

109TH CONGRESS  
1ST SESSION

# S. 1873

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

OCTOBER 17, 2005

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

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## A BILL

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, 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 “Biodefense and Pan-  
5 demic Vaccine and Drug Development Act of 2005”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Biomedical Advanced Research and Development Agency.
- Sec. 4. Clarification of countermeasures covered by Project BioShield.

- Sec. 5. Orphan drug market exclusivity for countermeasure products.  
 Sec. 6. Liability protections for pandemics, epidemics, and countermeasures.  
 Sec. 7. Compensation.  
 Sec. 8. Rebates and grants for research development, and manufacturing of vaccines, qualified countermeasures and pandemic or epidemic products.  
 Sec. 9. Technical assistance.  
 Sec. 10. Animal models for certain diseases.  
 Sec. 11. Animal Model/Research Tool Scientific Advisory Committee.  
 Sec. 12. Collaboration and coordination.  
 Sec. 13. Procurement.  
 Sec. 14. National Pathology Center.

1 **SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOP-**  
 2 **MENT AGENCY.**

3 Title III of the Public Health Service Act (42 U.S.C.  
 4 241 et seq.) is amended by inserting after section 319K  
 5 the following:

6 **“SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DE-**  
 7 **VELOPMENT AGENCY.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) BARDA.—The term ‘BARDA’ means the  
 10 Biomedical Advanced Research and Development  
 11 Agency.

12 “(2) FUND.—The term ‘Fund’ means the Bio-  
 13 defense Medical Countermeasure Development Fund  
 14 established under subsection (d).

15 “(3) OTHER TRANSACTIONS.—The term ‘other  
 16 transactions’ means transactions, other than pro-  
 17 curement contracts, grants, and cooperative agree-  
 18 ments, including transactions for prototypes, as pro-  
 19 vided to the Secretary of Defense under section  
 20 2371 of title 10, United States Code.

1           “(4) QUALIFIED COUNTERMEASURE.—The term  
2           ‘qualified countermeasure’ has the meaning given  
3           such term in section 319F–1.

4           “(5) QUALIFIED COUNTERMEASURE AND  
5           QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT AD-  
6           VANCED RESEARCH AND DEVELOPMENT.—

7           “(A) IN GENERAL.—The term ‘qualified  
8           countermeasure and qualified pandemic or epi-  
9           demic product advanced research and develop-  
10          ment’ means any applied research, testing, or  
11          evaluation (including those conducted on hu-  
12          mans or animals), related to the safety or effec-  
13          tiveness, that is required for approval, clear-  
14          ance, or licensing by the Secretary under this  
15          Act or the Federal Food, Drug, and Cosmetic  
16          Act, of such countermeasure or pandemic or  
17          epidemic product to diagnose, mitigate, prevent,  
18          or treat harm from a deliberate, accidental, or  
19          natural exposure to a chemical, biological, radi-  
20          ological, or nuclear agent, particularly such ex-  
21          posure resulting from an act of terrorism or po-  
22          tential pandemic infectious disease.

23          “(B) INCLUSION.—The term under sub-  
24          paragraph (A) includes any investigation to im-  
25          prove the manufacturing, formulation, finish,

1 fill, delivery, or shelf-life of such qualified coun-  
2 termeasures or qualified pandemic or epidemic  
3 products.

4 “(6) QUALIFIED PANDEMIC OR EPIDEMIC PROD-  
5 UCT.—The term ‘qualified pandemic or epidemic  
6 product’ has the meaning given the term in section  
7 319F–3(c)(5).

8 “(7) SECURITY COUNTERMEASURE.—The term  
9 ‘security countermeasure’ has the meaning given  
10 such term in section 319F–2.

11 “(8) PERSON.—The term ‘person’ includes an  
12 individual, partnership, corporation, association, en-  
13 tity, or public or private corporation, including a  
14 Federal, State, or local agency or department.

15 “(b) BIOMEDICAL ADVANCED RESEARCH AND DE-  
16 VELOPMENT AGENCY.—

17 “(1) ESTABLISHMENT.—There is established  
18 within the Department of Health and Human Serv-  
19 ices, the Biomedical Advanced Research and Devel-  
20 opment Agency.

21 “(2) PURPOSE.—It shall be the purpose of the  
22 BARDA to coordinate and oversee activities that  
23 support and accelerate qualified countermeasure or  
24 qualified pandemic or epidemic product (referred to

1 in this section as ‘countermeasure or product’) ad-  
2 vanced research and development by—

3 “(A) directing and coordinating collabora-  
4 tion among the Department of Health and  
5 Human Services, other Federal agencies, rel-  
6 evant industries, academia, and other persons,  
7 with respect to such advanced research and de-  
8 velopment;

9 “(B) supporting countermeasure and prod-  
10 uct advanced research and development;

11 “(C) recommending approaches to mod-  
12 ernize and streamline the countermeasure or  
13 product development process and reduce regu-  
14 latory burdens with respect to procurement of  
15 security countermeasures and qualified pan-  
16 demic or epidemic products; and

17 “(D) supporting innovation to reduce the  
18 time and cost of countermeasure and product  
19 advanced research and development.

20 “(3) DIRECTOR.—The BARDA shall be headed  
21 by a Director (referred to in this section as the ‘Di-  
22 rector’) who shall—

23 “(A) be appointed by the President, with  
24 the advice and consent of the Senate;

25 “(B) report to the Secretary; and

1           “(C) serve as the principal advisor to the  
2           Secretary on countermeasure and product ad-  
3           vanced research and development.

4           “(4) DUTIES OF DIRECTOR.—

5           “(A) COLLABORATION.—To carry out the  
6           purpose described in paragraph (2)(A), the Sec-  
7           retary, acting through the Director, shall—

8                   “(i) increase appropriate communica-  
9                   tion between the Federal Government and  
10                   relevant industries, academia, and other  
11                   interested persons with respect to counter-  
12                   measure and product advanced research  
13                   and development by establishing trans-  
14                   parent, expeditious, and direct processes  
15                   to—

16                           “(I) facilitate regular, ongoing  
17                           communication regarding the proc-  
18                           esses established under subparagraph  
19                           (C)(ii) and new countermeasures or  
20                           products of interest;

21                           “(II) solicit research and associ-  
22                           ated data on potential counter-  
23                           measures and products and related  
24                           technologies; and

1                   “(III) provide technical assist-  
2                   ance with respect to such processes  
3                   and the Food and Drug Administra-  
4                   tion approval process;

5                   “(ii) at least annually—

6                   “(I) convene meetings with rep-  
7                   resentatives from relevant industries,  
8                   academia, other Federal agencies,  
9                   international agencies, and other in-  
10                  terested persons; and

11                  “(II) sponsor relevant biodefense  
12                  countermeasure technology dem-  
13                  onstrations;

14                  “(iii) carry out the activities described  
15                  in subsection (g) of section 2 of the Clay-  
16                  ton Act; and

17                  “(iv) encourage and coordinate coun-  
18                  termeasure or product advanced research  
19                  and development, including by convening  
20                  working groups as identified in paragraph  
21                  (5).

22                  “(B) SUPPORT ADVANCED RESEARCH AND  
23                  DEVELOPMENT.—To carry out the purpose de-  
24                  scribed in paragraph (2)(B), the Secretary, act-  
25                  ing through the Director, shall—

1           “(i) conduct continuous searches and  
2 support calls for potential countermeasures  
3 or products for drugs, biological products,  
4 devices, or research tools to diagnose, miti-  
5 gate, prevent, or treat harm from existing,  
6 emerging, or possible chemical, biological,  
7 radiological, and nuclear agents or poten-  
8 tial pandemic infectious diseases that  
9 threaten public health and national secu-  
10 rity, as identified by the Assistant Sec-  
11 retary for Public Health Emergency Pre-  
12 paredness;

13           “(ii) direct the countermeasure and  
14 product advanced research and develop-  
15 ment activities of the Department of  
16 Health and Human Services, in consulta-  
17 tion with the Assistant Secretary for Pub-  
18 lic Health Emergency Preparedness, the  
19 Director of the National Institutes of  
20 Health, the Director of the Centers for the  
21 Disease Control and Prevention, and the  
22 Commissioner of Food and Drugs; and

23           “(iii) award contracts, grants, cooper-  
24 ative agreements, and enter into other  
25 transactions, to include use of simplified

1 acquisition authorities provided under sec-  
2 tions 319F-1 and 319F-2(e)(7)(C)(iii), to  
3 public and private persons, including for-  
4 profit and nonprofit persons, federally  
5 funded research and development centers,  
6 and universities, to—

7 “(I) support the cost of counter-  
8 measure and product advanced re-  
9 search and development; and

10 “(II) ensure accelerated develop-  
11 ment of countermeasures and prod-  
12 ucts.

13 “(C) STREAMLINE PROCESSES.—To carry  
14 out the purpose described in paragraph (2)(C),  
15 the Secretary, acting through the Director,  
16 shall—

17 “(i) receive from the Assistant Sec-  
18 retary for Public Health Emergency Pre-  
19 paredness, requirements for national civil-  
20 ian biodefense needs, particularly counter-  
21 measures or products and other tech-  
22 nologies, to diagnose, mitigate, prevent, or  
23 treat harm from existing, emerging, or po-  
24 tential chemical, biological, radiological, or

1 nuclear agents or potential pandemic infec-  
2 tious diseases;

3 “(ii) establish transparent, expedi-  
4 tious, and direct processes for selecting  
5 promising countermeasures and products,  
6 supporting them through advanced re-  
7 search and development and recommending  
8 them for procurement;

9 “(iii) establish an office within the  
10 BARDA, in consultation with the Commis-  
11 sioner of Food and Drugs, to—

12 “(I) facilitate regular and ongo-  
13 ing communication between the  
14 BARDA and the Food and Drug Ad-  
15 ministration regarding the status of  
16 BARDA advanced research and devel-  
17 opment activities;

18 “(II) ensure that such activities  
19 are coordinated with the approval re-  
20 quirements of the Food and Drug Ad-  
21 ministration, with the goal of expe-  
22 diting the development and approval  
23 of countermeasures and products; and

24 “(III) connect interested persons  
25 with additional technical assistance

1           made available under section 565 of  
2           the Federal Food, Drug, and Cos-  
3           metic Act;

4           “(iv) coordinate with the Food and  
5           Drug Administration to facilitate regu-  
6           latory review and approval of promising  
7           classes of countermeasures or products  
8           through the development of research tools;  
9           and

10           “(v) recommend to the Secretary,  
11           through the Assistant Secretary for Public  
12           Health Emergency Preparedness, procure-  
13           ment of the most promising eligible secu-  
14           rity countermeasures or qualified pandemic  
15           or epidemic products identified in clause  
16           (i).

17           “(D) SUPPORTING INNOVATION.—To carry  
18           out the purpose described in paragraph (2)(D),  
19           the Secretary, acting through the Director,  
20           shall award contracts, grants, cooperative  
21           agreements, or enter into other transactions, to  
22           include use of simplified acquisition authorities  
23           provided under sections 319F–1 and 319F–  
24           2(c)(7)(C)(iii), to the entities described in sub-  
25           paragraph (B)(iii), to promote innovation in

1 technologies supporting the advanced research  
2 and development and production of qualified or  
3 security countermeasures or qualified pandemic  
4 or epidemic products, such as research tools,  
5 manufacturing, countermeasure administration,  
6 storage, and bioinformatics and other devices.

7 “(E) OTHER DUTIES.—

8 “(i) IN GENERAL.—The Director  
9 may—

10 “(I) prepare and submit to the  
11 President and Congress, an annual  
12 budget estimate for qualified counter-  
13 measure and pandemic or epidemic  
14 product advanced research and devel-  
15 opment and other BARDA activities,  
16 after opportunity for comment by the  
17 Secretary; and

18 “(II) receive from the President  
19 and the Office of Management and  
20 Budget directly all funds appropriated  
21 by Congress for obligation and ex-  
22 penditure by the BARDA.

