
17                           with any other organization that en-  
18                           gages in intentional crimes of violence;  
19                           or

20                           (III) being an agent of a foreign  
21                           power (as defined in section 1801 of  
22                           title 50, United States Code).

23                   (C) NOTIFICATION BY ATTORNEY GEN-  
24                   ERAL REGARDING SUBMITTED NAMES.—After  
25                   the receipt of a name and other identifying in-



1           formation under paragraph (2)(B), the Attor-  
2           ney General shall promptly notify the Secretary  
3           whether the individual is within any of the cat-  
4           egories specified in subparagraph (B).

5           (4) NOTIFICATIONS BY SECRETARY.—The Sec-  
6           retary, after receiving notice under paragraph (3)  
7           regarding an individual, shall promptly notify the  
8           registered person involved of whether the individual  
9           is granted or denied access under paragraph (2). If  
10          the individual is denied such access, the Secretary  
11          shall promptly notify the individual of the denial.

12          (5) EXPEDITED REVIEW.—Regulations under  
13          subsections (b) and (c) shall provide for a procedure  
14          through which, upon request to the Secretary by a  
15          registered person who submits names and other  
16          identifying information under paragraph (2)(B) and  
17          who demonstrates good cause, the Secretary may, as  
18          determined appropriate by the Secretary—

19                (A) request the Attorney General to expe-  
20                dite the process of identification under para-  
21                graph (3)(A) and notification of the Secretary  
22                under paragraph (3)(C); and

23                (B) expedite the notification of the reg-  
24                istered person by the Secretary under para-  
25                graph (4).



1           (6) PROCESS REGARDING PERSONS SEEKING TO  
2 REGISTER.—

3           (A) INDIVIDUALS.—Regulations under sub-  
4 sections (b) and (c) shall provide that an indi-  
5 vidual who seeks to register under either of  
6 such subsections is subject to the same proc-  
7 esses described in paragraphs (2) through (4)  
8 as apply to names and other identifying infor-  
9 mation submitted to the Attorney General  
10 under paragraph (2)(B). Paragraph (5) does  
11 not apply for purposes of this subparagraph.

12           (B) OTHER PERSONS.—Regulations under  
13 subsections (b) and (c) shall provide that, in de-  
14 termining whether to deny or revoke registra-  
15 tion by a person other than an individual, the  
16 Secretary shall submit the name of such person  
17 to the Attorney General, who shall use criminal,  
18 immigration, national security, and other elec-  
19 tronic databases available to the Federal Gov-  
20 ernment, as appropriate for the purpose of  
21 promptly notifying the Secretary whether the  
22 person, or, where relevant, the individual who  
23 owns or controls such person, is within any of  
24 the categories described in section 175b(d)(1)  
25 of title 18, United States Code (relating to re-



1           stricted persons), or is reasonably suspected by  
2           any Federal law enforcement or intelligence  
3           agency of being within any category specified in  
4           paragraph (3)(B)(ii) (as applied to persons, in-  
5           cluding individuals). Such regulations shall pro-  
6           vide that a person who seeks to register under  
7           either of such subsections is subject to the same  
8           processes described in paragraphs (2) and (4)  
9           as apply to names and other identifying infor-  
10          mation submitted to the Attorney General  
11          under paragraph (2)(B). Paragraph (5) does  
12          not apply for purposes of this subparagraph.  
13          The Secretary may exempt Federal, State, or  
14          local governmental agencies from the require-  
15          ments of this subparagraph.

16          (7) REVIEW.—

17                (A) ADMINISTRATIVE REVIEW.—

18                   (i) IN GENERAL.—Regulations under  
19                   subsections (b) and (c) shall provide for an  
20                   opportunity for a review by the  
21                   Secretary—

22                           (I) when requested by the indi-  
23                           vidual involved, of a determination  
24                           under paragraph (2) to deny the indi-



1                   vidual access to listed agents and tox-  
2                   ins; and

3                   (II) when requested by the per-  
4                   son involved, of a determination under  
5                   under paragraph (6) to deny or revoke  
6                   registration for such person.

7                   (ii) EX PARTE REVIEW.—During a re-  
8                   view under clause (i), the Secretary may  
9                   consider information relevant to the review  
10                  ex parte to the extent that disclosure of  
11                  the information could compromise national  
12                  security or an investigation by any law en-  
13                  forcement agency.

14                  (iii) FINAL AGENCY ACTION.—The de-  
15                  cision of the Secretary in a review under  
16                  clause (i) constitutes final agency action  
17                  for purposes of section 702 of title 5,  
18                  United States Code.

19                  (B) CERTAIN PROCEDURES.—

20                  (i) SUBMISSION OF EX PARTE MATE-  
21                  RIALS IN JUDICIAL PROCEEDINGS.—When  
22                  reviewing a decision of the Secretary under  
23                  subparagraph (A), and upon request made  
24                  ex parte and in writing by the United  
25                  States, a court, upon a sufficient showing,



1           may review and consider ex parte docu-  
2           ments containing information the disclo-  
3           sure of which could compromise national  
4           security or an investigation by any law en-  
5           forcement agency. If the court determines  
6           that portions of the documents considered  
7           ex parte should be disclosed to the person  
8           involved to allow a response, the court  
9           shall authorize the United States to delete  
10          from such documents specified items of in-  
11          formation the disclosure of which could  
12          compromise national security or an inves-  
13          tigation by any law enforcement agency, or  
14          to substitute a summary of the information  
15          to which the person may respond. Any  
16          order by the court authorizing the disclo-  
17          sure of information that the United States  
18          believes could compromise national security  
19          or an investigation by any law enforcement  
20          agency shall be subject to the processes set  
21          forth in subparagraphs (A) and (B)(i) of  
22          section 2339B(f)(5) of title 18, United  
23          States Code (relating to interlocutory ap-  
24          peal and expedited consideration).



1 (ii) DISCLOSURE OF INFORMATION.—

2 In a review under subparagraph (A), and  
3 in any judicial proceeding conducted pursu-  
4 ant to such review, neither the Secretary  
5 nor the Attorney General may be required  
6 to disclose to the public any information  
7 that under subsection (h) shall not be dis-  
8 closed under section 552 of title 5, United  
9 States Code.

10 (8) NOTIFICATIONS REGARDING THEFT OR  
11 LOSS OF AGENTS.—Requirements under paragraph  
12 (1) shall include the prompt notification of the Sec-  
13 retary, and appropriate Federal, State, and local law  
14 enforcement agencies, of the theft or loss of listed  
15 agents and toxins.

16 (9) TECHNICAL ASSISTANCE FOR REGISTERED  
17 PERSONS.—The Secretary, in consultation with the  
18 Attorney General, may provide technical assistance  
19 to registered persons to improve security of the fa-  
20 cilities of such persons.

21 (f) INSPECTIONS.—The Secretary shall have the au-  
22 thority to inspect persons subject to regulations under  
23 subsection (b) or (c) to ensure their compliance with such  
24 regulations, including prohibitions on restricted persons  
25 and other provisions of subsection (e).



1 (g) EXEMPTIONS.—

2 (1) OVERLAP AGENTS AND TOXINS.—

3 (A) IN GENERAL.—

4 (i) LIMITATION.—In the case of over-  
5 lap agents and toxins, exemptions from the  
6 applicability of provisions of regulations  
7 under subsection (b) or (c) may be granted  
8 only to the extent provided in this para-  
9 graph.

10 (ii) DEFINITIONS.—For purposes of  
11 this section:

12 (I) The term “overlap agents and  
13 toxins” means biological agents and  
14 toxins that—

15 (aa) are listed pursuant to  
16 subsection (a)(1); and

17 (bb) are listed pursuant to  
18 section 315A(a)(1) of the Public  
19 Health Service Act.

20 (II) The term “overlap agent or  
21 toxin” means a biological agent or  
22 toxin that—

23 (aa) is listed pursuant to  
24 subsection (a)(1); and



1 (bb) is listed pursuant to  
2 section 315A(a)(1) of the Public  
3 Health Service Act.

4 (B) CLINICAL OR DIAGNOSTIC LABORA-  
5 TORIES.—Regulations under subsections (b)  
6 and (c) shall exempt clinical or diagnostic lab-  
7 oratories and other persons who possess, use, or  
8 transfer overlap agents or toxins that are con-  
9 tained in specimens presented for diagnosis,  
10 verification, or proficiency testing, provided  
11 that—

12 (i) the identification of such agents or  
13 toxins is reported to the Secretary, and  
14 when required under Federal, State, or  
15 local law, to other appropriate authorities;  
16 and

17 (ii) such agents or toxins are trans-  
18 ferred or destroyed in a manner set forth  
19 by the Secretary by regulation.

20 (C) PRODUCTS.—

21 (i) IN GENERAL.—Regulations under  
22 subsections (b) and (c) shall exempt prod-  
23 ucts that are, bear, or contain overlap  
24 agents or toxins and are cleared, approved,  
25 licensed, or registered under any of the



1 Acts specified in clause (ii), unless the Sec-  
2 retary by order determines that applying  
3 additional regulation under subsection (b)  
4 or (c) to a specific product is necessary to  
5 protect animal or plant health, or animal  
6 or plant products.

7 (ii) RELEVANT LAWS.—For purposes  
8 of clause (i), the Acts specified in this  
9 clause are the following:

10 (I) The Federal Food, Drug, and  
11 Cosmetic Act.

12 (II) Section 351 of the Public  
13 Health Service Act.

14 (III) The Act commonly known  
15 as the Virus-Serum-Toxin Act (the  
16 eighth paragraph under the heading  
17 ‘Bureau of Animal Industry’ in the  
18 Act of March 4, 1913; 21 U.S.C. 151-  
19 159).

20 (IV) The Federal Insecticide,  
21 Fungicide, and Rodenticide Act.

22 (iii) INVESTIGATIONAL USE.—

23 (I) IN GENERAL.—The Secretary  
24 may exempt an investigational prod-  
25 uct that is, bears, or contains an over-



1 lap agent or toxin from the applica-  
2 bility of provisions of regulations  
3 under subsection (b) or (c) when such  
4 product is being used in an investiga-  
5 tion authorized under any Federal Act  
6 and the Secretary determines that ap-  
7 plying additional regulation under  
8 subsection (b) or (c) to such product  
9 is not necessary to protect animal and  
10 plant health, and animal and plant  
11 products.

12 (II) CERTAIN PROCESSES.—Reg-  
13 ulations under subsections (b) and (c)  
14 shall set forth the procedures for ap-  
15 plying for an exemption under sub-  
16 clause (I). In the case of investiga-  
17 tional products authorized under any  
18 of the Acts specified in clause (ii), the  
19 Secretary shall make a determination  
20 regarding a request for an exemption  
21 not later than 14 days after the first  
22 date on which both of the following  
23 conditions have been met by the per-  
24 son requesting the exemption:



1                   (aa) The person has sub-  
2                   mitted to the Secretary an appli-  
3                   cation for the exemption meeting  
4                   the requirements established by  
5                   the Secretary.

6                   (bb) The person has notified  
7                   the Secretary that the investiga-  
8                   tion has been authorized under  
9                   such an Act.

10                   (D) AGRICULTURAL EMERGENCIES.— The  
11                   Secretary may temporarily exempt a person  
12                   from the applicability of the requirements of  
13                   this section with respect to an overlap agent or  
14                   toxin, in whole or in part, if the Secretary de-  
15                   termines that such exemption is necessary to  
16                   provide for the timely participation of the per-  
17                   son in a response to a domestic or foreign agri-  
18                   cultural emergency that involves such an agent  
19                   or toxin. With respect to the emergency in-  
20                   volved, the exemption under this subparagraph  
21                   for a person may not exceed 30 days, except  
22                   that the Secretary, after review of whether such  
23                   exemption remains necessary, may provide one  
24                   extension of an additional 30 days.



1 (E) PUBLIC HEALTH EMERGENCIES.—

2 Upon request of the Secretary of Health and  
3 Human Services, after the granting by such  
4 Secretary of an exemption under 351A(g)(3) of  
5 the Public Health Service Act pursuant to a  
6 finding that there is a public health emergency,  
7 the Secretary of Agriculture may temporarily  
8 exempt a person from the applicability of the  
9 requirements of this section with respect to an  
10 overlap agent or toxin, in whole or in part, to  
11 provide for the timely participation of the per-  
12 son in a response to the public health emer-  
13 gency. With respect to the emergency involved,  
14 such exemption for a person may not exceed 30  
15 days, except that upon request of the Secretary  
16 of Health and Human Services, the Secretary  
17 of Agriculture may, after review of whether  
18 such exemption remains necessary, provide one  
19 extension of an additional 30 days.

20 (2) GENERAL AUTHORITY FOR EXEMPTIONS

21 NOT INVOLVING OVERLAP AGENTS OR TOXINS.—In  
22 the case of listed agents or toxins that are not over-  
23 lap agents or toxins, the Secretary may grant ex-  
24 emptions from the applicability of provisions of regu-  
25 lations under subsection (b) or (c) if the Secretary



1 determines that such exemptions are consistent with  
2 protecting animal and plant health, and animal and  
3 plant products.

4 (h) DISCLOSURE OF INFORMATION.—

5 (1) NONDISCLOSURE OF CERTAIN INFORMA-  
6 TION.—No Federal agency specified in paragraph  
7 (2) shall disclose under section 552 of title 5, United  
8 States Code, any of the following:

9 (A) Any registration or transfer docu-  
10 mentation submitted under subsections (b) and  
11 (c), or permits issued prior to the date of the  
12 enactment of this Act, for the possession, use or  
13 transfer of a listed agent or toxin; or informa-  
14 tion derived therefrom to the extent that it  
15 identifies the listed agent or toxin possessed,  
16 used or transferred by a specific person or dis-  
17 closes the identity or location of a specific per-  
18 son.

19 (B) The national database developed pur-  
20 suant to subsection (d), or any other compila-  
21 tion of the registration or transfer information  
22 submitted under subsections (b) and (c) to the  
23 extent that such compilation discloses site-spe-  
24 cific registration or transfer information.



1 (C) Any portion of a record that discloses  
2 the site-specific or transfer-specific safeguard  
3 and security measures used by a registered per-  
4 son to prevent unauthorized access to listed  
5 agents and toxins.

6 (D) Any notification of a release of a listed  
7 agent or toxin submitted under subsections (b)  
8 and (c), or any notification of theft or loss sub-  
9 mitted under such subsections.

10 (E) Any portion of an evaluation or report  
11 of an inspection of a specific registered person  
12 conducted under subsection (f) that identifies  
13 the listed agent or toxin possessed by a specific  
14 registered person or that discloses the identity  
15 or location of a specific registered person if the  
16 agency determines that public disclosure of the  
17 information would endanger animal or plant  
18 health, or animal or plant products.

19 (2) COVERED AGENCIES.—For purposes of  
20 paragraph (1) only, the Federal agencies specified in  
21 this paragraph are the following:

22 (A) The Department of Health and  
23 Human Services, the Department of Justice,  
24 the Department of Agriculture, and the Depart-  
25 ment of Transportation.



1 (B) Any Federal agency to which informa-  
2 tion specified in paragraph (1) is transferred by  
3 any agency specified in subparagraph (A) of  
4 this paragraph.

5 (C) Any Federal agency that is a reg-  
6 istered person, or has a sub-agency component  
7 that is a registered person.

8 (D) Any Federal agency that awards  
9 grants or enters into contracts or cooperative  
10 agreements involving listed agents and toxins to  
11 or with a registered person, and to which infor-  
12 mation specified in paragraph (1) is transferred  
13 by any such registered person.

14 (3) OTHER EXEMPTIONS.—This subsection may  
15 not be construed as altering the application of any  
16 exemptions to public disclosure under section 552 of  
17 title 5, United States Code, except as to subsection  
18 552(b)(3) of such title, to any of the information  
19 specified in paragraph (1).

