

107TH CONGRESS  
1ST SESSION

# H. R. 3457

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

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 11, 2001

Mr. SCHROCK (for himself and Mr. BARTLETT of Maryland) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To ensure the prompt research, development, manufacture, and distribution of new lifesaving drugs, biologics, and medical devices that prevent or mitigate the consequences of a 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 BIOLOGICAL AGENTS OR**  
14 **TOXINS.—**

15 **“(1) IN GENERAL.—**The Secretary, in consulta-  
16 tion with the Secretary of Defense and the Attorney  
17 General, shall identify biological agents or toxins  
18 that may be identified, prevented, or treated  
19 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 biological  
9           agents and toxins identified under paragraph (1) for  
10          which the Secretary desires to encourage the devel-  
11          opment of, or new uses for, covered products or the  
12          manufacture or distribution of such covered prod-  
13          ucts.

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 2801(a), 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 2801(a); 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 under paragraph (1), the Secretary  
7           and participating parties may file a written re-  
8           quest with the Attorney General for a limited  
9           exemption from the antitrust laws to allow ap-  
10          propriate parties to enter into agreements or  
11          engage in conduct relating to the development,  
12          manufacture, distribution, or sale of counter-  
13          measures prioritized under section 2801(a).  
14          Any such request shall set forth the intended  
15          purpose of the agreement, including an expla-  
16          nation as to why a cooperative effort among po-  
17          tential competitors is necessary to achieve the  
18          objective of the agreement. The request shall  
19          state with specificity the substance of the agree-  
20          ment, the methods that will be utilized to  
21          achieve the objectives of the agreement, and  
22          any other relevant information relating to the  
23          development and production of countermeasures  
24          that are prioritized under section 2801(a).

1           “(B) GRANT OF EXEMPTION.—Not later  
2 than 60 days after receipt of a request filed  
3 pursuant to subparagraph (A), the Attorney  
4 General, in consultation with the Chairman of  
5 the Federal Trade Commission shall make a de-  
6 termination to grant, deny, grant in part and  
7 deny in part, or propose modifications to any  
8 request made pursuant to subparagraph (A) for  
9 exemption from the antitrust laws. In making  
10 the determination, the Attorney General shall  
11 consider factors including the following:

12                   “(i) Whether such agreement would  
13 promote the purposes of this title.

14                   “(ii) Whether the exemption from the  
15 antitrust laws would promote the public in-  
16 terest.

17                   “(iii) The competitive impact to areas  
18 not directly related to the development and  
19 production of countermeasures prioritized  
20 under section 2801(a).

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 and 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(a). 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 before 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 Govern-  
3 ment if the contractor fails to develop the covered product  
4 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(a); 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(a), 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 and contracts, enter into cooperative  
8 agreements, and provide technical or nonmonetary assist-  
9 ance, to provide security to facilities that conduct research  
10 and development, production, distribution, and storage of  
11 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 section 1 of the Clayton Act  
9 (15 U.S.C. 12(a)), except that such term in-  
10 cludes section 5 of the Federal Trade Commis-  
11 sion Act (15 U.S.C. 45) to the extent such sec-  
12 tion 5 applies to unfair methods of competition;  
13 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 terms ‘biological agent’ and ‘toxin’ have the mean-  
18 ings given such terms in section 178 of title 18,  
19 United States Code.

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

1 lations, resulting from an attack or threatened at-  
2 tack using 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 postmarket or postapproval 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) BIOLOGICAL AGENTS OR TOXINS.—

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

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



1 unteers without a proven treatment, and when adequate  
2 field trials assessing the use of the drug (in situations such  
3 as after accidental or hostile exposure to the substance)  
4 have not been feasible, the Secretary may grant approval,  
5 including approval for pediatric populations, based on evi-  
6 dence derived from appropriate studies in animals or other  
7 information. The Secretary may use authority under sec-  
8 tion 506 or other relevant provisions to order post-  
9 marketing approval studies. Drugs approved solely under  
10 the authority of the preceding two sentences shall be for  
11 purposes of identifying, treating, or preventing infection,  
12 disease, injury, or other health condition or consequence  
13 resulting from a disabling toxic chemical, biological, radio-  
14 logical, or nuclear attack or potential attack, or other sig-  
15 nificant disease emergency as the Secretary may deter-  
16 mine appropriate.”.

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

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

22 “(1) IN GENERAL.—In the case of biological  
23 products for use against a potentially lethal or per-  
24 manently disabling toxic chemical, biological, radio-  
25 logical, nuclear, or other agent or toxins, when ade-

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

12           “(2) POSTMARKETING APPROVAL STUDIES.—  
13      With respect to products described in paragraph (1),  
14      the Secretary may use authority under section 506  
15      of the Federal Food, Drug, and Cosmetic Act to  
16      order postmarketing approval studies.