23 “(ii) SECRETARY DUTIES.—The Sec-  
24 retary, acting through the Director, may—

1           “(I) enter into such contracts,  
2 leases, cooperative agreements, or  
3 other transactions, as may be nec-  
4 essary to carry out the functions of  
5 BARDA, without regard to section  
6 3648 and 3709 of the Revised Stat-  
7 utes of the United States (31 U.S.C.  
8 3324(a) and (b)), (41 U.S.C. 5), with  
9 any public agency, any firm, associa-  
10 tion, corporation, or educational insti-  
11 tution, or any other person;

12           “(II) support advanced research  
13 and development and innovation of  
14 potential countermeasures or products  
15 by highly qualified foreign nationals  
16 outside the United States that may  
17 inure to the benefit of the American  
18 people and collaborative research in-  
19 volving American and foreign partici-  
20 pants;

21           “(III) administer grants using  
22 milestone-based awards and pay-  
23 ments; and

24           “(IV) establish 1 or more feder-  
25 ally funded research and development

1 centers or university affiliated re-  
2 search centers in accordance with sec-  
3 tion 253(c)(3) of title 41, United  
4 States Code.

5 “(5) VULNERABLE POPULATIONS.—In carrying  
6 out the activities under this section, the Director, in  
7 consultation with the Vulnerable Populations Work-  
8 ing Group, may give priority to supporting and fa-  
9 cilitating advanced research and development of  
10 countermeasures or products, and formulations of  
11 countermeasures or products, that are likely to be  
12 safe and effective for pediatric populations, pregnant  
13 women, and other vulnerable populations.

14 “(6) WORKING GROUPS.—

15 “(A) IDENTIFICATION OF TECH-  
16 NOLOGIES.—

17 “(i) IN GENERAL.—The Director may  
18 establish and convene, or enter into a con-  
19 tract with a public or private research in-  
20 stitution to convene, one or more working  
21 groups that consists of experts on counter-  
22 measure technology to identify innovative  
23 technologies that have the potential to be  
24 developed as countermeasures or products.

1           “(ii) MEETINGS.—A working group  
2 established under clause (i) shall partici-  
3 pate in regular meetings with sponsors of  
4 countermeasures, products, or related tech-  
5 nologies to—

6                   “(I) review the scientific evidence  
7 or concept of such countermeasures,  
8 products, or related technologies;

9                   “(II) provide guidance on re-  
10 search protocols or studies; and

11                   “(III) provide guidance on the  
12 regulatory approval process for coun-  
13 termeasures, products, and related  
14 technologies.

15           “(iii) RECOMMENDATIONS.—Not later  
16 than 30 days after each meeting with a  
17 sponsor of a countermeasure, product, or  
18 related technology, the working group shall  
19 make recommendations to the Director  
20 concerning such countermeasure, product,  
21 or related technology.

22           “(iv) CONFIDENTIALITY.—Any com-  
23 mercial confidential or proprietary infor-  
24 mation that is disclosed to the working  
25 group in a meeting under this section shall

1 remain confidential and shall not be dis-  
2 closed other than to the Secretary or the  
3 Director, or their designees.

4 “(v) CONSTRUCTION.—Nothing in  
5 this subparagraph shall be construed to  
6 prohibit a sponsor from meeting with the  
7 Director to discuss potential counter-  
8 measures, products, or related tech-  
9 nologies.

10 “(B) PUBLIC WORKING GROUP.—The Di-  
11 rector may establish and convene one or more  
12 working groups composed of private citizens  
13 and officials of Federal, State, and local govern-  
14 ments to advise such Director with respect to  
15 the functions of the BARDA and the Director.

16 “(C) VULNERABLE POPULATIONS WORK-  
17 ING GROUP.—The Director shall establish and  
18 convene a Vulnerable Populations Working  
19 Group composed of experts on pediatric popu-  
20 lations, pregnant women, and other vulnerable  
21 populations to advise such Director with respect  
22 to—

23 “(i) supporting and facilitating ad-  
24 vanced research and development of coun-  
25 termeasures, and formulations of counter-

1           measures, that are safe and effective for  
2           such populations; and

3           “(ii) other activities of the BARDA  
4           that effect such populations.

5           “(7) PERSONNEL AUTHORITIES.—

6           “(A) SPECIALLY QUALIFIED SCIENTIFIC  
7           AND PROFESSIONAL PERSONNEL.—In hiring  
8           personnel for the BARDA, the Director shall  
9           have the hiring and management authorities de-  
10          scribed in section 1101 of the Strom Thurmond  
11          National Defense Authorization Act for Fiscal  
12          Year 1999 (5 U.S.C. 3104 note; Public Law  
13          105–261). With respect to the personnel of the  
14          BARDA, the term of appointments for employ-  
15          ees referred to under subsection (c)(1) of that  
16          section may not exceed 5 years before the  
17          granting of any extension under subsection  
18          (c)(2) of that section.

19          “(B) SPECIAL CONSULTANTS.—The Direc-  
20          tor may accept special consultants as personnel  
21          for the BARDA under section 207(f).

22          “(C) INTERGOVERNMENTAL PERSONNEL  
23          ACT.—The Director may accept as personnel  
24          for the BARDA, employees under subchapter

1 VI of chapter 33 of subpart B of part III of  
2 title 5, United States Code.

3 “(D) OTHER SERVICES.—The Director  
4 may accept voluntary and uncompensated serv-  
5 ices.

6 “(c) NATIONAL BIODEFENSE ADVISORY BOARD.—

7 “(1) IN GENERAL.—

8 “(A) PURPOSE.—The National Biodefense  
9 Advisory Board shall provide expert advice and  
10 guidance to the Secretary on the threats, chal-  
11 lenges, and opportunities presented by advances  
12 in biological and life sciences and the threat  
13 from natural infectious diseases and chemical,  
14 biological, radiological, and nuclear threats.

15 “(B) MEMBERSHIP.—There is established  
16 the National Biodefense Advisory Board (here-  
17 inafter in this section referred to as the  
18 ‘Board’) to be composed of 23 members who  
19 represent the Nation’s preeminent scientific,  
20 public health, and medical experts on the sub-  
21 ject of biological, chemical, nuclear, and radio-  
22 logical threats, whether naturally occurring, ac-  
23 cidental, or deliberate, as follows:

1           “(i) EX OFFICIO.—The following  
2 members shall serve on the Board ex offi-  
3 cio:

4           “(I) The Assistant to the Presi-  
5 dent for Homeland Security and  
6 Counterterrorism.

7           “(II) The Director of the Office  
8 of Science and Technology Policy.

9           “(III) The Assistant Secretary  
10 for Public Health Emergency Pre-  
11 paredness.

12           “(IV) The Director of the Na-  
13 tional Institutes of Health.

14           “(V) The Director of the Centers  
15 for Disease Control and Prevention.

16           “(VI) The Commissioner of Food  
17 and Drugs.

18           “(VII) The Director of BARDA.

19           “(VIII) The Assistant Secretary  
20 of Defense for Health Affairs.

21           “(IX) The Assistant Secretary of  
22 Homeland Security for Science and  
23 Technology.

24           “(X) The Secretary of Agri-  
25 culture (or a designee).

1                   “(ii) APPOINTED MEMBERS.—The fol-  
2                   lowing individuals, as appointed by the  
3                   Secretary:

4                   “(I) Four representatives of the  
5                   pharmaceutical and biotechnology in-  
6                   dustries.

7                   “(II) Four representatives of aca-  
8                   demia.

9                   “(III) Five other members as de-  
10                  termined appropriate by the Sec-  
11                  retary.

12                 “(C) TERM OF APPOINTMENT.—A member  
13                 of the Board described in subparagraph (B)(ii)  
14                 shall serve for a term of 3 years, except that  
15                 the Secretary may adjust the terms of the ini-  
16                 tial Board appointees in order to provide for a  
17                 staggered term of appointment for all members.

18                 “(D) CONSECUTIVE APPOINTMENTS; MAX-  
19                 IMUM TERMS.—A member may be appointed to  
20                 serve not more than 3 terms on the Board and  
21                 may serve not more than 2 consecutive terms.

22                 “(2) DUTIES.—The Board shall—

23                 “(A) advise the Secretary on major bio-  
24                 defense initiatives and review ongoing and pro-

1           posed biodefense programs, which may include  
2           potential activities of the BARDA; and

3           “(B) in consultation with the Director of  
4           BARDA, and in coordination with the Director  
5           of National Institute of Allergy and Infectious  
6           Diseases, provide to the Secretary, rec-  
7           ommendations and findings for an expanded,  
8           intensified, and coordinated biodefense research  
9           program encompassing the programs of the  
10          BARDA and other Federal agencies and related  
11          programs of the other research institutes.

12          “(3) MEETINGS.—The Board shall meet at the  
13          call of the Secretary, but in no case less than twice  
14          annually to provide to the Secretary updated assess-  
15          ments, findings, and recommendations of the current  
16          trends, challenges, and opportunities posed in bio-  
17          technology and genetic engineering.

18          “(4) VACANCIES.—Any vacancy in the Board  
19          shall not affect its powers, but shall be filled in the  
20          same manner as the original appointment.

21          “(5) CHAIRPERSON.—The Secretary shall ap-  
22          point a chairperson from among the members of the  
23          Board.

24          “(6) POWERS.—

1           “(A) HEARINGS.—The Board may hold  
2 such hearings, sit and act at such times and  
3 places, take such testimony, and receive such  
4 evidence as the Board considers advisable to  
5 carry out this subsection.

6           “(B) POSTAL SERVICES.—The Board may  
7 use the United States mails in the same man-  
8 ner and under the same conditions as other de-  
9 partments and agencies of the Federal Govern-  
10 ment.

11           “(7) PERSONNEL.—

12           “(A) OFFICERS OF THE FEDERAL GOV-  
13 ERNMENT.—A member of the Board that is an  
14 employee of the Federal Government may not  
15 receive additional pay, allowances, or benefits  
16 by reason of the member’s service on the  
17 Board.

18           “(B) OTHER MEMBERS.—A member of the  
19 Board that is not an employee of the Federal  
20 Government shall be compensated at a rate  
21 equivalent to the daily equivalent of the annual  
22 rate of basic pay prescribed for level IV of the  
23 Executive Schedule under section 5315 of title  
24 5, United States Code, for each day (including  
25 travel time) during which the member is en-

1 gaged in the actual performance of duties as a  
2 member of the Board.

3 “(C) TRAVEL EXPENSES.—Each member  
4 of the Board shall receive travel expenses, in-  
5 cluding per diem in lieu of subsistence, in ac-  
6 cordance with applicable provisions under sub-  
7 chapter I of chapter 57 of title 5, United States  
8 Code.

9 “(D) DETAIL OF GOVERNMENT EMPLOY-  
10 EES.—Any Federal Government employee may  
11 be detailed to the Board without reimburse-  
12 ment, and such detail shall be without interrup-  
13 tion or loss of civil service status or privilege.

14 “(d) FUND.—

15 “(1) ESTABLISHMENT.—There is established  
16 the Biodefense Medical Countermeasure Develop-  
17 ment Fund, which shall be administered by the Di-  
18 rector of the BARDA.

19 “(2) FUNDS.—

20 “(A) FIRST FISCAL YEAR.—Of the  
21 amounts appropriated to carry out the Project  
22 BioShield Act of 2004 (Public Law 108–276)  
23 and not obligated, \$1,000,000,000 shall be  
24 available to the Fund to carry out this section

1           for fiscal year 2006. Such amounts shall remain  
2           available until expended.