20 (4) RULE OF CONSTRUCTION.—Except as spe-  
21 cifically provided in paragraph (1), this subsection  
22 may not be construed as altering the authority of  
23 any Federal agency to withhold under section 552 of  
24 title 5, United States Code, or the obligation of any  
25 Federal agency to disclose under section 552 of title



1 5, United States Code, any information, including  
2 information relating to—

3 (A) listed agents and toxins, or individuals  
4 seeking access to such agents and toxins;

5 (B) registered persons, or persons seeking  
6 to register their possession, use, or transfer of  
7 such agents and toxins;

8 (C) general safeguard and security policies  
9 and requirements under regulations under sub-  
10 sections (b) and (c); or

11 (D) summary or statistical information  
12 concerning registrations, registrants, denials or  
13 revocations of registrations, listed agents and  
14 toxins, inspection evaluations and reports, or in-  
15 dividuals seeking access to such agents and tox-  
16 ins.

17 (5) DISCLOSURES TO CONGRESS; OTHER DIS-  
18 CLOSURES.—This subsection may not be construed  
19 as providing any authority—

20 (A) to withhold information from the Con-  
21 gress or any committee or subcommittee there-  
22 of; or

23 (B) to withhold information from any per-  
24 son under any other Federal law or treaty.

25 (i) CIVIL MONEY PENALTY.—



1           (1) IN GENERAL.—In addition to any other  
2 penalties that may apply under law, any person who  
3 violates any provision of regulations under sub-  
4 section (b) or (c) shall be subject to the United  
5 States for a civil money penalty in an amount not  
6 exceeding \$250,000 in the case of an individual and  
7 \$500,000 in the case of any other person.

8           (2) APPLICABILITY OF CERTAIN PROVISIONS.—  
9 The provisions of sections 423 and 425(2) of the  
10 Plant Protection Act (7 U.S.C. 7733 and 7735(2))  
11 shall apply to a civil money penalty or activity under  
12 paragraph (1) in the same manner as such provi-  
13 sions apply to a penalty or activity under the Plant  
14 Protection Act.

15          (j) NOTIFICATION IN EVENT OF RELEASE.—Regula-  
16 tions under subsections (b) and (c) shall require the  
17 prompt notification of the Secretary by a registered person  
18 whenever a release, meeting criteria established by the  
19 Secretary, of a listed agent or toxin has occurred outside  
20 of the biocontainment area of a facility of the registered  
21 person. Upon receipt of such notification and a finding  
22 by the Secretary that the release poses a threat to animal  
23 or plant health, or animal or plant products, the Secretary  
24 shall take appropriate action to notify relevant Federal,  
25 State, and local authorities, and, if necessary, other appro-



1 priate persons (including the public). If the released listed  
2 agent or toxin is an overlap agent or toxin, the Secretary  
3 shall promptly notify the Secretary of Health and Human  
4 Services upon notification by the registered person.

5 (k) REPORTS.—The Secretary shall report to the  
6 Congress annually on the number and nature of notifica-  
7 tions received under subsection (e)(8) (relating to theft or  
8 loss) and subsection (j) (relating to releases).

9 (l) DEFINITIONS.—For purposes of this section:

10 (1) The terms “biological agent” and “toxin”  
11 have the meanings given such terms in section 178  
12 of title 18, United States Code.

13 (2) The term “listed agents and toxins” means  
14 biological agents and toxins listed pursuant to sub-  
15 section (a)(1).

16 (3) The term “listed agents or toxins” means  
17 biological agents or toxins listed pursuant to sub-  
18 section (a)(1).

19 (4) The terms “overlap agents and toxins” and  
20 “overlap agent or toxin” have the meaning given  
21 such terms in subsection (g)(1)(A)(ii).

22 (5) The term “person” includes Federal, State,  
23 and local governmental entities.





1 possession of biological agents or toxins included on the  
2 list referred to in subsection (a) shall notify the Secretary  
3 of such possession.

4 (c) DATE CERTAIN FOR PROMULGATION; EFFECTIVE  
5 DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—  
6 Not later than 180 days after the date of the enactment  
7 of this Act, the Secretary shall promulgate an interim final  
8 rule for carrying out section 212, other than for the list  
9 referred to in subsection (a) of this section (but such rule  
10 may incorporate by reference provisions promulgated pur-  
11 suant to subsection (a)). Such interim final rule shall take  
12 effect 60 days after the date on which such rule is promul-  
13 gated, including for purposes of—

14 (1) section 175b(c) of title 18, United States  
15 Code (relating to criminal penalties), as added by  
16 section 231(a)(5) of this Act; and

17 (2) section 212(i) of this Act (relating to civil  
18 penalties).

19 (d) TRANSITIONAL PROVISION REGARDING CURRENT  
20 RESEARCH AND EDUCATION.—The interim final rule  
21 under subsection (c) shall include time frames for the ap-  
22 plicability of the rule that minimize disruption of research  
23 or educational projects that involve biological agents and  
24 toxins listed pursuant to section 212(a)(1) and that were  
25 underway as of the effective date of such rule.



1 **Subtitle C—Interagency Coordina-**  
2 **tion Regarding Overlap Agents**  
3 **and Toxins**

4 **SEC. 221. INTERAGENCY COORDINATION.**

5 (a) IN GENERAL.—

6 (1) COORDINATION.—The Secretary of Agri-  
7 culture and the Secretary of Health and Human  
8 Services shall in accordance with this section coordi-  
9 nate activities regarding overlap agents and toxins.

10 (2) OVERLAP AGENTS AND TOXINS; OTHER  
11 TERMS.—For purposes of this section:

12 (A) The term “overlap agent or toxin”  
13 means a biological agent or toxin that—

14 (i) is listed pursuant to section  
15 315A(a)(1) of the Public Health Service  
16 Act, as added by section 201 of this Act;  
17 and

18 (ii) is listed pursuant to section  
19 212(a)(1) of this Act.

20 (B) The term “section 351A program”  
21 means the program under section 351A of the  
22 Public Health Service Act.

23 (C) The term “section 212 program”  
24 means the program under section 212 of this  
25 Act.



1 (b) CERTAIN MATTERS.—In carrying out the section  
2 351A program and the section 212 program, the Secretary  
3 of Health and Human Services and the Secretary of Agri-  
4 culture shall, to the greatest extent practicable, coordinate  
5 activities to achieve the following purposes:

6 (1) To minimize any conflicts between the regu-  
7 lations issued under, and activities carried out  
8 under, such programs.

9 (2) To minimize the administrative burden on  
10 persons subject to regulation under both of such  
11 programs.

12 (3) To ensure the appropriate availability of bi-  
13 ological agents and toxins for legitimate biomedical,  
14 agricultural or veterinary research, education, or  
15 other such purposes.

16 (4) To ensure that registration information for  
17 overlap agents and toxins under the section 351A  
18 and section 212 programs is contained in both the  
19 national database under the section 351A program  
20 and the national database under the section 212  
21 program.

22 (c) MEMORANDUM OF UNDERSTANDING.—

23 (1) IN GENERAL.—Promptly after the date of  
24 the enactment of this Act, the Secretary of Agri-  
25 culture and the Secretary of Health and Human



1 Services shall enter into a memorandum of under-  
2 standing regarding overlap agents and toxins that is  
3 in accordance with paragraphs (2) through (4) and  
4 contains such additional provisions as the Secretary  
5 of Agriculture and the Secretary of Health and  
6 Human Services determine to be appropriate.

7 (2) SINGLE REGISTRATION SYSTEM REGARDING  
8 REGISTERED PERSONS.—The memorandum of un-  
9 derstanding under paragraph (1) shall provide for  
10 the development and implementation of a single sys-  
11 tem of registration for persons who possess, use, or  
12 transfer overlap agents or toxins and are required to  
13 register under both the section 351A program and  
14 the section 212 program. For purposes of such sys-  
15 tem, the memorandum shall provide for the develop-  
16 ment and implementation of the following:

17 (A) A single registration form through  
18 which the person submitting the form provides  
19 all information that is required for registration  
20 under the section 351A program and all infor-  
21 mation that is required for registration under  
22 the section 212 program.

23 (B) A procedure through which a person  
24 may choose to submit the single registration  
25 form to the agency administering the section



1 351A program (in the manner provided under  
2 such program), or to the agency administering  
3 the section 212 program (in the manner pro-  
4 vided under such program).

5 (C) A procedure through which a copy of  
6 a single registration form received pursuant to  
7 subparagraph (B) by the agency administering  
8 one of such programs is promptly provided to  
9 the agency administering the other program.

10 (D) A procedure through which the agency  
11 receiving the single registration form under one  
12 of such programs obtains the concurrence of the  
13 agency administering the other program that  
14 the requirements for registration under the  
15 other program have been met.

16 (E) A procedure through which—

17 (i) the agency receiving the single reg-  
18 istration form under one of such programs  
19 informs the agency administering the other  
20 program whether the receiving agency has  
21 denied the registration; and

22 (ii) each of such agencies ensures that  
23 registrations are entered into the national  
24 database of registered persons that is  
25 maintained by each such agency.



1           (3) PROCESS OF IDENTIFICATION.—With re-  
2           spect to the process of identification under the sec-  
3           tion 351A program and the section 212 program for  
4           names and other identifying information submitted  
5           to the Attorney General (relating to certain cat-  
6           egories of individuals and entities), the memo-  
7           randum of understanding under paragraph (1) shall  
8           provide for the development and implementation of  
9           the following:

10                   (A) A procedure through which a person  
11                   who is required to submit information pursuant  
12                   to such process makes (in addition to the sub-  
13                   mission to the Attorney General) a submission,  
14                   at the option of the person, to either the agency  
15                   administering the section 351A program or the  
16                   agency administering the section 212 program,  
17                   but not both, which submission satisfies the re-  
18                   quirement of submission for both of such pro-  
19                   grams.

20                   (B) A procedure for the sharing by both of  
21                   such agencies of information received from the  
22                   Attorney General by one of such agencies pur-  
23                   suant to the submission under subparagraph  
24                   (A).



1 (C) A procedure through which the agen-  
2 cies administering such programs concur in de-  
3 terminations that access to overlap agents and  
4 toxins will be granted.

5 (4) COORDINATION OF INSPECTIONS AND EN-  
6 FORCEMENT.—The memorandum of understanding  
7 under paragraph (1) shall provide for the develop-  
8 ment and implementation of procedures under which  
9 Federal personnel under the section 351A program  
10 and the section 212 program may share responsibil-  
11 ities for inspections and enforcement activities under  
12 such programs regarding overlap agents and toxins.  
13 Activities carried out under such procedures by one  
14 of such programs on behalf of the other may be car-  
15 ried out with or without reimbursement by the agen-  
16 cy that administers the other program.

17 (5) DATE CERTAIN FOR IMPLEMENTATION.—  
18 The memorandum of understanding under para-  
19 graph (1) shall be implemented not later than 180  
20 days after the date of the enactment of this Act.  
21 Until the single system of registration under para-  
22 graph (2) is implemented, persons who possess, use,  
23 or transfer overlap agents or toxins shall register  
24 under both the section 351A program and the sec-  
25 tion 212 program.



1 (d) JOINT REGULATIONS.—Not later than 18 months  
2 after the date on which the single system of registration  
3 under subsection (c)(2) is implemented, the Secretary of  
4 Health and Human Services and the Secretary of Agri-  
5 culture shall jointly issue regulations for the possession,  
6 use, and transfer of overlap agents and toxins that meet  
7 the requirements of both the section 351A program and  
8 the section 212 program.

9 **Subtitle D—Criminal Penalties Re-**  
10 **garding Certain Biological**  
11 **Agents and Toxins**

12 **SEC. 231. CRIMINAL PENALTIES.**

13 (a) IN GENERAL.—Section 175b of title 18, United  
14 States Code, as added by section 817 of Public Law 107–  
15 56, is amended—

16 (1) by striking “(a)” and inserting “(a)(1)”;

17 (2) by transferring subsection (c) from the cur-  
18 rent placement of the subsection and inserting the  
19 subsection before subsection (b);

20 (3) by striking “(c)” and inserting “(2);

21 (4) by redesignating subsection (b) as sub-  
22 section (d); and

23 (5) by inserting before subsection (d) (as so re-  
24 designated) the following subsections:

25 “(b) TRANSFER TO UNREGISTERED PERSON.—



1           “(1) SELECT AGENTS.—Whoever transfers a se-  
2           lect agent to a person who the transferor knows or  
3           has reasonable cause to believe is not registered as  
4           required by regulations under subsection (b) or (c)  
5           of section 351A of the Public Health Service Act  
6           shall be fined under this title, or imprisoned for not  
7           more than 5 years, or both.

8           “(2) CERTAIN OTHER BIOLOGICAL AGENTS AND  
9           TOXINS.—Whoever transfers a biological agent or  
10          toxin listed pursuant to section 212(a)(1) of the Ag-  
11          ricultural Bioterrorism Protection Act of 2002 to a  
12          person who the transferor knows or has reasonable  
13          cause to believe is not registered as required by reg-  
14          ulations under subsection (b) or (c) of section 212  
15          of such Act shall be fined under this title, or impris-  
16          oned for not more than 5 years, or both.

17          “(c) UNREGISTERED FOR POSSESSION.—

18                 “(1) SELECT AGENTS.—Whoever knowingly  
19                 possesses a biological agent or toxin where such  
20                 agent or toxin is a select agent for which such per-  
21                 son has not obtained a registration required by regu-  
22                 lations under section 351A(c) of the Public Health  
23                 Service Act shall be fined under this title, or impris-  
24                 oned for not more than 5 years, or both.



1           “(2) CERTAIN OTHER BIOLOGICAL AGENTS AND  
2           TOXINS.—Whoever knowingly possesses a biological  
3           agent or toxin where such agent or toxin is a biologi-  
4           cal agent or toxin listed pursuant to section  
5           212(a)(1) of the Agricultural Bioterrorism Protec-  
6           tion Act of 2002 for which such person has not ob-  
7           tained a registration required by regulations under  
8           section 212(c) of such Act shall be fined under this  
9           title, or imprisoned for not more than 5 years, or  
10          both.”.

11          (b) CONFORMING AMENDMENTS.—Chapter 10 of  
12 title 18, United States Code, is amended—

13           (1) in section 175b (as added by section 817 of  
14           Public Law 107–56 and amended by subsection (a)  
15           of this section)—

16           (A) in subsection (d)(1), by striking “The  
17           term” and all that follows through “does not in-  
18           clude” and inserting the following: “The term  
19           ‘select agent’ means a biological agent or toxin  
20           to which subsection (a) applies. Such term (in-  
21           cluding for purposes of subsection (a)) does not  
22           include”; and

23           (B) in the heading for the section, by  
24           striking “**Possession by restricted per-**



1           **sons**” and inserting “**Select agents; cer-**  
2           **tain other agents**”; and

3           (2) in the chapter analysis, in the item relating  
4           to section 175b, by striking “Possession by re-  
5           stricted persons.” and inserting “Select agents; cer-  
6           tain other agents.”.

