

107TH CONGRESS
1ST SESSION

S. 1635

To ensure the prompt research, development, manufacture, and distribution of new life-saving drugs, biologics, and medical devices that prevent or mitigate the consequences of a chemical or biological bioterrorist attack, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 6, 2001

Mr. HUTCHINSON (for himself and Mr. GREGG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To ensure the prompt research, development, manufacture, and distribution of new life-saving drugs, biologics, and medical devices that prevent or mitigate the consequences of a chemical or biological bioterrorist attack, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pathogen Research,
5 Emergency Preparedness and Response Efforts Act of
6 2001” or the “PREPARE Act”.

1 **SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
2 **ACT.**

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

5 **“TITLE XXVIII—DEVELOPING**
6 **NEW COUNTERMEASURES**
7 **AND PROTECTING EXISTING**
8 **COUNTERMEASURES**
9 **AGAINST BIOTERRORISM**

10 **“SEC. 2801. DEVELOPMENT OF DRUGS, BIOLOGICAL PROD-**
11 **UCTS, AND MEDICAL DEVICES TO COMBAT**
12 **BIOTERRORISM.**

13 **“(a) IDENTIFICATION OF CHEMICAL OR BIOLOGICAL**
14 **AGENTS OR TOXINS.—**

15 **“(1) IN GENERAL.—**The Secretary, in consulta-
16 tion with the Secretary of Defense and the Attorney
17 General, shall identify chemical or biological agents
18 or toxins that may be identified, prevented, or treat-
19 ed through—

20 **“(A) the development of new covered prod-**
21 **ucts;**

22 **“(B) the development of new uses, includ-**
23 **ing pediatric uses, for approved covered prod-**
24 **ucts; or**

25 **“(C) the manufacture or distribution of**
26 **covered products that would otherwise not be**

1 manufactured or distributed in sufficient quan-
2 tities.

3 “(2) PUBLICATION AND AVAILABILITY.—Not
4 later than 180 days after the date of enactment of
5 this title, and annually thereafter, the Secretary
6 shall publish in the Federal Register, or otherwise
7 make available to manufacturers or potential manu-
8 facturers of covered products, a list of the chemical
9 or biological agents and toxins identified under para-
10 graph (1) for which the Secretary desires to encour-
11 age the development of, or new uses for, covered
12 products or the manufacture or distribution of such
13 covered products.

14 “(b) CONSULTATION.—In carrying out this section,
15 the Secretary shall consult with experts in the pharma-
16 ceutical, biotechnology, and medical device industries, aca-
17 demic medical centers, and research institutions, including
18 those with pediatric expertise.

19 “(c) LIMITED ANTITRUST EXEMPTION.—

20 “(1) COUNTERMEASURES DEVELOPMENT MEET-
21 INGS.—

22 “(A) SCHEDULING COUNTERMEASURES
23 DEVELOPMENT MEETINGS.—The antitrust laws
24 shall not apply to meetings or consultations
25 conducted by the Secretary with parties in-

1 involved in the development of countermeasures
2 for the purpose of the development, manufac-
3 ture, distribution, and sale of countermeasures
4 that are prioritized under section 2841(c), con-
5 sistent with the purposes of this title. The Sec-
6 retary shall give notice to the Assistant Attor-
7 ney General of Antitrust of meetings scheduled
8 pursuant to this subsection.

9 “(B) MEETING CONDITIONS.—Any meet-
10 ing under subparagraph (A)—

11 “(i) shall be chaired by the Secretary;

12 “(ii) shall be open to parties involved
13 in the development of countermeasures, as
14 determined by the Secretary;

15 “(iii) shall be open to the Attorney
16 General and the Federal Trade Commis-
17 sion;

18 “(iv) shall be limited to discussions in-
19 volving the development, manufacture, dis-
20 tribution, or sale of countermeasures that
21 are prioritized under section 2841(c); and

22 “(v) shall be conducted in such man-
23 ner as to ensure that national security,
24 confidential, and proprietary information is
25 not disclosed outside the meeting.

1 “(C) MINUTES.—The Secretary shall en-
2 sure that minutes of the meeting are main-
3 tained.

