

Calendar No. 257

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.

IN THE SENATE OF THE UNITED STATES

OCTOBER 17, 2005

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

OCTOBER 24, 2005

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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”.*

1 SEC. 2. TABLE OF CONTENTS.

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

- See. 1. Short title.
- See. 2. Table of contents.
- See. 3. Biomedical Advanced Research and Development Agency.
- See. 4. Clarification of countermeasures covered by Project BioShield.
- See. 5. Orphan drug market exclusivity for countermeasure products.
- See. 6. Liability protections for pandemics, epidemics, and countermeasures.
- See. 7. Compensation.
- See. 8. Rebates and grants for research development, and manufacturing of vaccines, qualified countermeasures and pandemic or epidemic products.
- See. 9. Technical assistance.
- See. 10. Animal models for certain diseases.
- See. 11. Animal Model/Research Tool Scientific Advisory Committee.
- See. 12. Collaboration and coordination.
- See. 13. Procurement.
- See. 14. National Pathology Center.

3 SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AGENCY.

4 MENT AGENCY.

5 Title III of the Public Health Service Act (42 U.S.C.

6 241 et seq.) is amended by inserting after section 319K

7 the following:

8 “SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AGENCY.

9 **“(a) DEFINITIONS.—In this section:**

10 **“(1) BARDA.—The term ‘BARDA’ means the**

11 **Biomedical Advanced Research and Development**

12 **Agency.**

13 **“(2) FUND.—The term ‘Fund’ means the Bio-**

14 **defense Medical Countermeasure Development Fund**

15 **established under subsection (d).**

16 **“(3) OTHER TRANSACTIONS.—The term ‘other**

17 **transactions’ means transactions, other than pro-**

1 eurement contracts, grants, and cooperative agree-
2 ments, including transactions for prototypes, as pro-
3 vided to the Secretary of Defense under section
4 2371 of title 10, United States Code.

5 “(4) QUALIFIED COUNTERMEASURE.—The term
6 ‘qualified countermeasure’ has the meaning given
7 such term in section 319F-1.

8 “(5) QUALIFIED COUNTERMEASURE AND
9 QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT AD-
10 VANCED RESEARCH AND DEVELOPMENT.—

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

1 posure resulting from an act of terrorism or po-
2 tential pandemic infectious disease.

3 “(B) INCLUSION.—The term under sub-
4 paragraph (A) includes any investigation to im-
5 prove the manufacturing, formulation, finish,
6 fill, delivery, or shelf-life of such qualified coun-
7 termeasures or qualified pandemic or epidemic
8 products.

9 “(6) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
10 UCT.—The term ‘qualified pandemic or epidemic
11 product’ has the meaning given the term in section
12 319F 3(e)(5).

13 “(7) SECURITY COUNTERMEASURE.—The term
14 ‘security countermeasure’ has the meaning given
15 such term in section 319F-2.

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

20 "(b) BIOMEDICAL ADVANCED RESEARCH AND DE-
21 VELOPMENT AGENCY.—

22 “(1) ESTABLISHMENT.—There is established
23 within the Department of Health and Human Serv-
24 ices, the Biomedical Advanced Research and Devel-
25 opment Agency.

1 “(2) PURPOSE.—It shall be the purpose of the
2 BARDA to coordinate and oversee activities that
3 support and accelerate qualified countermeasure or
4 qualified pandemic or epidemic product (referred to
5 in this section as ‘countermeasure or product’) ad-
6 vanced research and development by—

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

13 “(B) supporting countermeasure and prod-
14 uct advanced research and development;

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

21 “(D) supporting innovation to reduce the
22 time and cost of countermeasure and product
23 advanced research and development.

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

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

6 “(B) report to the Secretary; and

7 “(C) serve as the principal advisor to the
8 Secretary on countermeasure and product ad-
9 vanced research and development.

10 “(4) DUTIES OF DIRECTOR.—

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

14 “(i) increase appropriate communica-
15 tion between the Federal Government and
16 relevant industries, academia, and other
17 interested persons with respect to counter-
18 measure and product advanced research
19 and development by establishing trans-
20 parent, expeditious, and direct processes
21 to—

22 “(I) facilitate regular, ongoing
23 communication regarding the pro-
24 cesses established under subparagraph

1 (C)(ii) and new countermeasures or
2 products of interest;

3 “(II) solicit research and associated
4 data on potential counter-
5 measures and products and related
6 technologies; and

7 “(III) provide technical assistance with respect to such processes
8 and the Food and Drug Administra-
9 tion approval process;

10 “(ii) at least annually—

11 “(I) convene meetings with rep-
12 resentatives from relevant industries,
13 academia, other Federal agencies,
14 international agencies, and other in-
15 terested persons; and

16 “(II) sponsor relevant biodefense
17 countermeasure technology dem-
18 onstrations;

19 “(iii) carry out the activities described
20 in subsection (g) of section 2 of the Clay-
21 ton Act; and

22 “(iv) encourage and coordinate coun-
23 termeasure or product advanced research
24 and development, including by convening

1 working groups as identified in paragraph
2 (5).

3 ~~“(B) SUPPORT ADVANCED RESEARCH AND~~
4 ~~DEVELOPMENT.—To carry out the purpose de-~~
5 ~~scribed in paragraph (2)(B), the Secretary, act-~~
6 ~~ing through the Director, shall—~~

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

19 “(ii) direct the countermeasure and
20 product advanced research and develop-
21 ment activities of the Department of
22 Health and Human Services, in consulta-
23 tion with the Assistant Secretary for Pub-
24 lie Health Emergency Preparedness, the
25 Director of the National Institutes of

Health, the Director of the Centers for the Disease Control and Prevention, and the Commissioner of Food and Drugs; and

“(iii) award contracts, grants, cooperative agreements, and enter into other transactions, to include use of simplified acquisition authorities provided under sections 319F-1 and 319F-2(e)(7)(C)(iii), to public and private persons, including for-profit and nonprofit persons, federally funded research and development centers, and universities, to—

"(I) support the cost of counter-measure and product advanced research and development; and

“(H) ensure accelerated development of countermeasures and products.

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

“(i) receive from the Assistant Secretary for Public Health Emergency Preparedness, requirements for national civil-

1 ian biodefense needs, particularly counter-
2 measures or products and other tech-
3 nologies, to diagnose, mitigate, prevent, or
4 treat harm from existing, emerging, or po-
5 tential chemical, biological, radiological, or
6 nuclear agents or potential pandemic infec-
7 tious diseases;

8 “(ii) establish transparent, expedi-
9 tious, and direct processes for selecting
10 promising countermeasures and products,
11 supporting them through advanced re-
12 search and development and recommending
13 them for procurement;

14 “(iii) establish an office within the
15 BARDA, in consultation with the Commis-
16 sioner of Food and Drugs, to—

17 “(I) facilitate regular and ongo-
18 ing communication between the
19 BARDA and the Food and Drug Ad-
20 ministration regarding the status of
21 BARDA advanced research and devel-
22 opment activities;

23 “(II) ensure that such activities
24 are coordinated with the approval re-
25 quirements of the Food and Drug Ad-

1 ministration, with the goal of expediting the development and approval
2 of countermeasures and products; and
3

4 “(III) connect interested persons
5 with additional technical assistance
6 made available under section 565 of
7 the Federal Food, Drug, and Cosmetic Act;
8

9 “(iv) coordinate with the Food and
10 Drug Administration to facilitate regulatory review and approval of promising
11 classes of countermeasures or products
12 through the development of research tools;
13 and
14

15 “(v) recommend to the Secretary,
16 through the Assistant Secretary for Public
17 Health Emergency Preparedness, procurement
18 of the most promising eligible security
19 countermeasures or qualified pandemic
20 or epidemic products identified in clause
21 (i).

22 **“(D) SUPPORTING INNOVATION.—**To carry
23 out the purpose described in paragraph (2)(D),
24 the Secretary, acting through the Director,
25 shall award contracts, grants, cooperative

1 agreements, or enter into other transactions, to
2 include use of simplified acquisition authorities
3 provided under sections ~~319F-1~~ and ~~319F-~~
4 ~~2(e)(7)(C)(iii)~~, to the entities described in sub-
5 paragraph (B)(iii), to promote innovation in
6 technologies supporting the advanced research
7 and development and production of qualified or
8 security countermeasures or qualified pandemic
9 or epidemic products, such as research tools,
10 manufacturing, countermeasure administration,
11 storage, and bioinformatics and other devices.

12 “(E) OTHER DUTIES.—

13 “(i) IN GENERAL.—The Director
14 may—

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

23 “(II) receive from the President
24 and the Office of Management and
25 Budget directly all funds appropriated

1 by Congress for obligation and ex-
2 penditure by the BARDA.

3 "(ii) SECRETARY DUTIES.—The See-
4 retary, acting through the Director, may—

5 “(I) enter into such contracts,
6 leases, cooperative agreements, or
7 other transactions, as may be nee-
8 cessary to carry out the functions of
9 BARDA, without regard to section
10 3648 and 3709 of the Revised Stat-
11 utes of the United States (31 U.S.C.
12 3324(a) and (b)), (41 U.S.C. 5), with
13 any public agency, any firm, associa-
14 tion, corporation, or educational insti-
15 tution, or any other person;

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

1 “(III) administer grants using
2 milestone-based awards and pay-
3 ments; and

4 “(IV) establish 1 or more feder-
5 ally funded research and development
6 centers or university affiliated re-
7 search centers in accordance with sec-
8 tion 253(e)(3) of title 41, United
9 States Code.

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

19 “(6) WORKING GROUPS.—

20 “(A) IDENTIFICATION OF TECHNOLOGIES.—

21 “(i) IN GENERAL.—The Director may
22 establish and convene, or enter into a con-
23 tract with a public or private research in-
24 stitution to convene, one or more working

1 groups that consists of experts on counter-
2 measure technology to identify innovative
3 technologies that have the potential to be
4 developed as countermeasures or products.

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

10 “(I) review the scientific evidence
11 or concept of such countermeasures,
12 products, or related technologies;

13 “(II) provide guidance on re-
14 search protocols or studies; and

15 “(III) provide guidance on the
16 regulatory approval process for coun-
17 termeasures, products, and related
18 technologies.

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

1 “(iv) CONFIDENTIALITY.—Any com-
2 mercial confidential or proprietary infor-
3 mation that is disclosed to the working
4 group in a meeting under this section shall
5 remain confidential and shall not be dis-
6 closed other than to the Secretary or the
7 Director, or their designees.

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

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

20 “(C) VULNERABLE POPULATIONS WORK-
21 ING GROUP.—The Director shall establish and
22 convene a Vulnerable Populations Working
23 Group composed of experts on pediatric popu-
24 lations, pregnant women, and other vulnerable

1 populations to advise such Director with respect
2 to—

3 “(i) supporting and facilitating ad-
4 vanced research and development of coun-
5 termeasures; and formulations of counter-
6 measures, that are safe and effective for
7 such populations; and

8 “(ii) other activities of the BARDA
9 that effect such populations.

10 “(7) PERSONNEL AUTHORITIES.—

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

1 “(B) SPECIAL CONSULTANTS.—The Director
2 may accept special consultants as personnel
3 for the BARDA under section 207(f).

4 “(C) INTEGOVERNMENTAL PERSONNEL
5 ACT.—The Director may accept as personnel
6 for the BARDA, employees under subchapter
7 VI of chapter 33 of subpart B of part III of
8 title 5, United States Code.

9 “(D) OTHER SERVICES.—The Director
10 may accept voluntary and uncompensated serv-
11 ices.

12 “(e) NATIONAL BIODEFENSE ADVISORY BOARD.—

13 “(1) IN GENERAL.—

14 “(A) PURPOSE.—The National Biodefense
15 Advisory Board shall provide expert advice and
16 guidance to the Secretary on the threats, chal-
17 lenges, and opportunities presented by advances
18 in biological and life sciences and the threat
19 from natural infectious diseases and chemical,
20 biological, radiological, and nuclear threats.

21 “(B) MEMBERSHIP.—There is established
22 the National Biodefense Advisory Board (here-
23 inafter in this section referred to as the
24 ‘Board’) to be composed of 23 members who
25 represent the Nation’s preeminent scientific,

1 public health, and medical experts on the sub-
2 ject of biological, chemical, nuclear, and radio-
3 logical threats, whether naturally occurring, ac-
4 idental, or deliberate, as follows:

5 “(i) Ex OFFICIO.—The following
6 members shall serve on the Board ex offi-
7 cio:

8 “(I) The Assistant to the Presi-
9 dent for Homeland Security and
10 Counterterrorism.

11 “(II) The Director of the Office
12 of Science and Technology Policy.

13 “(III) The Assistant Secretary
14 for Public Health Emergency Pre-
15 paredness.

16 “(IV) The Director of the Na-
17 tional Institutes of Health.

18 “(V) The Director of the Centers
19 for Disease Control and Prevention.

20 “(VI) The Commissioner of Food
21 and Drugs.

22 “(VII) The Director of BARDA.

23 “(VIII) The Assistant Secretary
24 of Defense for Health Affairs.

1 “(IX) The Assistant Secretary of
2 Homeland Security for Science and
3 Technology.

4 “(X) The Secretary of Agricul-
5 ture (or a designee).

6 “(ii) APPOINTED MEMBERS.—The fol-
7 lowing individuals, as appointed by the
8 Secretary:

9 “(I) Four representatives of the
10 pharmaceutical and biotechnology in-
11 dustries.

12 “(II) Four representatives of aca-
13 demia.

14 “(III) Five other members as de-
15 termined appropriate by the Sec-
16 retary.

17 “(C) TERM OF APPOINTMENT.—A member
18 of the Board described in subparagraph (B)(ii)
19 shall serve for a term of 3 years; except that
20 the Secretary may adjust the terms of the ini-
21 tial Board appointees in order to provide for a
22 staggered term of appointment for all members.

23 “(D) CONSECUTIVE APPOINTMENTS; MAX-
24 IMUM TERMS.—A member may be appointed to

1 serve not more than 3 terms on the Board and
2 may serve not more than 2 consecutive terms.

3 “(2) DUTIES.—The Board shall—

4 “(A) advise the Secretary on major bio-
5 defense initiatives and review ongoing and pro-
6 posed biodefense programs, which may include
7 potential activities of the BARDA; and

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

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

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

1 “(5) CHAIRPERSON.—The Secretary shall ap-
2 point a chairperson from among the members of the
3 Board.

4 “(6) POWERS.—

5 “(A) HEARINGS.—The Board may hold
6 such hearings; sit and act at such times and
7 places; take such testimony; and receive such
8 evidence as the Board considers advisable to
9 carry out this subsection.

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

15 “(7) PERSONNEL.—

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

22 “(B) OTHER MEMBERS.—A member of the
23 Board that is not an employee of the Federal
24 Government shall be compensated at a rate
25 equivalent to the daily equivalent of the annual

1 rate of basic pay prescribed for level IV of the
2 Executive Schedule under section 5315 of title
3 5, United States Code, for each day (including
4 travel time) during which the member is en-
5 gaged in the actual performance of duties as a
6 member of the Board.