7           (c) TECHNICAL CORRECTIONS.—Chapter 10 of title  
8           18, United States Code, as amended by section 817 of  
9           Public Law 107–56 and subsections (a) and (b) of this  
10          section, is amended—

11           (1) in section 175(c), by striking “protective”  
12           and all that follows and inserting “protective, bona  
13           fide research, or other peaceful purposes.”;

14           (2) in section 175b—

15           (A) in subsection (a)(1), by striking “de-  
16           scribed in subsection (b)” and all that follows  
17           and inserting the following: “shall ship or  
18           transport in or affecting interstate or foreign  
19           commerce, or possess in or affecting interstate  
20           or foreign commerce, any biological agent or  
21           toxin, or receive any biological agent or toxin  
22           that has been shipped or transported in inter-  
23           state or foreign commerce, if the biological  
24           agent or toxin is listed as a select agent in Ap-  
25           pendix A of part 72 of title 42, Code of Federal



1 Regulations, pursuant to section 351A of the  
2 Public Health Service Act, and is not exempted  
3 under subsection (h) of section 72.6, or Appen-  
4 dix A of part 72, of title 42, Code of Federal  
5 Regulations.”; and

6 (B) in subsection (d)(3), by striking “sec-  
7 tion 1010(a)(3)” and inserting “section  
8 101(a)(3)”;

9 (3) in section 176(a)(1)(A), by striking “exists  
10 by reason of” and inserting “pertains to”; and

11 (4) in section 178—

12 (A) in paragraph (1), by striking “means  
13 any micro-organism” and all that follows  
14 through “product, capable of” and inserting the  
15 following: “means any microorganism (includ-  
16 ing, but not limited to, bacteria, viruses, fungi,  
17 rickettsiae or protozoa), or infectious substance,  
18 or any naturally occurring, bioengineered or  
19 synthesized component of any such microorga-  
20 nism or infectious substance, capable of”;

21 (B) in paragraph (2), by striking “means  
22 the toxic” and all that follows through “includ-  
23 ing—” and inserting the following: “means the  
24 toxic material or product of plants, animals,  
25 microorganisms (including, but not limited to,



1 bacteria, viruses, fungi, rickettsiae or protozoa),  
2 or infectious substances, or a recombinant or  
3 synthesized molecule, whatever their origin and  
4 method of production, and includes—”; and

5 (C) in paragraph (4), by striking “recom-  
6 binant molecule,” and all that follows through  
7 “biotechnology,” and inserting “recombinant or  
8 synthesized molecule,”.

9 (d) ADDITIONAL TECHNICAL CORRECTION.—Section  
10 2332a of title 18, United States Code, is amended—

11 (1) in subsection (a), in the matter preceding  
12 paragraph (1), by striking “section 229F)” and all  
13 that follows through “section 178)—” and inserting  
14 “section 229F)—”; and

15 (2) in subsection (c)(2)(C), by striking “a dis-  
16 ease organism” and inserting “a biological agent,  
17 toxin, or vector (as those terms are defined in sec-  
18 tion 178 of this title)”.



1 **TITLE III—PROTECTING SAFETY**  
2 **AND SECURITY OF FOOD AND**  
3 **DRUG SUPPLY**

4 **Subtitle A—Protection of Food**  
5 **Supply**

6 **SEC. 301. FOOD SAFETY AND SECURITY STRATEGY.**

7 (a) IN GENERAL.—The President’s Council on Food  
8 Safety (as established by Executive Order 13100) shall,  
9 in consultation with the Secretary of Transportation, the  
10 Secretary of the Treasury, other relevant Federal agen-  
11 cies, the food industry, consumer and producer groups,  
12 scientific organizations, and the States, develop a crisis  
13 communications and education strategy with respect to  
14 bioterrorist threats to the food supply. Such strategy shall  
15 address threat assessments; technologies and procedures  
16 for securing food processing and manufacturing facilities  
17 and modes of transportation; response and notification  
18 procedures; and risk communications to the public.

19 (b) AUTHORIZATION OF APPROPRIATIONS.—For the  
20 purpose of implementing the strategy developed under  
21 subsection (a), there are authorized to be appropriated  
22 \$750,000 for fiscal year 2002, and such sums as may be  
23 necessary for each subsequent fiscal year.



1 **SEC. 302. PROTECTION AGAINST ADULTERATION OF FOOD.**

2 (a) INCREASING INSPECTIONS FOR DETECTION OF  
3 ADULTERATION OF FOOD.—Section 801 of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amend-  
5 ed by adding at the end the following subsection:

6 “(h)(1) The Secretary shall give high priority to in-  
7 creasing the number of inspections under this section for  
8 the purpose of enabling the Secretary to inspect food of-  
9 fered for import at ports of entry into the United States,  
10 with the greatest priority given to inspections to detect  
11 the intentional adulteration of food.”.

12 (b) IMPROVEMENTS TO INFORMATION MANAGEMENT  
13 SYSTEMS.—Section 801(h) of the Federal Food, Drug,  
14 and Cosmetic Act, as added by subsection (a) of this sec-  
15 tion, is amended by adding at the end the following para-  
16 graph:

17 “(2) The Secretary shall give high priority to making  
18 necessary improvements to the information management  
19 systems of the Food and Drug Administration that con-  
20 tain information related to foods imported or offered for  
21 import into the United States for purposes of improving  
22 the ability of the Secretary to allocate resources, detect  
23 the intentional adulteration of food, and facilitate the im-  
24 portation of food that is in compliance with this Act.”.

25 (c) LINKAGES WITH APPROPRIATE PUBLIC ENTI-  
26 TIES.—Section 801(h) of the Federal Food, Drug, and



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

4 “(3) The Secretary shall improve linkages with other  
5 regulatory agencies of the Federal Government that share  
6 responsibility for food safety, and shall with respect to  
7 such safety improve linkages with the States and Indian  
8 tribes (as defined in section 4(e) of the Indian Self-Deter-  
9 mination and Education Assistance Act (25 U.S.C.  
10 450b(e))).”.

11 (d) TESTING FOR RAPID DETECTION OF ADULTERA-  
12 TION OF FOOD.—Section 801 of the Federal Food, Drug,  
13 and Cosmetic Act, as amended by subsection (a) of this  
14 section, is amended by adding at the end the following:

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

18 “(A) whose purpose is to test food in order to  
19 rapidly detect the adulteration of the food, with the  
20 greatest priority given to detect the intentional adul-  
21 teration of food; and

22 “(B) whose results offer significant improve-  
23 ments over the available technology in terms of accu-  
24 racy, timing, or costs.



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

5           “(3) In providing for research under paragraph (1),  
6 the Secretary shall as appropriate coordinate with the Di-  
7 rector of the Centers for Disease Control and Prevention,  
8 the Director of the National Institutes of Health, the Ad-  
9 ministrator of the Environmental Protection Agency, and  
10 the Secretary of Agriculture.

11           “(4) The Secretary shall annually submit to the Com-  
12 mittee on Energy and Commerce of the House of Rep-  
13 resentatives, and the Committee on Health, Education,  
14 Labor, and Pensions of the Senate, a report describing  
15 the progress made in research under paragraph (1), in-  
16 cluding progress regarding paragraph (2).”.

17           (e) ASSESSMENT OF THREAT OF INTENTIONAL  
18 ADULTERATION OF FOOD.—The Secretary of Health and  
19 Human Services, acting through the Commissioner of  
20 Food and Drugs, shall ensure that, not later than six  
21 months after the date of the enactment of this Act—

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



1           (2) a report describing the findings of the as-  
2           sessment is submitted to the Committee on Energy  
3           and Commerce of the House of Representatives and  
4           to the Committee on Health, Education, Labor, and  
5           Pensions of the Senate.

6           (f) AUTHORIZATION OF APPROPRIATIONS.—For the  
7           purpose of carrying out this section and the amendments  
8           made by this section, there are authorized to be appro-  
9           priated \$100,000,000 for fiscal year 2002, and such sums  
10          as may be necessary for each of the fiscal years 2003  
11          through 2006, in addition to other authorizations of ap-  
12          propriations that are available for such purpose.

13   **SEC. 303. ADMINISTRATIVE DETENTION.**

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

17               “(h) ADMINISTRATIVE DETENTION OF FOODS.—

18                       “(1) DETENTION AUTHORITY.—

19                               “(A) IN GENERAL.—An officer or qualified  
20                               employee of the Food and Drug Administration  
21                               may order the detention, in accordance with  
22                               this subsection, of any article of food that is  
23                               found during an inspection, examination, or in-  
24                               vestigation under this Act conducted by such  
25                               officer or qualified employee, if the officer or



1 qualified employee has credible evidence or in-  
2 formation indicating that such article presents  
3 a threat of serious adverse health consequences  
4 or death to humans or animals.

5 “(B) SECRETARY’S APPROVAL.—An article  
6 of food may be ordered detained under subpara-  
7 graph (A) only if the Secretary or an official  
8 designated by the Secretary approves the order.  
9 An official may not be so designated unless the  
10 official is the director of the district under this  
11 Act in which the article involved is located, or  
12 is an official senior to such director.

13 “(2) PERIOD OF DETENTION.—An article of  
14 food may be detained under paragraph (1) for a rea-  
15 sonable period, not to exceed 20 days, unless a  
16 greater period, not to exceed 30 days, is necessary,  
17 to enable the Secretary to institute an action under  
18 subsection (a) or section 302. The Secretary shall by  
19 regulation provide for procedures for instituting such  
20 action on an expedited basis with respect to perish-  
21 able foods.

22 “(3) SECURITY OF DETAINED ARTICLE.—An  
23 order under paragraph (1) with respect to an article  
24 of food may require that such article be labeled or  
25 marked as detained, and shall require that the arti-



1       cle be removed to a secure facility, as appropriate.  
2       An article subject to such an order shall not be  
3       transferred by any person from the place at which  
4       the article is ordered detained, or from the place to  
5       which the article is so removed, as the case may be,  
6       until released by the Secretary or until the expira-  
7       tion of the detention period applicable under such  
8       order, whichever occurs first. This subsection may  
9       not be construed as authorizing the delivery of the  
10      article pursuant to the execution of a bond while the  
11      article is subject to the order, and section 801(b)  
12      does not authorize the delivery of the article pursu-  
13      ant to the execution of a bond while the article is  
14      subject to the order.

15           “(4) APPEAL OF DETENTION ORDER.—

16           “(A) IN GENERAL.—With respect to an ar-  
17      ticle of food ordered detained under paragraph  
18      (1), any person who would be entitled to be a  
19      claimant for such article if the article were  
20      seized under subsection (a) may appeal the  
21      order to the Secretary. Within five days after  
22      such an appeal is filed, the Secretary, after pro-  
23      viding opportunity for an informal hearing,  
24      shall confirm or terminate the order involved,  
25      and such confirmation by the Secretary shall be



1           considered a final agency action for purposes of  
2           section 702 of title 5, United States Code. If  
3           during such five-day period the Secretary fails  
4           to provide such an opportunity, or to confirm or  
5           terminate such order, the order is deemed to be  
6           terminated.

7                   “(B) EFFECT OF INSTITUTING COURT AC-  
8           TION.—The process under subparagraph (A)  
9           for the appeal of an order under paragraph (1)  
10          terminates if the Secretary institutes an action  
11          under subsection (a) or section 302 regarding  
12          the article of food involved.”.

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

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

20          (c) TEMPORARY HOLDS AT PORTS OF ENTRY.—Sec-  
21          tion 801 of the Federal Food, Drug, and Cosmetic Act,  
22          as amended by section 302(d) of this Act, is amended by  
23          adding at the end the following:

24                   “(j)(1) If an officer or qualified employee of the Food  
25          and Drug Administration has credible evidence or infor-



1 mation indicating that an article of food presents a threat  
2 of serious adverse health consequences or death to humans  
3 or animals, and such officer or qualified employee is un-  
4 able to inspect, examine, or investigate such article upon  
5 the article being offered for import at a port of entry into  
6 the United States, the officer or qualified employee shall  
7 request the Secretary of Treasury to hold the food at the  
8 port of entry for a reasonable period of time, not to exceed  
9 24 hours, for the purpose of enabling the Secretary to in-  
10 spect, examine, or investigate the article as appropriate.

11       “(2) The Secretary shall request the Secretary of  
12 Treasury to remove an article held pursuant to paragraph  
13 (1) to a secure facility, as appropriate. During the period  
14 of time that such article is so held, the article shall not  
15 be transferred by any person from the port of entry into  
16 the United States for the article, or from the secure facil-  
17 ity to which the article has been removed, as the case may  
18 be. Subsection (b) does not authorize the delivery of the  
19 article pursuant to the execution of a bond while the arti-  
20 cle is so held.

21       “(3) An officer or qualified employee of the Food and  
22 Drug Administration may make a request under para-  
23 graph (1) only if the Secretary or an official designated  
24 by the Secretary approves the request. An official may not  
25 be so designated unless the official is the director of the



1 district under this Act in which the article involved is lo-  
2 cated, or is an official senior to such director.

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

9 **SEC. 304. DEBARMENT FOR REPEATED OR SERIOUS FOOD**  
10 **IMPORT VIOLATIONS.**

11 (a) DEBARMENT AUTHORITY.—

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

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

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

19 (C) by adding at the end the following sub-  
20 paragraph:

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

24 (2) AMENDMENT REGARDING DEBARMENT  
25 GROUNDS.—Section 306(b)) of the Federal Food,



1 Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is  
2 amended—

3 (A) in paragraph (2), in the matter pre-  
4 ceeding subparagraph (A), by inserting “sub-  
5 paragraph (A) or (B) of” before “paragraph  
6 (1)”;

7 (B) by redesignating paragraph (3) as  
8 paragraph (4); and

9 (C) by inserting after paragraph (2) the  
10 following paragraph:

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

14 “(A) the person has been convicted of a  
15 felony for conduct relating to the importation  
16 into the United States of any food; or

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

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



1 (1) in subsection (a), in the heading for the  
2 subsection, by striking “MANDATORY DEBAR-  
3 MENT.—” and inserting “MANDATORY DEBARMENT;  
4 CERTAIN DRUG APPLICATIONS.—”;

5 (2) in subsection (b)—

6 (A) in the heading for the subsection, by  
7 striking “PERMISSIVE DEBARMENT.—” and in-  
8 serting “PERMISSIVE DEBARMENT; CERTAIN  
9 DRUG APPLICATIONS; FOOD IMPORTS.—”; and

10 (B) in paragraph (2), in the heading for  
11 the paragraph, by striking “PERMISSIVE DE-  
12 BARMENT.—” and inserting “PERMISSIVE DE-  
13 BARMENT; CERTAIN DRUG APPLICATIONS.—”;

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

17 (4) in subsection (d)(3)—

18 (A) in subparagraph (A)(i), by striking “or  
19 (b)(2)(A)” and inserting “ or paragraph (2)(A)  
20 or (3) of subsection (b)”;

21 (B) in subparagraph (A)(ii)(II), by insert-  
22 ing “in applicable cases,” before “sufficient au-  
23 dits”;



1 (C) in subparagraph (B), in each of  
2 clauses (i) and (ii), by inserting “or subsection  
3 (b)(3)” after “subsection (b)(2)(B)”; and

4 (D) in subparagraph (B)(ii), by inserting  
5 before the period the following: “or the food im-  
6 portation process, as the case may be”.

7 (c) EFFECTIVE DATES.—Section 306(l)(2) of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9 335a(l)(2)) is amended—

10 (1) in the first sentence—

11 (A) by striking “and” after “subsection  
12 (b)(2),”; and

13 (B) by inserting “, and subsection  
14 (b)(3)(A)” after “subsection (b)(2)(B)”; and

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

17 (d) PROHIBITED ACT.—Section 301 of the Federal  
18 Food, Drug, and Cosmetic Act, as amended by section  
19 303(b) of this Act, is amended by adding at the end the  
20 following:

21 “(cc) The importing or offering for import into the  
22 United States of an article of food by, with the assistance  
23 of, or at the direction of, a person debarred under section  
24 306(b)(3).”.



1 (e) IMPORTATION BY DEBARRED PERSONS.—Section  
2 801 of the Federal Food, Drug, and Cosmetic Act, as  
3 amended by section 303(c) of this Act, is amended by add-  
4 ing at the end the following subsection:

5 “(k)(1) If an article of food is being imported or of-  
6 fered for import into the United States, and the importer,  
7 owner, or consignee of the article is a person who has been  
8 debarred under section 306(b)(3), such article shall be  
9 held at the port of entry for the article, and may not be  
10 delivered to such person. Subsection (b) does not authorize  
11 the delivery of the article pursuant to the execution of a  
12 bond while the article is so held. The article shall be re-  
13 moved to a secure facility, as appropriate. During the pe-  
14 riod of time that such article is so held, the article shall  
15 not be transferred by any person from the port of entry  
16 into the United States for the article, or from the secure  
17 facility to which the article has been removed, as the case  
18 may be.