4 “(2) APPLYING FOR LIMITED EXEMPTION.—

5 “(A) FILING PROCEDURES.—As a result of
6 meetings in paragraph (1), the Secretary and
7 participating parties may file a written request
8 with the Attorney General for a limited exemp-
9 tion from the antitrust laws to allow appro-
10 priate parties to enter into agreements or en-
11 gage in conduct relating to the development,
12 manufacture, distribution, or sale of counter-
13 measures prioritized under section 2841(c). Any
14 such request shall set forth the intended pur-
15 pose of the agreement, including an explanation
16 as to why a cooperative effort among potential
17 competitors is necessary to achieve the objective
18 of the agreement. The request shall state with
19 specificity the substance of the agreement, the
20 methods that will be utilized to achieve the ob-
21 jectives of the agreement, and other relevant in-
22 formation relating to the development and pro-
23 duction of countermeasures that are prioritized
24 under section 2841(c).

1 “(B) GRANT OF EXEMPTION.—The Attor-
2 ney General, in consultation with the Chairman
3 of the Federal Trade Commission shall grant,
4 deny, grant in part and deny in part, or pro-
5 pose modifications to any request made pursu-
6 ant to subparagraph (A) for exemption from
7 the antitrust laws. In making the determination
8 to grant, deny, grant in part and deny in part,
9 or propose modifications to any such request,
10 the Attorney General shall consider among
11 other things: whether such agreement would
12 promote the purposes of this Act, whether the
13 exemption from the antitrust laws would pro-
14 mote the public interest, and the competitive
15 impact to areas not directly related to the devel-
16 opment and production of countermeasures
17 prioritized under section 2841(c). The Attorney
18 General shall make a determination on a re-
19 quest filed pursuant to subparagraph (A) within
20 60 days.

21 “(C) SUNSET.—The authority of the At-
22 torney General to grant a limited antitrust ex-
23 emption under this section expires at the end of
24 the 2-year period beginning on the date of en-
25 actment of the Pathogen Research, Emergency

1 Preparedness and Response Efforts Act of
2 2001.

3 **“SEC. 2802. CONTRACTS FOR DEVELOPMENT OF COVERED**
4 **PRODUCTS.**

5 “(a) **AUTHORITY.**—The Secretary may enter into
6 contracts, cooperative research and development agree-
7 ments pursuant to section 11(a) of the Stevenson-Wydler
8 Technology Innovation Act of 1980 (15 U.S.C. 3710(a)),
9 material transfer agreements, or other agreements, or
10 agree to the amendment or modification of existing or fu-
11 ture contracts or agreements, for the development, manu-
12 facture or distribution of covered products for uses or new
13 uses identified by the Secretary pursuant to section
14 2801(b). A contract or agreement entered into, or amend-
15 ed or modified, under this subsection may address 1 or
16 more aspects of the development, manufacture, or dis-
17 tribution of 1 or more uses of 1 or more covered products.
18 Such contracts or agreements may set forth guaranteed
19 minimum quantities of products and negotiated unit
20 prices.

21 “(b) **TIMING OF CONTRACT.**—Notwithstanding any
22 other provision of law, the Secretary may enter into a con-
23 tract or agreement under subsection (a) even prior to the
24 development, approval, or clearance of the covered product
25 that is the subject of the contract or agreement. Such con-

1 tract or agreement may provide for the termination of the
2 contract or agreement for the convenience of the Federal
3 Government if the contractor fails to develop the covered
4 product involved.

5 “(c) PAYMENTS.—Payments under a contract or
6 agreement under subsection (a) may be made from—

7 “(1) funds obligated for the performance of the
8 contract or agreement involved;

9 “(2) funds available for the development, manu-
10 facture, distribution, or purchase of covered prod-
11 ucts for uses referred to in section 2801(b); or

12 “(3) any other funds available to the Secretary.

13 “(d) CONTRACTS.—In administering the provisions of
14 this section, the Secretary may enter into contracts in ad-
15 vance of appropriations and incur obligations without re-
16 gard to provisions of law relating to contracts, including
17 sections 1341, 1342, 1349, 1350, and 1351, and sub-
18 chapter II of chapter 15, of title 31, United States Code.

19 **“SEC. 2803. INDEMNIFICATION.**

20 “The Secretary shall, in any contract or agreement
21 for the manufacture, development, distribution, or the
22 purchase of a covered product intended for a use identified
23 by the Secretary pursuant to section 2801(b), indemnify
24 and hold harmless the contractor consistent with the fol-
25 lowing principles:

1 “(1) USES COVERED.—Indemnification only ex-
2 tends to uses of the covered product pursuant to a
3 contract entered into by the Secretary under section
4 2802.