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

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

18 “(d) FUND.—

19 “(1) ESTABLISHMENT.—There is established
20 the Biodefense Medical Countermeasure Develop-
21 ment Fund, which shall be administered by the Di-
22 rector of the BARDA.

23 “(2) FUNDS.—

24 “(A) FIRST FISCAL YEAR.—Of the
25 amounts appropriated to carry out the Project

1 BioShield Act of 2004 (Public Law 108-276)
2 and not obligated, \$1,000,000,000 shall be
3 available to the Fund to carry out this section
4 for fiscal year 2006. Such amounts shall remain
5 available until expended.

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

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

17 “(f) INAPPLICABILITY OF CERTAIN ACTS.—

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

22 “(2) FOIA.—Information that relates to the ac-
23 tivities, working groups, and advisory boards of the
24 BARDA shall not be subject to disclosure under sec-
25 tion 552 of title 5, United States Code, unless the

1 Secretary or Director determines that such disclo-
2 sure would pose no threat to national security. Such
3 a determination shall not be subject to judicial re-
4 view.

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

18 SEC. 4. CLARIFICATION OF COUNTERMEASURES COVERED

19 BY PROJECT BIOSHIELD.

20 (a) QUALIFIED COUNTERMEASURE.—Section 319F
21 1(a) of the Public Health Service Act (42 U.S.C. 247d-
22 6a(a)) is amended by striking paragraph (2) and inserting
23 the following:

24 **"(2) DEFINITIONS.** In this section:

1 “(A) QUALIFIED COUNTERMEASURE.—The
2 term ‘qualified countermeasure’ means a drug
3 (as that term is defined by section 201(g)(1) of
4 the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 321(g)(1))), biological product (as that
6 term is defined by section 351(i) of this Act (42
7 U.S.C. 262(i))), device (as that term is defined
8 by section 201(h) of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 321(h))), or re-
10 search tool (as that term is defined in section
11 201(rr) of the Federal Food, Drug, and Cos-
12 metic Act) that the Secretary determines to be
13 a priority (consistent with sections 302(2) and
14 304(a) of the Homeland Security Act of 2002)
15 to—

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

23 “(ii) diagnose, mitigate, prevent, or
24 treat harm from a condition that may re-
25 sult in adverse health consequences or

1 death and may be caused by administering
2 a drug, biological product, or device that is
3 used as described in this subparagraph, or
4 “(iii) in the case of a research tool,
5 enable the rapid and effective identifica-
6 tion, assessment, or development of a drug,
7 biological product, or device to diagnose,
8 mitigate, prevent, or treat harm, as de-
9 scribed in clause (i) or (ii).

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

16 (b) SECURITY COUNTERMEASURE.—Section 319F-
17 2(e)(1)(B) is amended by—

18 (A) striking “treat, identify, or prevent”
19 each place it appears and inserting “diagnose,
20 mitigate, prevent, or treat”; and

21 (B) inserting “agent (including organisms
22 that cause an infectious disease) or toxin” after
23 “any biological”.

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

4 “(rr) RESEARCH TOOL.—The term ‘research tool’ in-
 5 eludes the full range of tools and systems that assist in
 6 the discovery, development, or manufacture of drugs, bio-
 7 logical products (as defined in section 351 of the Public
 8 Health Service Act), or devices.”.

9 **SEC. 5. ORPHAN DRUG MARKET EXCLUSIVITY FOR COUN-**

10 **TERMEASURE PRODUCTS.**

11 (a) MARKET EXCLUSIVITY.—Subchapter A of chap-
 12 ter V of the Federal Food, Drug, and Cosmetic Act (21
 13 U.S.C. 351 et seq.) is amended by inserting after section
 14 505B the following:

15 **“SEC. 505C. ORPHAN DRUG MARKET EXCLUSIVITY FOR**
 16 **COUNTERMEASURE PRODUCTS.**

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

22 “(b) DEFINITION.—For the purpose of this section,
 23 the term ‘countermeasure’ means a drug or biological
 24 product (as such term is defined by section 351(i) of the
 25 Public Health Service Act) that the Secretary determines

1 to be a priority (consistent with sections 302(2) and
2 304(a) of the Homeland Security Act of 2002) to diag-
3 nose, mitigate, prevent, or treat harm from any biological,
4 chemical, radiological, or nuclear agent (including orga-
5 nisms that cause an infectious disease) or toxin identified
6 as a material threat under subsection (e)(2)(A)(ii) of sec-
7 tion 319F-2 of the Public Health Service Act.”.

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

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

1 **SEC. 6. LIABILITY PROTECTIONS FOR PANDEMICS,**2 **EPIDEMICS, AND COUNTERMEASURES.**

3 Part B of title III of the Public Health Service Act

4 is amended by inserting after section ~~319F-2~~ (42 U.S.C.5 ~~247d-6b~~) the following:6 **“SEC. 319F-3. LIABILITY PROTECTIONS FOR PANDEMIC AND**7 **EPIDEMIC PRODUCTS AND SECURITY COUN-**8 **TERMEASURES.**

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

20 “(b) LITIGATION MANAGEMENT.—

21 “(1) LIMITATION ON CAUSE OF ACTION.—

22 “(A) IN GENERAL.—

23 “(i) IN GENERAL.—No cause of action
24 shall exist against a person described in
25 subsection (a) for claims for loss of prop-
26 erty, personal injury, or death arising out

1 of, reasonably relating to, or resulting from
2 the design, development, clinical testing
3 and investigation, manufacture, labeling,
4 distribution, sale, purchase, donation, dis-
5 pensing, prescribing, administration, or use
6 of a security countermeasure or qualified
7 pandemic or epidemic product distributed,
8 sold, purchased, donated, dispensed, pre-
9 scribed, administered, or used in anticipa-
10 tion of and preparation for, in defense
11 against, or in response to, or recovery from
12 an actual or potential public health emer-
13 gency that is a designated security coun-
14 termeasure or a qualified pandemic or epi-
15 demic product by the Secretary in a de-
16 claration described in paragraph (2).

17 “(ii) RULE OF CONSTRUCTION.—For
18 purposes of this section, the phrase ‘aris-
19 ing out of, reasonably relating to, or re-
20 sulting from’ shall not be construed to
21 apply to loss of property, personal injury,
22 or death that has no alleged or potential
23 causal relationship with the design, devel-
24 opment, clinical testing and investigation,
25 manufacture, labeling, distribution, sale,

1 purchase, donation, dispensing, pre-
2 scribing, administration, or use of a prod-
3 uct described in clause (i).

4 **“(B) RULE.—”**

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

15 **“(ii) PRIVATE DONATION OR SALE.”**
16 The protections set forth in subsection (a)
17 and subparagraph (A) shall apply to all
18 claims identified in subparagraph (A) that
19 involve security countermeasures or qual-
20 fied pandemic or epidemic products distrib-
21 uted, sold, purchased, donated, dispensed,
22 prescribed, administered, or used during
23 the effective period set forth in the des-
24 ignation provided for in paragraph (2) by
25 a manufacturer through the commercial

1 market, provided that the security counter-
2 measures or the qualified pandemic or epi-
3 demic product are the security counter-
4 measure or qualified pandemic or epidemic
5 product described in a declaration de-
6 scribed in paragraph (2) and the Secretary
7 does not specifically prohibit such private
8 donation or sale in such declaration.

9 **“(C) POTENTIAL LIABILITY UPON DETER-**
10 **MINATION.—**

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

18 “(ii) **INVESTIGATION BY SEC-**
19 **RETARY.**—A party seeking a determination
20 under subparagraph (D) may petition the
21 Secretary to investigate allegations against
22 a manufacturer, distributor, administrator,
23 or health care provider arising out of, re-
24 lating to, or resulting from the design, de-
25 velopment, clinical testing and investiga-

Nothing in this section shall be construed to abrogate or limit the application of subtitle H of chapter 5 and chapter 7 of title 5, United States Code (commonly known as the Administrative Procedure Act).

15 “(D) DETERMINATION BY SECRETARY.—

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

21 “(I) the manufacturer, dis-
22 tributor, administrator, or health care
23 provider violated a provision of the
24 Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 301 et seq.) or this
2 Act; and

3 “(II) in violating such Act, such
4 manufacturer, distributor, adminis-
5 trator, or health care provider acted
6 with willful misconduct.

7 “(ii) EFFECT OF DETERMINATION.—

8 If the Secretary finds such clear and con-
9 vincing evidence under clause (i), the Sec-
10 retary shall examine whether such willful
11 misconduct to violate an Act under such
12 clause—

13 “(I) caused the product to
14 present a significant or unreasonable
15 risk to human health; and

16 “(II) proximately caused the in-
17 jury alleged by the party.

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

1 “(iv) EFFECT OF DETERMINATION.—

2 Subject to subsection (e), the sole exception to the immunity from suit and liability
3 of manufacturers, distributors, administrators,
4 or healthcare providers set forth in
5 subsection (a) and subparagraph (A) shall
6 be for actions against a manufacturer, dis-
7 tributor, administrator, or healthcare pro-
8 vider as provided in subparagraph (A).

9
10 “(v) JUDICIAL REVIEW.—At any time

11 prior to the 90th day following a deter-
12 mination by the Secretary under clause (i),
13 any manufacturer, distributor, adminis-
14 trator, or health care provider named in
15 such determination may file a petition with
16 the United States Court District Court for
17 the District of Columbia, for a judicial re-
18 view of such determination. A copy of the
19 petition shall be forthwith transmitted by
20 the clerk of the court to the Secretary or
21 other officer designated by the Secretary
22 for that purpose. The Secretary thereupon
23 shall file in the court the record of the
24 findings on which the Secretary based his
25 or her determination. The filing of a peti-

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

17 “(vi) TOLLING OF STATUTE OF LI-
18 MITATIONS.—The computation of the statute
19 of limitations for any action against a
20 manufacturer, distributor, administrator,
21 or health care provider described under
22 this subparagraph shall not include any
23 time occurring before the determination by
24 the Secretary under this subparagraph.

1 “(vii) REGULATORY AUTHORITY.—

2 The Secretary, in consultation with the Attorney General, shall promulgate regulations defining what actions by a manufacturer, distributor, administrator, or healthcare provider of a security countermeasure or a qualified pandemic and epidemic product shall be deemed to constitute ‘willful misconduct’ for purposes of clause (i). In promulgating such regulations, the Secretary shall consider the nature of the actual or potential public health emergency, the timing and extent of any vaccination or countermeasure program, and any other circumstances they deem significant, so that any civil actions permitted under this subsection will not adversely affect the public health. The Secretary may specify the period of time for which such regulations apply.

21 “(viii) EVIDENCE REQUIRED.—The

22 Secretary, in consultation with the Attorney General, shall promulgate regulations that require, in order to be a party under

1 this section, that an individual present evi-
2 dence that reasonably demonstrates that—

3 “(I) such individual has suffered
4 a loss as a direct result of the design,
5 development, clinical testing and in-
6 vestigation, manufacture, labeling,
7 distribution, sale, purchase, donation,
8 dispensing, prescribing, or administra-
9 tion of a security countermeasure or
10 qualified epidemic or pandemic prod-
11 uct; and

12 “(II) the loss as described in sub-
13 clause (I) was a direct result of the
14 willful misconduct of the manufac-
15 turer, distributor, administrator, or
16 health care provider in violating the
17 Federal Food, Drug, and Cosmetic
18 Act or this Act.

19 “(E) SCOPE.—Subparagraph (C) shall
20 apply regardless of whether the suit or liability
21 described in subsection (a) or the claim de-
22 scribed in subparagraph (A) arises from the de-
23 sign, development, clinical testing and investiga-
24 tion, manufacture, labeling, distribution, sale,
25 purchase, donation, dispensing, prescribing, ad-

1 ministration, or use by the Federal Government
2 or by any person.

3 **“(2) DECLARATION BY SECRETARY.—**

4 **“(A) IN GENERAL.—** The Secretary may
5 issue a declaration, pursuant to this paragraph,
6 that an actual or potential public health emer-
7 gency makes advisable the distribution, admin-
8 istrations, or use of a security countermeasure
9 or qualified pandemic or epidemic product.

10 **“(B) SECURITY COUNTERMEASURE OR**
11 **QUALIFIED PANDEMIC OR EPIDEMIC PROD-**
12 **UCT.—** The Secretary shall specify in such de-
13 clarations the security countermeasures or quali-
14 fied pandemic or epidemic products to be sold
15 by, purchased from, or donated by a manufac-
16 turer or drawn from the Strategic National
17 Stockpile.

18 **“(C) EFFECTIVE PERIOD.—** The Secretary
19 shall specify in such declaration the beginning
20 and the ending dates of the effective period of
21 the declaration, which shall be not longer than
22 6 months. The Secretary may subsequently
23 amend such declaration to shorten or extend
24 such effective period, provided that the new

1 ending date is after the date on which the dec-
2 laration is amended.

3 “(D) PUBLICATION.—The Secretary shall
4 promptly publish each such declaration and
5 amendment in the Federal Register.

6 “(e) ACTIONS BY THE UNITED STATES.—Nothing in
7 this section shall be construed to abrogate or limit any
8 right, remedy, or authority that the United States or any
9 agency thereof may possess under any other provision of
10 law.

11 “(d) DEFINITIONS.—In this section:

12 “(1) ADMINISTRATOR.—The term ‘adminis-
13 trator’ means a person employed by the State or
14 local government, or their designee, who supervised
15 or administered a program with respect to the ad-
16 ministration, dispensing, distribution, or provision of
17 a security countermeasure or a qualified pandemic
18 or epidemic product, including a person who has es-
19 tablished requirements; provided policy guidance;
20 supplied technical or scientific advice or assistance.

21 “(2) HEALTH CARE PROVIDER.—The term
22 ‘health care provider’ means a person, including a
23 volunteer, who distributes, prescribes, administers,
24 dispenses, provides a facility to administer, or super-
25 vises or oversees the administration of a security

1 countermeasure or a qualified pandemic or epidemic
2 product, including persons who distribute, prescribe,
3 administer, dispense, or provide a facility to admin-
4 ister in accordance with a designation under sub-
5 section (b)(2).

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

9 “(4) **MANUFACTURER.**—The term ‘manufac-
10 turer’ includes—

11 “(A) a contractor or subcontractor of a
12 manufacturer;

13 “(B) a supplier of any product or service,
14 research tool, or component to the manufac-
15 turer; and

16 “(C) any or all of the parents, subsidiaries,
17 affiliates, successors, and assigns of a manufac-
18 turer.

19 “(5) **QUALIFIED PANDEMIC OR EPIDEMIC PROD-**
20 **UCT.**—The term ‘qualified pandemic or epidemic
21 product’ means a drug (as such term is defined in
22 section 201(g)(1) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 321(g)(1))), biological
24 product (as such term is defined by section 351(i)
25 of this Act) or device (as such term is defined by

1 section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h))) designed, developed,
2 modified, or procured to diagnose, mitigate, prevent,
3 treat, or cure a pandemic or epidemic or limit the
4 harm such pandemic or epidemic might otherwise
5 cause or a serious or life-threatening disease or condition caused by such a product, that—
6

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

10 “(B) is a product for which the Secretary
11 determines that sufficient and satisfactory clinical
12 experience or research data (including data,
13 if available, from pre-clinical and clinical trials)
14 support a reasonable conclusion that the product
15 will qualify for approval or licensing within
16 8 years after the date the Secretary makes a
17 declaration under paragraph (2); or
18

19 “(C) is authorized for emergency use section
20 564 of the Federal Food, Drug, and Cosmetic Act, except that subsection (b) of such
21 section shall not apply.