3           “(B) SUBSEQUENT FISCAL YEARS.—There  
4           are authorized to be appropriated such sums as  
5           may be necessary to carry out this section for  
6           fiscal year 2007 and each subsequent fiscal  
7           year. Such sums shall remain available until ex-  
8           pended.

9           “(e) EFFECT OF SECTION.—Nothing in this section  
10          shall be construed to limit any authority of the Depart-  
11          ment of Health and Human Services, including those au-  
12          thorities provided under the Project BioShield Act of 2004  
13          (Public Law 108–276).

14          “(f) INAPPLICABILITY OF CERTAIN ACTS.—

15                 “(1) FACA.—The Federal Advisory Committee  
16          Act (5 U.S.C. App.) shall not apply to the duties,  
17          activities, working groups, and advisory boards of  
18          the BARDA.

19                 “(2) FOIA.—Information that relates to the ac-  
20          tivities, working groups, and advisory boards of the  
21          BARDA shall not be subject to disclosure under sec-  
22          tion 552 of title 5, United States Code, unless the  
23          Secretary or Director determines that such disclo-  
24          sure would pose no threat to national security. Such

1 a determination shall not be subject to judicial re-  
2 view.

3 “(3) CERTAIN COST PRINCIPLES AND COST AC-  
4 COUNTING STANDARDS.—Notwithstanding any other  
5 provision of law, the cost principles set forth under  
6 part 31 of title 48, Code of Federal Regulations, the  
7 cost accounting standards set forth under chapter  
8 99 of title 48, Code of Federal Regulations, and the  
9 requirement for the submission of certified cost and  
10 pricing information under section 304A of the Fed-  
11 eral Property and Administrative Services Act of  
12 1949 (41 U.S.C. 254b), shall not apply to any con-  
13 tract, grant, cooperative agreement, or other trans-  
14 action entered into under the Project BioShield Act  
15 of 2004 (Public Law 108–276).”

16 **SEC. 4. CLARIFICATION OF COUNTERMEASURES COVERED**  
17 **BY PROJECT BIOSHIELD.**

18 (a) QUALIFIED COUNTERMEASURE.—Section 319F–  
19 1(a) of the Public Health Service Act (42 U.S.C. 247d–  
20 6a(a)) is amended by striking paragraph (2) and inserting  
21 the following:

22 “(2) DEFINITIONS.—In this section:

23 “(A) QUALIFIED COUNTERMEASURE.—The  
24 term ‘qualified countermeasure’ means a drug  
25 (as that term is defined by section 201(g)(1) of

1 the Federal Food, Drug, and Cosmetic Act (21  
2 U.S.C. 321(g)(1))), biological product (as that  
3 term is defined by section 351(i) of this Act (42  
4 U.S.C. 262(i))), device (as that term is defined  
5 by section 201(h) of the Federal Food, Drug,  
6 and Cosmetic Act (21 U.S.C. 321(h))), or re-  
7 search tool (as that term is defined in section  
8 201(rr) of the Federal Food, Drug, and Cos-  
9 metic Act) that the Secretary determines to be  
10 a priority (consistent with sections 302(2) and  
11 304(a) of the Homeland Security Act of 2002)  
12 to—

13 “(i) diagnose, mitigate, prevent, or  
14 treat harm from any biological agent (in-  
15 cluding organisms that cause an infectious  
16 disease) or toxins, chemical, radiological,  
17 or nuclear agent that may cause a public  
18 health emergency affecting national secu-  
19 rity;

20 “(ii) diagnose, mitigate, prevent, or  
21 treat harm from a condition that may re-  
22 sult in adverse health consequences or  
23 death and may be caused by administering  
24 a drug, biological product, or device that is  
25 used as described in this subparagraph; or

1           “(iii) in the case of a research tool,  
2           enable the rapid and effective identifica-  
3           tion, assessment, or development of a drug,  
4           biological product, or device to diagnose,  
5           mitigate, prevent, or treat harm, as de-  
6           scribed in clause (i) or (ii).

7           “(B) INFECTIOUS DISEASE.—The term ‘in-  
8           fectious disease’ means a disease potentially  
9           caused by a pathogenic organism (including a  
10          bacteria, virus, fungus, or parasite) that is ac-  
11          quired by a person and that reproduces in that  
12          person.”.

13          (b) SECURITY COUNTERMEASURE.—Section 319F-  
14          2(c)(1)(B) is amended by—

15                 (A) striking “treat, identify, or prevent”  
16                 each place it appears and inserting “diagnose,  
17                 mitigate, prevent, or treat”; and

18                 (B) inserting “agent (including organisms  
19                 that cause an infectious disease) or toxin” after  
20                 “any biological”.

21          (c) RESEARCH TOOL.—Section 201 of the Federal  
22          Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amend-  
23          ed by adding at the end the following:

24                 “(rr) RESEARCH TOOL.—The term ‘research tool’ in-  
25          cludes the full range of tools and systems that assist in

1 the discovery, development, or manufacture of drugs, bio-  
2 logical products (as defined in section 351 of the Public  
3 Health Service Act), or devices.”.

4 **SEC. 5. ORPHAN DRUG MARKET EXCLUSIVITY FOR COUN-**  
5 **TERMEASURE PRODUCTS.**

6 (a) MARKET EXCLUSIVITY.—Subchapter A of chap-  
7 ter V of the Federal Food, Drug, and Cosmetic Act (21  
8 U.S.C. 351 et seq.) is amended by inserting after section  
9 505B the following:

10 **“SEC. 505C. ORPHAN DRUG MARKET EXCLUSIVITY FOR**  
11 **COUNTERMEASURE PRODUCTS.**

12 “(a) IN GENERAL.—With respect to countermeasure  
13 products (as such term is defined in this section), if a  
14 countermeasure product is designated under section 526  
15 for a rare disease or condition, the period referred to in  
16 section 527(a) shall be 10 years instead of 7 years.

17 “(b) DEFINITION.—For the purpose of this section,  
18 the term ‘countermeasure’ means a drug or biological  
19 product (as such term is defined by section 351(i) of the  
20 Public Health Service Act) that the Secretary determines  
21 to be a priority (consistent with sections 302(2) and  
22 304(a) of the Homeland Security Act of 2002) to diag-  
23 nose, mitigate, prevent, or treat harm from any biological,  
24 chemical, radiological, or nuclear agent (including orga-  
25 nisms that cause an infectious disease) or toxin identified

1 as a material threat under subsection (c)(2)(A)(ii) of sec-  
2 tion 319F-2 of the Public Health Service Act.”.

3 (b) ORPHAN DRUGS.—For purposes of section 526  
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 360bb) a biological, chemical, radiological, or nuclear  
6 agent (including organisms that cause an infectious dis-  
7 ease) or toxin identified as a material threat under sub-  
8 section (c)(2)(A)(ii) of section 319F-2 of the Public  
9 Health Service Act shall be considered to be a “rare dis-  
10 ease or condition” within the meaning of such term in  
11 such section 526. The Secretary may designate antibiotics  
12 and anti-infective products that treat infectious diseases  
13 as designated drugs or biological products under such sec-  
14 tion 526.

15 (c) EFFECT OF SECTION.—This section, and the  
16 amendments made by this section, shall apply to new drug  
17 applications and biological product licenses approved  
18 under the Federal Food, Drug, and Cosmetic Act or the  
19 Public Health Service Act after the date of enactment of  
20 this Act.

21 **SEC. 6. LIABILITY PROTECTIONS FOR PANDEMICS,**  
22 **EPIDEMICS, AND COUNTERMEASURES.**

23 Part B of title III of the Public Health Service Act  
24 is amended by inserting after section 319F-2 (42 U.S.C.  
25 247d-6b) the following:

1 **“SEC. 319F-3. LIABILITY PROTECTIONS FOR PANDEMIC AND**  
2 **EPIDEMIC PRODUCTS AND SECURITY COUN-**  
3 **TERMEASURES.**

4 “(a) **AUTHORITY.**—As provided in subsection (b),  
5 and subject to subsection (b)(1)(C), a manufacturer,  
6 distributor, or administrator of a security countermeasure,  
7 or a qualified pandemic and epidemic product, described  
8 in subsection (b)(1)(A) or a health care provider shall be  
9 immune from suit or liability caused by or arising out of  
10 the design, development, clinical testing and investigation,  
11 manufacture, labeling, distribution, sale, purchase, dona-  
12 tion, dispensing, prescribing, administration, or use of a  
13 security countermeasure, or a qualified pandemic and epi-  
14 demic product, described in subsection (b)(1)(A).

15 “(b) **LITIGATION MANAGEMENT.**—

16 “(1) **LIMITATION ON CAUSE OF ACTION.**—

17 “(A) **IN GENERAL.**—

18 “(i) **IN GENERAL.**—No cause of action  
19 shall exist against a person described in  
20 subsection (a) for claims for loss of prop-  
21 erty, personal injury, or death arising out  
22 of, reasonably relating to, or resulting from  
23 the design, development, clinical testing  
24 and investigation, manufacture, labeling,  
25 distribution, sale, purchase, donation, dis-  
26 pensing, prescribing, administration, or use

1 of a security countermeasure or qualified  
2 pandemic or epidemic product distributed,  
3 sold, purchased, donated, dispensed, pre-  
4 scribed, administered, or used in anticipa-  
5 tion of and preparation for, in defense  
6 against, or in response to, or recovery from  
7 an actual or potential public health emer-  
8 gency that is a designated security coun-  
9 termeasure or a qualified pandemic or epi-  
10 demic product by the Secretary in a dec-  
11 laration described in paragraph (2).

12 “(ii) RULE OF CONSTRUCTION.—For  
13 purposes of this section, the phrase ‘aris-  
14 ing out of, reasonably relating to, or re-  
15 sulting from’ shall not be construed to  
16 apply to loss of property, personal injury,  
17 or death that has no alleged or potential  
18 causal relationship with the design, devel-  
19 opment, clinical testing and investigation,  
20 manufacture, labeling, distribution, sale,  
21 purchase, donation, dispensing, pre-  
22 scribing, administration, or use of a prod-  
23 uct described in clause (i).

24 “(B) RULE.—

1           “(i) SUBSEQUENT INJURY.—The pro-  
2           tections set forth in subsection (a) and  
3           subparagraph (A) shall apply to all claims  
4           identified in subparagraph (A) that involve  
5           products distributed, sold, purchased, do-  
6           nated, dispensed, prescribed, administered,  
7           or used during the effective period set  
8           forth in the designation provided for in  
9           paragraph (2), regardless of the date of al-  
10          leged injury.

11          “(ii) PRIVATE DONATION OR SALE.—  
12          The protections set forth in subsection (a)  
13          and subparagraph (A) shall apply to all  
14          claims identified in subparagraph (A) that  
15          involve security countermeasures or quali-  
16          fied pandemic or epidemic products distrib-  
17          uted, sold, purchased, donated, dispensed,  
18          prescribed, administered, or used during  
19          the effective period set forth in the des-  
20          ignation provided for in paragraph (2) by  
21          a manufacturer through the commercial  
22          market, provided that the security counter-  
23          measures or the qualified pandemic or epi-  
24          demic product are the security counter-  
25          measure or qualified pandemic or epidemic

1 product described in a declaration de-  
2 scribed in paragraph (2) and the Secretary  
3 does not specifically prohibit such private  
4 donation or sale in such declaration.

5 “(C) POTENTIAL LIABILITY UPON DETER-  
6 MINATION.—

7 “(i) IN GENERAL.—A manufacturer,  
8 distributor, administrator, or health care  
9 provider shall not be immune under sub-  
10 section (a) or exempted from a cause of ac-  
11 tion under subparagraph (A) if the Sec-  
12 retary makes a determination as provided  
13 for in subparagraph (D).