5 “(2) ENTITIES COVERED.—The Secretary may
6 indemnify contractors, subcontractors, distributors,
7 persons who administer covered products, or other
8 parties as determined appropriate by the Secretary
9 pursuant to contracts entered into under section
10 2802.

11 “(3) LIMITS.—No indemnification shall be pro-
12 vided for intentional torts by the contractor or torts
13 by the contractor involving gross negligence or reck-
14 lessness.

15 **“SEC. 2804. HIGH QUALITY PRODUCTION.**

16 “The Secretary may, with the agreement of the man-
17 ufacturer of a drug, biological product, or medical device
18 that is approved, licensed, or cleared (or awaiting ap-
19 proval, licensure or clearance) under section 505, 510,
20 513, or 515 of the Federal Food, Drug, and Cosmetic Act,
21 or section 351 of this Act, and is a covered product, pro-
22 vide intensive assistance, including on-site assistance,
23 when necessary, in order to facilitate prompt compliance
24 with good manufacturing practice regulations under sec-
25 tions 210, 211, 225, 226, 600, 601, 606, or 820 of title

1 21, Code of Federal Regulations, in the manufacturing,
2 processing, packing, or holding of the drug, biological
3 product, or medical device.

4 **“SEC. 2805. SECURITY FOR RESEARCH AND PRODUCTION.**

5 “(a) IN GENERAL.—The Secretary, in consultation
6 with the Attorney General and the Secretary of Defense,
7 may award grants, contracts, or enter into cooperative
8 agreements, and provide technical or nonmonetary assist-
9 ance, to provide security to facilities that conduct re-
10 search, development, production, distribution, and storage
11 of covered products.

12 “(b) BEST PRACTICES.—The Secretary shall develop
13 guidelines and best practices to enable entities eligible for
14 funding under this section to secure their facilities against
15 potential bioterrorist attack.

16 **“SEC. 2806. MOBILITY OF STOCKPILE.**

17 “(a) SPECIAL EVENTS.—In managing the National
18 Pharmaceutical Stockpile, the Secretary, in consultation
19 with State and local government officials, shall take into
20 consideration the timing and location of special events, in-
21 cluding designated national security events.

22 “(b) LOCATION OF CERTAIN STOCKS.—In carrying
23 out subsection (a), the Secretary shall ensure that medical
24 supplies from the National Pharmaceutical Stockpile are

1 located in appropriate proximity to the site of the special
2 event.

3 **“SEC. 2807. DEFINITIONS.**

4 “In this title:

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

7 “(A) has the meaning given such term in
8 subsection (a) of the first section of the Clayton
9 Act (15 U.S.C. 12(a)), except that such term
10 includes section 5 of the Federal Trade Com-
11 mission Act (15 U.S.C. 45) to the extent such
12 section 5 applies to unfair methods of competi-
13 tion; and

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

16 “(2) BIOLOGICAL AGENTS OR TOXINS.—The
17 term ‘biological agents or toxins’ has the meaning
18 given in section 178 of title 18, United States Code.

19 “(3) COVERED PRODUCTS.—The term ‘covered
20 products’ includes drugs, biological products includ-
21 ing vaccines, and medical devices including in vitro
22 diagnostics, that may be developed or produced to
23 identify, prevent, or treat disease or harm in hu-
24 mans, including children and other vulnerable popu-

1 lations, resulting from an attack or threatened at-
2 tack using chemical or biological agents or toxins.

3 “(4) DEVELOPMENT.—The term ‘development’
4 includes the identification of suitable compounds or
5 biological materials, the conduct of preclinical and
6 clinical studies, the preparation of an application for
7 marketing approval or clearance, the conduct of
8 post-market or post-approval studies, and any other
9 actions related to preparation of a covered prod-
10 uct.”.

11 **SEC. 3. EXPEDITING FDA REVIEW AND APPROVAL.**

12 (a) AMENDMENT.—Section 506 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 356) is amended by
14 adding at the end the following:

15 “(e) CHEMICAL OR BIOLOGICAL AGENTS OR TOX-
16 INS.—

17 “(1) IN GENERAL.—The Secretary may des-
18 ignate an unapproved covered product identified pur-
19 suant to section 2801(b) of the Public Health Serv-
20 ice Act as a fast-track product pursuant to this sec-
21 tion. Such a designation may be made prior to the
22 submission of—

23 “(A) a request for designation by the spon-
24 sor; or

1 adequate field trials assessing the use of the drug (in situ-
2 ations such as after accidental or hostile exposure to the
3 substance) have not been feasible, the Secretary may grant
4 approval, including approval for pediatric populations,
5 based on evidence derived from appropriate studies in ani-
6 mals or other information. The Secretary may use author-
7 ity under section 506 or other relevant provisions to order
8 post-marketing approval studies. Drugs approved solely
9 under the authority of the preceding two sentences shall
10 be for purposes of identifying, treating, or preventing in-
11 fection, disease, injury, or other health condition or con-
12 sequence resulting from a disabling toxic chemical, biologi-
13 cal, radiological, nuclear attack, potential attack, or other
14 significant disease emergency as the Secretary may deter-
15 mine appropriate.”.