22 “(6) PARTY.— The term ‘party’ means an individual who can reasonably demonstrate to the Secretary that such individual has suffered a loss (as

1 defined in paragraph (3)) as a direct result of the
 2 willful misconduct of a manufacturer, distributor,
 3 administrator, or health care provider.

4 **(7) PERSON.**—The term ‘person’ includes an
 5 individual, partnership, corporation, association, en-
 6 tity, or public or private corporation, including a
 7 Federal, State, or local agency or department.

8 **(8) SECURITY COUNTERMEASURE.**—The term
 9 ‘security countermeasure’ has the meaning given
 10 such term in section 319F-2(e)(1)(B).”.

11 SEC. 7. COMPENSATION.

12 Title II of the Public Health Service Act (42 U.S.C.
 13 202 et seq.) is amended by adding at the end the fol-
 14 lowing:

15 “PART D—OTHER COMPENSATION PROGRAMS

16 “SEC. 271. COVERED COUNTERMEASURES PROGRAM.

17 **(a) IN GENERAL.**—If the Secretary issues a Procla-
 18 mation stating that there is a critical public health need
 19 for a covered individual to receive a covered counter-
 20 measure during the effective period of the Proclamation,
 21 the Secretary shall establish a process to provide com-
 22 pensation to such covered individuals for a covered injury,
 23 consistent with the Smallpox Emergency Personnel Pro-
 24 tection program under part C.

25 **(b) DEFINITION.**—For purposes of this section:

1 “(1) COVERED COUNTERMEASURE.—The term
2 ‘covered countermeasure’ means a qualified pan-
3 demic or epidemic (as defined in section 319F-
4 3(e)(5)) or a security countermeasure (as defined in
5 section 319F-2(e)(1)(B)) specified in the Proclama-
6 tion.

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

9 “(A) who is a health care worker, law en-
10 forcement officer, firefighter, security per-
11 sonnel, emergency medical personnel, other
12 public health or safety personnel, or support
13 personnel for such occupational specialties;

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

18 “(C) who has volunteered and been se-
19 lected to be a member of an emergency re-
20 sponse plan; and

21 “(D) to whom a covered countermeasure is
22 administered pursuant to such approved plan
23 during the effective period of the Proclamation
24 and prior to the time at which the Secretary de-
25 clares a public health emergency pursuant to

1 section 319 related to a covered countermeasure
2 specified in the Proclamation.

3 “(3) COVERED INJURY.—The term ‘covered in-
4 jury’ means an injury, disability, illness, condition,
5 or death (other than a minor injury such as minor
6 scarring or minor local reaction) determined by the
7 Secretary to have been sustained by a covered indi-
8 vidual as the direct result of administration to the
9 individual of a covered countermeasure.

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

14 “(5) EMERGENCY RESPONSE PLAN.—The term
15 ‘emergency response plan’ or ‘plan’ means a re-
16 sponse plan detailing actions to be taken in prepara-
17 tion for a pandemic, epidemic, or biological, chem-
18 ical, nuclear agent or toxin that presents, or may
19 present, a public health emergency.

20 “(6) PROCLAMATION.—The term ‘Proclama-
21 tion’ means a Proclamation regarding the critical
22 public health need for the administration of a cov-
23 ered countermeasure issued by the Secretary and
24 published in the Federal Register. Such Proclama-

1 tion shall specify the specific covered counter-
2 measure recommended for administration.

3 “(e) RULE OF CONSTRUCTION.—Nothing in this see-
4 tion shall be construed to require the creation of a com-
5 pensation program if the covered injuries are only minor
6 injuries consistent with section (b)(3).”.

7 SEC. 8. REBATES AND GRANTS FOR RESEARCH DEVELOP-
8 MENT, AND MANUFACTURING OF VACCINES,
9 QUALIFIED COUNTERMEASURES AND PAN-
10 DEMIC OR EPIDEMIC PRODUCTS.

11 (a) IN GENERAL.—The Secretary of Health and
12 Human Services (referred to in this section as the “Sec-
13 retary”) may award to a person with respect to an invest-
14 ment described in this section (or an amendment made
15 by this section)—

16 (1) a rebate pursuant to subsection (b); or
17 (2) a grant pursuant to section 319M of the
18 Public Health Service Act (as added by subsection
19 (e)).

20 (b) SURGE CAPACITY AND RESEARCH REBATES.—

21 (1) IN GENERAL.—The Secretary may award
22 rebates out of any money in the Treasury not other-
23 wise appropriated to persons for the expansion of
24 surge capacity for manufacturing vaccines, qualified
25 countermeasures (as defined in ~~319F-1~~ of the Pub-

1 lie Health Service Act, as amended by this Act) or
2 qualified pandemic or epidemic products (as defined
3 in ~~319F-3(e)(5)~~ of such Act, as added by this Act)
4 (referred to in this section as “vaccines, counter-
5 measures or products”) and for vaccines, counter-
6 measures, or products research.

7 (2) VACCINES, COUNTERMEASURES OR PROD-
8 UCTS MANUFACTURING FACILITIES INVESTMENT RE-
9 BATE.—

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

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

1 (C) VACCINES, COUNTERMEASURES AND
2 PRODUCTS MANUFACTURING FACILITIES PROP-
3 ERTY.—For purposes of this subsection, the
4 term “vaccines, countermeasures and products
5 manufacturing facilities property” means real
6 and tangible personal property—

- 7 (i)(I) the original use of which com-
8 mences with the person applying for the
9 rebate; or
- 10 (II) which is acquired through pur-
11 chase (as defined by section 179(d)(2) of
12 the Internal Revenue Code of 1986);
- 13 (ii) which is depreciable under section
14 167 of the Internal Revenue Code of 1986;
- 15 (iii) which is physically located in a
16 State;
- 17 (iv) which is used for the manufac-
18 ture, distribution, or research and develop-
19 ment of vaccines, countermeasures, or
20 products; and
- 21 (v) which is in compliance with appli-
22 cable good manufacturing practice and
23 with any other applicable requirements
24 which are promulgated by the Secretary,
25 the Occupational Safety and Health Ad-

1 ministration, or the Environmental Protection
2 Agency, and which are applicable to
3 such property.

4 (D) DENIAL OF DOUBLE BENEFIT FOR
5 MANUFACTURING FACILITIES EXPENSES.—If
6 any portion of the vaccines, countermeasures,
7 and products manufacturing facilities property
8 investment expenses is otherwise allowable as a
9 deduction for the taxable year involved, the Secretary
10 shall only provide a rebate under this
11 section for the portion of such expenses not cov-
12 ered by the rebate determined by such deduc-
13 tion.

14 (E) ELIGIBILITY.—To be eligible to receive
15 a rebate under this subsection, a manufacturer
16 shall submit to the Secretary an application at
17 such time, in such manner, and containing such
18 information as the Secretary may require, in-
19 cluding—

20 (i) a detailed description and intended
21 use of the facilities that is the basis of ap-
22 plication;

23 (ii) a detailed description of the vac-
24 cine, countermeasure, or product being

1 produced or that may be produced at the
2 facility;

3 (iii) a detailed accounting of qualified
4 manufacturing facilities investment of the
5 person;

6 (iv) a certification as to the compliance
7 of the person with clauses (i) through
8 (iv) of subparagraph (C); and

9 (v) copies of tax returns for the taxable
10 year involved.

11 (F) EFFECTIVE DATE.—This paragraph
12 shall apply to property placed in service after
13 December 31, 2005.

14 (G) TERMINATION.—This paragraph shall
15 not apply to any property placed in service after
16 December 31, 2010.

17 (3) MEDICAL RESEARCH RELATED TO DEVELOPING VACCINES, COUNTERMEASURES OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS REBATE.—

18 (A) IN GENERAL.—For purposes of this
19 subsection, the research rebate determined
20 under this section for the taxable year involved
21 (as determined as provided for in paragraph
22 (2)(A)) is an amount equal to 35 percent of the
23 vaccines, qualified countermeasures, or qualified
24 countermeasures, qualified countermeasures, or qualified

1 pandemic or epidemic products (referred to in
2 this section as “vaccine, countermeasure, or
3 product”) research expenses for the taxable
4 year.

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

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

1 (D) DENIAL OF DOUBLE BENEFIT FOR
2 VACCINES, COUNTERMEASURES, OR PRODUCTS
3 RESEARCH EXPENSES.—If any portion of the
4 vaccines, countermeasures, or products research
5 expenses is otherwise allowable as a deduction
6 for the taxable year involved, the Secretary
7 shall only provide a rebate under this section
8 for the portion of such expenses not covered by
9 any rebate determined by such deduction.

10 (E) ELIGIBILITY.—To be eligible to receive
11 a rebate under this paragraph, a manufacturer
12 or researcher shall submit to the Secretary an
13 application at such time, in such manner, and
14 containing such information as the Secretary
15 may require, including—

- 16 (i) a detailed description of the vaccine,
17 countermeasure, or product being researched or developed;
- 18 (ii) a detailed description of the research that is the subject of the rebate;
- 19 (iii) a detailed accounting of the qualified research expenses involved;
- 20 (iv) an assurance that the researcher
21 or manufacturer is following good laboratory practice, as required by the Secretary

1 pursuant to the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 301 et seq.) and
3 the Public Health Service Act (42 U.S.C.
4 201 et seq.); and

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

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

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

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

1 **"SEC. 319M. GRANTS TO EXPAND AND IMPROVE RESEARCH**
2 **AND DEVELOPMENT AND MANUFACTURING**
3 **OF VACCINES, QUALIFIED COUNTER-**
4 **MEASURES OR QUALIFIED PANDEMIC OR EPI-**
5 **DEMIC PRODUCTS.**

6 "**(a) IN GENERAL.**—The Secretary may award grants
7 to a manufacturer to purchase or improve real property
8 and tangible personal property used in the research and
9 development, manufacture, or distribution of a vaccine,
10 qualified countermeasure (as defined in section 319F-1)
11 or qualified pandemic or epidemic product (as defined in
12 section 319F-3(e)(5)).

13 "**(b) ELIGIBILITY.**—To be eligible to receive a grant
14 under subsection (a), a manufacturer shall submit to the
15 Secretary an application at such time, in such manner,
16 and containing such information as the Secretary may re-
17 quire, including—

18 "**(1)** a detailed description of the planned ex-
19 pansion;

20 "**(2)** a detailed description of the equipment, fa-
21 cility, or property involved;

22 "**(3)** a certification that such facility or prop-
23 erty is physically located in a State;

24 "**(4)** a detailed description of the vaccine, qual-
25 fied countermeasure or qualified pandemic or epi-
26 demic product involved;

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

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

5 “(7) a description of whether such equipment,
6 facility, or property can be used for the research and
7 development, manufacture, or distribution of a drug,
8 biological product, device or other countermeasure
9 not described in paragraph (4); and

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

13 “(c) RECAPTURE.—

14 “(1) IN GENERAL.—If, at any time prior to the
15 expiration of the 20-year period beginning on the
16 date on which a grant is awarded under this section,
17 the facility or property involved ceases to be used for
18 the purpose for which the grant was awarded, the
19 United States shall be entitled to recover from the
20 manufacturer an amount bearing the same ratio to
21 the value of the facility or property at such time as
22 the amount of the grant bore to the total cost of the
23 purchase or improvement involved. The value of the
24 facility or property at such time may be determined
25 by agreement of the manufacturer and the Sec-

1 retary, or by order of the United States District
2 Court for the district in which such facility or prop-
3 erty is situated.

4 “(2) **LIMITATION.**—The Secretary may not re-
5 capture the facility or property under this subsection
6 if the Secretary determines, in accordance with regu-
7 lations promulgated by the Secretary, that there is
8 good cause for the failure of proper use.

9 “(d) **AUTHORIZATION OF APPROPRIATIONS.**—There
10 is authorized to be appropriated such sums as may be nec-
11 essary to carry out this section.”.

12 **SEC. 9. TECHNICAL ASSISTANCE.**

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

16 **“SEC. 565. TECHNICAL ASSISTANCE.**

17 “The Secretary, in consultation with the Commis-
18 sioner of Food and Drugs, shall establish within the Food
19 and Drug Administration a team of experts on manufac-
20 turing and regulatory activities (including compliance with
21 current Good Manufacturing Practices) to provide both
22 off-site and on-site technical assistance to the manufactur-
23 ers of qualified countermeasures (as defined in section
24 319F-1 of the Public Health Service Act), security coun-
25 termeasures (as defined in section 319F-2 of such Act),

1 or vaccines, at the request of such a manufacturer and
2 at the discretion of the Secretary, if the Secretary deter-
3 mines that a shortage or potential shortage may occur in
4 the United States in the supply of such vaccines or prod-
5 ucts and that the provision of such assistance would be
6 beneficial in helping alleviate or avert such shortage.”.

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

8 Part B of title IV of the Public Health Service Act
9 (~~42 U.S.C. 284 et seq.~~) is amended by adding at the end
10 the following:

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

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

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

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

3 “(A) has access to an appropriate biosafety
4 laboratory or facility, as determined by the Sec-
5 retary; and

6 “(B) will follow good laboratory practices;

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

10 “(A) a detailed description of the animal
11 model involved;

12 “(B) a detailed description of the chemical,
13 biological, radiological, nuclear, or other infe-
14 tious agents involved;

15 “(C) a detailed description of how the ani-
16 mal model will be used for the development of
17 a drug, biological product, or device for use as
18 a countermeasure;

19 “(D) a detailed description of validation
20 methods; and

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

23 “(3) agree to submit the results of the research
24 funded under the grant to the Director of the Bio-

1 medical Advanced Research and Development Agen-
2 ey and the Director of NIH.

3 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated such sums as may be
5 necessary to carry out this section.”.

6 **SEC. 11. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC AD-**

7 **VISORY COMMITTEE.**

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

12 **“SEC. 566. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC**

13 **ADVISORY COMMITTEE.**

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

20 “(b) MEMBERSHIP.—

21 “(1) IN GENERAL.—The Secretary shall appoint
22 as members of the Advisory Committee individuals
23 who are technically qualified by training and experi-
24 ence, including in medicine, veterinarian medicine,
25 biology, technology involving the manufacture, eval-

1 nation, or use of research tools, who are of appro-
2 priately diversified professional backgrounds to
3 evaluate the priority animal models and research
4 tools.

5 “(2) EX OFFICIO MEMBERS.—The Secretary
6 may appoint Federal officials, including at least 1
7 representative of the Biomedical Advanced Research
8 and Development Agency, to serve as ex officio
9 members of the Advisory Committee.

10 “(3) CHAIRPERSON.—The Secretary shall des-
11 ignate 1 of the members of the Advisory Committee
12 to serve as the chairperson.