19 “(2) An article of food held under paragraph (1) may  
20 be delivered to a person who is not a debarred person  
21 under section 306(b)(3) if such person affirmatively estab-  
22 lishes, at the expense of the person, that the article com-  
23 plies with the requirements of this Act, as determined by  
24 the Secretary.”



1 **SEC. 305. REGISTRATION OF FOOD FACILITIES.**

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

5 **“SEC. 415. REGISTRATION OF FOOD FACILITIES.**

6 “(a) REGISTRATION.—

7 “(1) IN GENERAL.—The Secretary shall by reg-  
8 ulation require that any facility engaged in manufac-  
9 turing, processing, packing, or holding food for con-  
10 sumption in the United States be registered with the  
11 Secretary. To be registered—

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

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

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



1 the Secretary through guidance, the general food  
2 category (as identified under section 170.3 of title  
3 21, Code of Federal Regulations) of any food manu-  
4 factured, processed, packed, or held at such facility.  
5 The registrant shall notify the Secretary in a timely  
6 manner of changes 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 any reg-  
15 istration documents submitted pursuant to this sub-  
16 section shall not be subject to disclosure under sec-  
17 tion 552 of title 5, United States Code. Information  
18 derived from such list or registration documents  
19 shall not be subject to disclosure under section 552  
20 of title 5, United States Code, to the extent that it  
21 discloses the identity or location of a specific reg-  
22 istered person.

23 “(b) FACILITY.—For purposes of this section:

24 “(1) The term ‘facility’ includes any factory,  
25 warehouse, or establishment (including a factory,



1 warehouse, or establishment of an importer) that  
2 manufactures, processes, packs, or holds food. Such  
3 term does not include farms; restaurants; other re-  
4 tail food establishments; nonprofit food establish-  
5 ments in which food is prepared for or served di-  
6 rectly to the consumer; or fishing vessels (except  
7 such vessels engaged in processing as defined in sec-  
8 tion 123.3(k) of title 21, Code of Federal Regula-  
9 tions).

10 “(2) The term ‘domestic facility’ means a facil-  
11 ity located in any of the States or Territories.

12 “(3)(A) The term ‘foreign facility’ means a fa-  
13 cility that manufacturers, processes, packs, or holds  
14 food, but only if food from such facility is exported  
15 to the United States without further processing or  
16 packaging outside the United States.

17 “(B) A food may not be considered to have un-  
18 dergone further processing or packaging for pur-  
19 poses of subparagraph (A) solely on the basis that  
20 labeling was added or that any similar activity of a  
21 de minimis nature was carried out with respect to  
22 the food.

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



1 (b) PROHIBITED ACTS.—Section 301 of the Federal  
2 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as  
3 amended by section 304(d) of this Act, is amended by add-  
4 ing at the end the following:

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

7 (c) IMPORTATION; FAILURE TO REGISTER.—Section  
8 801 of the Federal Food, Drug, and Cosmetic Act, as  
9 amended by section 304(e) of this Act, is amended by add-  
10 ing at the end the following subsection:

11 “(l)(1) If an article of food is being imported or of-  
12 fered for import into the United States, and such article  
13 is from a foreign facility for which a registration has not  
14 been submitted to the Secretary under section 415, such  
15 article shall be held at the port of entry for the article,  
16 and may not be delivered to the importer, owner, or con-  
17 signee of the article, until the foreign facility is so reg-  
18 istered. Subsection (b) does not authorize the delivery of  
19 the article pursuant to the execution of a bond while the  
20 article is so held. The article shall be removed to a secure  
21 facility, as appropriate. During the period of time that  
22 such article is so held, the article shall not be transferred  
23 by any person from the port of entry into the United  
24 States for the article, or from the secure facility to which  
25 the article has been removed, as the case may be.”.



1 (d) ELECTRONIC FILING.—For the purpose of reduc-  
2 ing paperwork and reporting burdens, the Secretary of  
3 Health and Human Services may provide for, and encour-  
4 age the use of, electronic methods of submitting to the  
5 Secretary registrations required pursuant to this section.  
6 In providing for the electronic submission of such registra-  
7 tions, the Secretary shall ensure adequate authentication  
8 protocols are used to enable identification of the registrant  
9 and validation of the data as appropriate.

10 (e) RULEMAKING; EFFECTIVE DATE.—Not later  
11 than 18 months after the date of the enactment of this  
12 Act, the Secretary of Health and Human Services shall  
13 promulgate proposed and final regulations for the require-  
14 ment of registration under section 415 of the Federal  
15 Food, Drug, and Cosmetic Act (as added by subsection  
16 (a) of this section). Such requirement of registration takes  
17 effect—

18 (1) upon the effective date of such final regula-  
19 tions; or

20 (2) upon the expiration of such 18-month pe-  
21 riod if the final regulations have not been made ef-  
22 fective as of the expiration of such period, subject to  
23 compliance with the final regulations when the final  
24 regulations are made effective.



1 **SEC. 306. MAINTENANCE AND INSPECTION OF RECORDS**  
2 **FOR FOODS.**

3 (a) IN GENERAL.—Chapter IV of the Federal Food,  
4 Drug, and Cosmetic Act, as amended by section 305 of  
5 this Act, is amended by inserting before section 415 the  
6 following section:

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

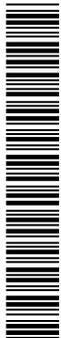
8 “(a) RECORDS INSPECTION.—If the Secretary has a  
9 reasonable belief that an article of food is adulterated and  
10 presents a threat of serious adverse health consequences  
11 or death to humans or animals, each person (excluding  
12 farms and restaurants) who manufactures, processes,  
13 packs, distributes, receives, holds, or imports such article  
14 shall, at the request of an officer or employee duly des-  
15 ignated by the Secretary, permit such officer or employee,  
16 upon presentation of appropriate credentials and a written  
17 notice to such person, at reasonable times and within rea-  
18 sonable limits and in a reasonable manner, to have access  
19 to and copy all records relating to such article that are  
20 needed to assist the Secretary in determining whether the  
21 food is adulterated and presents a threat of serious ad-  
22 verse health consequences or death to humans or animals.  
23 The requirement under the preceding sentence applies to  
24 all records relating to the manufacture, processing, pack-  
25 ing, distribution, receipt, holding, or importation of such  
26 article maintained by or on behalf of such person in any



1 format (including paper and electronic formats) and at  
2 any location.

3       “(b) REGULATIONS CONCERNING RECORD-  
4 KEEPING.—The Secretary, in consultation and coordina-  
5 tion, as appropriate, with other Federal departments and  
6 agencies with responsibilities for regulating food safety,  
7 may by regulation establish requirements regarding the es-  
8 tablishment and maintenance, for not longer than two  
9 years, of records by persons (excluding farms and res-  
10 taurants) who manufacture, process, pack, transport, dis-  
11 tribute, receive, hold, or import food, which records are  
12 needed by the Secretary for inspection to allow the Sec-  
13 retary to identify the immediate previous sources and the  
14 immediate subsequent recipients of food, including its  
15 packaging, in order to address credible threats of serious  
16 adverse health consequences or death to humans or ani-  
17 mals. The Secretary shall take into account the size of  
18 a business in promulgating regulations under this section.

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



1       “(d) LIMITATIONS.—This section shall not be  
2 construed—

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

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

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

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

22       (b) FACTORY INSPECTION.—Section 704(a) of the  
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a))  
24 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 a reasonable  
8 belief that an article of food is adulterated and pre-  
9 sents a threat of serious adverse health consequences  
10 or death to humans or animals, subject to the limi-  
11 tations 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 of the Federal  
16 Food, Drug and Cosmetic Act (21 U.S.C. 331) is  
17 amended—

18           (1) in paragraph (e)—

19                   (A) by striking “by section 412, 504, or  
20 703” and inserting “by section 412, 414, 504,  
21 703, or 704(a)”; and

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

24           (2) in paragraph (j), by inserting “414,” after  
25 “412.”.



1 (d) EXPEDITED RULEMAKING.—Not later than 18  
2 months after the date of the enactment of this Act, the  
3 Secretary shall promulgate proposed and final regulations  
4 establishing recordkeeping requirements under subsection  
5 414(b) of the Federal Food, Drug, and Cosmetic Act (as  
6 added by subsection (a)).

7 **SEC. 307. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.**

8 (a) IN GENERAL.—Section 801 of the Federal Food,  
9 Drug, and Cosmetic Act, as amended by section 305(c)  
10 of this Act, is amended by adding at the end the following  
11 subsection:

12 “(m)(1) In the case of an article of food that is being  
13 imported or offered for import into the United States, the  
14 Secretary, after consultation with the Secretary of the  
15 Treasury, shall by regulation require, for the purpose of  
16 enabling such article to be inspected at ports of entry into  
17 the United States, the submission to the Secretary of a  
18 notice providing the identity of each of the following: The  
19 article; the manufacturer and shipper of the article; if  
20 known within the specified period of time that notice is  
21 required to be provided, the grower of the article; the  
22 country from which the article originates; the country  
23 from which the article is shipped; and the anticipated port  
24 of entry for the article. An article of food imported or of-  
25 fered for import without submission of such notice in ac-



1 cordance with the requirements under this paragraph shall  
2 be refused admission into the United States. Nothing in  
3 this section may be construed as a limitation on the port  
4 of entry for an article of food.

5 “(2)(A) Regulations under paragraph (1) shall re-  
6 quire that a notice under such paragraph be provided by  
7 a specified period of time in advance of the time of the  
8 importation of the article of food involved or the offering  
9 of the food for import, which period shall be no less than  
10 the minimum amount of time necessary for the Secretary  
11 to receive, review, and appropriately respond to such noti-  
12 fication, but may not exceed five days. In determining the  
13 specified period of time required under this subparagraph,  
14 the Secretary may consider, but is not limited to consider-  
15 ation of, the effect on commerce of such period of time,  
16 the locations of the various ports of entry into the United  
17 States, the various modes of transportation, the types of  
18 food imported into the United States, and any other such  
19 consideration. Nothing in the preceding sentence may be  
20 construed as a limitation on the obligation of the Secretary  
21 to receive, review, and appropriately respond to any notice  
22 under paragraph (1).

23 “(B)(i) If an article of food is being imported or of-  
24 fered for import into the United States and a notice under  
25 paragraph (1) is not provided in advance in accordance



1 with the requirements under paragraph (1), such article  
2 shall be held at the port of entry for the article, and may  
3 not be delivered to the importer, owner, or consignee of  
4 the article, until such notice is submitted to the Secretary,  
5 and the Secretary examines the notice and determines that  
6 the notice is in accordance with the requirements under  
7 paragraph (1). Subsection (b) does not authorize the deliv-  
8 ery of the article pursuant to the execution of a bond while  
9 the article is so held. The article shall be removed to a  
10 secure facility, as appropriate. During the period of time  
11 that such article is so held, the article shall not be trans-  
12 ferred by any person from the port of entry into the  
13 United States for the article, or from the secure facility  
14 to which the article has been removed, as the case may  
15 be.

16 “(ii) In carrying out clause (i) with respect to an arti-  
17 cle of food, the Secretary shall determine whether there  
18 is in the possession of the Secretary any 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 “(3)(A) This subsection may not be construed as lim-  
23 iting the authority of the Secretary to obtain information  
24 under any other provision of this Act.



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

9       (b) PROHIBITED ACT.—Section 301 of the Federal  
10 Food, Drug, and Cosmetic Act, as amended by section  
11 305(b) of this Act, is amended by adding at the end the  
12 following:

13       “(ee) The importing or offering for import into the  
14 United States of an article of food in violation of the re-  
15 quirements under section 801(m).”.

16       (c) RULEMAKING; EFFECTIVE DATE.—

17           (1) IN GENERAL.—Not later than 18 months  
18 after the date of the enactment of this Act, the Sec-  
19 retary of Health and Human Services shall promul-  
20 gate proposed and final regulations for the require-  
21 ment of providing notice in accordance with section  
22 801(m) of the Federal Food, Drug, and Cosmetic  
23 Act (as added by subsection (a) of this section).  
24 Such requirement of notification takes effect—



1 (A) upon the effective date of such final  
2 regulations; or

3 (B) upon the expiration of such 18-month  
4 period if the final regulations have not been  
5 made effective as of the expiration of such pe-  
6 riod, subject to compliance with the final regu-  
7 lations when the final regulations are made ef-  
8 fective.

9 (2) DEFAULT; MINIMUM PERIOD OF ADVANCE  
10 NOTICE.—If under paragraph (1) the requirement  
11 for providing notice in accordance with section  
12 801(m) of the Federal Food, Drug, and Cosmetic  
13 Act takes effect without final regulations having  
14 been made effective, then for purposes of such re-  
15 quirement, the specified period of time that the no-  
16 tice is required to be made in advance of the time  
17 of the importation of the article of food involved or  
18 the offering of the food for import shall be not fewer  
19 than eight hours and not more than five days, which  
20 shall remain in effect until the final regulations are  
21 made effective.

22 **SEC. 308. AUTHORITY TO MARK ARTICLES REFUSED ADMIS-**  
23 **SION INTO UNITED STATES.**

24 (a) IN GENERAL.—Section 801 of the Federal Food,  
25 Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended



1 by section 307(a) of this Act, is amended by adding at  
2 the end the following:

3 “(n)(1) If a food has been refused admission under  
4 subsection (a), other than such a food that is required to  
5 be destroyed, the Secretary may require the owner or con-  
6 signee of the food to affix to the container of the food  
7 a label that clearly and conspicuously bears the statement:  
8 ‘UNITED STATES: REFUSED ENTRY’.

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

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

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

20 “(v) If—

21 “(1) it fails to bear a label required by the Sec-  
22 retary under section 801(n)(1) (relating to food re-  
23 fused admission into the United States);



1           “(2) the Secretary finds that the food presents  
2           a threat of serious adverse health consequences or  
3           death to humans or animals; and

4           “(3) upon or after notifying the owner or con-  
5           signee involved that the label is required under sec-  
6           tion 801, the Secretary informs the owner or con-  
7           signee that the food presents such a threat.”.

8           (c) **RULE OF CONSTRUCTION.**—With respect to arti-  
9           cles of food that are imported or offered for import into  
10          the United States, nothing in this section shall be con-  
11          strued to limit the authority of the Secretary of Health  
12          and Human Services or the Secretary of the Treasury to  
13          require the marking of refused articles of food under any  
14          other provision of law.

15          **SEC. 309. PROHIBITION AGAINST PORT SHOPPING.**

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

19          “(h) If it is an article of food imported or offered  
20          for import into the United States and the article of food  
21          has previously been refused admission under section  
22          801(a), unless the person reoffering the article affirma-  
23          tively establishes, at the expense of the owner or consignee  
24          of the article, that the article complies with the applicable



1 requirements of this Act, as determined by the Sec-  
2 retary.”.

3 **SEC. 310. NOTICES TO STATES REGARDING IMPORTED**  
4 **FOOD.**

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

8 **“SEC. 908. NOTICES TO STATES REGARDING IMPORTED**  
9 **FOOD.**

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

23 “(b) **RULE OF CONSTRUCTION.**—Subsection (a) may  
24 not be construed as limiting the authority of the Secretary



1 with respect to food under any other provision of this  
2 Act.”.