16 (b) NEW BIOLOGICAL PRODUCTS.—Section 351 of
17 the Public Health Service Act (42 U.S.C. 262) is amended
18 by adding at the end the following:

19 “(k) APPROVAL OF CERTAIN PRODUCTS BASED ON
20 ANIMAL TRIALS.—

21 “(1) IN GENERAL.—In the case of biological
22 products for use against a potentially lethal or per-
23 manently disabling toxic chemical, biological, radio-
24 logical, nuclear, or other agent or toxins, when ade-
25 quate and well-controlled studies in humans cannot

1 ethically be conducted because the studies would in-
2 volve administering such an agent or toxin to human
3 volunteers without a proven treatment, and when
4 adequate field trials assessing the use of the biologi-
5 cal product (in situations such as after accidental or
6 hostile exposure to the substance) have not been fea-
7 sible, the Secretary may grant approval, including
8 approval for pediatric populations, based on evidence
9 derived from appropriate studies in animals or other
10 information.

11 “(2) POST-APPROVAL STUDIES.—With respect
12 to products described in paragraph (1), the Sec-
13 retary may use authority under section 506 of the
14 Federal Food, Drug, and Cosmetic Act to order
15 post-marketing approval studies.

16 “(3) LIMITATIONS.—Biological products ap-
17 proved solely under the authority of this subsection
18 shall be for purposes of identifying, treating, or pre-
19 venting infection, disease, injury, or other health
20 condition or consequence resulting from a potentially
21 disabling toxic chemical, biological, radiological, nu-
22 clear attack, potential attack, or other significant
23 disease emergency as the Secretary may determine
24 appropriate.”.

1 (c) FINAL RULE.—Not later than 60 days after the
 2 date of enactment of Pathogen Research, Emergency Pre-
 3 paredness and Response Efforts Act of 2001, the Sec-
 4 retary shall finalize the proposed rule published on Octo-
 5 ber 5, 1999 regarding the use of animal trials in the ap-
 6 proval of products.

7 **SEC. 5. CHEMICAL OR BIOLOGICAL AGENTS AND TOXINS.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
 9 Drug and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 10 ed by adding at the end the following:

11 **“PART E—CHEMICAL OR BIOLOGICAL AGENTS**
 12 **AND TOXINS**

13 **“SEC. 570. AUTHORITY TO RESTRICT TRANSPORTATION**
 14 **AND USE.**

15 “(a) IN GENERAL.—The Secretary shall undertake a
 16 program that, through inspections and other containment
 17 procedures, will prohibit the unauthorized shipment or
 18 transportation in interstate or foreign commerce, the pos-
 19 session or other use in or affecting commerce, or assist-
 20 ance to another person in such transportation, shipment,
 21 or other use by any person of chemical or biological agents
 22 or toxins or the receipt of such chemical or biological
 23 agents or toxins so shipped or transported.

24 “(b) DEFINITIONS.—In this section:

1 “(1) CHEMICAL OR BIOLOGICAL AGENTS AND
2 TOXINS.—The term ‘chemical or biological agents
3 and toxins’ has the meaning given such term in sec-
4 tion 2801(a) of the Public Health Service Act refers
5 to a biological agent or toxin listed as a ‘select
6 agent’ in section 72.6(j) of title 42, Code of Federal
7 Regulations, which is not exempt under section
8 72.6(h) or appendix A of such title and which does
9 not include any such biological agent or toxin that
10 is in its naturally-occurring environment and that
11 has not been cultivated, collected, or otherwise ex-
12 tracted from its natural source.

13 “(2) PERSON.—The term ‘person’ includes an
14 alien (other than an alien admitted for permanent
15 residence) who is a national of a country as to which
16 the Secretary of State has made a determination
17 (that is in effect) that such country has repeatedly
18 provided support for acts of international ter-
19 rorism.”.