13 “(e) DUTIES.—The Advisory Committee shall provide
14 advice, information, and recommendations to the Sec-
15 retary on—

16 “(1) accepted animal models for diseases and
17 conditions associated with any biological (including
18 organisms that cause infectious diseases), chemical,
19 radiological, or nuclear agent or toxin or potential
20 pandemic infectious disease;

21 “(2) strategies to accelerate animal model and
22 research tool development and validation; and

23 “(3) scientific issues raised in applications as
24 requested by the Secretary.

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

3 “(e) COMPENSATION, SUPPORT, FACA.—

4 “(1) COMPENSATION AND TRAVEL.—Members
5 of the Advisory Committee who are not officers or
6 employees of the United States, while attending con-
7 ferences or meetings of the committee or otherwise
8 engaged in its business, shall be entitled to receive
9 compensation at rates to be fixed by the Secretary,
10 which may not exceed daily equivalent of the rate in
11 effect for level 4 of the Senior Executive Schedule
12 under section 5382 of title 5, United States Code,
13 for each day (including travel time) they are so en-
14 gaged, and while so serving away from their homes
15 or regular places of business each member may be
16 allowed travel expenses, including per diem in lieu of
17 subsistence, as authorized by section 5703 of title 5,
18 United States Code, for persons in the Federal Gov-
19 ernment service employed intermittently.

20 “(2) ADMINISTRATIVE SUPPORT.—The Sec-
21 retary shall furnish the Advisory Committee clerical
22 and other assistance.

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

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

7 **SEC. 12. COLLABORATION AND COORDINATION.**

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

10 “(g) LIMITED ANTITRUST EXEMPTION.—

11 “(1) SECURITY COUNTERMEASURES, QUALIFIED
12 COUNTERMEASURES AND QUALIFIED PANDEMIC OR
13 EPIDEMIC PRODUCT DEVELOPMENT MEETINGS.—

14 “(A) COUNTERMEASURES AND PRODUCTS
15 DEVELOPMENT MEETINGS AND CONSULTA-
16 TIONS.—The Secretary of Health and Human
17 Services (referred to in this subsection as the
18 ‘Secretary’) or the Director of the Biomedical
19 Advanced Research and Development Agency
20 (referred to in this subsection as the ‘Director’),
21 in coordination with the Attorney General and
22 the Secretary of Homeland Security, may con-
23 duct meetings and consultations with parties in-
24 volved in the development of security counter-
25 measures (as defined in section 319F–2 of the

1 Public Health Service Act) qualified counter-
2 measures (as defined in section ~~319F-1~~ of the
3 Public Health Service Act) or qualified pan-
4 demic or epidemic products (as defined in sec-
5 tion ~~319F-3(e)(5)~~ of the Public Health Service
6 Act) (referred to in this section as “counter-
7 measures or products”) for the purpose of the
8 development, manufacture, distribution, pur-
9 chase, sale, or storage of countermeasures or
10 products consistent with the purposes of this
11 title. The Secretary or Director may convene
12 such meeting or consultation at the request of
13 any person, the Secretary of Homeland Secu-
14 rity, the Attorney General, the Chairperson of
15 the Federal Trade Commission, an industry
16 representative or member, or upon initiation by
17 such Secretary. The Secretary or Director shall
18 give notice of such meetings and consultations
19 to the Chairperson of the Federal Trade Com-
20 mission (referred to in this subsection as the
21 ‘Chairperson’) and the Attorney General.

22 “(B) MEETING AND CONSULTATION CON-
23 DITIONS.—A meeting or consultation conducted
24 under subparagraph (A) shall—

1 “(i) be chaired or, in the case of a
2 consultation, facilitated by the Secretary or
3 Director;

4 “(ii) be open to parties involved in the
5 development, manufacture, distribution,
6 purchase, or sale of countermeasures or
7 products, as determined by the Secretary
8 or Director;

9 “(iii) be open to the Attorney General,
10 the Secretary of Homeland Security, and
11 the Chairperson;

12 “(iv) be limited to discussions involving
13 the development, manufacture, dis-
14 tribution, or sale of countermeasures or
15 products, consistent with the purposes of
16 this title; and

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

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

24 “(D) MINUTES.—The Secretary or Direc-
25 tor shall maintain minutes of meetings and con-

1 sultations under this subsection, which shall not
2 be disclosed under section 552 of title 5, United
3 States Code, unless such Secretary or Director,
4 in consultation with the Attorney General, de-
5 termines that disclosure would pose no threat to
6 national security. Such determination shall not
7 be subject to judicial review.

8 **“(E) EXEMPTION.—**

9 **“(i) IN GENERAL.**—The antitrust laws

10 shall not apply to meetings and consulta-
11 tions under this paragraph.

12 **“(ii) LIMITATION.**—Clause (i) shall

13 not apply to any agreement or conduct

14 that results from a meeting or consultation

15 and that does not receive an exemption

16 pursuant to this subsection.

17 **“(2) WRITTEN AGREEMENTS.**—The Secretary

18 or the Director shall file a written agreement regard-
19 ing covered activities, made pursuant to meetings or
20 consultations conducted under paragraph (1) and
21 that is consistent with this paragraph, with the At-
22 torney General and the Chairperson for a determina-
23 tion of the compliance of such agreement with anti-
24 trust laws. In addition to the proposed agreement
25 itself, any such filing shall include—

1 “(A) an explanation of the intended pur-
2 pose of the agreement;

3 “(B) a specific statement of the substance
4 of the agreement;

5 “(C) a description of the methods that will
6 be utilized to achieve the objectives of the
7 agreement;

8 “(D) an explanation of the necessity of a
9 cooperative effort among the particular partici-
10 pating parties to achieve the objectives of the
11 agreement; and

12 “(E) any other relevant information deter-
13 mined necessary by the Secretary or Director in
14 consultation with the Attorney General and the
15 Chairperson.

16 “(3) DETERMINATION.—The Attorney General,
17 in consultation with the Chairperson, shall determine
18 whether an agreement regarding covered activities
19 referred to in paragraph (2) would likely—

20 “(A) be in compliance with the antitrust
21 laws, and so inform the Secretary or Director
22 and the participating parties; or

23 “(B) violate the antitrust laws, in which
24 case, the filing shall be deemed to be a request
25 for an exemption from the antitrust laws, lim-

1 ited to the performance of the agreement con-
2 sistent with the purposes of this title.

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

4 “(A) IN GENERAL.—The Attorney General,
5 in consultation with the Chairperson, shall
6 grant, deny, grant in part and deny in part, or
7 propose modifications to a request for exemp-
8 tion from the antitrust laws under paragraph
9 (3) within 15 business days of the receipt of
10 such request.

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

19 “(C) DETERMINATION.—In granting an
20 exemption under this paragraph, the Attorney
21 General, in consultation with the Chairperson
22 and the Secretary or Director—

23 “(i) shall find—

1 “(I) that the agreement involved
2 is necessary to ensure the availability
3 of countermeasures or products;

4 “(II) that the exemption from
5 the antitrust laws would promote the
6 public interest; and

7 “(III) that there is no substantial
8 competitive impact to areas not di-
9 rectly related to the purposes of the
10 agreement; and

11 “(ii) may consider any other factors
12 determined relevant by the Attorney Gen-
13 eral and the Chairperson.

14 **“(5) LIMITATION ON AND RENEWAL OF EXEM-
15 TIONS.**—An exemption granted under paragraph (4)
16 shall be limited to covered activities, and shall be re-
17 newed (with modifications, as appropriate) on the
18 date that is 3 years after the date on which the ex-
19 emption becomes effective (and at 3-year intervals
20 thereafter, if renewed) unless the Attorney General
21 in consultation with the Chairperson determines that
22 the exemption should not be renewed (with modifica-
23 tions, as appropriate) considering the factors de-
24 scribed in paragraph (4).

1 “(6) LIMITATION ON PARTIES.—The use of any
2 information acquired under an exempted agreement
3 by the parties to such an agreement for any pur-
4 poses other than those specified in the antitrust ex-
5 emption granted by the Attorney General shall be
6 subject to the antitrust laws and any other applica-
7 ble laws.

8 “(7) GUIDELINES.—The Attorney General and
9 the Chairperson may develop and issue guidelines to
10 implement this subsection.

11 “(8) REPORT.—Not later than 1 year after the
12 date of enactment of the Biodefense and Pandemic
13 Vaccine and Drug Development Act of 2005, and
14 annually thereafter, the Attorney General and the
15 Chairperson shall report to Congress on the use and
16 continuing need for the exemption from the antitrust
17 laws provided by this subsection.

18 “(9) STATUS OF MEMORANDUMS.—Minutes
19 maintained by the Secretary or Director pursuant to
20 paragraph (1)(D) shall not be disclosed under sec-
21 tion 552 of title 5, United States Code, if the ex-
22 emption is not renewed under paragraph (5), or if
23 meetings are no longer conducted, unless the Sec-
24 retary or Director, in consultation with the Attorney
25 General, determines that the disclosure would pose

1 no threat to national security. Such determination
2 shall not be subject to judicial review.

3 “(h) SUNSET.—The authority of the Attorney Gen-
4 eral to grant or renew a limited antitrust exemption under
5 this section shall expire at the end of the 6-year period
6 that begins on the date of enactment of the Biodefense
7 and Pandemic Vaccine and Drug Development Act of
8 2005.

9 “(i) DEFINITIONS.—In this section:

10 “(1) ANTITRUST LAWS.—The term ‘antitrust
11 laws’—

12 “(A) has the meaning given such term in
13 subsection (a) of the first section of this Act,
14 except that such term includes the Act of June
15 19, 1936 (15 U.S.C. 13 et seq.) (commonly
16 known as the Robinson-Patman Act), and sec-
17 tion 5 of the Federal Trade Commission Act
18 (15 U.S.C. 45) to the extent such section 5 ap-
19 plies to unfair methods of competition; and

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

22 “(2) COVERED ACTIVITIES.—

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (B), the term ‘covered activities’
25 means any group of activities or conduct, in-

1 eluding attempting to make, making, or per-
2 forming a contract or agreement or engaging in
3 other conduct, for the purpose of—

4 “(i) theoretical analysis, experimen-
5 tation, or the systematic study of phe-
6 nomena or observable facts necessary to
7 the development of countermeasures or
8 products;

9 “(ii) the development or testing of
10 basic engineering techniques necessary to
11 the development of countermeasures or
12 products;

13 “(iii) the extension of investigative
14 findings or theory of a scientific or tech-
15 nical nature into practical application for
16 experimental and demonstration purposes,
17 including the experimental production and
18 testing of models, prototypes, equipment,
19 materials, and processes necessary to the
20 development of countermeasures or prod-
21 ucts;

22 “(iv) the production, distribution, or
23 marketing of a product, process, or service
24 that is a countermeasures or products;

1 “(v) the testing in connection with the
2 production of a product, process, or serv-
3 ices necessary to the development of coun-
4 termeasures or products;

5 “(vi) the collection, exchange, and
6 analysis of research or production informa-
7 tion necessary to the development of coun-
8 termeasures or products; or

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

11 and such term may include the establishment
12 and operation of facilities for the conduct of
13 covered activities described in clauses (i)
14 through (vi), the conduct of such covered activi-
15 ties on a protracted and proprietary basis, and
16 the processing of applications for patents and
17 the granting of licenses for the results of such
18 covered activities.

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

22 “(i) Exchanging information among
23 competitors relating to costs, profitability,
24 marketing, or distribution of any product,
25 process, or service if such information is

1 not reasonably necessary to carry out the
2 purposes of covered activities.

3 “(ii) Entering into any agreement or
4 engaging in any other conduct—

5 “(I) to restrict or require the
6 sale, licensing, or sharing of inventions,
7 developments, products, processes,
8 or services not developed
9 through, produced by, or distributed
10 or sold through such covered activi-
11 ties; or

12 “(II) to restrict or require par-
13 ticipation by any person who is a
14 party to such covered activities in
15 other research and development activi-
16 ties, that is not reasonably necessary
17 to prevent the misappropriation of
18 proprietary information contributed
19 by any person who is a party to such
20 covered activities or of the results of
21 such covered activities.

22 “(iii) Entering into any agreement or
23 engaging in any other conduct allocating a
24 market with a competitor that is not ex-
25 pressly exempted from the antitrust laws

1 by a determination under subsection
2 (g)(4).

3 “(iv) Exchanging information among
4 competitors relating to production (other
5 than production by such covered activities)
6 of a product, process, or service if such in-
7 formation is not reasonably necessary to
8 carry out the purpose of such covered ac-
9 tivities.

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

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

1 “(vii) Entering into any agreement or
2 engaging in any other conduct restricting
3 or setting the price at which a product is
4 offered for sale, whether by bid or other-
5 wise.

6 “(3) DEVELOPMENT.—The term ‘development’
7 includes the identification of suitable compounds or
8 biological materials, the conduct of preclinical and
9 clinical studies, the preparation of an application for
10 marketing approval, and any other actions related to
11 preparation of a countermeasure or product.”.

12 **SEC. 13. PROCUREMENT.**

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

15 (1) in the section heading, by inserting “**AND**
16 **SECURITY COUNTERMEASURE PROCUREMENT**
17 **MENTS”** before the period; and

18 (2) in subsection (e)—

19 (A) in the subsection heading, by striking
20 “**BIOMEDICAL”**;

21 (B) in paragraph (5)(B)(i), by striking “to
22 meet the needs of the stockpile” and inserting
23 “to meet the stockpile needs”;

24 (C) in paragraph (7)(C)(ii)—

1 (i) by amending clause (I) to read as
2 follows:

3 “(I) PAYMENT CONDITIONED ON
4 DELIVERY.—The contract shall pro-
5 vide that no payment may be made
6 until delivery of a portion, acceptable
7 to the Secretary, of the total number
8 of units contracted for, except that,
9 notwithstanding any other provision of
10 law, the contract may provide that, if
11 the Secretary determines (as the Sec-
12 retary’s discretion) that an advance
13 payment, partial payment for signifi-
14 cant milestones, or payment to in-
15 crease manufacturing capacity is nee-
16 ssary to ensure success of a project,
17 the Secretary shall pay an amount,
18 not to exceed 10 percent of the con-
19 tract amount, in advance of delivery.
20 The contract shall provide that such
21 advance payment is required to be re-
22 paid if there is a failure to perform by
23 the vendor under the contract. The
24 contract may also provide for up to 3
25 additional advance payments of 5 per-

1 cent each for meeting the milestones
2 specified in such contract. Provided
3 that the specified milestones are
4 reached, these advanced payments of
5 5 percent shall not be required to be
6 repaid. Nothing in this subclause shall
7 be construed as affecting the rights of
8 vendors under provisions of law or
9 regulation (including the Federal Ac-
10 quisition Regulation) relating to the
11 termination of contracts for the con-
12 venience of the Government.”; and
13 (ii) by adding at the end the fol-
14 lowing:

15 “(VII) SALES EXCLUSIVITY.—
16 The contract may provide that the
17 vendor is the sole and exclusive sup-
18 plier of the product to the Federal
19 Government for a specified period of
20 time, not to exceed 15 years, on the
21 condition that the vendor is able to
22 satisfy the needs of the Government.
23 During the agreed period of sales ex-
24 clusivity, the vendor shall not assign
25 its rights of sales exclusivity to an-

1 other entity or entities without ap-
2 proval by the Secretary.