14 “(ii) INVESTIGATION BY SEC-  
15 RETARY.—A party seeking a determination  
16 under subparagraph (D) may petition the  
17 Secretary to investigate allegations against  
18 a manufacturer, distributor, administrator,  
19 or health care provider arising out of, re-  
20 lating to, or resulting from the design, de-  
21 velopment, clinical testing and investiga-  
22 tion, manufacture, labeling, distribution,  
23 sale, purchase, donation, dispensing, pre-  
24 scribing, administration, or use of products  
25 as provided for in subparagraph (A)(i).

1           The decision to undertake such investiga-  
2           tion shall be within the Secretary’s discre-  
3           tion and shall not be subject to judicial re-  
4           view.

5           “(iii) RULE OF CONSTRUCTION.—  
6           Nothing in this section shall be construed  
7           to abrogate or limit the application of sub-  
8           title II of chapter 5 and chapter 7 of title  
9           5, United States Code (commonly known  
10          as the Administrative Procedure Act).

11          “(D) DETERMINATION BY SECRETARY.—

12           “(i) IN GENERAL.—In making a de-  
13           termination under this subparagraph, the  
14           Secretary, acting through an administra-  
15           tive law judge, must find clear and con-  
16           vincing evidence that—

17           “(I) the manufacturer, dis-  
18           tributor, administrator, or health care  
19           provider violated a provision of the  
20           Federal Food, Drug, and Cosmetic  
21           Act (21 U.S.C. 301 et seq.) or this  
22           Act; and

23           “(II) in violating such Act, such  
24           manufacturer, distributor, adminis-

1           trator, or health care provider acted  
2           with willful misconduct.

3           “(ii) EFFECT OF DETERMINATION.—  
4           If the Secretary finds such clear and con-  
5           vincing evidence under clause (i), the Sec-  
6           retary shall examine whether such willful  
7           misconduct to violate an Act under such  
8           clause—

9                   “(I) caused the product to  
10                   present a significant or unreasonable  
11                   risk to human health; and

12                   “(II) proximately caused the in-  
13                   jury alleged by the party.

14           “(iii) NOTICE AND HEARING.—Prior  
15           to the Secretary’s making a determination  
16           under clause (i), the manufacturer, dis-  
17           tributor, administrator, or health care pro-  
18           vider shall have notice and a right to a for-  
19           mal hearing in accordance with section 556  
20           of title 5, United States Code.

21           “(iv) EFFECT OF DETERMINATION.—  
22           Subject to subsection (c), the sole excep-  
23           tion to the immunity from suit and liability  
24           of manufacturers, distributors, administra-  
25           tors, or healthcare providers set forth in

1 subsection (a) and subparagraph (A) shall  
2 be for actions against a manufacturer, dis-  
3 tributor, administrator, or healthcare pro-  
4 vider as provided in subparagraph (A).

5 “(v) JUDICIAL REVIEW.—At any time  
6 prior to the 90th day following a deter-  
7 mination by the Secretary under clause (i),  
8 any manufacturer, distributor, adminis-  
9 trator, or health care provider named in  
10 such determination may file a petition with  
11 the United States Court District Court for  
12 the District of Columbia, for a judicial re-  
13 view of such determination. A copy of the  
14 petition shall be forthwith transmitted by  
15 the clerk of the court to the Secretary or  
16 other officer designated by the Secretary  
17 for that purpose. The Secretary thereupon  
18 shall file in the court the record of the  
19 findings on which the Secretary based his  
20 or her determination. The filing of a peti-  
21 tion under this clause shall automatically  
22 stay the Secretary’s determination for the  
23 duration of the judicial proceeding. The  
24 sole parties to the judicial proceeding shall  
25 be the Secretary and the petitioner. Inter-

1           vention by third parties in the judicial pro-  
2           ceeding shall not be permitted. No sub-  
3           poenas shall be issued nor shall other com-  
4           pulsory process apply. The court’s review  
5           of a determination by the Secretary under  
6           this clause shall conform to the procedures  
7           for judicial review of administrative orders  
8           set forth in paragraphs (2) through (6) of  
9           section 701(f) of the Federal Food, Drug,  
10          and Cosmetic Act (21 U.S.C. 371(f)) to  
11          the extent consistent with this section.

12           “(vi) TOLLING OF STATUTE OF LIM-  
13          TATIONS.—The computation of the statute  
14          of limitations for any action against a  
15          manufacturer, distributor, administrator,  
16          or health care provider described under  
17          this subparagraph shall not include any  
18          time occurring before the determination by  
19          the Secretary under this subparagraph.

20           “(vii) REGULATORY AUTHORITY.—  
21          The Secretary, in consultation with the At-  
22          torney General, shall promulgate regula-  
23          tions defining what actions by a manufac-  
24          turer, distributor, administrator, or  
25          healthcare provider of a security counter-

1 measure or a qualified pandemic and epi-  
2 demic product shall be deemed to con-  
3 stitute ‘willful misconduct’ for purposes of  
4 clause (i). In promulgating such regula-  
5 tions, the Secretary shall consider the na-  
6 ture of the actual or potential public health  
7 emergency, the timing and extent of any  
8 vaccination or countermeasure program,  
9 and any other circumstances they deem  
10 significant, so that any civil actions per-  
11 mitted under this subsection will not ad-  
12 versely affect the public health. The Sec-  
13 retary may specify the period of time for  
14 which such regulations apply.

15 “(viii) EVIDENCE REQUIRED.—The  
16 Secretary, in consultation with the Attor-  
17 ney General, shall promulgate regulations  
18 that require, in order to be a party under  
19 this section, that an individual present evi-  
20 dence that reasonably demonstrates that—

21 “(I) such individual has suffered  
22 a loss as a direct result of the design,  
23 development, clinical testing and in-  
24 vestigation, manufacture, labeling,  
25 distribution, sale, purchase, donation,

1                   dispensing, prescribing, or administra-  
2                   tion of a security countermeasure or  
3                   qualified epidemic or pandemic prod-  
4                   uct; and

5                   “(II) the loss as described in sub-  
6                   clause (I) was a direct result of the  
7                   willful misconduct of the manufac-  
8                   turer, distributor, administrator, or  
9                   health care provider in violating the  
10                  Federal Food, Drug, and Cosmetic  
11                  Act or this Act.

12                  “(E) SCOPE.—Subparagraph (C) shall  
13                  apply regardless of whether the suit or liability  
14                  described in subsection (a) or the claim de-  
15                  scribed in subparagraph (A) arises from the de-  
16                  sign, development, clinical testing and investiga-  
17                  tion, manufacture, labeling, distribution, sale,  
18                  purchase, donation, dispensing, prescribing, ad-  
19                  ministration, or use by the Federal Government  
20                  or by any person.

21                  “(2) DECLARATION BY SECRETARY.—

22                  “(A) IN GENERAL.—The Secretary may  
23                  issue a declaration, pursuant to this paragraph,  
24                  that an actual or potential public health emer-  
25                  gency makes advisable the distribution, admin-

1           istration, or use of a security countermeasure  
2           or qualified pandemic or epidemic product.

3           “(B) SECURITY COUNTERMEASURE OR  
4           QUALIFIED PANDEMIC OR EPIDEMIC PROD-  
5           UCT.—The Secretary shall specify in such dec-  
6           laration the security countermeasures or quali-  
7           fied pandemic or epidemic products to be sold  
8           by, purchased from, or donated by a manufac-  
9           turer or drawn from the Strategic National  
10          Stockpile.

11          “(C) EFFECTIVE PERIOD.—The Secretary  
12          shall specify in such declaration the beginning  
13          and the ending dates of the effective period of  
14          the declaration, which shall be not longer than  
15          6 months. The Secretary may subsequently  
16          amend such declaration to shorten or extend  
17          such effective period, provided that the new  
18          ending data is after the date on which the dec-  
19          laration is amended.

20          “(D) PUBLICATION.—The Secretary shall  
21          promptly publish each such declaration and  
22          amendment in the Federal Register.

23          “(c) ACTIONS BY THE UNITED STATES.—Nothing in  
24          this section shall be construed to abrogate or limit any  
25          right, remedy, or authority that the United States or any

1 agency thereof may possess under any other provision of  
2 law.

3 “(d) DEFINITIONS.—In this section:

4 “(1) ADMINISTRATOR.—The term ‘adminis-  
5 trator’ means a person employed by the State or  
6 local government, or their designee, who supervised  
7 or administered a program with respect to the ad-  
8 ministration, dispensing, distribution, or provision of  
9 a security countermeasure or a qualified pandemic  
10 or epidemic product, including a person who has es-  
11 tablished requirements, provided policy guidance,  
12 supplied technical or scientific advice or assistance.

13 “(2) HEALTH CARE PROVIDER.—The term  
14 ‘health care provider’ means a person, including a  
15 volunteer, who distributes, prescribes, administers,  
16 dispenses, provides a facility to administer, or super-  
17 vises or oversees the administration of a security  
18 countermeasure or a qualified pandemic or epidemic  
19 product, including persons who distribute, prescribe,  
20 administer, dispense, or provide a facility to admin-  
21 ister in accordance with a designation under sub-  
22 section (b)(2).

23 “(3) LOSS.—The term ‘loss’ means death, phys-  
24 ical injury, or loss of or damage to property, includ-  
25 ing business interruption loss.

1           “(4) MANUFACTURER.—The term ‘manufac-  
2 turer’ includes—

3           “(A) a contractor or subcontractor of a  
4 manufacturer;

5           “(B) a supplier of any product or service,  
6 research tool, or component to the manufac-  
7 turer; and

8           “(C) any or all of the parents, subsidiaries,  
9 affiliates, successors, and assigns of a manufac-  
10 turer.

11           “(5) QUALIFIED PANDEMIC OR EPIDEMIC PROD-  
12 UCT.—The term ‘qualified pandemic or epidemic  
13 product’ means a drug (as such term is defined in  
14 section 201(g)(1) of the Federal Food, Drug, and  
15 Cosmetic Act (21 U.S.C. 321(g)(1))), biological  
16 product (as such term is defined by section 351(i)  
17 of this Act) or device (as such term is defined by  
18 section 201(h) of the Federal Food, Drug and Cos-  
19 metic Act (21 U.S.C. 321(h))) designed, developed,  
20 modified, or procured to diagnose, mitigate, prevent,  
21 treat, or cure a pandemic or epidemic or limit the  
22 harm such pandemic or epidemic might otherwise  
23 cause or a serious or life-threatening disease or con-  
24 dition caused by such a product, that—

1           “(A) is approved or cleared under chapter  
2           V of the Federal Food, Drug, and Cosmetic Act  
3           or licensed under section 351 of this Act;

4           “(B) is a product for which the Secretary  
5           determines that sufficient and satisfactory clin-  
6           ical experience or research data (including data,  
7           if available, from pre-clinical and clinical trials)  
8           support a reasonable conclusion that the prod-  
9           uct will qualify for approval or licensing within  
10          8 years after the date the Secretary makes a  
11          declaration under paragraph (2); or

12          “(C) is authorized for emergency use sec-  
13          tion 564 of the Federal Food, Drug, and Cos-  
14          metic Act, except that subsection (b) of such  
15          section shall not apply.

16          “(6) PARTY.— The term ‘party’ means an indi-  
17          vidual who can reasonably demonstrate to the Sec-  
18          retary that such individual has suffered a loss (as  
19          defined in paragraph (3)) as a direct result of the  
20          willful misconduct of a manufacturer, distributor,  
21          administrator, or health care provider.