20 (b) ENFORCEMENT.—Section 301 of the Federal
21 Food, Drug and Cosmetic Act (21 U.S.C. 331) is amended
22 by adding at the end the following:

23 “(aa) The shipment, transportation, possession or
24 other use, assistance with respect to, or receipt of a bio-
25 logical agent or toxin in violation of section 570.”.

1 **SEC. 6. REGULATION OF CHEMICAL OR BIOLOGICAL**
2 **AGENTS AND TOXINS POSING POTENTIAL NA-**
3 **TIONAL SECURITY THREAT.**

4 (a) REDESIGNATION AND CLARIFICATION OF CHEM-
5 ICAL OR BIOLOGICAL AGENTS; REGULATORY PROVISIONS
6 OF ANTITERRORISM AND EFFECTIVE DEATH PENALTY
7 ACT OF 1996.—

8 (1) IN GENERAL.—Part F of title III of the
9 Public Health Service Act (42 U.S.C. 262 et seq.)
10 is amended by inserting after section 351, the fol-
11 lowing:

12 **“SEC. 351A. ENHANCED CONTROL OF CHEMICAL OR BIO-**
13 **LOGICAL AGENTS AND TOXINS.**

14 “(a) REGULATORY CONTROL OF CHEMICAL OR BIO-
15 LOGICAL AGENTS AND TOXINS.—

16 “(1) LIST OF CHEMICAL OR BIOLOGICAL
17 AGENTS AND TOXINS.—The Secretary shall, through
18 regulations promulgated under subsection (c), estab-
19 lish and maintain a list of each biological agent and
20 each toxin that has the potential to pose a severe
21 threat to public health and safety.

22 “(2) CRITERIA.—In determining whether to in-
23 clude an agent or toxin on the list under subsection
24 (a), the Secretary shall—

25 “(A) consider—

1 “(i) the effect on human health of ex-
2 posure to the agent or toxin;

3 “(ii) the degree of contagiousness of
4 the agent or toxin and the methods by
5 which the agent or toxin is transferred to
6 humans;

7 “(iii) the availability and effectiveness
8 of pharmacotherapies and immunizations
9 to treat or prevent any illness resulting
10 from infection by the agent or toxin; and

11 “(iv) any other criteria that the Sec-
12 retary considers appropriate; and

13 “(B) consult with scientific experts rep-
14 resenting appropriate professional groups.

15 “(b) REGULATION OF TRANSFERS OF LISTED CHEM-
16 ICAL OR BIOLOGICAL AGENTS AND TOXINS.—The Sec-
17 retary shall, through regulations promulgated under sub-
18 section (c), provide for—

19 “(1) the establishment and enforcement of safe-
20 ty procedures for the transfer of chemical or biologi-
21 cal agents and toxins listed pursuant to subsection
22 (a)(1), including measures to ensure—

23 “(A) proper training and appropriate skills
24 to handle such agents and toxins; and

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

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

6 “(3) the establishment of procedures to protect
7 the public in the event of a transfer or potential
8 transfer of a biological agent or toxin in violation of
9 the safety procedures established under paragraph
10 (1) or the safeguards established under paragraph
11 (2); and

12 “(4) appropriate availability of chemical or bio-
13 logical agents and toxins for research, education and
14 other legitimate purposes.

15 “(c) REGULATIONS.—The Secretary shall promulgate
16 regulations to carry out this section.

17 “(d) DEFINITIONS.—For purposes of this section and
18 section 351B, the term ‘biological agent and toxin’ shall
19 have the meaning given such term in section 2801(a).”.

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

24 (3) EFFECTIVE DATE.—The amendments made
25 by this subsection shall take effect as if incorporated

1 in the Antiterrorism and Effective Death Penalty
2 Act of 1996.

3 (b) REGULATION OF CHEMICAL OR BIOLOGICAL
4 AGENTS AND TOXINS POSING POTENTIAL NATIONAL SE-
5 CURITY THREAT.—

6 (1) IN GENERAL.—Part F of title III of the
7 Public Health Service Act (42 U.S.C. 262 et seq.),
8 as amended by subsection (a)(1), is further amended
9 by inserting after section 351A, the following:

10 **“SEC. 351B. REGULATION OF CHEMICAL OR BIOLOGICAL**
11 **AGENTS AND TOXINS POSING POTENTIAL NA-**
12 **TIONAL SECURITY THREAT.**

13 “(a) IN GENERAL.—

14 “(1) LIST OF CHEMICAL OR BIOLOGICAL
15 AGENTS AND TOXINS POSING NATIONAL SECURITY
16 THREAT.—The Secretary shall, through regulations
17 promulgated under subsection (d), establish and
18 maintain a list of those chemical or biological agents
19 and toxins listed pursuant to section 351A(a)(1)
20 that the Secretary determines to be a potential na-
21 tional security threat.