3 “(VIII) SURGE CAPACITY.—The
4 contract may provide that the vendor
5 establish domestic manufacturing ca-
6 pacity of the product to ensure that
7 additional production of the product is
8 available in the event that the Sec-
9 retary determines that there is a need
10 to quickly purchase additional quan-
11 tities of the product. Such contract
12 may provide a fee to the vendor for
13 establishing and maintaining such ca-
14 pacity in excess of the initial require-
15 ment for the purchase of the product.
16 Additionally, the cost of maintaining
17 the domestic manufacturing capacity
18 shall be an allowable and allocable di-
19 rect cost of the contract.

20 “(IX) CONTRACT TERMS.—The
21 Secretary, in any contract for procure-
22 ment under this section, may speci-
23 fy—

24 “(aa) the dosing and admin-
25 istration requirements for coun-

1 Project BioShield Act of 2004, for the procure-
2 ment of countermeasures under section 319F—
3 4 or 319F-2.”

4 **SEC. 14. NATIONAL PATHOLOGY CENTER.**

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

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

9 “(H) The National Pathology Center.”; and

10 (2) by adding at the end of part E (42 U.S.C.
11 287 et seq.) the following:

12 **“Subpart 7—National Pathology Center**

13 **“SEC. 485A. ESTABLISHMENT OF NATIONAL PATHOLOGY**
14 **CENTER.**

15 “In order to provide pathology consultation for civil-
16 ian and military health professionals (including Depart-
17 ment of Veterans Affairs health professionals) there is es-
18 tablished the National Pathology Center (in this subpart
19 referred to as the ‘Center’). The Center shall be headed
20 by a director, who shall be appointed by the Secretary.
21 The Director of the Center shall report directly to the Di-
22 rector of NIH.

23 **“SEC. 485B. PURPOSES AND FUNCTIONS OF THE CENTER.**

24 “(a) PURPOSES OF THE CENTER.—The general pur-
25 poses of the Center are to—

1 “(1) conduct and support research, education,
2 training, and other programs with respect to the
3 science and clinical practice of pathology;

4 “(2) maintain and improve a pathology tissue
5 repository; and

6 “(3) provide pathology consultation services.

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

10 “(1) shall—

11 “(A) maintain and improve a comprehensive
12 repository of pathological specimens;

13 “(B) provide consultations on request re-
14 garding clinical cases;

15 “(C) conduct educational programs and
16 publish educational materials on the science
17 and clinical practice of pathology;

18 “(D) maintain and improve registries on
19 such clinical conditions as the Director of the
20 Center determines appropriate; and

21 “(E) conduct and support research on pa-
22 thology; and

23 “(2) may—

1 “(A) collect reasonable and appropriate
2 fees for the activities described in paragraph
3 (1)(B); and

4 “(B) conduct such other activities as the
5 Director of the Center determines appropriate
6 to carry out the purposes described in sub-
7 sektion (a).

8 “(e) AUTHORITY FOR EXPERT OPINIONS.—The Di-
9 rector of the Center may enter into memoranda of under-
10 standing with officials at the Department of Veterans Af-
11 fairs and the Department of Defense to provide expert see-
12 ond opinion pathology consultations and pathology edu-
13 cation or training if the Secretary of either such Depart-
14 ment determines that such provision would be in the best
15 interest of either of their respective departments.

16 **“SEC. 485C. BOARD OF REGENTS.**

17 “(a) MEMBERSHIP.—

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

21 “(A) the Surgeons General of—

22 “(i) the Public Health Service;

23 “(ii) the Army;

24 “(iii) the Navy; and

25 “(iv) the Air Force;

1 “(B) the Chief Medical Director of the De-
2 partment of Medicine and Surgery of the De-
3 partment of Veterans Affairs;

4 “(C) the Deputy Director of the National
5 Library of Medicine;

6 “(D) the Assistant Secretary of Health of
7 the Department of Defense;

8 “(E) the Dean of the Uniformed Services
9 University of the Health Sciences; and

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

13 “(2) EX OFFICIO MEMBERS.—The members of
14 the Board described in subparagraphs (A) through
15 (E) of paragraph (1) shall serve as ex officio mem-
16 bers of the Board.

17 “(3) CHAIRPERSON.—The members of the
18 Board appointed under paragraph (1)(F) shall an-
19 nually elect one of such members to serve as the
20 Chairperson of the Board until the next election.

21 “(b) DUTIES OF THE BOARD.—It shall be the duty
22 of the Board to advise, consult with, and make rec-
23 ommendations to the Director of NIH on important mat-
24 ters of policy in regard to the Center, including such mat-
25 ters as the scope, content and organization of the research,

1 education and consultative services provided by the Cen-
2 ter. The Board shall make recommendations to the Direc-
3 tor of NIH regarding the rules under which specimens
4 from the tissue repository will be used and under which
5 it's publications, facilities and services will be made avail-
6 able to various kinds of users.

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

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

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

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

5 **“SEC. 485E. CENTER FACILITIES.**

6 “There are authorized to be appropriated amounts
7 sufficient for the erection and equipment of suitable and
8 adequate buildings and facilities for use of the Center. The
9 Administrator of General Services may acquire, by pur-
10 chase, condemnation, donation, or otherwise, a suitable
11 site or sites, selected by the Secretary in accordance with
12 the direction of the Board, for such buildings and facilities
13 and to erect thereon, furnish, and equip such buildings
14 and facilities. The amounts authorized to be appropriated
15 by this section include the cost of preparation of drawings
16 and specifications, supervision of construction, and other
17 administrative expenses incident to the work. The Admin-
18 istrator of General Services shall prepare the plans and
19 specifications, make all necessary contracts, and supervise
20 construction.”.

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

25 (1) a review of all functions and duties of the
26 National Pathology Center under subpart 7 of part

1 E of title IV of the Public Health Service Act, as es-
2 tablished by subsection (a);

3 (2) areas where such functions and duties over-
4 lap with the functions and duties of the National In-
5 stitutes of Health; and

6 (3) recommendations concerning necessary
7 modifications to the National Pathology Center.

8 (e) TRANSFER OF THE ARMED FORCES INSTITUTE
9 OF PATHOLOGY.—

10 (1) IN GENERAL.—

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

23 (B) EXCEPTIONS.—The following compo-
24 nents of the Armed Forces Institute of Pathol-

1 ege shall not be transferred from the Depart-
2 ment of Defense pursuant to subparagraph (A):

3 (i) The Armed Forces Medical Exam-
4 iner.

5 (ii) The Department of Defense DNA
6 registry.

7 (iii) Accident Investigation Program.

8 (iv) The histopathology training pro-
9 gram.

10 (v) The patient safety center.

11 (vi) Department of Legal Medicine.

12 (vii) Center for Clinical Laboratory
13 Medicine.

14 (viii) Drug Testing and Quality As-
15 surance Program.

16 (ix) Subject to the discretion of the
17 Secretary of Defense, medical research
18 programs on the following:

19 (I) Body armor.

20 (II) Environmental sarcoidosis.

21 (III) Depleted uranium.

22 (IV) Military working dogs.

23 (V) Such other areas of research
24 related to pathology as the Secretary
25 of Defense shall choose to conduct.

1 (2) REFERENCES.—Any reference in any Federal
 2 law, Executive order, rule, regulation, or delega-
 3 tion of authority, or any document of or relating to
 4 the Armed Forces Institute of Pathology shall be
 5 deemed to be a reference to the National Pathology
 6 Center established under subpart 7 of part E of title
 7 IV of the Public Health Service Act.

8 **SECTION 1. SHORT TITLE.**

9 *This Act may be cited as the “Biodefense and Pan-
 10 demic Vaccine and Drug Development Act of 2005”.*

11 **SEC. 2. TABLE OF CONTENTS.**

12 *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.
- Sec. 15. Rule of construction.

13 **SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOP-
 14 MENT AGENCY.**

15 *Title III of the Public Health Service Act (42 U.S.C.
 16 241 et seq.) is amended by inserting after section 319K the
 17 following:*

1 **"SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DE-**

2 **VELOPMENT AGENCY.**

3 "*(a) DEFINITIONS.—In this section:*

4 "*(1) BARDA.—The term 'BARDA' means the Biomedical Advanced Research and Development Agency.*

5 "*(2) FUND.—The term 'Fund' means the Bio-defense Medical Countermeasure Development Fund established under subsection (d).*

6 "*(3) OTHER TRANSACTIONS.—The term 'other transactions' means transactions, other than procurement contracts, grants, and cooperative agreements, including transactions for prototypes, as provided to the Secretary of Defense under section 2371 of title 10, United States Code.*

7 "*(4) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' has the meaning given such term in section 319F-1.*

8 "*(5) QUALIFIED COUNTERMEASURE AND QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT ADVANCED RESEARCH AND DEVELOPMENT.—*

9 "*(A) IN GENERAL.—The term 'qualified countermeasure and qualified pandemic or epidemic product advanced research and development' means any applied research, testing, or evaluation (including those conducted on hu-*

1 *mans or animals), related to the safety or effec-*
2 *tiveness, that is required for approval, clearance,*
3 *or licensing by the Secretary under this Act or*
4 *the Federal Food, Drug, and Cosmetic Act, of*
5 *such countermeasure or pandemic or epidemic*
6 *product to diagnose, mitigate, prevent, or treat*
7 *harm from a deliberate, accidental, or natural*
8 *exposure to a chemical, biological, radiological,*
9 *or nuclear agent, particularly such exposure re-*
10 *sulting from an act of terrorism or potential*
11 *pandemic infectious disease.*

12 “(B) *INCLUSION.*—The term under subparagraph
13 (A) includes any investigation to improve
14 the manufacturing, formulation, finish, fill, de-
15 livery, or shelf-life of such qualified counter-
16 measures or qualified pandemic or epidemic
17 products.

18 “(6) *QUALIFIED PANDEMIC OR EPIDEMIC PROD-*
19 *UCT.*—The term ‘qualified pandemic or epidemic
20 product’ has the meaning given the term in section
21 319F–3(c)(5).

22 “(7) *SECURITY COUNTERMEASURE.*—The term
23 ‘security countermeasure’ has the meaning given such
24 term in section 319F–2.

1 “(8) PERSON.—The term ‘person’ includes an in-
2 dividual, partnership, corporation, association, enti-
3 ty, or public or private corporation, including a Fed-
4 eral, State, or local government agency or depart-
5 ment.

6 “(b) BIOMEDICAL ADVANCED RESEARCH AND DEVEL-
7 OPMENT AGENCY.—

8 “(1) ESTABLISHMENT.—There is established
9 within the Department of Health and Human Serv-
10 ices, the Biomedical Advanced Research and Develop-
11 ment Agency.

12 “(2) PURPOSE.—It shall be the purpose of the
13 BARDA to coordinate and oversee activities that sup-
14 port and accelerate qualified countermeasure or quali-
15 fied pandemic or epidemic product (referred to in this
16 section as ‘countermeasure or product’) advanced re-
17 search and development by—

18 “(A) facilitating collaboration among the
19 Department of Health and Human Services,
20 other Federal agencies, relevant industries, aca-
21 demia, and other persons, with respect to such
22 advanced research and development;

23 “(B) supporting countermeasure and prod-
24 uct advanced research and development;

1 “(C) recommending approaches to mod-
2 ernize and streamline the countermeasure or
3 product development process and reduce regu-
4 latory burdens with respect to procurement of se-
5 curity countermeasures and qualified pandemic
6 or epidemic products; and

7 “(D) supporting innovation to reduce the
8 time and cost of countermeasure and product ad-
9 vanced research and development.

10 “(3) DIRECTOR.—The BARDA shall be headed
11 by a Director (referred to in this section as the ‘Direc-
12 tor’) who shall—

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

15 “(B) report to the Secretary; and

16 “(C) serve as the principal advisor to the
17 Secretary on countermeasure and product ad-
18 vanced research and development.

19 “(4) DUTIES OF DIRECTOR.—

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

23 “(i) increase appropriate communica-
24 tion between the Federal Government and
25 relevant industries, academia, and other in-

1 *tered persons with respect to counter-*
2 *measure and product advanced research and*
3 *development by establishing transparent, ex-*
4 *peditious, and direct processes to—*

5 “(I) facilitate regular, ongoing
6 communication regarding the processes
7 established under subparagraph (C)(ii)
8 and new countermeasures or products
9 of interest;

10 “(II) solicit research and associ-
11 ated data on potential countermeasures
12 and products and related technologies;
13 and

14 “(III) provide technical assistance
15 with respect to such processes and the
16 Food and Drug Administration ap-
17 proval process;

18 “(ii) at least annually—

19 “(I) convene meetings with rep-
20 resentatives from relevant industries,
21 academia, other Federal agencies,
22 international agencies, and other inter-
23 ested persons; and

1 “(II) sponsor relevant biodefense
2 countermeasure technology demonstra-
3 tions;

4 “(iii) carry out the activities described
5 in subsection (g) of section 2 of the Clayton
6 Act; and

7 “(iv) encourage and coordinate coun-
8 termeasure or product advanced research
9 and development, including by convening
10 working groups as identified in paragraph
11 (5).

12 “(B) SUPPORT ADVANCED RESEARCH AND
13 DEVELOPMENT.—To carry out the purpose de-
14 scribed in paragraph (2)(B), the Secretary, act-
15 ing through the Director, shall—

16 “(i) conduct continuous searches and
17 support calls for potential countermeasures
18 or products for drugs, biological products,
19 devices, or research tools to diagnose, miti-
20 gate, prevent, or treat harm from existing,
21 emerging, or possible chemical, biological,
22 radiological, and nuclear agents or poten-
23 tial pandemic infectious diseases that
24 threaten public health and national secu-
25 rity, as identified by the Assistant Sec-

1 *retary for Public Health Emergency Pre-*
2 *paredness;*

3 “(ii) direct the countermeasure and
4 product advanced research and development
5 activities of the Department of Health and
6 Human Services, in consultation with the
7 Assistant Secretary for Public Health
8 Emergency Preparedness, the Director of the
9 National Institutes of Health, the Director
10 of the Centers for the Disease Control and
11 Prevention, and the Commissioner of Food
12 and Drugs; and

13 “(iii) award contracts, grants, coopera-
14 tive agreements, and enter into other trans-
15 actions, to include use of simplified acquisi-
16 tion authorities provided under sections
17 319F–1 and 319F–2(c)(7)(C)(iii), to public
18 and private persons, including for-profit
19 and nonprofit persons, federally funded re-
20 search and development centers, and univer-
21 sities, to—

22 “(I) support the cost of counter-
23 measure and product advanced re-
24 search and development; and

1 “(II) ensure accelerated develop-
2 ment of countermeasures and products.