3 **SEC. 311. GRANTS TO STATES FOR INSPECTIONS.**

4 Chapter IX of the Federal Food, Drug and Cosmetic  
5 Act, as amended by section 310 of this Act, is amended  
6 by adding at the end the following section:

7 **“SEC. 909. GRANTS TO STATES FOR INSPECTIONS.**

8 “(a) IN GENERAL.—The Secretary is authorized to  
9 make grants to States, territories, and Indian tribes (as  
10 defined in section 4(e) of the Indian Self-Determination  
11 and Education Assistance Act (25 U.S.C. 450b(e))) that  
12 undertake examinations, inspections, and investigations,  
13 and related activities under section 702. The funds pro-  
14 vided under such grants shall only be available for the  
15 costs of conducting such examinations, inspections, inves-  
16 tigation, and related activities.

17 “(b) NOTICES REGARDING ADULTERATED IM-  
18 PORTED FOOD.—The Secretary may make grants to the  
19 States for the purpose of assisting the States with the  
20 costs of taking appropriate action to protect the public  
21 health in response to notification under section 908, in-  
22 cluding planning and otherwise preparing to take such ac-  
23 tion.

24 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the  
25 purpose of carrying out this section, there are authorized



1 to be appropriated \$10,000,000 for fiscal year 2002, and  
2 such sums as may be necessary for each of the fiscal years  
3 2003 through 2006.”.

4 **SEC. 312. SURVEILLANCE AND INFORMATION GRANTS AND**  
5 **AUTHORITIES.**

6 Part B of title III of the Public Health Service Act  
7 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
8 tion 317P the following:

9 **“SEC. 317R. FOOD SAFETY GRANTS.**

10 “(a) IN GENERAL.—The Secretary may award grants  
11 to States and Indian tribes (as defined in section 4(e) of  
12 the Indian Self-Determination and Education Assistance  
13 Act (25 U.S.C. 450b(e))) to expand participation in net-  
14 works to enhance Federal, State, and local food safety ef-  
15 forts, including meeting the costs of establishing and  
16 maintaining the food safety surveillance, technical, and  
17 laboratory capacity needed for such participation.

18 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the  
19 purpose of carrying out this section, there are authorized  
20 to be appropriated \$19,500,000 for fiscal year 2002, and  
21 such sums as may be necessary for each of the fiscal years  
22 2003 through 2006.”.

23 **SEC. 313. SURVEILLANCE OF ZONOTIC DISEASES.**

24 The Secretary of Health and Human Services,  
25 through the Commissioner of Food and Drugs and the Di-



1 rector of the Centers for Disease Control and Prevention,  
2 and the Secretary of Agriculture shall coordinate the sur-  
3 veillance of zoonotic diseases.

4 **SEC. 314. AUTHORITY TO COMMISSION OTHER FEDERAL**  
5 **OFFICIALS TO CONDUCT INSPECTIONS.**

6 Section 702(a) of the Federal Food, Drug and Cos-  
7 metic Act (21 U.S.C. 372(a)) is amended—

8 (1) by striking “(a)” and inserting “(a)(1)”;

9 (2) by striking “In the case of food packed”  
10 and inserting the following:

11 “(3) In the case of food packed”;

12 (3) by striking “For the purposes of this sub-  
13 section” and inserting the following:

14 “(4) For the purposes of this subsection,”; and

15 (4) by inserting after paragraph (1) (as des-  
16 igned by paragraph (1) of this section) the fol-  
17 lowing paragraph:

18 “(2)(A) In addition to the authority established in  
19 paragraph (1), the Secretary, pursuant to a memorandum  
20 of understanding between the Secretary and the head of  
21 another Federal department or agency, is authorized to  
22 conduct examinations and investigations for the purposes  
23 of this Act through the officers and employees of such  
24 other department or agency, subject to subparagraph (B).

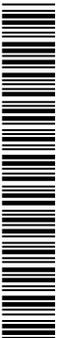
25 Such a memorandum shall include provisions to ensure



1 adequate training of such officers and employees to con-  
2 duct the examinations and investigations. The memo-  
3 randum of understanding shall contain provisions regard-  
4 ing reimbursement. Such provisions may, at the sole dis-  
5 cretion of the head of the other department or agency,  
6 require reimbursement, in whole or in part, from the Sec-  
7 retary for the examinations or investigations performed  
8 under this section by the officers or employees of the other  
9 department or agency.

10       “(B) A memorandum of understanding under sub-  
11 paragraph (A) between the Secretary and another Federal  
12 department or agency is effective only in the case of ex-  
13 aminations or inspections at facilities or other locations  
14 that are jointly regulated by the Secretary and such de-  
15 partment or agency.

16       “(C) For any fiscal year in which the Secretary and  
17 the head of another Federal department or agency carries  
18 out one or more examinations or inspections under a  
19 memorandum of understanding under subparagraph (A),  
20 the Secretary and the head of such department or agency  
21 shall with respect to their respective departments or agen-  
22 cies submit to the committees of jurisdiction (authorizing  
23 and appropriating) in the House of Representatives and  
24 the Senate a report that provides, for such year—



1           “(i) the number of officers or employees that  
2           carried out one or more programs, projects, or ac-  
3           tivities under such memorandum;

4           “(ii) the number of additional articles that were  
5           inspected or examined as a result of such memo-  
6           randum; and

7           “(iii) the number of additional examinations or  
8           investigations that were carried out pursuant to such  
9           memorandum.”.

10 **SEC. 315. RULE OF CONSTRUCTION.**

11           Nothing in this title, or an amendment made by this  
12 title, shall be construed to alter the jurisdiction between  
13 the Secretaries of Agriculture and of Health and Human  
14 Services, under applicable statutes and regulations.

15           **Subtitle B—Protection of Drug**  
16           **Supply**

17 **SEC. 321. ANNUAL REGISTRATION OF FOREIGN MANUFAC-**  
18           **TURERS; SHIPPING INFORMATION; DRUG**  
19           **AND DEVICE LISTING.**

20           (a) ANNUAL REGISTRATION; LISTING.—Section 510  
21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 360) is amended—

23           (1) in subsection (i)(1)—



1 (A) by striking “Any establishment” and  
2 inserting “On or before December 31 of each  
3 year, any establishment”; and

4 (B) by striking “shall register” and all  
5 that follows and inserting the following: “shall,  
6 through electronic means in accordance with  
7 the criteria of the Secretary, register with the  
8 Secretary the name and place of business of the  
9 establishment, the name of the United States  
10 agent for the establishment, the name of each  
11 importer of such drug or device in the United  
12 States that is known to the establishment, and  
13 the name of each person who imports or offers  
14 for import such drug or device to the United  
15 States for purposes of importation.”; and

16 (2) in subsection (j)(1), in the first sentence, by  
17 striking “or (d)” and inserting “(d), or (i)”.

18 (b) IMPORTATION; STATEMENT REGARDING REG-  
19 ISTRATION OF MANUFACTURER.—

20 (1) IN GENERAL.—Section 801 of the Federal  
21 Food, Drug, and Cosmetic Act, as amended by sec-  
22 tion 308(a) of this Act, is amended by adding at the  
23 end the following subsection:

24 “(o) If an article that is a drug or device is being  
25 imported or offered for import into the United States, and



1 the importer, owner, or consignee of such article does not,  
2 at the time of offering the article for import, submit to  
3 the Secretary a statement that identifies the registration  
4 under section 510(i) of each establishment that with re-  
5 spect to such article is required under such section to reg-  
6 ister with the Secretary, the article may be refused admis-  
7 sion. If the article is refused admission for failure to sub-  
8 mit such a statement, the article shall be held at the port  
9 of entry for the article, and may not be delivered to the  
10 importer, owner, or consignee of the article, until such a  
11 statement is submitted to the Secretary. Subsection (b)  
12 does not authorize the delivery of the article pursuant to  
13 the execution of a bond while the article is so held. The  
14 article shall be removed to a secure facility, as appro-  
15 priate. During the period of time that such article is so  
16 held, the article shall not be transferred by any person  
17 from the port of entry into the United States for the arti-  
18 cle, or from the secure facility to which the article has  
19 been removed, as the case may be.”.

20 (2) PROHIBITED ACT.—Section 301 of the Fed-  
21 eral Food, Drug, and Cosmetic Act, as amended by  
22 section 307(b) of this Act, is amended by adding at  
23 the end the following:

24 “(ff) The importing or offering for import into the  
25 United States of a drug or device with respect to which



1 there is a failure to comply with a request of the Secretary  
2 to submit to the Secretary a statement under section  
3 801(o).”.

4 (c) EFFECTIVE DATE.—The amendments made by  
5 this section take effect upon the expiration of the 180-  
6 day period beginning on the date of the enactment of this  
7 Act.

8 **SEC. 322. REQUIREMENT OF ADDITIONAL INFORMATION**  
9 **REGARDING IMPORT COMPONENTS IN-**  
10 **TENDED FOR USE IN EXPORT PRODUCTS.**

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

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

23 (i) The importer of such article of a drug or  
24 device or importer of such article of a food additive,  
25 color additive, or dietary supplement submits to the



1 Secretary, at the time of initial importation, a state-  
2 ment in accordance with the following:

3 “(I) Such statement provides that such ar-  
4 ticle is intended to be further processed by the  
5 initial owner or consignee, or incorporated by  
6 the initial owner or consignee, into a drug, bio-  
7 logical product, device, food, food additive, color  
8 additive, or dietary supplement that will be ex-  
9 ported by the initial owner or consignee from  
10 the United States in accordance with subsection  
11 (e) or section 802, or with section 351(h) of the  
12 Public Health Service Act.

13 “(II) The statement identifies the manu-  
14 facturer of such article and each processor,  
15 packer, distributor, or other entity that had  
16 possession of the article in the chain of posses-  
17 sion of the article from the manufacturer to  
18 such importer of the article.

19 “(III) The statement is accompanied by  
20 such certificates of analysis as are necessary to  
21 identify such article, unless the article is a de-  
22 vice or is an article described in paragraph (4).

23 “(ii) At the time of initial importation and be-  
24 fore the delivery of such article to the importer or  
25 the initial owner or consignee, such owner or con-



1       signee executes a good and sufficient bond providing  
2       for the payment of such liquidated damages in the  
3       event of default as may be required pursuant to reg-  
4       ulations of the Secretary of the Treasury.

5               “(iii) Such article is used and exported by the  
6       initial owner or consignee in accordance with the in-  
7       tent described under clause (i)(I), except for any  
8       portions of the article that are destroyed.

9               “(iv) The initial owner or consignee maintains  
10       records on the use or destruction of such article or  
11       portions thereof, as the case may be, and submits to  
12       the Secretary any such records requested by the Sec-  
13       retary.

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

20               “(B) Notwithstanding subparagraph (A), the Sec-  
21       retary may refuse admission to an article that otherwise  
22       would be imported into the United States under such sub-  
23       paragraph if the Secretary determines that there is cred-  
24       ible evidence or information indicating that such article  
25       is not intended to be further processed by the initial owner



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

7 “(C) This section may not be construed as affecting  
8 the responsibility of the Secretary to ensure that articles  
9 imported into the United States under authority of sub-  
10 paragraph (A) meet each of the conditions established in  
11 such subparagraph for importation.”.

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

15 “(w) The making of a knowingly false statement in  
16 any statement, certificate of analysis, record, or report re-  
17 quired or requested under section 801(d)(3); the failure  
18 to submit a certificate of analysis as required under such  
19 section; the failure to maintain records or to submit  
20 records or reports as required by such section; the release  
21 into interstate commerce of any article or portion thereof  
22 imported into the United States under such section or any  
23 finished product made from such article or portion, except  
24 for export in accordance with section 801(e) or 802, or  
25 with section 351(h) of the Public Health Service Act; or



1 the failure to so export or to destroy such an article or  
2 portions thereof, or such a finished product.”.

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

6 **Subtitle C—General Provisions Re-**  
7 **lating to Upgrade of Agricul-**  
8 **tural Security**

9 **SEC. 331. EXPANSION OF ANIMAL AND PLANT HEALTH IN-**  
10 **SPECTION SERVICE ACTIVITIES.**

11 (a) IN GENERAL.—The Secretary of Agriculture (re-  
12 ferred to in this section as the “Secretary”) may utilize  
13 existing authorities to give high priority to enhancing and  
14 expanding the capacity of the Animal and Plant Health  
15 Inspection Service to conduct activities to—

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

18 (2) improve surveillance at ports of entry and  
19 customs;

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

23 (4) develop new and improve existing strategies  
24 and technologies for dealing with intentional out-  
25 breaks of plant and animal disease arising from acts



1 of terrorism or from unintentional introduction,  
2 including—

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

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

14 (i) State animal health commissions  
15 and regulatory agencies for livestock and  
16 poultry health; and

17 (ii) State agriculture departments;  
18 and

19 (5) otherwise improve the capacity of the Serv-  
20 ice to protect against the threat of bioterrorism.

21 (b) AUTOMATED RECORDKEEPING SYSTEM.—The  
22 Administrator of the Animal and Plant Health Inspection  
23 Service may implement a central automated recordkeeping  
24 system to provide for the reliable tracking of the status  
25 of animal and plant shipments, including those shipments



1 on hold at ports of entry and customs. The Secretary shall  
2 ensure that such a system shall be fully accessible to or  
3 fully integrated with the Food Safety Inspection Service.

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

8 **SEC. 332. EXPANSION OF FOOD SAFETY INSPECTION SERV-**  
9 **ICE ACTIVITIES.**

10 (a) IN GENERAL.—The Secretary of Agriculture may  
11 utilize existing authorities to give high priority to enhance-  
12 ing and expanding the capacity of the Food Safety Inspec-  
13 tion Service to conduct activities to—

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

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

21 (3) strengthen the ability of the Service to col-  
22 laborate with relevant agencies within the Depart-  
23 ment of Agriculture and with other entities in the  
24 Federal Government, the States, and Indian tribes  
25 (as defined in section 4(e) of the Indian Self-Deter-



1 mination and Education Assistance Act (25 U.S.C.  
2 450b(e)) through the sharing of information and  
3 technology; and

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

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

10 **SEC. 333. BIOSECURITY UPGRADES AT THE DEPARTMENT**  
11 **OF AGRICULTURE.**

12 There is authorized to be appropriated for fiscal year  
13 2002, \$180,000,000 for the purpose of enabling the Agri-  
14 cultural Research Service to conduct building upgrades to  
15 modernize existing facilities, of which (1) \$100,000,000  
16 shall be allocated for renovation, updating, and expansion  
17 of the Biosafety Level 3 laboratory and animal research  
18 facilities at the Plum Island Animal Disease Center  
19 (Greenport, New York), and of which (2) \$80,000,000  
20 shall be allocated for the Agricultural Research Service/  
21 Animal and Plant Health Inspection Service facility in  
22 Ames, Iowa. There are authorized to be appropriated such  
23 sums as may be necessary for fiscal years 2003 through  
24 2006 for the purpose described in the preceding sentence,  
25 for the planning and design of an Agricultural Research



1 Service biocontainment laboratory for poultry research in  
2 Athens, Georgia, and for the planning, updating, and ren-  
3 ovation of the Arthropod-Borne Animal Disease Labora-  
4 tory in Laramie, Wyoming.

5 **SEC. 334. AGRICULTURAL BIOSECURITY.**

6 (a) SECURITY AT COLLEGES AND UNIVERSITIES.—

7 (1) GRANTS.—The Secretary of Agriculture (re-  
8 ferred to in this section as the “Secretary”) may  
9 award grants to covered entities to review security  
10 standards and practices at their facilities in order to  
11 protect against bioterrorist attacks.

12 (2) COVERED ENTITIES.—Covered entities  
13 under this subsection are colleges or universities  
14 that—

15 (A) are colleges or universities as defined  
16 in section 1404 of the National Agricultural Re-  
17 search, Extension, and Teaching Policy Act of  
18 1977 (7 U.S.C. 3103); and

19 (B) have programs in food and agricultural  
20 sciences, as defined in such section.