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

1 (c) FINAL RULE.—Not later than 60 days after the  
2 date of enactment of the Pathogen Research, Emergency  
3 Preparedness, 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. 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 SUBCHAPTER E—BIOLOGICAL AGENTS AND TOXINS

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

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

23 “(b) DEFINITIONS.—In this section:

24 “(1) BIOLOGICAL AGENTS AND TOXINS.—The  
25 terms ‘biological agent’ and ‘toxin’ have the mean-

1       ings given such terms in section 2807 of the Public  
2       Health Service Act and refer to a biological agent or  
3       toxin listed as a ‘select agent’ in section 72.6(j) of  
4       title 42, Code of Federal Regulations, which is not  
5       exempt under section 72.6(h) or appendix A of such  
6       title and which does not include any such biological  
7       agent or toxin that is in its naturally occurring envi-  
8       ronment and that has not been cultivated, collected,  
9       or otherwise extracted from its natural source.

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

17       (b) ENFORCEMENT.—Section 301 of the Federal  
18       Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
19       ed by adding at the end the following:

20           “(bb) The shipment, transportation, possession, or  
21       other use, assistance with respect to, or receipt of a bio-  
22       logical agent or toxin in violation of section 570.”.



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 BIO-  
16          LOGICAL AGENTS AND TOXINS.—The Secretary shall,  
17          through regulations promulgated under subsection (c),  
18          provide for—

19                 “(1) the establishment and enforcement of safe-  
20                 ty procedures for the transfer of biological agents  
21                 and toxins listed pursuant to subsection (a)(1), in-  
22                 cluding 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) the establishment of safeguards to prevent  
4           access to such agents and toxins for use in domestic  
5           or international terrorism or for any other criminal  
6           purpose;

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

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

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

18          “(d) DEFINITIONS.—For purposes of this section and  
19          section 351B, the terms ‘biological agent’ and ‘toxin’ have  
20          the meanings given such term in section 2807.”.

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

1           (3) EFFECTIVE DATE.—The amendments made  
2           by this subsection shall take effect as if incorporated  
3           in the Antiterrorism and Effective Death Penalty  
4           Act of 1996.

5           (b) REGULATION OF BIOLOGICAL AGENTS AND TOX-  
6           INS POSING POTENTIAL NATIONAL SECURITY THREAT.—

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

11       **“SEC. 351B. REGULATION OF BIOLOGICAL AGENTS AND**  
12                               **TOXINS POSING POTENTIAL NATIONAL SECU-**  
13                               **RITY THREAT.**

14       “(a) IN GENERAL.—

15           “(1) LIST OF BIOLOGICAL AGENTS AND TOXINS  
16           POSING NATIONAL SECURITY THREAT.—The Sec-  
17           retary shall, through regulations promulgated under  
18           subsection (d), establish and maintain a list of those  
19           biological agents and toxins listed pursuant to sec-  
20           tion 351A(a)(1) that the Secretary determines to be  
21           a potential national 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), and any other criteria that  
3           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 BIO-  
8 LOGICAL AGENTS AND TOXINS.—The Secretary shall,  
9 through regulations promulgated under subsection (d),  
10 provide for the establishment and enforcement of stand-  
11 ards and procedures governing the possession, use, and  
12 transfer of biological agents and toxins listed pursuant to  
13 subsection (a)(1) that are designed to protect public safety  
14 and national security, including safeguards to prevent ac-  
15 cess to such agents and toxins for use in domestic or inter-  
16 national terrorism or for any other criminal purpose.

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

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

24           “(e) FREEDOM OF INFORMATION ACT EXEMP-  
25 TION.—Any information provided to the Secretary pursu-

1 ant to regulations issued under subsection (d) or under  
2 section 351A(c) shall not be disclosed under section 552  
3 of title 5, United States Code.”.

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

8 **SEC. 7. ADMINISTRATION.**

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

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

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

19 **SEC. 8. COORDINATION OF EFFORTS TO PROTECT AGAINST**  
20 **BIOTERRORISM.**

21 The Secretary of Health and Human Services and the  
22 Secretary of Defense shall coordinate in the planning, de-  
23 sign, and construction of a Department of Defense Gov-  
24 ernment-owned, contractor-operated vaccine production  
25 facility on a military installation, as appropriate.

1 **SEC. 9. ENHANCEMENT OF PENALTIES FOR ANIMAL ENTER-**  
2 **PRISE TERRORISM.**

3 Section 43 of title 18, United States Code, is  
4 amended—

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

7 (2) in subsection (b)—

8 (A) by redesignating paragraph (2) as  
9 paragraph (3);

10 (B) by inserting after paragraph (1) the  
11 following:

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

20 (C) in paragraph (3), as so redesignated,  
21 by striking “under this title and” and all that  
22 follows through the period and inserting “under  
23 this title and imprisoned for life or for any term  
24 of years.”; and

25 (3) in subsection (c)—

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

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

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

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

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