3 “(C) STREAMLINE PROCESSES.—To carry
4 out the purpose described in paragraph (2)(C),
5 the Secretary, acting through the Director,
6 shall—

7 “(i) receive from the Assistant Sec-
8 retary for Public Health Emergency Pre-
9 paredness, requirements for national civil-
10 ian biodefense needs, particularly counter-
11 measures or products and other technologies,
12 to diagnose, mitigate, prevent, or treat
13 harm from existing, emerging, or potential
14 chemical, biological, radiological, or nuclear
15 agents (consistent with sections 302(2) and
16 304(a) of the Homeland Security Act of
17 2002) or potential pandemic infectious dis-
18 eases;

19 “(ii) establish transparent, expeditious,
20 and direct processes for selecting promising
21 countermeasures and products, supporting
22 them through advanced research and devel-
23 opment and recommending them for pro-
24 curement;

1 “(iii) establish an office within the
2 BARDA, in consultation with the Commis-
3 sioner of Food and Drugs, to—

4 “(I) facilitate regular and ongoing
5 communication between the
6 BARDA and the Food and Drug Ad-
7 ministration regarding the status of
8 BARDA advanced research and devel-
9 opment activities;

10 “(II) ensure that such activities
11 are coordinated with the approval re-
12 quirements of the Food and Drug Ad-
13 ministration, with the goal of expe-
14 diting the development and approval of
15 countermeasures and products; and

16 “(III) connect interested persons
17 with additional technical assistance
18 made available under section 565 of
19 the Federal Food, Drug, and Cosmetic
20 Act;

21 “(iv) coordinate with the Food and
22 Drug Administration to facilitate regu-
23 latory review and approval of promising
24 classes of countermeasures or products

1 *through the development of research tools;*

2 *and*

3 “(v) recommend to the Secretary,
4 *through the Assistant Secretary for Public
5 Health Emergency Preparedness, procure-
6 ment of the most promising eligible security
7 countermeasures or qualified pandemic or
8 epidemic products identified in clause (i).*

9 “(D) SUPPORTING INNOVATION.—To carry
10 out the purpose described in paragraph (2)(D),
11 the Secretary, acting through the Director, may
12 award contracts, grants, cooperative agreements,
13 or enter into other transactions, such as prize
14 payments, to include use of simplified acquisi-
15 tion authorities provided under sections 319F–1
16 and 319F–2(c)(7)(C)(iii), to the entities de-
17 scribed in subparagraph (B)(iii), to promote in-
18 novation in technologies supporting the advanced
19 research and development and production of
20 qualified or security countermeasures or quali-
21 fied pandemic or epidemic products, such as re-
22 search tools, manufacturing, countermeasure ad-
23 ministration, storage, and bioinformatics and
24 other devices.

25 “(E) OTHER DUTIES.—

1 “(i) *IN GENERAL.*—The Director
2 *may*—

3 “(I) *prepare and submit to the*
4 *President and Congress, an annual*
5 *budget estimate for qualified counter-*
6 *measure and pandemic or epidemic*
7 *product advanced research and devel-*
8 *opment and other BARDA activities,*
9 *after opportunity for comment by the*
10 *Secretary; and*

11 “(II) *receive from the President*
12 *and the Office of Management and*
13 *Budget directly all funds appropriated*
14 *by Congress for obligation and expend-*
15 *iture by the BARDA.*

16 “(ii) *SECRETARY DUTIES.*—The Sec-
17 *retary, acting through the Director, may*—

18 “(I) *enter into such contracts,*
19 *leases, cooperative agreements, or other*
20 *transactions, as may be necessary to*
21 *carry out the functions of BARDA,*
22 *without regard to section 3648 and*
23 *3709 of the Revised Statutes of the*
24 *United States (31 U.S.C. 3324(a) and*
25 *(b), (41 U.S.C. 5), with any public*

1 *agency, any firm, association, corpora-*
2 *tion, or educational institution, or any*
3 *other person;*

4 “(II) support advanced research
5 and development and innovation of po-
6 tential countermeasures or products by
7 highly qualified foreign national per-
8 sons outside the United States that
9 may inure to the benefit of the Amer-
10 ican people and collaborative research
11 involving American and foreign par-
12 ticipants;

13 “(III) administer grants using
14 milestone-based awards and payments;
15 and

16 “(IV) establish 1 or more federally
17 funded research and development cen-
18 ters or university affiliated research
19 centers in accordance with section
20 253(c)(3) of title 41, United States
21 Code.

22 “(5) VULNERABLE POPULATIONS.—In carrying
23 out the activities under this section, the Director, in
24 consultation with the Vulnerable Populations Working
25 Group, may give priority to supporting and facili-

1 *tating advanced research and development of counter-*
2 *measures or products, and formulations of counter-*
3 *measures or products, that are likely to be safe and*
4 *effective for pediatric populations, pregnant women,*
5 *and other vulnerable populations.*

6 “(6) WORKING GROUPS.—

7 “(A) IDENTIFICATION OF TECHNOLOGIES.—

8 “(i) IN GENERAL.—*The Director may*
9 *establish and convene, or enter into a con-*
10 *tract with a public or private research in-*
11 *stitution to convene, one or more working*
12 *groups that consists of experts on counter-*
13 *measure technology to identify innovative*
14 *technologies that have the potential to be de-*
15 *veloped as countermeasures or products.*

16 “(ii) MEETINGS.—*A working group es-*
17 *tablished under clause (i) shall participate*
18 *in regular meetings with sponsors of coun-*
19 *termeasures, products, or related tech-*
20 *nologies to—*

21 “(I) review the scientific evidence
22 *or concept of such countermeasures,*
23 *products, or related technologies;*

24 “(II) provide guidance on re-
25 *search protocols or studies; and*

1 “(III) provide guidance on the
2 regulatory approval process for coun-
3 termeasures, products, and related
4 technologies.

5 “(iii) *RECOMMENDATIONS*.—Not later
6 than 30 days after concluding a meeting
7 with a sponsor of a countermeasure, prod-
8 uct, or related technology, the working
9 group shall make recommendations to the
10 Director concerning such countermeasure,
11 product, or related technology.

12 “(iv) *CONFIDENTIALITY*.—Any com-
13 mercial confidential or proprietary infor-
14 mation that is disclosed to the working
15 group in a meeting under this section shall
16 remain confidential and shall not be dis-
17 closed other than to the Secretary or the Di-
18 rector, or their designees.

19 “(v) *CONSTRUCTION*.—Nothing in this
20 subparagraph shall be construed to prohibit
21 a sponsor from meeting with the Director to
22 discuss potential countermeasures, products,
23 or related technologies.

24 “(B) *PUBLIC WORKING GROUP*.—The Direc-
25 tor may establish and convene one or more work-

1 *ing groups composed of private citizens and offi-*
2 *cials of Federal, State, and local governments to*
3 *advise such Director with respect to the functions*
4 *of the BARDA and the Director.*

5 “(C) *VULNERABLE POPULATIONS WORKING*
6 *GROUP.—The Director shall establish and con-*
7 *vene a Vulnerable Populations Working Group*
8 *composed of experts on pediatric populations,*
9 *pregnant women, and other vulnerable popu-*
10 *lations to advise such Director with respect to—*

11 “(i) *supporting and facilitating ad-*
12 *vanced research and development of counter-*
13 *measures, and formulations of counter-*
14 *measures, that are safe and effective for*
15 *such populations; and*

16 “(ii) *other activities of the BARDA*
17 *that effect such populations.*

18 “(7) *PERSONNEL AUTHORITIES.—*

19 “(A) *SPECIALLY QUALIFIED SCIENTIFIC AND*
20 *PROFESSIONAL PERSONNEL.—In hiring per-*
21 *sonnel for the BARDA, the Director shall have*
22 *the hiring and management authorities described*
23 *in section 9903 of title 5, United States Code (as*
24 *added by section 1101 of the National Defense*
25 *Authorization Act for Fiscal Year 2004 (Public*

1 *Law 108–136)). With respect to the personnel of*
2 *the BARDA, the term of appointments for em-*
3 *ployees referred to under subsection (c)(1) of that*
4 *section may not exceed 5 years before the grant-*
5 *ing of any extension under subsection (c)(2) of*
6 *that section.*

7 “(B) SPECIAL CONSULTANTS.—*The Director*
8 *may accept special consultants as personnel for*
9 *the BARDA under section 207(f).*

10 “(C) INTERGOVERNMENTAL PERSONNEL
11 ACT.—*The Director may accept as personnel for*
12 *the BARDA, employees under subchapter VI of*
13 *chapter 33 of subpart B of part III of title 5,*
14 *United States Code.*

15 “(D) OTHER SERVICES.—*The Director may*
16 *accept voluntary and uncompensated services.*

17 “(c) NATIONAL BIODEFENSE ADVISORY BOARD.—

18 “(1) IN GENERAL.—

19 “(A) PURPOSE.—*The National Biodefense*
20 *Advisory Board shall provide expert advice and*
21 *guidance to the Secretary on the threats, chal-*
22 *lenges, and opportunities presented by advances*
23 *in biological and life sciences and the threat*
24 *from natural infectious diseases and chemical,*
25 *biological, radiological, and nuclear threats.*

1 “(B) *MEMBERSHIP.*—There is established
2 the National Biodefense Advisory Board (herein-
3 after in this section referred to as the ‘Board’) to
4 be composed of 23 members who represent the
5 Nation’s preeminent scientific, public health, and
6 medical experts on the subject of biological,
7 chemical, nuclear, and radiological threats,
8 whether naturally occurring, accidental, or deliberate,
9 as follows:

10 “(i) *EX OFFICIO.*—The following mem-
11 bers shall serve on the Board *ex officio*:

12 “(I) *The Assistant to the Presi-*
13 *dent for Homeland Security and*
14 *Counterterrorism.*

15 “(II) *The Director of the Office of*
16 *Science and Technology Policy.*

17 “(III) *The Assistant Secretary for*
18 *Public Health Emergency Prepared-*
19 *ness.*

20 “(IV) *The Director of the National*
21 *Institutes of Health.*

22 “(V) *The Director of the Centers*
23 *for Disease Control and Prevention.*

24 “(VI) *The Commissioner of Food*
25 *and Drugs.*

1 “(VII) *The Director of BARDA.*

2 “(VIII) *The Assistant Secretary of*
3 *Defense for Health Affairs.*

4 “(IX) *The Under Secretary of*
5 *Homeland Security for Science and*
6 *Technology.*

7 “(X) *The Secretary of Agriculture*
8 *(or a designee).*

9 “(ii) *APPOINTED MEMBERS.*—*The fol-*
10 *lowing individuals, as appointed by the*
11 *Secretary:*

12 “(I) *Four representatives of the*
13 *pharmaceutical, biotechnology, and de-*
14 *vice industries.*

15 “(II) *Four representatives of aca-*
16 *demia.*

17 “(III) *Five other members as de-*
18 *termined appropriate by the Secretary.*

19 “(C) *TERM OF APPOINTMENT.*—*A member*
20 *of the Board described in subparagraph (B)(ii)*
21 *shall serve for a term of 3 years, except that the*
22 *Secretary may adjust the terms of the initial*
23 *Board appointees in order to provide for a stag-*
24 *gered term of appointment for all members.*

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

5 “(2) DUTIES.—The Board shall—

6 “(A) advise the Secretary on major bio-
7 defense initiatives and review ongoing and pro-
8 posed biodefense programs, which may include
9 potential activities of the BARDA; and

10 “(B) in consultation with the Director of
11 BARDA, and in coordination with the Director
12 of National Institute of Allergy and Infectious
13 Diseases, provide to the Secretary, recommenda-
14 tions and findings for an expanded, intensified,
15 and coordinated biodefense research program en-
16 compassing the programs of the BARDA and
17 other Federal agencies and related programs of
18 the other research institutes.

19 “(3) MEETINGS.—The Board shall meet at the
20 call of the Secretary, but in no case less than twice
21 annually to provide to the Secretary updated assess-
22 ments, findings, and recommendations of the current
23 trends, challenges, and opportunities posed in life
24 sciences biotechnology and genetic engineering.

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

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

7 “(6) POWERS.—

8 “(A) HEARINGS.—The Board may hold
9 such hearings, sit and act at such times and
10 places, take such testimony, and receive such evi-
11 dence as the Board considers advisable to carry
12 out this subsection.

13 “(B) POSTAL SERVICES.—The Board may
14 use the United States mails in the same manner
15 and under the same conditions as other depart-
16 ments and agencies of the Federal Government.

17 “(7) PERSONNEL.—

18 “(A) OFFICERS OF THE FEDERAL GOVERN-
19 MENT.—A member of the Board that is an em-
20 ployee of the Federal Government may not re-
21 ceive additional pay, allowances, or benefits by
22 reason of the member’s service on the Board.

23 “(B) OTHER MEMBERS.—A member of the
24 Board that is not an employee of the Federal
25 Government shall be compensated at a rate

1 *equivalent to the daily equivalent of the annual*
2 *rate of basic pay prescribed for level IV of the*
3 *Executive Schedule under section 5315 of title 5,*
4 *United States Code, for each day (including*
5 *travel time) during which the member is engaged*
6 *in the actual performance of duties as a member*
7 *of the Board.*

8 “(C) TRAVEL EXPENSES.—*Each member of*
9 *the Board shall receive travel expenses, including*
10 *per diem in lieu of subsistence, in accordance*
11 *with applicable provisions under subchapter I of*
12 *chapter 57 of title 5, United States Code.*

13 “(D) DETAIL OF GOVERNMENT EMPLOY-
14 *EES.—Any Federal Government employee may*
15 *be detailed to the Board with the approval for*
16 *the contributing agency without reimbursement,*
17 *and such detail shall be without interruption or*
18 *loss of civil service status or privilege.*

19 “(d) FUND.—

20 “(1) ESTABLISHMENT.—*There is established the*
21 *Biodefense Medical Countermeasure Development*
22 *Fund, which shall be administered by the Director of*
23 *the BARDA.*

24 “(2) FUNDS.—

1 “(A) FIRST FISCAL YEAR.—Of the amounts
2 appropriated to carry out the Project BioShield
3 Act of 2004 (Public Law 108–276) and not obli-
4 gated, \$1,000,000,000 shall be available to the
5 Fund to carry out this section for fiscal year
6 2006. Such amounts shall remain available until
7 expended.

8 “(B) SUBSEQUENT FISCAL YEARS.—There
9 are authorized to be appropriated such sums as
10 may be necessary to carry out this section for fis-
11 cal year 2007 and each subsequent fiscal year.
12 Such sums shall remain available until ex-
13 pended.

14 “(e) EFFECT OF SECTION.—Nothing in this section
15 shall be construed to limit any authority of the Department
16 of Health and Human Services, including those authorities
17 provided under the Project BioShield Act of 2004 (Public
18 Law 108–276).

19 “(f) INAPPLICABILITY OF CERTAIN ACTS.—

20 “(1) FACIA.—The Federal Advisory Committee
21 Act (5 U.S.C. App.) shall not apply to the duties, ac-
22 tivities, working groups, and advisory boards of the
23 BARDA.