22          “(7) PERSON.—The term ‘person’ includes an  
23          individual, partnership, corporation, association, en-  
24          tity, or public or private corporation, including a  
25          Federal, State, or local agency or department.

1           “(8) SECURITY COUNTERMEASURE.—The term  
2           ‘security countermeasure’ has the meaning given  
3           such term in section 319F–2(c)(1)(B).”.

4 **SEC. 7. COMPENSATION.**

5           Title II of the Public Health Service Act (42 U.S.C.  
6 202 et seq.) is amended by adding at the end the fol-  
7 lowing:

8           **“PART D—OTHER COMPENSATION PROGRAMS**

9           **“SEC. 271. COVERED COUNTERMEASURES PROGRAM.**

10           “(a) IN GENERAL.—If the Secretary issues a Procla-  
11 mation stating that there is a critical public health need  
12 for a covered individual to receive a covered counter-  
13 measure during the effective period of the Proclamation,  
14 the Secretary shall establish a process to provide com-  
15 pensation to such covered individuals for a covered injury,  
16 consistent with the Smallpox Emergency Personnel Pro-  
17 tection program under part C.

18           “(b) DEFINITION.—For purposes of this section:

19           “(1) COVERED COUNTERMEASURE.—The term  
20           ‘covered countermeasure’ means a qualified pan-  
21           demic or epidemic (as defined in section 319F–  
22           3(c)(5)) or a security countermeasure (as defined in  
23           section 319F–2(c)(1)(B)) specified in the Proclama-  
24           tion.

1           “(2) COVERED INDIVIDUAL.—The term ‘cov-  
2           ered individual’ means an individual—

3                   “(A) who is a health care worker, law en-  
4                   forcement officer, firefighter, security per-  
5                   sonnel, emergency medical personnel, other  
6                   public health or safety personnel, or support  
7                   personnel for such occupational specialties;

8                   “(B) who is or will be functioning in a role  
9                   identified in a State, local, or Department of  
10                  Health and Human Services emergency re-  
11                  sponse plan approved by the Secretary;

12                  “(C) who has volunteered and been se-  
13                  lected to be a member of an emergency re-  
14                  sponse plan; and

15                  “(D) to whom a covered countermeasure is  
16                  administered pursuant to such approved plan  
17                  during the effective period of the Proclamation  
18                  and prior to the time at which the Secretary de-  
19                  clares a public health emergency pursuant to  
20                  section 319 related to a covered countermeasure  
21                  specified in the Proclamation.

22           “(3) COVERED INJURY.—The term ‘covered in-  
23           jury’ means an injury, disability, illness, condition,  
24           or death (other than a minor injury such as minor  
25           scarring or minor local reaction) determined by the

1 Secretary to have been sustained by a covered indi-  
2 vidual as the direct result of administration to the  
3 individual of a covered countermeasure.

4 “(4) EFFECTIVE PERIOD OF THE PROCLAMA-  
5 TION.—The term ‘effective period of the Proclama-  
6 tion’ means the effective period specified in the  
7 Proclamation, unless extended by the Secretary.

8 “(5) EMERGENCY RESPONSE PLAN.—The term  
9 ‘emergency response plan’ or ‘plan’ means a re-  
10 sponse plan detailing actions to be taken in prepara-  
11 tion for a pandemic, epidemic, or biological, chem-  
12 ical, nuclear agent or toxin that presents, or may  
13 present, a public health emergency.

14 “(6) PROCLAMATION.—The term ‘Proclama-  
15 tion’ means a Proclamation regarding the critical  
16 public health need for the administration of a cov-  
17 ered countermeasure issued by the Secretary and  
18 published in the Federal Register. Such Proclama-  
19 tion shall specify the specific covered counter-  
20 measure recommended for administration.

21 “(c) RULE OF CONSTRUCTION.—Nothing in this sec-  
22 tion shall be construed to require the creation of a com-  
23 pensation program if the covered injuries are only minor  
24 injuries consistent with section (b)(3).”.

1 **SEC. 8. REBATES AND GRANTS FOR RESEARCH DEVELOP-**  
2 **MENT, AND MANUFACTURING OF VACCINES,**  
3 **QUALIFIED COUNTERMEASURES AND PAN-**  
4 **DEMIC OR EPIDEMIC PRODUCTS.**

5 (a) IN GENERAL.—The Secretary of Health and  
6 Human Services (referred to in this section as the “Sec-  
7 retary”) may award to a person with respect to an invest-  
8 ment described in this section (or an amendment made  
9 by this section)—

10 (1) a rebate pursuant to subsection (b); or

11 (2) a grant pursuant to section 319M of the  
12 Public Health Service Act (as added by subsection  
13 (c)).

14 (b) SURGE CAPACITY AND RESEARCH REBATES.—

15 (1) IN GENERAL.—The Secretary may award  
16 rebates out of any money in the Treasury not other-  
17 wise appropriated to persons for the expansion of  
18 surge capacity for manufacturing vaccines, qualified  
19 countermeasures (as defined in 319F–1 of the Pub-  
20 lic Health Service Act, as amended by this Act) or  
21 qualified pandemic or epidemic products (as defined  
22 in 319F–3(c)(5) of such Act, as added by this Act)  
23 (referred to in this section as “vaccines, counter-  
24 measures or products”) and for vaccines, counter-  
25 measures, or products research.

1           (2) VACCINES, COUNTERMEASURES OR PROD-  
2           UCTS MANUFACTURING FACILITIES INVESTMENT RE-  
3           BATE.—

4           (A) IN GENERAL.—For purposes of this  
5           section, vaccines, countermeasures or products  
6           manufacturing facilities investment rebate for  
7           any taxable year for a person (as defined with  
8           respect to such person for purposes of the In-  
9           ternal Revenue Code of 1986) shall be an  
10          amount equal to 20 percent of the qualified in-  
11          vestment for such taxable year.

12          (B) VACCINES, COUNTERMEASURES OR  
13          PRODUCTS MANUFACTURING FACILITIES IN-  
14          VESTMENT.—For purposes of subparagraph  
15          (A), the qualified investment for any taxable  
16          year for a person is the basis of each vaccines,  
17          countermeasures or products manufacturing fa-  
18          cilities property placed in service by the person  
19          during the taxable year involved.

20          (C) VACCINES, COUNTERMEASURES AND  
21          PRODUCTS MANUFACTURING FACILITIES PROP-  
22          ERTY.—For purposes of this subsection, the  
23          term “vaccines, countermeasures and products  
24          manufacturing facilities property” means real  
25          and tangible personal property—

1 (i)(I) the original use of which com-  
2 mences with the person applying for the  
3 rebate; or

4 (II) which is acquired through pur-  
5 chase (as defined by section 179(d)(2) of  
6 the Internal Revenue Code of 1986);

7 (ii) which is depreciable under section  
8 167 of the Internal Revenue Code of 1986;

9 (iii) which is physically located in a  
10 State;

11 (iv) which is used for the manufac-  
12 ture, distribution, or research and develop-  
13 ment of vaccines, countermeasures, or  
14 products; and

15 (v) which is in compliance with appli-  
16 cable good manufacturing practice and  
17 with any other applicable requirements  
18 which are promulgated by the Secretary,  
19 the Occupational Safety and Health Ad-  
20 ministration, or the Environmental Protec-  
21 tion Agency, and which are applicable to  
22 such property.

23 (D) DENIAL OF DOUBLE BENEFIT FOR  
24 MANUFACTURING FACILITIES EXPENSES.—If  
25 any portion of the vaccines, countermeasures,

1 and products manufacturing facilities property  
2 investment expenses is otherwise allowable as a  
3 deduction for the taxable year involved, the Sec-  
4 retary shall only provide a rebate under this  
5 section for the portion of such expenses not cov-  
6 ered by the rebate determined by such deduc-  
7 tion.

8 (E) ELIGIBILITY.—To be eligible to receive  
9 a rebate under this subsection, a manufacturer  
10 shall submit to the Secretary an application at  
11 such time, in such manner, and containing such  
12 information as the Secretary may require, in-  
13 cluding—

14 (i) a detailed description and intended  
15 use of the facilities that is the basis of ap-  
16 plication;

17 (ii) a detailed description of the vac-  
18 cine, countermeasure, or product being  
19 produced or that may be produced at the  
20 facility;

21 (iii) a detailed accounting of qualified  
22 manufacturing facilities investment of the  
23 person;

1                   (iv) a certification as to the compli-  
2                   ance of the person with clauses (i) through  
3                   (iv) of subparagraph (C); and

4                   (v) copies of tax returns for the tax-  
5                   able year involved.

6                   (F) EFFECTIVE DATE.—This paragraph  
7                   shall apply to property placed in service after  
8                   December 31, 2005.

9                   (G) TERMINATION.—This paragraph shall  
10                  not apply to any property placed in service after  
11                  December 31, 2010.

12                  (3) MEDICAL RESEARCH RELATED TO DEVEL-  
13                  OPING VACCINES, COUNTERMEASURES OR QUALIFIED  
14                  PANDEMIC OR EPIDEMIC PRODUCTS REBATE.—

15                  (A) IN GENERAL.—For purposes of this  
16                  subsection, the research rebate determined  
17                  under this section for the taxable year involved  
18                  (as determined as provided for in paragraph  
19                  (2)(A)) is an amount equal to 35 percent of the  
20                  vaccines, qualified countermeasures, or qualified  
21                  pandemic or epidemic products (referred to in  
22                  this section as “vaccine, countermeasure, or  
23                  product”) research expenses for the taxable  
24                  year.

1           (B) VACCINES, COUNTERMEASURES, OR  
2           PRODUCTS RESEARCH EXPENSES.—Except as  
3           otherwise provided in this paragraph, the term  
4           “vaccines, countermeasures, or products re-  
5           search expenses” means the amounts which are  
6           paid or incurred by the researcher or manufac-  
7           turer during the taxable year with respect to  
8           any research and development of vaccines,  
9           countermeasures, or products. Qualified re-  
10          search and development expenses include ex-  
11          penses related to reformulating existing vac-  
12          cines, countermeasures, or products.

13          (C) DETERMINING RESEARCH EX-  
14          PENSES.—Any vaccines, countermeasures, or  
15          products research expenses for any taxable year  
16          which are qualified research expenses (within  
17          the meaning of this subsection) shall be taken  
18          into account in determining base period re-  
19          search expenses for purposes of applying this  
20          paragraph to subsequent taxable years.

21          (D) DENIAL OF DOUBLE BENEFIT FOR  
22          VACCINES, COUNTERMEASURES, OR PRODUCTS  
23          RESEARCH EXPENSES.—If any portion of the  
24          vaccines, countermeasures, or products research  
25          expenses is otherwise allowable as a deduction

1 for the taxable year involved, the Secretary  
2 shall only provide a rebate under this section  
3 for the portion of such expenses not covered by  
4 any rebate determined by such deduction.

5 (E) ELIGIBILITY.—To be eligible to receive  
6 a rebate under this paragraph, a manufacturer  
7 or researcher shall submit to the Secretary an  
8 application at such time, in such manner, and  
9 containing such information as the Secretary  
10 may require, including—

11 (i) a detailed description of the vac-  
12 cine, countermeasure, or product being re-  
13 searched or developed;

14 (ii) a detailed description of the re-  
15 search that is the subject of the rebate;

16 (iii) a detailed accounting of the quali-  
17 fied research expenses involved;

18 (iv) an assurance that the researcher  
19 or manufacturer is following good labora-  
20 tory practice, as required by the Secretary  
21 pursuant to the Federal Food, Drug, and  
22 Cosmetic Act (21 U.S.C. 301 et seq.) and  
23 the Public Health Service Act (42 U.S.C.  
24 201 et seq.); and

1 (v) copies of tax returns for the tax-  
2 able year involved.