21 (3) LIMITATION.—Each individual covered enti-  
22 ty may be awarded one grant under paragraph (1),  
23 the amount of which shall not exceed \$50,000.

24 (4) CONTRACT AUTHORITY.—Colleges and uni-  
25 versities receiving grants under paragraph (1) may



1 use such grants to enter into contracts with inde-  
2 pendent private organizations with established and  
3 demonstrated security expertise to conduct the secu-  
4 rity reviews specified in such paragraph.

5 (b) GUIDELINES FOR AGRICULTURAL BIOSECU-  
6 RITY.—

7 (1) IN GENERAL.—The Secretary may award  
8 grants to associations of food producers or consortia  
9 of such associations for the development and imple-  
10 mentation of educational programs to improve bio-  
11 security on farms in order to ensure the security of  
12 farm facilities against potential bioterrorist attacks.

13 (2) LIMITATION.—Each individual association  
14 eligible under paragraph (1) may be awarded one  
15 grant under such paragraph, the amount of which  
16 shall not exceed \$100,000. Each consortium eligible  
17 under paragraph (1) may be awarded one grant  
18 under such paragraph, the amount of which shall  
19 not exceed \$100,000 per association participating in  
20 the consortium.

21 (3) CONTRACT AUTHORITY.—Associations of  
22 food producers receiving grants under paragraph (1)  
23 may use such grants to enter into contracts with  
24 independent private organizations with established  
25 and demonstrated expertise in biosecurity to assist



1 in the development and implementation of edu-  
2 cational programs to improve biosecurity specified in  
3 such paragraph.

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

7 **SEC. 335. AGRICULTURAL BIOTERRORISM RESEARCH AND**  
8 **DEVELOPMENT.**

9 (a) IN GENERAL.—The Secretary of Agriculture (re-  
10 ferred to in this section as the “Secretary”) may utilize  
11 existing research authorities and research programs to  
12 protect the food supply of the United States by conducting  
13 and supporting research activities to—

14 (1) enhance the capability of the Secretary to  
15 respond in a timely manner to emerging or existing  
16 bioterrorist threats to the food and agricultural sys-  
17 tem of the United States;

18 (2) develop new and continue partnerships with  
19 institutions of higher education and other institu-  
20 tions to help form stable, long-term programs to en-  
21 hance the biosecurity and food safety of the United  
22 States, including the coordination of the develop-  
23 ment, implementation, and enhancement of diverse  
24 capabilities for addressing threats to the nation’s ag-  
25 ricultural economy and food supply, with special em-



1 phasis on planning, training, outreach, and research  
2 activities related to vulnerability analyses, incident  
3 response, detection, and prevention technologies;

4 (3) strengthen coordination with the intelligence  
5 community to better identify research needs and  
6 evaluate materials or information acquired by the in-  
7 telligence community relating to potential threats to  
8 United States agriculture;

9 (4) expand the involvement of the Secretary  
10 with international organizations dealing with plant  
11 and animal disease control;

12 (5) continue research to develop rapid detection  
13 field test kits to detect biological threats to plants  
14 and animals and to provide such test kits to State  
15 and local agencies preparing for or responding to  
16 bioterrorism;

17 (6) develop an agricultural bioterrorism early  
18 warning surveillance system through enhancing the  
19 capacity of and coordination between State veteri-  
20 nary diagnostic laboratories, Federal and State agri-  
21 cultural research facilities, and public health agen-  
22 cies; and

23 (7) otherwise improve the capacity of the Sec-  
24 retary to protect against the threat of bioterrorism.



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

5 **SEC. 336. ANIMAL ENTERPRISE TERRORISM PENALTIES.**

6 (a) IN GENERAL.—Section 43(a) of title 18, United  
7 States Code, is amended to read as follows:

8 “(a) OFFENSE.—Whoever—

9 “(1) travels in interstate or foreign commerce,  
10 or uses or causes to be used the mail or any facility  
11 in interstate or foreign commerce for the purpose of  
12 causing physical disruption to the functioning of an  
13 animal enterprise; and

14 “(2) intentionally damages or causes the loss of  
15 any property (including animals or records) used by  
16 the animal enterprise, or conspires to do so,  
17 shall be punished as provided for in subsection (b).”.

18 (b) PENALTIES.—Section 43(b) of title 18, United  
19 States Code, is amended to read as follows:

20 “(b) PENALTIES.—

21 “(1) ECONOMIC DAMAGE.—Any person who, in  
22 the course of a violation of subsection (a), causes  
23 economic damage not exceeding \$10,000 to an ani-



1 mal enterprise shall be fined under this title or im-  
2 prisoned not more than 6 months, or both.

3 “(2) MAJOR ECONOMIC DAMAGE.—Any person  
4 who, in the course of a violation of subsection (a),  
5 causes economic damage exceeding \$10,000 to an  
6 animal enterprise shall be fined under this title or  
7 imprisoned not more than 3 years, or both.

8 “(3) SERIOUS BODILY INJURY.—Any person  
9 who, in the course of a violation of subsection (a),  
10 causes serious bodily injury to another individual  
11 shall be fined under this title or imprisoned not  
12 more than 20 years, or both.

13 “(4) DEATH.—Any person who, in the course of  
14 a violation of subsection (a), causes the death of an  
15 individual shall be fined under this title and impris-  
16 oned for life or for any term of years.”.

17 (c) RESTITUTION.—Section 43(c) of title 18, United  
18 States Code, is amended—

19 (1) in paragraph (1), by striking “and” at the  
20 end;

21 (2) in paragraph (2), by striking the period at  
22 the end and inserting “; and”; and

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

24 “(3) for any other economic damage resulting  
25 from the offense.”.



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

3   **SEC. 401. TERRORIST AND OTHER INTENTIONAL ACTS.**

4           The Safe Drinking Water Act (title XIV of the Public  
5 Health Service Act) is amended by inserting the following  
6 new section after section 1432:

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

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



1 ability assessments regarding which kinds of terrorist at-  
2 tacks or other intentional acts are the probable threats  
3 to—

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

7           “(B) otherwise present significant public health  
8 concerns.

9           “(2) Each community water system referred to in  
10 paragraph (1) shall certify to the Administrator that the  
11 system has conducted an assessment complying with para-  
12 graph (1) and shall submit to the Administrator a written  
13 copy of the assessment. Such certification and submission  
14 shall be made prior to:

15           “(A) March 31, 2003, in the case of systems  
16 serving a population of 100,000 or more.

17           “(B) December 31, 2003, in the case of sys-  
18 tems serving a population of 50,000 or more but less  
19 than 100,000.

20           “(C) June 30, 2004, in the case of systems  
21 serving a population greater than 3,300 but less  
22 than 50,000.

23           “(3) Except for information contained in a certifi-  
24 cation under this subsection identifying the system sub-  
25 mitting the certification and the date of the certification,



1 all information provided to the Administrator under this  
2 subsection and all information derived therefrom shall be  
3 exempt from disclosure under section 552 of title 5 of the  
4 United States Code.

5 “(4) No community water system shall be required  
6 under State or local law to provide an assessment de-  
7 scribed in this section to any State, regional, or local gov-  
8 ernmental entity solely by reason of the requirement set  
9 forth in paragraph (2) that the system submit such assess-  
10 ment to the Administrator.

11 “(5) Not later than November 30, 2002, the Adminis-  
12 trator, in consultation with appropriate Federal law en-  
13 forcement and intelligence officials, shall develop such pro-  
14 tocols as may be necessary to protect the copies of the  
15 assessments required to be submitted under this sub-  
16 section (and the information contained therein) from un-  
17 authorized disclosure. Such protocols shall ensure that—

18 “(A) each copy of such assessment, and all in-  
19 formation contained in or derived from the assess-  
20 ment, is kept in a secure location;

21 “(B) only individuals designated by the Admin-  
22 istrator may have access to the copies of the assess-  
23 ments; and

24 “(C) no copy of an assessment, or part of an  
25 assessment, or information contained in or derived



1 from an assessment shall be available to anyone  
2 other than an individual designated by the Adminis-  
3 trator.

4 At the earliest possible time prior to November 30, 2002,  
5 the Administrator shall complete the development of such  
6 protocols for the purpose of having them in place prior  
7 to receiving any vulnerability assessments from commu-  
8 nity water systems under this subsection.

9 “(6)(A) Except as provided in subparagraph (B), any  
10 individual referred to in paragraph (5)(B) who acquires  
11 the assessment submitted under paragraph (2), or any re-  
12 production of such assessment, or any information derived  
13 from such assessment, and who knowingly or recklessly  
14 reveals such assessment, reproduction, or information  
15 other than—

16 “(i) to an individual designated by the Adminis-  
17 trator under paragraph (5),

18 “(ii) for purposes of section 1445 or for actions  
19 under section 1431, or

20 “(iii) for use in any administrative or judicial  
21 proceeding to impose a penalty for failure to comply  
22 with this section,

23 shall upon conviction be imprisoned for not more than one  
24 year or fined in accordance with the provisions of chapter  
25 227 of title 18, United States Code, applicable to class



1 A misdemeanors, or both, and shall be removed from Fed-  
2 eral office or employment.

3 “(B) Notwithstanding subparagraph (A), an indi-  
4 vidual referred to in paragraph (5)(B) who is an officer  
5 or employee of the United States may discuss the contents  
6 of a vulnerability assessment submitted under this section  
7 with a State or local official.

8 “(7) Nothing in this section authorizes any person  
9 to withhold any information from Congress or from any  
10 committee or subcommittee of Congress.

11 “(b) EMERGENCY RESPONSE PLAN.—Each commu-  
12 nity water system serving a population greater than 3,300  
13 shall prepare or revise, where necessary, an emergency re-  
14 sponse plan that incorporates the results of vulnerability  
15 assessments that have been completed. Each such commu-  
16 nity water system shall certify to the Administrator, as  
17 soon as reasonably possible after the enactment of this  
18 section, but not later than 6 months after the completion  
19 of the vulnerability assessment under subsection (a), that  
20 the system has completed such plan. The emergency re-  
21 sponse plan shall include, but not be limited to, plans, pro-  
22 cedures, and identification of equipment that can be imple-  
23 mented or utilized in the event of a terrorist or other in-  
24 tentional attack on the public water system. The emer-  
25 gency response plan shall also include actions, procedures,



1 and identification of equipment which can obviate or sig-  
2 nificantly lessen the impact of terrorist attacks or other  
3 intentional actions on the public health and the safety and  
4 supply of drinking water provided to communities and in-  
5 dividuals. Community water systems shall, to the extent  
6 possible, coordinate with existing Local Emergency Plan-  
7 ning Committees established under the Emergency Plan-  
8 ning and Community Right-to-Know Act (42 U.S.C.  
9 11001, et seq.) when preparing or revising an emergency  
10 response plan under this subsection.

11 “(c) RECORD MAINTENANCE.—Each community  
12 water system shall maintain a copy of the emergency re-  
13 sponse plan completed pursuant to subsection (b) for 5  
14 years after such plan has been certified to the Adminis-  
15 trator under this section.

16 “(d) GUIDANCE TO SMALL PUBLIC WATER SYS-  
17 TEMS.—The Administrator shall provide guidance to com-  
18 munity water systems serving a population of less than  
19 3,300 persons on how to conduct vulnerability assess-  
20 ments, prepare emergency response plans, and address  
21 threats from terrorist attacks or other intentional actions  
22 designed to disrupt the provision of safe drinking water  
23 or significantly affect the public health or significantly af-  
24 fect the safety or supply of drinking water provided to  
25 communities and individuals.



1           “(e) FUNDING.—(1) There are authorized to be ap-  
2 propriated to carry out this section not more than  
3 \$160,000,000 for the fiscal year 2002 and such sums as  
4 may be necessary for the fiscal years 2003 through 2005.

5           “(2) The Administrator, in coordination with State  
6 and local governments, may use funds made available  
7 under paragraph (1) to provide financial assistance to  
8 community water systems for purposes of compliance with  
9 the requirements of subsections (a) and (b) and to commu-  
10 nity water systems for expenses and contracts designed  
11 to address basic security enhancements of critical impor-  
12 tance and significant threats to public health and the sup-  
13 ply of drinking water as determined by a vulnerability as-  
14 sessment conducted under subsection (a). Such basic secu-  
15 rity enhancements may include, but shall not be limited  
16 to the following:

17           “(A) the purchase and installation of equipment  
18 for detection of intruders;

19           “(B) the purchase and installation of fencing,  
20 gating, lighting, or security cameras;

21           “(C) the tamper-proofing of manhole covers,  
22 fire hydrants, and valve boxes;

23           “(D) the rekeying of doors and locks;



1           “(E) improvements to electronic, computer, or  
2           other automated systems and remote security sys-  
3           tems;

4           “(F) participation in training programs, and  
5           the purchase of training manuals and guidance ma-  
6           terials, relating to security against terrorist attacks;

7           “(G) improvements in the use, storage, or han-  
8           dling of various chemicals; and

9           “(H) security screening of employees or con-  
10          tractor support services.

11 Funding under this subsection for basic security enhance-  
12 ments shall not include expenditures for personnel costs,  
13 or monitoring, operation, or maintenance of facilities,  
14 equipment, or systems.

15          “(3) The Administrator may use not more than  
16 \$5,000,000 from the funds made available under para-  
17 graph (1) to make grants to community water systems to  
18 assist in responding to and alleviating any vulnerability  
19 to a terrorist attack or other intentional acts intended to  
20 substantially disrupt the ability of the system to provide  
21 a safe and reliable supply of drinking water (including  
22 sources of water for such systems) which the Adminis-  
23 trator determines to present an immediate and urgent se-  
24 curity need.



1       “(4) The Administrator may use not more than  
2 \$5,000,000 from the funds made available under para-  
3 graph (1) to make grants to community water systems  
4 serving a population of less than 3,300 persons for activi-  
5 ties and projects undertaken in accordance with the guid-  
6 ance provided to such systems under subsection (d).

7 **SEC. 402. OTHER SAFE DRINKING WATER ACT AMEND-**  
8 **MENTS.**

9       The Safe Drinking Water Act (title XIV of the Public  
10 Health Service Act) is amended by inserting the following  
11 new sections after section 1433 (as added by section 401  
12 of this Act):

13 **“SEC. 1434. CONTAMINANT PREVENTION, DETECTION AND**  
14 **RESPONSE.**

15       “(a) IN GENERAL.—The Administrator, in consulta-  
16 tion with the Centers for Disease Control and, after con-  
17 sultation with appropriate departments and agencies of  
18 the Federal Government and with State and local govern-  
19 ments, shall review (or enter into contracts or cooperative  
20 agreements to provide for a review of) current and future  
21 methods to prevent, detect and respond to the intentional  
22 introduction of chemical, biological or radiological con-  
23 taminants into community water systems and source  
24 water for community water systems, including each of the  
25 following:



1           “(1) Methods, means and equipment, including  
2           real time monitoring systems, designed to monitor  
3           and detect various levels of chemical, biological, and  
4           radiological contaminants or indicators of contami-  
5           nants and reduce the likelihood that such contami-  
6           nants can be successfully introduced into public  
7           water systems and source water intended to be used  
8           for drinking water.

9           “(2) Methods and means to provide sufficient  
10          notice to operators of public water systems, and in-  
11          dividuals served by such systems, of the introduction  
12          of chemical, biological or radiological contaminants  
13          and the possible effect of such introduction on public  
14          health and the safety and supply of drinking water.

15          “(3) Methods and means for developing edu-  
16          cational and awareness programs for community  
17          water systems.

18          “(4) Procedures and equipment necessary to  
19          prevent the flow of contaminated drinking water to  
20          individuals served by public water systems.