24 “(2) FOIA.—Information that relates to the ac-
25 tivities, working groups, and advisory boards of the

1 *BARDA shall not be subject to disclosure under sec-*
2 *tion 552 of title 5, United States Code, unless the Sec-*
3 *retary or Director determines that such disclosure*
4 *would pose no threat to national security. Such a de-*
5 *termination shall not be subject to judicial review.*

6 “(3) *CERTAIN COST PRINCIPLES AND COST AC-*
7 *COUNTING STANDARDS.*—*Notwithstanding any other*
8 *provision of law, the cost principles set forth under*
9 *part 31 of title 48, Code of Federal Regulations, the*
10 *cost accounting standards set forth under chapter 99*
11 *of title 48, Code of Federal Regulations, and the re-*
12 *quirement for the submission of certified cost and*
13 *pricing information under section 304A of the Fed-*
14 *eral Property and Administrative Services Act of*
15 *1949 (41 U.S.C. 254b), shall not apply to any con-*
16 *tract, grant, cooperative agreement, or other trans-*
17 *action entered into under the Project BioShield Act of*
18 *2004 (Public Law 108–276).*”.

19 **SEC. 4. CLARIFICATION OF COUNTERMEASURES COVERED**
20 **BY PROJECT BIOSHIELD.**

21 (a) *QUALIFIED COUNTERMEASURE.*—*Section 319F–*
22 *1(a) of the Public Health Service Act (42 U.S.C. 247d–*
23 *6a(a)) is amended by striking paragraph (2) and inserting*
24 *the following:*

25 “(2) *DEFINITIONS.*—*In this section:*

1 “(A) *QUALIFIED COUNTERMEASURE.*—The
2 term ‘qualified countermeasure’ means a drug
3 (as that term is defined by section 201(g)(1) of
4 the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 321(g)(1))), biological product (as that
6 term is defined by section 351(i) of this Act (42
7 U.S.C. 262(i))), device (as that term is defined
8 by section 201(h) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 321(h))), or research
10 tool (as that term is defined in section 201(rr)
11 of the Federal Food, Drug, and Cosmetic Act)
12 that the Secretary determines to be a priority
13 (consistent with sections 302(2) and 304(a) of
14 the Homeland Security Act of 2002) to—

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

22 “(ii) diagnose, mitigate, prevent, or
23 treat harm from a condition that may re-
24 sult in adverse health consequences or death
25 and may be caused by administering a

1 *drug, biological product, or device that is*
2 *used as described in this subparagraph; or*
3 *“(iii) in the case of a research tool, en-*
4 *able the rapid and effective identification,*
5 *assessment, or development of a drug, bio-*
6 *logical product, or device to diagnose, miti-*
7 *gate, prevent, or treat harm, as described in*
8 *clause (i) or (ii).*

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

15 (b) *SECURITY COUNTERMEASURE.—Section 319F—*
16 *2(c)(1)(B) is amended by—*

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

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

23 (c) *RESEARCH TOOL.—Section 201 of the Federal*
24 *Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended*
25 *by adding at the end the following:*

1 “(rr) *RESEARCH TOOL*.—The term ‘research tool’ in-
2 cludes the full range of tools and systems that assist in the
3 discovery, development, or manufacture of drugs, biological
4 products (as defined in section 351 of the Public Health
5 Service Act), or devices.”.

6 **SEC. 5. ORPHAN DRUG MARKET EXCLUSIVITY FOR COUN-**

7 **TERMEASURE PRODUCTS.**

8 “(a) *MARKET EXCLUSIVITY*.—Subchapter A of chapter
9 V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 351 et seq.) is amended by inserting after section 505B the
11 following:

12 **“SEC. 505C. ORPHAN DRUG MARKET EXCLUSIVITY FOR**
13 **COUNTERMEASURE PRODUCTS.**

14 “(a) *IN GENERAL*.—With respect to countermeasure
15 products (as such term is defined in this section), if a coun-
16 termeasure product is designated under section 526 for a
17 rare disease or condition, the period referred to in section
18 527(a) shall be 10 years instead of 7 years.

19 “(b) *DEFINITION*.—For the purpose of this section, the
20 term ‘countermeasure’ means a drug or biological product
21 (as such term is defined by section 351(i) of the Public
22 Health Service Act) that the Secretary determines to be a
23 priority (consistent with sections 302(2) and 304(a) of the
24 Homeland Security Act of 2002) to diagnose, mitigate, pre-
25 vent, or treat harm from any biological, chemical, radio-

1 logical, or nuclear agent (including organisms that cause
2 an infectious disease) or toxin identified as a material
3 threat under subsection (c)(2)(A)(ii) of section 319F-2 of
4 the Public Health Service Act.”.

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

16 (c) EFFECT OF SECTION.—This section, and the
17 amendments made by this section, shall apply to new drug
18 applications and biological product licenses approved under
19 the Federal Food, Drug, and Cosmetic Act or the Public
20 Health Service Act after the date of enactment of 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), and
5 subject to subsection (b)(1)(C), a manufacturer, distributor,
6 or administrator of a security countermeasure, or a quali-
7 fied pandemic and epidemic product, described in sub-
8 section (b)(1)(A) or a health care provider shall be immune
9 from suit or liability caused by or arising out of the design,
10 development, clinical testing and investigation, manufac-
11 ture, labeling, distribution, sale, purchase, donation, dis-
12 pensing, prescribing, administration, or use of a security
13 countermeasure, or a qualified pandemic and epidemic
14 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 and
24 investigation, manufacture, labeling, dis-
25 tribution, 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 counter-*
9 *measure 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 ‘arising*
14 *out of, reasonably relating to, or resulting*
15 *from’ shall not be construed to apply to loss*
16 *of property, personal injury, or death that*
17 *has no alleged or potential causal relation-*
18 *ship with the design, development, clinical*
19 *testing and investigation, manufacture, la-*
20 *beling, distribution, sale, purchase, dona-*
21 *tion, dispensing, prescribing, administra-*
22 *tion, or use of a product described in clause*
23 *(i).*

24 “*(B) RULE.*—

1 “(i) *SUBSEQUENT INJURY.*—*The pro-*
2 *tections set forth in subsection (a) and sub-*
3 *paragraph (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 forth*
8 *in the designation provided for in para-*
9 *graph (2), regardless of the date of alleged*
10 *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 the*
19 *effective period set forth in the designation*
20 *provided for in paragraph (2) by a manu-*
21 *facturer through the commercial market,*
22 *provided that the security countermeasures*
23 *or the qualified pandemic or epidemic prod-*
24 *uct are the security countermeasure or*
25 *qualified pandemic or epidemic product de-*

1 scribed in a declaration described in para-
2 graph (2) and the Secretary does not spe-
3 cifically prohibit such private donation or
4 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 SECRETARY.—
15 A party seeking a determination under sub-
16 paragraph (D) may petition the Secretary
17 to investigate allegations against a manu-
18 facturer, distributor, administrator, or
19 health care provider arising out of, relating
20 to, or resulting from the design, develop-
21 ment, clinical testing and investigation,
22 manufacture, labeling, distribution, sale,
23 purchase, donation, dispensing, prescribing,
24 administration, or use of products as pro-
25 vided for in subparagraph (A)(i). The deci-

1 *sion to undertake such investigation shall be*
2 *within the Secretary's discretion and shall*
3 *not be subject to judicial review.*

4 “*(iii) RULE OF CONSTRUCTION.*—*Noth-*
5 *ing in this section shall be construed to ab-*
6 *rogate or limit the application of subtitle II*
7 *of chapter 5 and chapter 7 of title 5, United*
8 *States Code (commonly known as the Ad-*
9 *ministrative Procedure Act).*

10 “*(D) DETERMINATION BY SECRETARY.*—

11 “*(i) IN GENERAL.*—*In making a deter-*
12 *mination under this subparagraph, the Sec-*
13 *retary, acting through an administrative*
14 *law judge, must find clear and convincing*
15 *evidence that—*

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

21 “*(II) in violating such Act, such*
22 *manufacturer, distributor, adminis-*
23 *trator, or health care provider acted*
24 *with willful misconduct.*

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

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

10 “(II) proximately caused the in-
11 jury alleged by the party.

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

19 “(iii) *EFFECT OF DETERMINATION.*—
20 Subject to subsection (c), the sole exception
21 to the immunity from suit and liability of
22 manufacturers, distributors, administrators,
23 or health care providers set forth in sub-
24 section (a) and subparagraph (A) shall be
25 for actions against a manufacturer, dis-

1 tributor, administrator, or health care pro-
2 vider as provided in subparagraph (A).

3 “(iv) JUDICIAL REVIEW.—At any time
4 prior to the 90th day following a deter-
5 mination by the Secretary under clause (i),
6 any manufacturer, distributor, adminis-
7 trator, or health care provider named in
8 such determination may file a petition with
9 the United States Court District Court for
10 the District of Columbia, for a judicial re-
11 view of such determination. A copy of the
12 petition shall be forthwith transmitted by
13 the clerk of the court to the Secretary or
14 other officer designated by the Secretary for
15 that purpose. The Secretary thereupon shall
16 file in the court the record of the findings
17 on which the Secretary based his or her de-
18 termination. The filing of a petition under
19 this clause shall automatically stay the Sec-
20 retary’s determination for the duration of
21 the judicial proceeding. The sole parties to
22 the judicial proceeding shall be the Sec-
23 retary and the petitioner. Intervention by
24 third parties in the judicial proceeding
25 shall not be permitted. No subpoenas shall

1 *be issued nor shall other compulsory process*
2 *apply. The court's review of a determina-*
3 *tion by the Secretary under this clause shall*
4 *conform to the procedures for judicial re-*
5 *view of administrative orders set forth in*
6 *paragraphs (2) through (6) of section 701(f)*
7 *of the Federal Food, Drug, and Cosmetic*
8 *Act (21 U.S.C. 371(f)) to the extent con-*
9 *sistent with this section.*

10 “*(v) TOLLING OF STATUTE OF LIMITA-*
11 *TIONS.—The computation of the statute of*
12 *limitations for any action against a manu-*
13 *facturer, distributor, administrator, or*
14 *health care provider described under this*
15 *subparagraph shall not include any time*
16 *occurring before the determination by the*
17 *Secretary under this subparagraph.*

18 “*(vi) REGULATORY AUTHORITY.—The*
19 *Secretary, in consultation with the Attorney*
20 *General, shall promulgate regulations defin-*
21 *ing what actions by a manufacturer, dis-*
22 *distributor, administrator, or health care pro-*
23 *vider of a security countermeasure or a*
24 *qualified pandemic and epidemic product*
25 *shall be deemed to constitute ‘willful mis-*

1 *conduct' for purposes of clause (i). In pro-*
2 *mulgating such regulations, the Secretary*
3 *shall consider the nature of the actual or*
4 *potential public health emergency, the tim-*
5 *ing and extent of any vaccination or coun-*
6 *termeasure program, and any other cir-*
7 *cumstances they deem significant, so that*
8 *any civil actions permitted under this sub-*
9 *section will not adversely affect the public*
10 *health. The Secretary may specify the pe-*
11 *riod of time for which such regulations*
12 *apply.*

13 “(vii) EVIDENCE REQUIRED.—The Sec-
14 *retary, in consultation with the Attorney*
15 *General, shall promulgate regulations that*
16 *require, in order to be a party under this*
17 *section, that an individual present evidence*
18 *that reasonably demonstrates that—*

19 “(I) such individual has suffered
20 *a loss as a direct result of the design,*
21 *development, clinical testing and inves-*
22 *tigation, manufacture, labeling, dis-*
23 *tribution, sale, purchase, donation, dis-*
24 *pensing, prescribing, or administration*
25 *of a security countermeasure or quali-*

1 fied epidemic or pandemic product;
2 and

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

10 “(E) SCOPE.—Subparagraph (C) shall
11 apply regardless of whether the suit or liability
12 described in subsection (a) or the claim described
13 in subparagraph (A) arises from the design, de-
14 velopment, clinical testing and investigation,
15 manufacture, labeling, distribution, sale, pur-
16 chase, donation, dispensing, prescribing, admin-
17 istration, or use by the Federal Government or
18 by any person.

19 “(2) DECLARATION BY SECRETARY.—

20 “(A) IN GENERAL.—The Secretary may
21 issue a declaration, pursuant to this paragraph,
22 that an actual or potential public health emer-
23 gency makes advisable the distribution, adminis-
24 tration, or use of a security countermeasure or
25 qualified pandemic or epidemic product.

1 “(B) SECURITY COUNTERMEASURE OR
2 QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—

3 *The Secretary shall specify in such declaration
4 the security countermeasures or qualified pan-
5 demic or epidemic products to be sold by, pur-
6 chased from, or donated by a manufacturer or
7 drawn from the Strategic National Stockpile.*

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

17 “(D) PUBLICATION.—*The Secretary shall
18 promptly publish each such declaration and
19 amendment in the Federal Register.*

20 “(c) ACTIONS BY THE UNITED STATES.—*Nothing in
21 this section shall be construed to abrogate or limit any
22 right, remedy, or authority that the United States or any
23 agency thereof may possess under any other provision of
24 law.*

25 “(d) DEFINITIONS.—*In this section:*

1 “(1) *ADMINISTRATOR.*—The term ‘administrator’
2 means a person employed by the State or local gov-
3 ernment, or their designee, who supervised or admin-
4 istered a program with respect to the administration,
5 dispensing, distribution, or provision of a security
6 countermeasure or a qualified pandemic or epidemic
7 product, including a person who has established re-
8 quirements, provided policy guidance, supplied tech-
9 nical or scientific advice or assistance.

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

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

23 “(4) *MANUFACTURER.*—The term ‘manufacturer’
24 includes—

1 “(A) a contractor or subcontractor of a
2 manufacturer;

3 “(B) a supplier of any product or service,
4 research tool, or component to the manufacturer;
5 and

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

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

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

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

9 “(C) is authorized for emergency use in ac-
10 cordance with section 564 of the Federal Food,
11 Drug, and Cosmetic Act, except that subsection
12 (b) of such section shall not apply.

13 “(6) PARTY.—The term ‘party’ means an indi-
14 vidual who can reasonably demonstrate to the Sec-
15 retary that such individual has suffered a loss (as de-
16 fined in paragraph (3)) as a direct result of the will-
17 ful misconduct of a manufacturer, distributor, admin-
18 istrator, or health care provider.

19 “(7) PERSON.—The term ‘person’ includes an in-
20 dividual, partnership, corporation, association, enti-
21 ty, or public or private corporation, including a Fed-
22 eral, State, or local government agency or depart-
23 ment.

1 “(8) SECURITY COUNTERMEASURE.—The term
2 ‘security countermeasure’ has the meaning given such
3 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 following:

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

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

9 “(a) IN GENERAL.—If the Secretary issues a Procla-
10 mation stating that there is a critical public health need
11 for a covered individual to receive a covered countermeasure
12 during the effective period of the Proclamation, the Sec-
13 retary shall establish a process to provide compensation to
14 such covered individuals for a covered injury, consistent
15 with the Smallpox Emergency Personnel Protection pro-
16 gram under part C.

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

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

24 “(2) COVERED INDIVIDUAL.—The term ‘covered
25 individual’ means an individual—

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

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

10 “(C) who has volunteered and been selected
11 to be a member of an emergency response plan;
12 and

13 “(D) to whom a covered countermeasure is
14 administered or used pursuant to such approved
15 plan during the effective period of the Proclama-
16 tion and prior to the time at which the Secretary
17 declares a public health emergency pursuant to
18 section 319 related to a covered countermeasure
19 specified in the Proclamation.