3 (F) EFFECTIVE DATE.—This paragraph  
4 shall apply to expenses for taxable years begin-  
5 ning after December 31, 2005.

6 (4) EXCLUSION FOR AMOUNTS FUNDED BY  
7 GRANTS, ETC.—The terms “vaccines, counter-  
8 measures, or products manufacturing investment”  
9 and “qualified research expenses” shall not include  
10 any amount to the extent such amount is funded by  
11 any grant, contract, or otherwise funded by another  
12 person (or any governmental entity).

13 (c) GRANTS TO EXPAND AND IMPROVE RESEARCH  
14 AND DEVELOPMENT AND MANUFACTURING OF VACCINES,  
15 COUNTERMEASURES OR PRODUCTS.—Part B of title III  
16 of the Public Health Service Act is amended by inserting  
17 after section 319L, as added by this Act, the following:

18 **“SEC. 319M. GRANTS TO EXPAND AND IMPROVE RESEARCH**  
19 **AND DEVELOPMENT AND MANUFACTURING**  
20 **OF VACCINES, QUALIFIED COUNTER-**  
21 **MEASURES OR QUALIFIED PANDEMIC OR EPI-**  
22 **DEMIC PRODUCTS.**

23 “(a) IN GENERAL.—The Secretary may award grants  
24 to a manufacturer to purchase or improve real property  
25 and tangible personal property used in the research and

1 development, manufacture, or distribution of a vaccine,  
2 qualified countermeasure (as defined in section 319F-1)  
3 or qualified pandemic or epidemic product (as defined in  
4 section 319F-3(c)(5)).

5 “(b) ELIGIBILITY.—To be eligible to receive a grant  
6 under subsection (a), a manufacturer shall submit to the  
7 Secretary an application at such time, in such manner,  
8 and containing such information as the Secretary may re-  
9 quire, including—

10 “(1) a detailed description of the planned ex-  
11 pansion;

12 “(2) a detailed description of the equipment, fa-  
13 cility, or property involved;

14 “(3) a certification that such facility or prop-  
15 erty is physically located in a State;

16 “(4) a detailed description of the vaccine, quali-  
17 fied countermeasure or qualified pandemic or epi-  
18 demic product involved;

19 “(5) a detailed description of the research and  
20 development, manufacturer, or distribution involved;

21 “(6) a description of how such equipment, facil-  
22 ity, or property is to be used;

23 “(7) a description of whether such equipment,  
24 facility, or property can be used for the research and  
25 development, manufacture, or distribution of a drug,

1 biological product, device or other countermeasure  
2 not described in paragraph (4); and

3 “(8) a certification that the equipment, facility,  
4 or property involved complies with all applicable  
5 Federal, State, and local laws.

6 “(c) RECAPTURE.—

7 “(1) IN GENERAL.—If, at any time prior to the  
8 expiration of the 20-year period beginning on the  
9 date on which a grant is awarded under this section,  
10 the facility or property involved ceases to be used for  
11 the purpose for which the grant was awarded, the  
12 United States shall be entitled to recover from the  
13 manufacturer an amount bearing the same ratio to  
14 the value of the facility or property at such time as  
15 the amount of the grant bore to the total cost of the  
16 purchase or improvement involved. The value of the  
17 facility or property at such time may be determined  
18 by agreement of the manufacturer and the Sec-  
19 retary, or by order of the United States District  
20 Court for the district in which such facility or prop-  
21 erty is situated.

22 “(2) LIMITATION.—The Secretary may not re-  
23 capture the facility or property under this subsection  
24 if the Secretary determines, in accordance with regu-

1 lations promulgated by the Secretary, that there is  
2 good cause for the failure of proper use.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
4 is authorized to be appropriated such sums as may be nec-  
5 essary to carry out this section.”.

6 **SEC. 9. TECHNICAL ASSISTANCE.**

7 Subchapter E of chapter V of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is  
9 amended by adding at the end the following:

10 **“SEC. 565. TECHNICAL ASSISTANCE.**

11 “The Secretary, in consultation with the Commis-  
12 sioner of Food and Drugs, shall establish within the Food  
13 and Drug Administration a team of experts on manufac-  
14 turing and regulatory activities (including compliance with  
15 current Good Manufacturing Practices) to provide both  
16 off-site and on-site technical assistance to the manufactur-  
17 ers of qualified countermeasures (as defined in section  
18 319F–1 of the Public Health Service Act), security coun-  
19 termeasures (as defined in section 319F–2 of such Act),  
20 or vaccines, at the request of such a manufacturer and  
21 at the discretion of the Secretary, if the Secretary deter-  
22 mines that a shortage or potential shortage may occur in  
23 the United States in the supply of such vaccines or prod-  
24 ucts and that the provision of such assistance would be  
25 beneficial in helping alleviate or avert such shortage.”.

1 **SEC. 10. ANIMAL MODELS FOR CERTAIN DISEASES.**

2 Part B of title IV of the Public Health Service Act  
3 (42 U.S.C. 284 et seq.) is amended by adding at the end  
4 the following:

5 **“SEC. 409J. ANIMAL MODELS FOR CERTAIN DISEASES.**

6 “(a) IN GENERAL.—The Secretary, acting through  
7 the Director of NIH, in coordination with the Director of  
8 the Biomedical Advanced Research and Development  
9 Agency, the Director of the Centers for Disease Control  
10 and Prevention, and the Commissioner of Food and  
11 Drugs, shall establish and award grants under this section  
12 to eligible entities, including other Federal agencies, to  
13 study the physiological responses of certain animal species  
14 and, where appropriate, juvenile models, to chemical, bio-  
15 logical, radiological, or nuclear agents or toxins or poten-  
16 tial pandemic infectious disease, and to develop and vali-  
17 date such animal models.

18 “(b) ELIGIBILITY.—To be eligible to receive a grant  
19 under this section, an entity shall—

20 “(1) provide assurances to the Secretary that  
21 the entity—

22 “(A) has access to an appropriate biosafety  
23 laboratory or facility, as determined by the Sec-  
24 retary; and

25 “(B) will follow good laboratory practices;

1           “(2) submit to the Secretary an application at  
2 such time, in such manner, and containing such in-  
3 formation as the Secretary may require, including—

4                   “(A) a detailed description of the animal  
5 model involved;

6                   “(B) a detailed description of the chemical,  
7 biological, radiological, nuclear, or other infec-  
8 tious agents involved;

9                   “(C) a detailed description of how the ani-  
10 mal model will be used for the development of  
11 a drug, biological product, or device for use as  
12 a countermeasure;

13                   “(D) a detailed description of validation  
14 methods; and

15                   “(E) an assurance that the entity will fol-  
16 low good laboratory practices; and

17           “(3) agree to submit the results of the research  
18 funded under the grant to the Director of the Bio-  
19 medical Advanced Research and Development Agen-  
20 cy and the Director of NIH.

21           “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
22 are authorized to be appropriated such sums as may be  
23 necessary to carry out this section.”.

1 **SEC. 11. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC AD-**  
2 **VISORY COMMITTEE.**

3 Subchapter E of chapter V of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as  
5 amended by this Act, is amended by adding at the end  
6 the following:

7 **“SEC. 566. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC**  
8 **ADVISORY COMMITTEE.**

9 “(a) ESTABLISHMENT.—Not later than 6 months  
10 after the date of enactment of this section, the Secretary  
11 shall establish an 11-member advisory committee to be  
12 known as the ‘Animal Model/Research Tool Scientific Ad-  
13 visory Committee’ (referred to in this section as the ‘Advi-  
14 sory Committee’).

15 “(b) MEMBERSHIP.—

16 “(1) IN GENERAL.—The Secretary shall appoint  
17 as members of the Advisory Committee individuals  
18 who are technically qualified by training and experi-  
19 ence, including in medicine, veterinarian medicine,  
20 biology, technology involving the manufacture, eval-  
21 uation, or use of research tools, who are of appro-  
22 priately diversified professional backgrounds to  
23 evaluate the priority animal models and research  
24 tools.

25 “(2) EX OFFICIO MEMBERS.—The Secretary  
26 may appoint Federal officials, including at least 1

1 representative of the Biomedical Advanced Research  
2 and Development Agency, to serve as ex officio  
3 members of the Advisory Committee.

4 “(3) CHAIRPERSON.—The Secretary shall des-  
5 ignate 1 of the members of the Advisory Committee  
6 to serve as the chairperson.

7 “(c) DUTIES.—The Advisory Committee shall provide  
8 advice, information, and recommendations to the Sec-  
9 retary on—

10 “(1) accepted animal models for diseases and  
11 conditions associated with any biological (including  
12 organisms that cause infectious diseases), chemical,  
13 radiological, or nuclear agent or toxin or potential  
14 pandemic infectious disease;

15 “(2) strategies to accelerate animal model and  
16 research tool development and validation; and

17 “(3) scientific issues raised in applications as  
18 requested by the Secretary.

19 “(d) PRIORITIES.—Priorities for animal models and  
20 research tools shall be established by the Secretary.

21 “(e) COMPENSATION; SUPPORT; FACA.—

22 “(1) COMPENSATION AND TRAVEL.—Members  
23 of the Advisory Committee who are not officers or  
24 employees of the United States, while attending con-  
25 ferences or meetings of the committee or otherwise

1 engaged in its business, shall be entitled to receive  
2 compensation at rates to be fixed by the Secretary,  
3 which may not exceed daily equivalent of the rate in  
4 effect for level 4 of the Senior Executive Schedule  
5 under section 5382 of title 5, United States Code,  
6 for each day (including travel time) they are so en-  
7 gaged, and while so serving away from their homes  
8 or regular places of business each member may be  
9 allowed travel expenses, including per diem in lieu of  
10 subsistence, as authorized by section 5703 of title 5,  
11 United States Code, for persons in the Federal Gov-  
12 ernment service employed intermittently.

13 “(2) ADMINISTRATIVE SUPPORT.—The Sec-  
14 retary shall furnish the Advisory Committee clerical  
15 and other assistance.

16 “(3) NONAPPLICATION OF FACA.—Section 14 of  
17 the Federal Advisory Committee Act (5 U.S.C.  
18 App.) shall not apply to the Advisory Committee.

19 “(f) PROCEEDINGS.—The Advisory Committee shall  
20 make and maintain a transcript of any proceeding of the  
21 Committee. The Committee shall delete from any tran-  
22 script made under this subsection information, which is  
23 exempt from disclosure under section 552(b) of title 5,  
24 United States Code.”.

1 **SEC. 12. COLLABORATION AND COORDINATION.**

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

4 “(g) LIMITED ANTITRUST EXEMPTION.—

5 “(1) SECURITY COUNTERMEASURES, QUALIFIED  
6 COUNTERMEASURES AND QUALIFIED PANDEMIC OR  
7 EPIDEMIC PRODUCT DEVELOPMENT MEETINGS.—

8 “(A) COUNTERMEASURES AND PRODUCTS  
9 DEVELOPMENT MEETINGS AND CONSULTA-  
10 TIONS.—The Secretary of Health and Human  
11 Services (referred to in this subsection as the  
12 ‘Secretary’) or the Director of the Biomedical  
13 Advanced Research and Development Agency  
14 (referred to in this subsection as the ‘Director’),  
15 in coordination with the Attorney General and  
16 the Secretary of Homeland Security, may con-  
17 duct meetings and consultations with parties in-  
18 volved in the development of security counter-  
19 measures (as defined in section 319F–2 of the  
20 Public Health Service Act) qualified counter-  
21 measures (as defined in section 319F–1 of the  
22 Public Health Service Act) or qualified pan-  
23 demic or epidemic products (as defined in sec-  
24 tion 319F–3(c)(5) of the Public Health Service  
25 Act) (referred to in this section as “counter-  
26 measures or products”) for the purpose of the

1 development, manufacture, distribution, pur-  
2 chase, sale, or storage of countermeasures or  
3 products consistent with the purposes of this  
4 title. The Secretary or Director may convene  
5 such meeting or consultation at the request of  
6 any person, the Secretary of Homeland Secu-  
7 rity, the Attorney General, the Chairperson of  
8 the Federal Trade Commission, an industry  
9 representative or member, or upon initiation by  
10 such Secretary. The Secretary or Director shall  
11 give notice of such meetings and consultations  
12 to the Chairperson of the Federal Trade Com-  
13 mission (referred to in this subsection as the  
14 ‘Chairperson’) and the Attorney General.