22 “(2) CRITERIA.—In determining whether to in-
23 clude an agent or toxin on the list under subsection
24 (a), the Secretary shall—

1 “(A) consider the criteria specified in sec-
2 tion 351A(a)(2)(A)(i), and any other criteria
3 that the Secretary considers appropriate; and

4 “(B) consult with scientific, intelligence,
5 and military experts representing appropriate
6 professional groups.

7 “(b) REGULATION OF TRANSFERS OF LISTED CHEM-
8 ICAL OR BIOLOGICAL AGENTS AND TOXINS.—The Sec-
9 retary shall, through regulations promulgated under sub-
10 section (d), provide for the establishment and enforcement
11 of standards and procedures governing the possession,
12 use, and transfer of chemical or biological agents and tox-
13 ins listed pursuant to subsection (a)(1) that are designed
14 to protect public safety and national security, including
15 safeguards to prevent access to such agents and toxins for
16 use in domestic or international terrorism or for any other
17 criminal purpose.

18 “(c) CIVIL MONEY PENALTIES.—A violation of a re-
19 quirement imposed by a regulation promulgated under this
20 section shall be subject, in addition to any other applicable
21 civil or criminal sanctions, to a civil money penalty in an
22 amount not to exceed \$250,000.

23 “(d) REGULATIONS.—The Secretary shall promul-
24 gate regulations to carry out this section.

1 “(e) FREEDOM OF INFORMATION ACT EXEMP-
2 TION.—Any information provided to the Secretary pursu-
3 ant to regulations issued under subsection (d) or under
4 section 351A(c) shall not be disclosed under section 552
5 of title 5, United States Code.”.

6 (2) EFFECTIVE DATE.—The amendment made
7 by this subsection shall take effect as if incorporated
8 in the Antiterrorism and Effective Death Penalty
9 Act of 1996.

10 **SEC. 7. ADMINISTRATION.**

11 In administering the provisions of this Act, the Sec-
12 retary of Health and Human Services shall—

13 (1) continue to recognize and honor rights re-
14 lating to patents, data, and copyrights; and

15 (2) comply with all applicable provisions of the
16 regulations relating to Federal acquisition, the Fed-
17 eral Trade Secrets Act, and all other laws protecting
18 confidential commercial information, trade secrets,
19 and intellectual property rights, and patent and non-
20 patent market exclusivity rights.

21 **SEC. 8. COORDINATION OF EFFORTS TO PROTECT AGAINST**
22 **BIOTERRORISM.**

23 The Secretary of Health and Human Services and the
24 Secretary of Defense shall coordinate in the planning, de-
25 sign, and construction of a Department of Defense govern-

1 ment-owned, contractor-operated vaccine production facil-
2 ity on a military installation, as appropriate.

3 **SEC. 9. ENHANCEMENT OF PENALTIES FOR ANIMAL ENTER-**
4 **PRISE TERRORISM.**

5 Section 43 of title 18, United States Code, is
6 amended—

7 (1) in subsection (a), by striking “one year”
8 and inserting “5 years”;

9 (2) in subsection (b)—

10 (A) by redesignating paragraph (2) as
11 paragraph (3);

12 (B) by inserting after paragraph (1) the
13 following:

14 “(2) EXPLOSIVES OR ARSON.—Whoever in the
15 course of a violation of subsection (a) maliciously
16 damages or destroys, or attempts to damage or de-
17 stroy, by means of fire or an explosive, any building,
18 vehicle, or other real or personal property used by
19 the animal enterprise shall be imprisoned for not
20 less than 5 years and not more than 20 years, fined
21 under this title, or both.”; and

22 (C) in paragraph (3), as so redesignated,
23 by striking “under this title and” and all that
24 follows through the period and inserting “under

1 this title, imprisoned for life or for any term of
2 years,”; and

3 (3) in subsection (c)—

4 (A) by striking “and” at the end of para-
5 graph (1);

6 (B) by striking the period at the end of
7 paragraph (2) and inserting “; and”; and

8 (C) by adding at the end the following:

9 “(3) for any other economic damage resulting
10 from the violation of this section.”.

○