21          “(5) Methods, means, and equipment which  
22          could negate or mitigate deleterious effects on public  
23          health and the safety and supply caused by the in-  
24          troduction of contaminants into water intended to be  
25          used for drinking water, including an examination of



1 the effectiveness of various drinking water tech-  
2 nologies in removing, inactivating, or neutralizing bi-  
3 ological, chemical, and radiological contaminants.

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

9 “(b) FUNDING.—For the authorization of appropria-  
10 tions to carry out this section, see section 1435(e).

11 **“SEC. 1435. SUPPLY DISRUPTION PREVENTION, DETECTION**  
12 **AND RESPONSE.**

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

24 “(1) Methods and means by which pipes and  
25 other constructed conveyances utilized in public



1 water systems could be destroyed or otherwise pre-  
2 vented from providing adequate supplies of drinking  
3 water meeting applicable public health standards.

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

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

18 “(4) Methods and means by which pipes, con-  
19 structed conveyances, collection, pretreatment, treat-  
20 ment, storage and distribution systems that are uti-  
21 lized in connection with public water systems could  
22 be reasonably protected from terrorist attacks or  
23 other acts intended to disrupt the supply or affect  
24 the safety of drinking water.



1           “(5) Methods and means by which information  
2           systems, including process controls and supervisory  
3           control and data acquisition and cyber systems at  
4           community water systems could be disrupted by ter-  
5           rorists or other groups.

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

11          “(c) REQUIREMENTS AND CONSIDERATIONS.—In  
12          carrying out this section and section 1434—

13                 “(1) the Administrator shall ensure that re-  
14                 views carried out under this section reflect the needs  
15                 of community water systems of various sizes and  
16                 various geographic areas of the United States; and

17                 “(2) the Administrator may consider the vul-  
18                 nerability of, or potential for forced interruption of  
19                 service for, a region or service area, including com-  
20                 munity water systems that provide service to the  
21                 National Capital area.

22          “(d) INFORMATION SHARING.—As soon as prac-  
23          ticable after reviews carried out under this section or sec-  
24          tion 1434 have been evaluated, the Administrator shall  
25          disseminate, as appropriate as determined by the Adminis-



1 trator, to community water systems information on the re-  
2 sults of the project through the Information Sharing and  
3 Analysis Center, or other appropriate means.

4 “(e) FUNDING.—There are authorized to be appro-  
5 priated to carry out this section and section 1434 not  
6 more than \$15,000,000 for the fiscal year 2002 and such  
7 sums as may be necessary for the fiscal years 2003  
8 through 2005.”.

9 **SEC. 403. MISCELLANEOUS AND TECHNICAL AMENDMENTS.**

10 The Safe Drinking Water Act is amended as follows:

11 (1) Section 1414(i)(1) is amended by inserting  
12 “1433” after “1417”.

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

20 (3) Section 1432 is amended as follows:

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

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



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

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

5 (4) Section 1442 is amended as follows:

6 (A) By striking “this subparagraph” in  
7 subsection (b) and inserting “this subsection”.

8 (B) By amending subsection (d) to read as  
9 follows:

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

14 **TITLE V—ADDITIONAL**  
15 **PROVISIONS**  
16 **Subtitle A—Prescription Drug User**  
17 **Fees**

18 **SEC. 501. SHORT TITLE.**

19 This subtitle may be cited as the “Prescription Drug  
20 User Fee Amendments of 2002”.

21 **SEC. 502. FINDINGS.**

22 The Congress finds that—

23 (1) prompt approval of safe and effective new  
24 drugs and other therapies is critical to the improve-  
25 ment of the public health so that patients may enjoy



1 the benefits provided by these therapies to treat and  
2 prevent illness and disease;

3 (2) the public health will be served by making  
4 additional funds available for the purpose of aug-  
5 menting the resources of the Food and Drug Admin-  
6 istration that are devoted to the process for the re-  
7 view of human drug applications and the assurance  
8 of drug safety;

9 (3) the provisions added by the Prescription  
10 Drug User Fee Act of 1992, as amended by the  
11 Food and Drug Administration Modernization Act of  
12 1997, have been successful in substantially reducing  
13 review times for human drug applications and  
14 should be—

15 (A) reauthorized for an additional 5 years,  
16 with certain technical improvements; and

17 (B) carried out by the Food and Drug Ad-  
18 ministration with new commitments to imple-  
19 ment more ambitious and comprehensive im-  
20 provements in regulatory processes of the Food  
21 and Drug Administration, including—

22 (i) strengthening and improving the  
23 review and monitoring of drug safety;

24 (ii) considering greater interaction be-  
25 tween the agency and sponsors during the



1 review of drugs and biologics intended to  
2 treat serious diseases and life-threatening  
3 diseases; and

4 (iii) developing principles for improv-  
5 ing first-cycle reviews; and

6 (4) the fees authorized by amendments made in  
7 this subtitle will be dedicated towards expediting the  
8 drug development process and the process for the re-  
9 view of human drug applications as set forth in the  
10 goals identified for purposes of part 2 of subchapter  
11 C of chapter VII of the Federal Food, Drug, and  
12 Cosmetic Act, in the letters from the Secretary of  
13 Health and Human Services to the chairman of the  
14 Committee on Energy and Commerce of the House  
15 of Representatives and the chairman of the Com-  
16 mittee on Health, Education, Labor and Pensions of  
17 the Senate, as set forth in the Congressional Record.

18 **SEC. 503. DEFINITIONS.**

19 Section 735 of the Federal Food, Drug, and Cosmetic  
20 Act (21 U.S.C. 379g) is amended—

21 (1) in paragraph (1), in the matter after and  
22 below subparagraph (C), by striking “licensure, as  
23 described in subparagraph (D)” and inserting “li-  
24 censure, as described in subparagraph (C)”;

25 (2) in paragraph (3)—



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

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

5 (C) by inserting after subparagraph (B)  
6 the following subparagraph:

7 “(C) which is on the list of products de-  
8 scribed in section 505(j)(7)(A) or is on a list  
9 created and maintained by the Secretary of  
10 products approved under human drug applica-  
11 tions under section 351 of the Public Health  
12 Service Act.”; and

13 (D) in the matter after and below subpara-  
14 graph (C) (as added by subparagraph (C) of  
15 this paragraph), by striking “Service Act,” and  
16 all that follows through “biological product”  
17 and inserting the following: “Service Act. Such  
18 term does not include a biological product”;

19 (3) in paragraph (6), by adding at the end the  
20 following subparagraph:

21 “(F) In the case of drugs approved after  
22 October 1, 2002, under human drug applica-  
23 tions or supplements: collecting, developing, and  
24 reviewing safety information on the drugs, in-  
25 cluding adverse event reports, during a period



1 of time after approval of such applications or  
2 supplements, not to exceed three years.”; and  
3 (4) in paragraph (8)—

4 (A) by striking the matter after and below  
5 subparagraph (B);

6 (B) by striking subparagraph (B);

7 (C) by striking “is the lower of” and all  
8 that follows through “Consumer Price Index”  
9 and inserting “is the Consumer Price Index”;  
10 and

11 (D) by striking “1997, or” and inserting  
12 “1997.”.

13 **SEC. 504. AUTHORITY TO ASSESS AND USE DRUG FEES.**

14 (a) TYPES OF FEES.—Section 736(a) of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is  
16 amended—

17 (1) in the matter preceding paragraph (1), by  
18 striking “fiscal year 1998” and inserting “fiscal year  
19 2003”;

20 (2) in paragraph (1)(A)—

21 (A) in each of clauses (i) and (ii), by strik-  
22 ing “in subsection (b)” and inserting “under  
23 subsection (c)(4)”;

24 (B) in clause (ii), by adding at the end the  
25 following sentence: “Such fee shall be half of



1 the amount of the fee established under clause  
2 (i).”;

3 (3) in paragraph (2)(A), in the matter after  
4 and below clause (ii)—

5 (A) by striking “in subsection (b)” and in-  
6 serting “under subsection (c)(4)”; and

7 (B) by striking “payable on or before Jan-  
8 uary 31” and inserting “payable on or before  
9 October 1”; and

10 (4) in paragraph (3)—

11 (A) by amending subparagraph (A) to read  
12 as follows:

13 “(A) IN GENERAL.—Except as provided in  
14 subparagraph (B), each person who is named  
15 as the applicant in a human drug application,  
16 and who, after September 1, 1992, had pending  
17 before the Secretary a human drug application  
18 or supplement, shall pay for each such prescrip-  
19 tion drug product the annual fee established  
20 under subsection (c)(4). Such fee shall be pay-  
21 able on or before October 1 of each year. Such  
22 fee shall be paid only once for each product for  
23 a fiscal year in which the fee is payable.”; and

24 (B) in subparagraph (B), by striking “The  
25 listing” and all that follows through “filed



1 under section 505(b)(2)” and inserting the fol-  
 2 lowing: “A prescription drug product shall not  
 3 be assessed a fee under subparagraph (A) if  
 4 such product is identified on the list compiled  
 5 under section 505(j)(7)(A) with a potency de-  
 6 scribed in terms of per 100 mL, or if such  
 7 product is the same product as another product  
 8 approved under an application filed under sec-  
 9 tion 505(b)”.

10 (b) FEE AMOUNTS.—Section 736(b) of the Federal  
 11 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is  
 12 amended to read as follows:

13 “(b) FEE REVENUE AMOUNTS.—Except as provided  
 14 in subsections (c), (d), (f), and (g), fees under subsection  
 15 (a) shall be established to generate the following revenue  
 16 amounts:

“Type of Fee Revenue	Fiscal Year 2003	Fiscal Year 2004	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007
Application/Supplement .....	\$74,300,000	\$77,000,000	\$84,000,000	\$86,434,000	\$86,434,000
Establishment .....	\$74,300,000	\$77,000,000	\$84,000,000	\$86,433,000	\$86,433,000
Product .....	\$74,300,000	\$77,000,000	\$84,000,000	\$86,433,000	\$86,433,000
Total Fee Revenue .....	\$222,900,000	\$231,000,000	\$252,000,000	\$259,300,000	\$259,300,000

17 If, after the date of the enactment of the Prescription  
 18 Drug User Fee Amendments of 2002, legislation is en-  
 19 acted requiring the Secretary to fund additional costs of  
 20 the retirement of Federal personnel, fee revenue amounts  
 21 shall be increased in each year by the amount necessary  
 22 to fully fund the portion of such additional costs that are



1 attributable to the process for the review of human drug  
2 applications.”.

3 (c) ADJUSTMENTS.—Section 736(c) of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is  
5 amended—

6 (1) in paragraph (1)—

7 (A) in the matter preceding subparagraph  
8 (A), by striking “fees and total fee revenues”  
9 and inserting “revenues”;

10 (B) in subparagraph (A)—

11 (i) by striking “during the preceding  
12 fiscal year”; and

13 (ii) by striking “, or” and inserting  
14 the following: “for the 12 month period  
15 ending June 30 preceding the fiscal year  
16 for which fees are being established, or”;

17 (C) in subparagraph (B), by striking “for  
18 such fiscal year” and inserting “for the pre-  
19 vious fiscal year”; and

20 (D) in the matter after and below subpara-  
21 graph (B), by striking “fiscal year 1997”; and  
22 inserting “fiscal year 2003”;

23 (2) by redesignating paragraphs (2) and (3) as  
24 paragraphs (4) and (5), respectively;



1           (3) by inserting after paragraph (1) the fol-  
2           lowing paragraphs:

3           “(2) WORKLOAD ADJUSTMENT.—Beginning  
4           with fiscal year 2004, after the fee revenues estab-  
5           lished in subsection (b) are adjusted for a fiscal year  
6           for inflation in accordance with paragraph (1), the  
7           fee revenues shall be adjusted further for such fiscal  
8           year to reflect changes in the workload of the Sec-  
9           retary for the process for the review of human drug  
10          applications. With respect to such adjustment:

11                   “(A) The adjustment shall be determined  
12                   by the Secretary based on a weighted average  
13                   of the change in the total number of human  
14                   drug applications, commercial investigational  
15                   new drug applications, efficacy supplements,  
16                   and manufacturing supplements submitted to  
17                   the Secretary. The Secretary shall publish in  
18                   the Federal Register the fee revenues and fees  
19                   resulting from the adjustment and the sup-  
20                   porting methodologies.

21                   “(B) Under no circumstances shall the ad-  
22                   justment result in fee revenues for a fiscal year  
23                   that are less than the fee revenues for the fiscal  
24                   year established in subsection (b), as adjusted  
25                   for inflation under paragraph (1).



1           “(3) FINAL YEAR ADJUSTMENT.—For fiscal  
2           year 2007, the Secretary may, in addition to adjust-  
3           ments under paragraphs (1) and (2), further in-  
4           crease the fee revenues and fees established in sub-  
5           section (b) if such an adjustment is necessary to  
6           provide for not more than three months of operating  
7           reserves of carryover user fees for the process for  
8           the review of human drug applications for the first  
9           three months of fiscal year 2008. If such an adjust-  
10          ment is necessary, the rationale for the amount of  
11          the increase shall be contained in the annual notice  
12          establishing fee revenues and fees for fiscal year  
13          2007. If the Secretary has carryover balances for  
14          such process in excess of three months of such oper-  
15          ating reserves, the adjustment under this paragraph  
16          shall not be made.”; and

17           (4) in paragraph (4) (as redesignated by para-  
18           graph (2) of this subsection), by amending such  
19           paragraph to read as follows:

20           “(4) ANNUAL FEE SETTING.—The Secretary  
21           shall, 60 days before the start of each fiscal year  
22           that begins after September 30, 2002, establish, for  
23           the next fiscal year, application, product, and estab-  
24           lishment fees under subsection (a), based on the rev-



1 enue amounts established under subsection (b) and  
2 the adjustments provided under this subsection.”.

3 (d) FEE WAIVER OR REDUCTION.—Section 736(d)  
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 379h(d)) is amended—

6 (1) in paragraph (1)—

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

9 (B) by striking subparagraph (D); and

10 (C) by redesignating subparagraph (E) as  
11 subparagraph (D); and

12 (2) in paragraph (3), in each of subparagraphs  
13 (A) and (B), by striking “paragraph (1)(E)” each  
14 place such term appears and inserting “paragraph  
15 (1)(D)”.

16 (e) ASSESSMENT OF FEES.—Section 736(f) of the  
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 379h(f)) is amended—

19 (1) in the heading for the subsection, by strik-  
20 ing “ASSESSMENT OF FEES.—” and inserting “LIM-  
21 ITATIONS.—”; and

22 (2) in paragraph (1), by striking the heading  
23 for the paragraph and all that follows through “fis-  
24 cal year beginning” and inserting the following: “IN



1 GENERAL.—Fees under subsection (a) shall be re-  
2 funded for a fiscal year beginning”.

3 (f) CREDITING AND AVAILABILITY OF FEES.—

4 (1) IN GENERAL.—Section 736(g)(1) of the  
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
6 379h(g)(1)) is amended by striking “Fees collected  
7 for a fiscal year” and all that follows through “fiscal  
8 year limitation.” and inserting the following: “Fees  
9 authorized under subsection (a) shall be collected  
10 and available for obligation only to the extent and in  
11 the amount provided in advance in appropriations  
12 Acts. Such fees are authorized to remain available  
13 until expended.”.