15 “(B) MEETING AND CONSULTATION CON-  
16 DITIONS.—A meeting or consultation conducted  
17 under subparagraph (A) shall—

18 “(i) be chaired or, in the case of a  
19 consultation, facilitated by the Secretary or  
20 Director;

21 “(ii) be open to parties involved in the  
22 development, manufacture, distribution,  
23 purchase, or sale of countermeasures or  
24 products, as determined by the Secretary  
25 or Director;

1                   “(iii) be open to the Attorney General,  
2                   the Secretary of Homeland Security, and  
3                   the Chairperson;

4                   “(iv) be limited to discussions involv-  
5                   ing the development, manufacture, dis-  
6                   tribution, or sale of countermeasures or  
7                   products, consistent with the purposes of  
8                   this title; and

9                   “(v) be conducted in such manner as  
10                  to ensure that national security, confiden-  
11                  tial, and proprietary information is not dis-  
12                  closed outside the meeting or consultation.

13                  “(C) LIMITATION.—The Secretary or Di-  
14                  rector may not require the disclosure of con-  
15                  fidential commercial or proprietary information.

16                  “(D) MINUTES.—The Secretary or Direc-  
17                  tor shall maintain minutes of meetings and con-  
18                  sultations under this subsection, which shall not  
19                  be disclosed under section 552 of title 5, United  
20                  States Code, unless such Secretary or Director,  
21                  in consultation with the Attorney General, de-  
22                  termines that disclosure would pose no threat to  
23                  national security. Such determination shall not  
24                  be subject to judicial review.

25                  “(E) EXEMPTION.—

1                   “(i) IN GENERAL.—The antitrust laws  
2                   shall not apply to meetings and consulta-  
3                   tions under this paragraph.

4                   “(ii) LIMITATION.—Clause (i) shall  
5                   not apply to any agreement or conduct  
6                   that results from a meeting or consultation  
7                   and that does not receive an exemption  
8                   pursuant to this subsection.

9                   “(2) WRITTEN AGREEMENTS.—The Secretary  
10                  or the Director shall file a written agreement regard-  
11                  ing covered activities, made pursuant to meetings or  
12                  consultations conducted under paragraph (1) and  
13                  that is consistent with this paragraph, with the At-  
14                  torney General and the Chairperson for a determina-  
15                  tion of the compliance of such agreement with anti-  
16                  trust laws. In addition to the proposed agreement  
17                  itself, any such filing shall include—

18                         “(A) an explanation of the intended pur-  
19                         pose of the agreement;

20                         “(B) a specific statement of the substance  
21                         of the agreement;

22                         “(C) a description of the methods that will  
23                         be utilized to achieve the objectives of the  
24                         agreement;

1           “(D) an explanation of the necessity of a  
2 cooperative effort among the particular partici-  
3 pating parties to achieve the objectives of the  
4 agreement; and

5           “(E) any other relevant information deter-  
6 mined necessary by the Secretary or Director in  
7 consultation with the Attorney General and the  
8 Chairperson.

9           “(3) DETERMINATION.—The Attorney General,  
10 in consultation with the Chairperson, shall determine  
11 whether an agreement regarding covered activities  
12 referred to in paragraph (2) would likely—

13           “(A) be in compliance with the antitrust  
14 laws, and so inform the Secretary or Director  
15 and the participating parties; or

16           “(B) violate the antitrust laws, in which  
17 case, the filing shall be deemed to be a request  
18 for an exemption from the antitrust laws, lim-  
19 ited to the performance of the agreement con-  
20 sistent with the purposes of this title.

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

22           “(A) IN GENERAL.—The Attorney General,  
23 in consultation with the Chairperson, shall  
24 grant, deny, grant in part and deny in part, or  
25 propose modifications to a request for exemp-

1           tion from the antitrust laws under paragraph  
2           (3) within 15 business days of the receipt of  
3           such request.

4           “(B) EXTENSION.—The Attorney General  
5           may extend the 15-day period referred to in  
6           subparagraph (A) for an additional period of  
7           not to exceed 10 days. Such additional period  
8           may be further extended only by the United  
9           States district court, upon an application by the  
10          Attorney General after notice to the Secretary  
11          or Director and the parties involved.

12          “(C) DETERMINATION.—In granting an  
13          exemption under this paragraph, the Attorney  
14          General, in consultation with the Chairperson  
15          and the Secretary or Director—

16                 “(i) shall find—

17                         “(I) that the agreement involved  
18                         is necessary to ensure the availability  
19                         of countermeasures or products;

20                         “(II) that the exemption from  
21                         the antitrust laws would promote the  
22                         public interest; and

23                         “(III) that there is no substantial  
24                         competitive impact to areas not di-

1                   rectly related to the purposes of the  
2                   agreement; and

3                   “(ii) may consider any other factors  
4                   determined relevant by the Attorney Gen-  
5                   eral and the Chairperson.

6                   “(5) LIMITATION ON AND RENEWAL OF EXEMP-  
7                   TIONS.—An exemption granted under paragraph (4)  
8                   shall be limited to covered activities, and shall be re-  
9                   newed (with modifications, as appropriate) on the  
10                  date that is 3 years after the date on which the ex-  
11                  emption becomes effective (and at 3-year intervals  
12                  thereafter, if renewed) unless the Attorney General  
13                  in consultation with the Chairperson determines that  
14                  the exemption should not be renewed (with modifica-  
15                  tions, as appropriate) considering the factors de-  
16                  scribed in paragraph (4).

17                  “(6) LIMITATION ON PARTIES.—The use of any  
18                  information acquired under an exempted agreement  
19                  by the parties to such an agreement for any pur-  
20                  poses other than those specified in the antitrust ex-  
21                  emption granted by the Attorney General shall be  
22                  subject to the antitrust laws and any other applica-  
23                  ble laws.

1           “(7) GUIDELINES.—The Attorney General and  
2 the Chairperson may develop and issue guidelines to  
3 implement this subsection.

4           “(8) REPORT.—Not later than 1 year after the  
5 date of enactment of the Biodefense and Pandemic  
6 Vaccine and Drug Development Act of 2005, and  
7 annually thereafter, the Attorney General and the  
8 Chairperson shall report to Congress on the use and  
9 continuing need for the exemption from the antitrust  
10 laws provided by this subsection.

11           “(9) STATUS OF MEMORANDUMS.—Minutes  
12 maintained by the Secretary or Director pursuant to  
13 paragraph (1)(D) shall not be disclosed under sec-  
14 tion 552 of title 5, United States Code, if the ex-  
15 emption is not renewed under paragraph (5), or if  
16 meetings are no longer conducted, unless the Sec-  
17 retary or Director, in consultation with the Attorney  
18 General, determines that the disclosure would pose  
19 no threat to national security. Such determination  
20 shall not be subject to judicial review.

21           “(h) SUNSET.—The authority of the Attorney Gen-  
22 eral to grant or renew a limited antitrust exemption under  
23 this section shall expire at the end of the 6-year period  
24 that begins on the date of enactment of the Biodefense

1 and Pandemic Vaccine and Drug Development Act of  
2 2005.

3 “(i) DEFINITIONS.—In this section:

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

6 “(A) has the meaning given such term in  
7 subsection (a) of the first section of this Act,  
8 except that such term includes the Act of June  
9 19, 1936 (15 U.S.C. 13 et seq.) (commonly  
10 known as the Robinson-Patman Act), and sec-  
11 tion 5 of the Federal Trade Commission Act  
12 (15 U.S.C. 45) to the extent such section 5 ap-  
13 plies to unfair methods of competition; and

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

16 “(2) COVERED ACTIVITIES.—

17 “(A) IN GENERAL.—Except as provided in  
18 subparagraph (B), the term ‘covered activities’  
19 means any group of activities or conduct, in-  
20 cluding attempting to make, making, or per-  
21 forming a contract or agreement or engaging in  
22 other conduct, for the purpose of—

23 “(i) theoretical analysis, experimen-  
24 tation, or the systematic study of phe-  
25 nomena or observable facts necessary to

1 the development of countermeasures or  
2 products;

3 “(ii) the development or testing of  
4 basic engineering techniques necessary to  
5 the development of countermeasures or  
6 products;

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

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

19 “(v) the testing in connection with the  
20 production of a product, process, or serv-  
21 ices necessary to the development of coun-  
22 termeasures or products;

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

1                   tion necessary to the development of coun-  
2                   termeasures or products; or

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

5                   and such term may include the establishment  
6                   and operation of facilities for the conduct of  
7                   covered activities described in clauses (i)  
8                   through (vi), the conduct of such covered activi-  
9                   ties on a protracted and proprietary basis, and  
10                  the processing of applications for patents and  
11                  the granting of licenses for the results of such  
12                  covered activities.

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

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

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

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

1 tions, developments, products, pro-  
2 cesses, or services not developed  
3 through, produced by, or distributed  
4 or sold through such covered activi-  
5 ties; or

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

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

22 “(iv) Exchanging information among  
23 competitors relating to production (other  
24 than production by such covered activities)  
25 of a product, process, or service if such in-

1 formation is not reasonably necessary to  
2 carry out the purpose of such covered ac-  
3 tivities.

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

11 “(vi) Except as otherwise provided in  
12 this subsection, entering into any agree-  
13 ment or engaging in any other conduct to  
14 restrict or require participation by any per-  
15 son who is a party to such activities, in  
16 any unilateral or joint activity that is not  
17 reasonably necessary to carry out the pur-  
18 pose of such covered activities.

19 “(vii) Entering into any agreement or  
20 engaging in any other conduct restricting  
21 or setting the price at which a product is  
22 offered for sale, whether by bid or other-  
23 wise.

24 “(3) DEVELOPMENT.—The term ‘development’  
25 includes the identification of suitable compounds or

1 biological materials, the conduct of preclinical and  
2 clinical studies, the preparation of an application for  
3 marketing approval, and any other actions related to  
4 preparation of a countermeasure or product.”.

5 **SEC. 13. PROCUREMENT.**

6 Section 319F–2 of the Public Health Service Act (42  
7 U.S.C. 247d–6b) is amended—

8 (1) in the section heading, by inserting “**AND**  
9 **SECURITY COUNTERMEASURE PROCURE-**  
10 **MENTS**” before the period; and

11 (2) in subsection (c)—

12 (A) in the subsection heading, by striking  
13 “BIOMEDICAL”;

14 (B) in paragraph (5)(B)(i), by striking “to  
15 meet the needs of the stockpile” and inserting  
16 “to meet the stockpile needs”;

17 (C) in paragraph (7)(C)(ii)—

18 (i) by amending clause (I) to read as  
19 follows:

20 “(I) PAYMENT CONDITIONED ON  
21 DELIVERY.—The contract shall pro-  
22 vide that no payment may be made  
23 until delivery of a portion, acceptable  
24 to the Secretary, of the total number  
25 of units contracted for, except that,

1                   notwithstanding any other provision of  
2                   law, the contract may provide that, if  
3                   the Secretary determines (as the Sec-  
4                   retary's discretion) that an advance  
5                   payment, partial payment for signifi-  
6                   cant milestones, or payment to in-  
7                   crease manufacturing capacity is nec-  
8                   essary to ensure success of a project,  
9                   the Secretary shall pay an amount,  
10                  not to exceed 10 percent of the con-  
11                  tract amount, in advance of delivery.  
12                  The contract shall provide that such  
13                  advance payment is required to be re-  
14                  paid if there is a failure to perform by  
15                  the vendor under the contract. The  
16                  contract may also provide for up to 3  
17                  additional advance payments of 5 per-  
18                  cent each for meeting the milestones  
19                  specified in such contract. Provided  
20                  that the specified milestones are  
21                  reached, these advanced payments of  
22                  5 percent shall not be required to be  
23                  repaid. Nothing in this subclause shall  
24                  be construed as affecting the rights of  
25                  vendors under provisions of law or

1 regulation (including the Federal Ac-  
2 quisition Regulation) relating to the  
3 termination of contracts for the con-  
4 venience of the Government.”; and

5 (ii) by adding at the end the fol-  
6 lowing:

7 “(VII) SALES EXCLUSIVITY.—

8 The contract may provide that the  
9 vendor is the sole and exclusive sup-  
10 plier of the product to the Federal  
11 Government for a specified period of  
12 time, not to exceed 15 years, on the  
13 condition that the vendor is able to  
14 satisfy the needs of the Government.  
15 During the agreed period of sales ex-  
16 clusivity, the vendor shall not assign  
17 its rights of sales exclusivity to an-  
18 other entity or entities without ap-  
19 proval by the Secretary.

20 “(VIII) SURGE CAPACITY.—The

21 contract may provide that the vendor  
22 establish domestic manufacturing ca-  
23 pacity of the product to ensure that  
24 additional production of the product is  
25 available in the event that the Sec-

1           retary determines that there is a need  
2           to quickly purchase additional quan-  
3           tities of the product. Such contract  
4           may provide a fee to the vendor for  
5           establishing and maintaining such ca-  
6           pacity in excess of the initial require-  
7           ment for the purchase of the product.  
8           Additionally, the cost of maintaining  
9           the domestic manufacturing capacity  
10          shall be an allowable and allocable di-  
11          rect cost of the contract.

12                   “(IX) CONTRACT TERMS.—The  
13          Secretary, in any contract for procure-  
14          ment under this section, may speci-  
15          fy—

16                           “(aa) the dosing and admin-  
17                           istration requirements for coun-  
18                           termeasures to be developed and  
19                           procured;

20                           “(bb) the amount of funding  
21                           that will be dedicated by the Sec-  
22                           retary for research and develop-  
23                           ment of the countermeasure; and

24                           “(cc) the specifications the  
25                           countermeasure must meet to

1                   qualify for procurement under a  
2                   contract under this section.”; and

3                   (D) in paragraph (8)(A), by adding at the  
4                   end the following: “Such agreements may allow  
5                   other executive agencies to order qualified and  
6                   security countermeasures under procurement  
7                   contracts or other agreements established by  
8                   the Secretary. Such ordering process (including  
9                   transfers of appropriated funds between an  
10                  agency and the Department of Health and  
11                  Human Services as reimbursements for such or-  
12                  ders for countermeasures) may be conducted  
13                  under the authority of section 1535 of title 31,  
14                  United States Code, except that all such orders  
15                  shall be processed under the terms established  
16                  under the Biodefense and Pandemic Vaccine  
17                  and Drug Development Act of 2005 and the  
18                  Project BioShield Act of 2004, for the procure-  
19                  ment of countermeasures under section 319F-  
20                  1 or 319F-2.”

21 **SEC. 14. NATIONAL PATHOLOGY CENTER.**

22                  (a) IN GENERAL.—Title IV of the Public Health  
23                  Service Act (42 U.S.C. 281 et seq.) is amended—

24                         (1) in section 401(b)(2), by adding at the end  
25                         the following:



1       “(b) ACTIVITIES OF THE DIRECTOR.—In order to  
2 carry out the purposes of the Center described in sub-  
3 section (a), the Director of the Center—

4           “(1) shall—

5               “(A) maintain and improve a comprehen-  
6 sive repository of pathological specimens;

7               “(B) provide consultations on request re-  
8 garding clinical cases;

9               “(C) conduct educational programs and  
10 publish educational materials on the science  
11 and clinical practice of pathology;

12               “(D) maintain and improve registries on  
13 such clinical conditions as the Director of the  
14 Center determines appropriate; and

15               “(E) conduct and support research on pa-  
16 thology; and

17           “(2) may—

18               “(A) collect reasonable and appropriate  
19 fees for the activities described in paragraph  
20 (1)(B); and

21               “(B) conduct such other activities as the  
22 Director of the Center determines appropriate  
23 to carry out the purposes described in sub-  
24 section (a).

1       “(c) AUTHORITY FOR EXPERT OPINIONS.—The Di-  
2       rector of the Center may enter into memoranda of under-  
3       standing with officials at the Department of Veterans Af-  
4       fairs and the Department of Defense to provide expert sec-  
5       ond opinion pathology consultations and pathology edu-  
6       cation or training if the Secretary of either such Depart-  
7       ment determines that such provision would be in the best  
8       interest of either of their respective departments.

9       **“SEC. 485C. BOARD OF REGENTS.**

10       “(a) MEMBERSHIP.—

11               “(1) IN GENERAL.—There is established a  
12       Board of Regents of the Center (in this subpart re-  
13       ferred to as the ‘Board’) consisting of—

14                       “(A) the Surgeons General of—

15                               “(i) the Public Health Service;

16                               “(ii) the Army;

17                               “(iii) the Navy; and

18                               “(iv) the Air Force;

19                       “(B) the Chief Medical Director of the De-  
20       partment of Medicine and Surgery of the De-  
21       partment of Veterans Affairs;

22                       “(C) the Deputy Director of the National  
23       Library of Medicine;

24                       “(D) the Assistant Secretary of Health of  
25       the Department of Defense;

1           “(E) the Dean of the Uniformed Services  
2           University of the Health Sciences; and

3           “(F) 11 members to be appointed by the  
4           Secretary from among leaders in pathology re-  
5           search, education and clinical practice.

6           “(2) EX OFFICIO MEMBERS.—The members of  
7           the Board described in subparagraphs (A) through  
8           (E) of paragraph (1) shall serve as ex officio mem-  
9           bers of the Board.

10          “(3) CHAIRPERSON.—The members of the  
11          Board appointed under paragraph (1)(F) shall an-  
12          nually elect one of such members to serve as the  
13          Chairperson of the Board until the next election.

14          “(b) DUTIES OF THE BOARD.—It shall be the duty  
15          of the Board to advise, consult with, and make rec-  
16          ommendations to the Director of NIH on important mat-  
17          ters of policy in regard to the Center, including such mat-  
18          ters as the scope, content and organization of the research,  
19          education and consultative services provided by the Cen-  
20          ter. The Board shall make recommendations to the Direc-  
21          tor of NIH regarding the rules under which specimens  
22          from the tissue repository will be used and under which  
23          it’s publications, facilities and services will be made avail-  
24          able to various kinds of users.

1           “(c) TERMS OF OFFICE.—Each appointed member of  
2 the Board shall hold office for a term of 4 years, except  
3 that any member appointed to fill a vacancy occurring  
4 prior to the expiration of the term for which the prede-  
5 cessor of such member was appointed shall be appointed  
6 for the remainder of such term. None of the appointed  
7 members shall be eligible for reappointment within 1 year  
8 after the end of the preceding term of such member.

9           “(d) COMPENSATION.—Appointed members of the  
10 Board who are not otherwise in the employ of the United  
11 States, while attending conferences of the Board or other-  
12 wise serving at the request of the Secretary in connection  
13 with the administration of the Board, shall be entitled to  
14 receive compensation, per diem in lieu of subsistence, and  
15 travel expenses in the same manner and under the same  
16 conditions as that prescribed under section 208(c).

17 **“SEC. 485D. GIFTS TO THE CENTER.**

18           “Section 231 shall be applicable to the acceptance  
19 and administration of gifts made for the benefit of the  
20 Center or for carrying out any of its functions.

21 **“SEC. 485E. CENTER FACILITIES.**

22           “There are authorized to be appropriated amounts  
23 sufficient for the erection and equipment of suitable and  
24 adequate buildings and facilities for use of the Center. The  
25 Administrator of General Services may acquire, by pur-

1 chase, condemnation, donation, or otherwise, a suitable  
2 site or sites, selected by the Secretary in accordance with  
3 the direction of the Board, for such buildings and facilities  
4 and to erect thereon, furnish, and equip such buildings  
5 and facilities. The amounts authorized to be appropriated  
6 by this section include the cost of preparation of drawings  
7 and specifications, supervision of construction, and other  
8 administrative expenses incident to the work. The Admin-  
9 istrator of General Services shall prepare the plans and  
10 specifications, make all necessary contracts, and supervise  
11 construction.”.

12 (b) REPORT.—Not later than 12 months after the  
13 date of enactment of this Act, the Secretary of Health and  
14 Human Services shall submit a report to the appropriate  
15 committees of Congress that contains—

16 (1) a review of all functions and duties of the  
17 National Pathology Center under subpart 7 of part  
18 E of title IV of the Public Health Service Act, as es-  
19 tablished by subsection (a);

20 (2) areas where such functions and duties over-  
21 lap with the functions and duties of the National In-  
22 stitutes of Health; and

23 (3) recommendations concerning necessary  
24 modifications to the National Pathology Center.

1           (c) TRANSFER OF THE ARMED FORCES INSTITUTE  
2 OF PATHOLOGY.—

3           (1) IN GENERAL.—

4                   (A) IN GENERAL.—Except as provided in  
5 subparagraph (B), there are transferred to the  
6 National Pathology Center established under  
7 subpart 7 of part E of title IV of the Public  
8 Health Service Act all functions, duties, per-  
9 sonnel, assets, liabilities, contracts, property,  
10 records, and unexpended balances of appropria-  
11 tions of the Armed Forces Institute of Pathol-  
12 ogy. The preceding sentence shall not affect any  
13 proceedings, pending applications, suits, or  
14 other actions pending on the date of enactment  
15 of this Act.

16                   (B) EXCEPTIONS.—The following compo-  
17 nents of the Armed Forces Institute of Pathol-  
18 ogy shall not be transferred from the Depart-  
19 ment of Defense pursuant to subparagraph (A):

20                           (i) The Armed Forces Medical Exam-  
21 iner.

22                           (ii) The Department of Defense DNA  
23 registry.

24                           (iii) Accident Investigation Program.

1 (iv) The histopathology training pro-  
2 gram.

3 (v) The patient safety center.

4 (vi) Department of Legal Medicine.

5 (vii) Center for Clinical Laboratory  
6 Medicine.

7 (viii) Drug Testing and Quality As-  
8 surance Program.

9 (ix) Subject to the discretion of the  
10 Secretary of Defense, medical research  
11 programs on the following:

12 (I) Body armor.

13 (II) Environmental sarcoidosis.

14 (III) Depleted uranium.

15 (IV) Military working dogs.

16 (V) Such other areas of research  
17 related to pathology as the Secretary  
18 of Defense shall choose to conduct.

19 (2) REFERENCES.—Any reference in any Fed-  
20 eral law, Executive order, rule, regulation, or delega-  
21 tion of authority, or any document of or relating to  
22 the Armed Forces Institute of Pathology shall be  
23 deemed to be a reference to the National Pathology

- 1 Center established under subpart 7 of part E of title
- 2 IV of the Public Health Service Act.

○