14 (2) COLLECTIONS AND APPROPRIATION ACTS.—  
15 Section 736(g)(2) of the Federal Food, Drug, and  
16 Cosmetic Act (21 U.S.C. 379h(g)(2)) is amended—

17 (A) by redesignating subparagraphs (A)  
18 and (B) as clauses (i) and (ii), respectively;

19 (B) by striking “(2) COLLECTIONS” and  
20 all that follows through “the amount specified”  
21 in clause (i) (as so redesignated) and inserting  
22 the following:

23 “(2) COLLECTIONS AND APPROPRIATION  
24 ACTS.—



1           “(A) IN GENERAL.—The fees authorized  
2           by this section—

3                   “(i) shall be retained in each fiscal  
4                   year in an amount not to exceed the  
5                   amount specified”;

6                   (C) by moving clause (ii) (as so redesignig-  
7                   nated) two ems to the right; and

8                   (D) by adding at the end the following  
9                   subparagraph:

10                   “(B) COMPLIANCE.—The Secretary shall  
11                   be considered to have met the requirements of  
12                   subparagraph (A)(ii) in any fiscal year if the  
13                   costs funded by appropriations and allocated for  
14                   the process for the review of human drug  
15                   applications—

16                           “(i) are not more than 3 percent  
17                           below the level specified in subparagraph  
18                           (A)(ii); or

19                           “(ii)(I) are more than 3 percent below  
20                           the level specified in subparagraph (A)(ii),  
21                           and fees assessed for the fiscal year fol-  
22                           lowing the subsequent fiscal year are de-  
23                           creased by the amount in excess of 3 per-  
24                           cent by which such costs fell below the  
25                           level specified in such subparagraph; and



1                   “(II) such costs are not more than 5  
2                   percent below the level specified in such  
3                   subparagraph.”.

4                   (3) AUTHORIZATION OF APPROPRIATIONS.—  
5                   Section 736(g)(3) of the Federal Food, Drug, and  
6                   Cosmetic Act (21 U.S.C. 379h(g)(3)) is amended by  
7                   striking subparagraphs (A) through (E) and insert-  
8                   ing the following:

9                   “(A) \$222,900,000 for fiscal year 2003;

10                   “(B) \$231,000,000 for fiscal year 2004;

11                   “(C) \$252,000,000 for fiscal year 2005;

12                   “(D) \$259,300,000 for fiscal year 2006;

13                   and

14                   “(E) \$259,300,000 for fiscal year 2007;”.

15 **SEC. 505. ACCOUNTABILITY AND REPORTS.**

16                   (a) PUBLIC ACCOUNTABILITY.—

17                   (1) CONSULTATION.—In developing rec-  
18                   ommendations to the Congress for the goals and  
19                   plans for meeting the goals for the process for the  
20                   review of human drug applications for the fiscal  
21                   years after fiscal year 2007, and for the reauthoriza-  
22                   tion of sections 735 and 736 of the Federal Food,  
23                   Drug, and Cosmetic Act, the Secretary of Health  
24                   and Human Services (referred to in this section as  
25                   the “Secretary”) shall consult with the Committee



1 on Energy and Commerce of the House of Rep-  
2 resentatives, the Committee on Health, Education,  
3 Labor, and Pensions of the Senate, appropriate sci-  
4 entific and academic experts, health care profes-  
5 sionals, representatives of patient and consumer ad-  
6 vocacy groups, and the regulated industry.

7 (2) RECOMMENDATIONS.—The Secretary shall  
8 publish in the Federal Register recommendations  
9 under paragraph (1), after negotiations with the reg-  
10 ulated industry; shall present such recommendations  
11 to the congressional committees specified in such  
12 paragraph; shall hold a meeting at which the public  
13 may present its views on such recommendations; and  
14 shall provide for a period of 30 days for the public  
15 to provide written comments on such recommenda-  
16 tions.

17 (b) PERFORMANCE REPORT.—Beginning with fiscal  
18 year 2003, not later than 60 days after the end of each  
19 fiscal year during which fees are collected under part 2  
20 of subchapter C of chapter VII of the Federal Food, Drug,  
21 and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary  
22 of Health and Human Services shall prepare and submit  
23 to the President, the Committee on Energy and Commerce  
24 of the House of Representatives, and the Committee on  
25 Health, Education, Labor, and Pensions of the Senate a



1 report concerning the progress of the Food and Drug Ad-  
2 ministration in achieving the goals identified in the letters  
3 described in section 502(4) during such fiscal year and  
4 the future plans of the Food and Drug Administration for  
5 meeting the goals.

6 (c) FISCAL REPORT.—Beginning with fiscal year  
7 2003, not later than 120 days after the end of each fiscal  
8 year during which fees are collected under the part de-  
9 scribed in subsection (b), the Secretary of Health and  
10 Human Services shall prepare and submit to the Com-  
11 mittee on Energy and Commerce of the House of Rep-  
12 resentatives, and the Committee on Health, Education,  
13 Labor, and Pensions of the Senate, a report on the imple-  
14 mentation of the authority for such fees during such fiscal  
15 year and the use, by the Food and Drug Administration,  
16 of the fees collected during such fiscal year for which the  
17 report is made.

18 **SEC. 506. REPORTS OF POSTMARKETING STUDIES.**

19 Section 506B of the Federal Food, Drug, and Cos-  
20 metic Act (21 U.S.C. 356b) is amended by adding at the  
21 end the following subsections:

22 “(d) DISCLOSURE.—If a sponsor fails to complete an  
23 agreed upon study required by this section by its original  
24 or otherwise negotiated deadline, the Secretary shall pub-  
25 lish a statement on the Internet site of the Food and Drug



1 Administration stating that the study was not completed  
2 and, if the reasons for such failure to complete the study  
3 were not satisfactory to the Secretary, a statement that  
4 such reasons were not satisfactory to the Secretary.

5 “(e) NOTIFICATION.—With respect to studies of the  
6 type required under section 506(b)(2)(A) or under section  
7 314.510 or 601.41 of title 21, Code of Federal Regula-  
8 tions, as each of such sections was in effect on the day  
9 before the effective date of this subsection, the Secretary  
10 may require that a sponsor who, for reasons not satisfac-  
11 tory to the Secretary, fails to complete by its deadline a  
12 study under any of such sections of such type for a drug  
13 or biological product (including such a study conducted  
14 after such effective date) notify practitioners who pre-  
15 scribe such drug or biological product of the failure to  
16 complete such study and the questions of clinical benefit,  
17 and, where appropriate, questions of safety, that remain  
18 unanswered as a result of the failure to complete such  
19 study. Nothing in this subsection shall be construed as al-  
20 tering the requirements of the types of studies required  
21 under section 506(b)(2)(A) or under section 314.510 or  
22 601.41 of title 21, Code of Federal Regulations, as so in  
23 effect, or as prohibiting the Secretary from modifying such  
24 sections of title 21 of such Code to provide for studies  
25 in addition to those of such type.”.



1 **SEC. 507. SAVINGS CLAUSE.**

2 Notwithstanding section 107 of the Food and Drug  
3 Administration Modernization Act of 1997, and notwith-  
4 standing the amendments made by this subtitle, part 2  
5 of subchapter C of chapter VII of the Federal Food, Drug,  
6 and Cosmetic Act, as in effect on the day before the date  
7 of the enactment of this Act, continues to be in effect with  
8 respect to human drug applications and supplements (as  
9 defined in such part as of such day) that, on or after Octo-  
10 ber 1, 1997, but before October 1, 2002, were accepted  
11 by the Food and Drug Administration for filing.

12 **SEC. 508. EFFECTIVE DATE.**

13 The amendments made by this subtitle shall take ef-  
14 fect October 1, 2002.

15 **SEC. 509. SUNSET CLAUSE.**

16 The amendments made by sections 503 and 504  
17 cease to be effective October 1, 2007, and section 505  
18 ceases to be effective 120 days after such date.

19 **Subtitle B—Funding Provisions Re-**  
20 **garding Food and Drug Admin-**  
21 **istration**

22 **SEC. 521. OFFICE OF DRUG SAFETY.**

23 Of the amounts appropriated for the Food and Drug  
24 Administration for a fiscal year, the Secretary of Health  
25 and Human Services shall reserve for the Office of Drug



1 Safety (within such Administration), the following  
2 amounts:

3 (1) For fiscal year 2003, an amount equal to  
4 the sum of \$5,000,000 and the amount made avail-  
5 able under appropriations Acts for such Office for  
6 fiscal year 2002.

7 (2) For fiscal year 2004, an amount equal to  
8 the sum of \$10,000,000 and the amount made avail-  
9 able under appropriations Acts for such Office for  
10 fiscal year 2002.

11 (3) For each subsequent fiscal year, an amount  
12 equal to the sum of the amount made available  
13 under appropriations Acts for such Office for fiscal  
14 year 2004 and an amount sufficient to offset the ef-  
15 fects of inflation occurring after the beginning of fis-  
16 cal year 2004.

17 **SEC. 522. DIVISION OF DRUG MARKETING, ADVERTISING,**  
18 **AND COMMUNICATIONS.**

19 For the Division of Drug Marketing, Advertising, and  
20 Communications (within the Office of Medical Policy,  
21 Food and Drug Administration), there are authorized to  
22 be appropriated the following amounts, stated as increases  
23 above the amount made available under appropriations  
24 Acts for such Division for fiscal year 2002:



1           (1) For fiscal year 2003, an increase of  
2           \$2,500,000.

3           (2) For fiscal year 2004, an increase of  
4           \$4,000,000.

5           (3) For fiscal year 2005, an increase of  
6           \$5,500,000.

7           (4) For fiscal year 2006, an increase of  
8           \$7,500,000.

9           (5) For fiscal year 2007, an increase of  
10          \$7,500,000.

11 **SEC. 523. OFFICE OF GENERIC DRUGS.**

12          For the Office of Generic Drugs (within the Food and  
13 Drug Administration), there are authorized to be appro-  
14 priated the following amounts, stated as increases above  
15 the amount made available under appropriations Acts for  
16 such Office for fiscal year 2002:

17           (1) For fiscal year 2003, an increase of  
18           \$3,000,000.

19           (2) For fiscal year 2004, an increase of  
20           \$6,000,000.

21           (3) For fiscal year 2005, an increase of  
22           \$9,000,000.

23           (4) For fiscal year 2006, an increase of  
24           \$12,000,000.



1           (5) For fiscal year 2007, an increase of  
2           \$15,000,000.

3           **Subtitle C—Additional Provisions**

4           **SEC. 531. TRANSITION TO DIGITAL TELEVISION.**

5           (a) PAIR ASSIGNMENT REQUIRED.—In order to fur-  
6 ther promote the orderly transition to digital television,  
7 and to promote the equitable allocation and use of digital  
8 channels by television broadcast permittees and licensees,  
9 the Federal Communications Commission, at the request  
10 of an eligible licensee or permittee, shall, within 90 days  
11 after the date of enactment of this Act, allot, if necessary,  
12 and assign a paired digital television channel to that li-  
13 censee or permittee, provided that—

14           (1) such channel can be allotted and assigned  
15 without further modification of the tables of allot-  
16 ments as set forth in sections 73.606 and 73.622 of  
17 the Commission’s regulations (47 CFR 73.606,  
18 73.622); and

19           (2) such allotment and assignment is otherwise  
20 consistent with the Commission’s rules (47 CFR  
21 part 73).

22           (b) ELIGIBLE TRANSITION LICENSEE OR PER-  
23 MITTEE.—For purposes of subsection (a), the term “eligi-  
24 ble licensee or permittee” means only a full power tele-



1 vision broadcast licensee or permittee (or its successor in  
2 interest) that—

3 (1) had an application pending for an analog  
4 television station construction permit as of October  
5 24, 1991, which application was granted after April  
6 3, 1997; and

7 (2) as of the date of enactment of this Act, is  
8 the permittee or licensee of that station.

9 (c) REQUIREMENTS ON LICENSEE OR PERMITTEE.—

10 (1) CONSTRUCTION DEADLINE.—Any licensee  
11 or permittee receiving a paired digital channel pur-  
12 suant to this section—

13 (A) shall be required to construct the dig-  
14 ital television broadcast facility within 18  
15 months of the date on which the Federal Com-  
16 munications Commission issues a construction  
17 permit therefore, and

18 (B) shall be prohibited from obtaining or  
19 receiving an extension of time from the Com-  
20 mission beyond the construction deadline estab-  
21 lished by paragraph (1).

22 (2) PROHIBITION OF ANALOG OPERATION  
23 USING DIGITAL PAIR.— Any licensee or permittee re-  
24 ceiving a paired digital channel pursuant to this sec-  
25 tion shall be prohibited from giving up its current



1 paired analog assignment and becoming a single-  
2 channel broadcaster and operating in analog on such  
3 paired digital channel.

4 (d) RELIEF RESTRICTED.—Any paired digital allot-  
5 ment and assignment made under this section shall not  
6 be available to any other applicant unless such applicant  
7 is an eligible licensee or permittee within the meaning of  
8 subsection (b).

9 **SEC. 532. 3-YEAR DELAY IN LOCK IN PROCEDURES FOR**  
10 **MEDICARE+CHOICE PLANS; CHANGE IN CER-**  
11 **TAIN MEDICARE+CHOICE DEADLINES AND**  
12 **ANNUAL, COORDINATED ELECTION PERIOD**  
13 **FOR 2003, 2004, AND 2005.**

14 (a) LOCK-IN DELAY.—Section 1851(e) of the Social  
15 Security Act (42 U.S.C. 1395w-21(e)) is amended—

16 (1) in paragraph (2)(A), by striking “THROUGH  
17 2001” and “during 1998, 1999, 2000, and 2001”  
18 and inserting “THROUGH 2004” and “during the pe-  
19 riod beginning January 1, 1998, and ending on De-  
20 cember 31, 2004”, respectively;

21 (2) in the heading to paragraph (2)(B), by  
22 striking “DURING 2002” and inserting “DURING  
23 2005”;



1 (3) in paragraphs (2)(B)(i) and (2)(C)(i), by  
2 striking “2002” and inserting “2005” each place it  
3 appears;

4 (4) in paragraph (2)(D), by striking “2001”  
5 and inserting “2004”; and

6 (5) in paragraph (4), by striking “2002” and  
7 inserting “2005” each place it appears.

8 (b) CHANGE IN REPORTING DEADLINE.—

9 (1) IN GENERAL.—Section 1854(a)(1) of such  
10 Act (42 U.S.C. 1395w-24(a)(1)) is amended by  
11 striking “Not later than July 1 of each year” and  
12 inserting “Not later than the second Monday in Sep-  
13 tember of 2002, 2003, and 2004 (or July 1 of each  
14 other year)”.

15 (2) EFFECTIVE DATE.—The amendment made  
16 by paragraph (1) shall apply to information sub-  
17 mitted for years beginning with 2003.

18 (c) DELAY IN ANNUAL, COORDINATED ELECTION  
19 PERIOD.—

20 (1) IN GENERAL.—Section 1851(e) of such Act  
21 (42 U.S.C. 1395w-21(e)) is amended—

22 (A) in paragraph (3)(B), by striking  
23 “means” and all that follows and inserting the  
24 following: “means, with respect to a year before  
25 2003 and after 2005, the month of November



1 before such year and with respect to 2003,  
2 2004, and 2005, the period beginning on No-  
3 vember 15 and ending on December 31 of the  
4 year before such year.”; and

5 (B) in paragraph (6)(A), by striking “each  
6 subsequent year (as provided in paragraph  
7 (3))” and inserting “during the annual, coordi-  
8 nated election period under paragraph (3) for  
9 each subsequent year”.

10 (2) EFFECTIVE DATE.—The amendment made  
11 by paragraph (1) shall apply to the annual, coordi-  
12 nated election period for years beginning with 2003.

13 (d) CHANGE TO ANNUAL ANNOUNCEMENT OF PAY-  
14 MENT RATES.—

15 (1) IN GENERAL.—Section 1853(b)(1) of such  
16 Act (42 U.S.C. 1395w-23(b)(1)) is amended by  
17 striking “not later than March 1 before the calendar  
18 year concerned” and inserting “for years before  
19 2004 and after 2005 not later than March 1 before  
20 the calendar year concerned and for 2004 and 2005  
21 not later than the second Monday in May before the  
22 respective calendar year”.

23 (2) EFFECTIVE DATE.—The amendment made  
24 by paragraph (1) shall first apply to announcements  
25 for years after 2003.