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

1 *vidual as the direct result of administration or use to*
2 *the individual of a covered countermeasure.*

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

7 “(5) *EMERGENCY RESPONSE PLAN.*—The term
8 ‘emergency response plan’ or ‘plan’ means a response
9 plan detailing actions to be taken in preparation for
10 a pandemic, epidemic, or biological, chemical, radio-
11 logical, nuclear agent or toxin that presents, or may
12 present, a public health emergency.

13 “(6) *PROCLAMATION.*—The term ‘Proclamation’
14 means a Proclamation regarding the critical public
15 health need for the administration or use of a covered
16 countermeasure issued by the Secretary and published
17 in the Federal Register. Such Proclamation shall
18 specify the specific covered countermeasure rec-
19 ommended for administration.

20 “(c) *RULE OF CONSTRUCTION.*—Nothing in this sec-
21 tion shall be construed to require the creation of a com-
22 pensation program if the covered injuries are only minor
23 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 by*
9 *this section)—*

- 10 (1) *a rebate pursuant to subsection (b); or*
11 (2) *a grant pursuant to section 319M of the Pub-*
12 *lic Health Service Act (as added by subsection (c)).*

13 (b) **SURGE CAPACITY AND RESEARCH REBATES.—**

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

25 (2) **VACCINES, COUNTERMEASURES OR PRODUCTS**
26 **MANUFACTURING FACILITIES INVESTMENT REBATE.—**

1 (A) *IN GENERAL.*—For purposes of this sec-
2 tion, vaccines, countermeasures or products man-
3 ufacturing facilities investment rebate for any
4 taxable year for a person (as defined with respect
5 to such person for purposes of the Internal Rev-
6 enue Code of 1986) shall be an amount equal to
7 20 percent of the qualified investment for such
8 taxable year.

9 (B) *VACCINES, COUNTERMEASURES OR*
10 *PRODUCTS MANUFACTURING FACILITIES INVEST-*
11 *MENT.*—For purposes of subparagraph (A), the
12 qualified investment for any taxable year for a
13 person is the basis of each vaccines, counter-
14 measures or products manufacturing facilities
15 property placed in service by the person during
16 the taxable year involved.

17 (C) *VACCINES, COUNTERMEASURES AND*
18 *PRODUCTS MANUFACTURING FACILITIES PROP-*
19 *ERTY.*—For purposes of this subsection, the term
20 “vaccines, countermeasures and products manu-
21 facturing facilities property” means real and
22 tangible personal property—

23 (i)(I) the original use of which com-
24 mences with the person applying for the re-
25 bate; or

1 (II) which is acquired through pur-
2 chase (as defined by section 179(d)(2) of the
3 Internal Revenue Code of 1986);
4 (ii) which is depreciable under section
5 167 of the Internal Revenue Code of 1986;
6 (iii) which is physically located in a
7 State;
8 (iv) which is used for the manufacture,
9 distribution, or research and development of
10 vaccines, countermeasures, or products; and
11 (v) which is in compliance with appli-
12 cable good manufacturing practice and with
13 any other applicable requirements which
14 are promulgated by the Secretary, the Occu-
15 pational Safety and Health Administration,
16 or the Environmental Protection Agency,
17 and which are applicable to such property.

18 (D) DENIAL OF DOUBLE BENEFIT FOR MAN-
19 UFACTURING FACILITIES EXPENSES.—If any
20 portion of the vaccines, countermeasures, and
21 products manufacturing facilities property in-
22 vestment expenses is otherwise allowable as a de-
23 duction for the taxable year involved, the Sec-
24 retary shall only provide a rebate under this sec-

1 *tion for the portion of such expenses not covered*
2 *by the rebate determined by such deduction.*

3 *(E) ELIGIBILITY.—To be eligible to receive*
4 *a rebate under this subsection, a manufacturer*
5 *shall submit to the Secretary an application at*
6 *such time, in such manner, and containing such*
7 *information as the Secretary may require, in-*
8 *cluding—*

9 (i) *a detailed description and intended*
10 *use of the facilities that is the basis of ap-*
11 *plication;*

12 (ii) *a detailed description of the vac-*
13 *cine, countermeasure, or product being pro-*
14 *duced or that may be produced at the facil-*
15 *ity;*

16 (iii) *a detailed accounting of qualified*
17 *manufacturing facilities investment of the*
18 *person;*

19 (iv) *a certification as to the compli-*
20 *ance of the person with clauses (i) through*
21 *(iv) of subparagraph (C); and*

22 (v) *copies of tax returns for the taxable*
23 *year involved.*

1 (F) *EFFECTIVE DATE.*—This paragraph
2 shall apply to property placed in service after
3 December 31, 2005.

4 (G) *TERMINATION.*—This paragraph shall
5 not apply to any property placed in service after
6 December 31, 2010.

7 (3) *MEDICAL RESEARCH RELATED TO DEVEL-
8 OPING VACCINES, COUNTERMEASURES OR QUALIFIED
9 PANDEMIC OR EPIDEMIC PRODUCTS REBATE.*—

10 (A) *IN GENERAL.*—For purposes of this sub-
11 section, the research rebate determined under this
12 section for the taxable year involved (as deter-
13 mined as provided for in paragraph (2)(A)) is
14 an amount equal to 35 percent of the vaccines,
15 qualified countermeasures, or qualified pandemic
16 or epidemic products (referred to in this section
17 as “vaccine, countermeasure, or product”) re-
18 search expenses for the taxable year.

19 (B) *VACCINES, COUNTERMEASURES, OR
20 PRODUCTS RESEARCH EXPENSES.*—Except as
21 otherwise provided in this paragraph, the term
22 “vaccines, countermeasures, or products research
23 expenses” means the amounts which are paid or
24 incurred by the researcher or manufacturer dur-
25 ing the taxable year with respect to any research

1 *and development of vaccines, countermeasures, or*
2 *products. Qualified research and development ex-*
3 *penses include expenses related to reformulating*
4 *existing vaccines, countermeasures, or products.*

5 (C) *DETERMINING RESEARCH EXPENSES.—*
6 *Any vaccines, countermeasures, or products re-*
7 *search expenses for any taxable year which are*
8 *qualified research expenses (within the meaning*
9 *of this subsection) shall be taken into account in*
10 *determining base period research expenses for*
11 *purposes of applying this paragraph to subse-*
12 *quent taxable years.*

13 (D) *DENIAL OF DOUBLE BENEFIT FOR VAC-*
14 *CINES, COUNTERMEASURES, OR PRODUCTS RE-*
15 *SEARCH EXPENSES.—If any portion of the vac-*
16 *cines, countermeasures, or products research ex-*
17 *penses is otherwise allowable as a deduction for*
18 *the taxable year involved, the Secretary shall*
19 *only provide a rebate under this section for the*
20 *portion of such expenses not covered by any re-*
21 *bate determined by such deduction.*

22 (E) *ELIGIBILITY.—To be eligible to receive*
23 *a rebate under this paragraph, a manufacturer*
24 *or researcher shall submit to the Secretary an*
25 *application at such time, in such manner, and*

1 *containing such information as the Secretary
2 may require, including—*

3 *(i) a detailed description of the vac-
4 cine, countermeasure, or product being re-
5 searched or developed;*

6 *(ii) a detailed description of the re-
7 search that is the subject of the rebate;*

8 *(iii) a detailed accounting of the quali-
9 fied research expenses involved;*

10 *(iv) an assurance that the researcher or
11 manufacturer is following good laboratory
12 practice, as required by the Secretary pur-
13 suant to the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 301 et seq.) and the
15 Public Health Service Act (42 U.S.C. 201 et
16 seq.); and*

17 *(v) copies of tax returns for the taxable
18 year involved.*

19 *(F) EFFECTIVE DATE.—This paragraph
20 shall apply to expenses for taxable years begin-
21 ning after December 31, 2005.*

22 *(4) EXCLUSION FOR AMOUNTS FUNDED BY
23 GRANTS, ETC.—The terms “vaccines, countermeasures,
24 or products manufacturing investment” and “quali-
25 fied research expenses” shall not include any amount*

1 *to the extent such amount is funded by any grant,*
2 *contract, or otherwise funded by another person (or*
3 *any governmental entity).*

4 *(c) GRANTS TO EXPAND AND IMPROVE RESEARCH AND*
5 *DEVELOPMENT AND MANUFACTURING OF VACCINES, COUN-*
6 *TERMEASURES OR PRODUCTS.—Part B of title III of the*
7 *Public Health Service Act is amended by inserting after*
8 *section 319L, as added by this Act, the following:*

9 **“SEC. 319M. GRANTS TO EXPAND AND IMPROVE RESEARCH**
10 **AND DEVELOPMENT AND MANUFACTURING**
11 **OF VACCINES, QUALIFIED COUNTER-**
12 **MEASURES OR QUALIFIED PANDEMIC OR EPI-**
13 **DEMIC PRODUCTS.**

14 “(a) *IN GENERAL.—The Secretary may award grants*
15 *to a manufacturer to purchase or improve real property*
16 *and tangible personal property used in the research and*
17 *development, manufacture, or distribution of a vaccine,*
18 *qualified countermeasure (as defined in section 319F–1) or*
19 *qualified pandemic or epidemic product (as defined in sec-*
20 *tion 319F–3(c)(5)).*

21 “(b) *ELIGIBILITY.—To be eligible to receive a grant*
22 *under subsection (a), a manufacturer shall submit to the*
23 *Secretary an application at such time, in such manner, and*
24 *containing such information as the Secretary may require,*
25 *including—*

1 “(1) a detailed description of the planned expan-
2 sion;

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

5 “(3) a certification that such facility or property
6 is physically located in a State;

7 “(4) a detailed description of the vaccine, quali-
8 fied countermeasure or qualified pandemic or epi-
9 demic product involved;

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

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

14 “(7) a description of whether such equipment, fa-
15 cility, or property can be used for the research and
16 development, manufacture, or distribution of a drug,
17 biological product, device or other countermeasure not
18 described in paragraph (4); and

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

22 “(c) RECAPTURE.—

23 “(1) IN GENERAL.—If, at any time prior to the
24 expiration of the 20-year period beginning on the date
25 on which a grant is awarded under this section, the

1 *facility or property involved ceases to be used for the*
2 *purpose for which the grant was awarded, the United*
3 *States shall be entitled to recover from the manufac-*
4 *turer an amount bearing the same ratio to the value*
5 *of the facility or property at such time as the amount*
6 *of the grant bore to the total cost of the purchase or*
7 *improvement involved. The value of the facility or*
8 *property at such time may be determined by agree-*
9 *ment of the manufacturer and the Secretary, or by*
10 *order of the United States District Court for the dis-*
11 *trict in which such facility or property is situated.*

12 “(2) *LIMITATION.*—*The Secretary may not re-*
13 *capture the facility or property under this subsection*
14 *if the Secretary determines, in accordance with regu-*
15 *lations promulgated by the Secretary, that there is*
16 *good cause for the failure of proper use.*

17 “(d) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
18 *authorized to be appropriated such sums as may be nec-*
19 *essary to carry out this section.”.*

20 **SEC. 9. TECHNICAL ASSISTANCE.**

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

1 **“SEC. 565. TECHNICAL ASSISTANCE.**

2 “*The Secretary, in consultation with the Commis-*
3 *sioner of Food and Drugs, shall establish within the Food*
4 *and Drug Administration a team of experts on manufac-*
5 *turing and regulatory activities (including compliance with*
6 *current Good Manufacturing Practices) to provide both off-*
7 *site and on-site technical assistance to the manufacturers*
8 *of qualified countermeasures (as defined in section 319F–*
9 *1 of the Public Health Service Act), security counter-*
10 *measures (as defined in section 319F–2 of such Act), or vac-*
11 *cines, at the request of such a manufacturer and at the dis-*
12 *cretion of the Secretary, if the Secretary determines that*
13 *a shortage or potential shortage may occur in the United*
14 *States in the supply of such vaccines or products and that*
15 *the provision of such assistance would be beneficial in help-*
16 *ing alleviate or avert such shortage.”.*

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

18 *Part B of title IV of the Public Health Service Act*
19 *(42 U.S.C. 284 et seq.) is amended by adding at the end*
20 *the following:*

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

22 “(a) *IN GENERAL.—The Secretary, acting through the*
23 *Director of NIH, in coordination with the Director of the*
24 *Biomedical Advanced Research and Development Agency,*
25 *the Director of the Centers for Disease Control and Preven-*
26 *tion, and the Commissioner of Food and Drugs, shall estab-*

1 lish and award grants under this section to eligible entities,
2 including other Federal agencies, to study the physiological
3 responses of certain animal species and, where appropriate,
4 juvenile models, to chemical, biological, radiological, or nu-
5 clear agents or toxins or potential pandemic infectious dis-
6 ease, and to develop and validate such animal models.

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

9 “(1) provide assurances to the Secretary that the
10 entity—

11 “(A) has access to an appropriate biosafety
12 laboratory or facility, as determined by the Sec-
13 retary; and

14 “(B) will follow good laboratory practices;

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

18 “(A) a detailed description of the animal
19 model involved;

20 “(B) a detailed description of the chemical,
21 biological, radiological, nuclear, or other infec-
22 tious agents involved;

23 “(C) a detailed description of how the ani-
24 mal model will be used for the development of a

1 *drug, biological product, or device for use as a*
2 *countermeasure;*

3 “(D) a detailed description of validation
4 methods; and

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

7 “(3) agree to submit the results of the research
8 funded under the grant to the Director of the Bio-
9 medical Advanced Research and Development Agency
10 and the Director of NIH.

11 “(c) **AUTHORIZATION OF APPROPRIATIONS.**—There are
12 authorized to be appropriated such sums as may be nec-
13 essary to carry out this section.”.

14 **SEC. 11. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC ADVI-**
15 **SORY COMMITTEE.**

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

19 **“SEC. 566. ANIMAL MODEL/RESEARCH TOOL SCIENTIFIC AD-**
20 **VISORY COMMITTEE.**

21 “(a) **ESTABLISHMENT.**—Not later than 6 months after
22 the date of enactment of this section, the Secretary shall
23 establish an 11-member advisory committee to be known as
24 the ‘Animal Model/Research Tool Scientific Advisory Com-

1 mittee' (referred to in this section as the 'Advisory Com-
2 mittee').

3 “(b) *MEMBERSHIP.*—

4 “(1) *IN GENERAL.*—The Secretary shall appoint
5 as members of the Advisory Committee individuals
6 who are technically qualified by training and experi-
7 ence, including in medicine, veterinarian medicine,
8 biology, technology involving the manufacture, eval-
9 uation, or use of research tools, who are of appro-
10 priately diversified professional backgrounds to evalu-
11 ate the priority animal models and research tools.

12 “(2) *EX OFFICIO MEMBERS.*—The Secretary may
13 appoint Federal officials, including at least 1 rep-
14 resentative of the Biomedical Advanced Research and
15 Development Agency, to serve as ex officio members of
16 the Advisory Committee.

17 “(3) *CHAIRPERSON.*—The Secretary shall des-
18 ignate 1 of the members of the Advisory Committee to
19 serve as the chairperson.

20 “(c) *DUTIES.*—The Advisory Committee shall provide
21 advice, information, and recommendations to the Secretary
22 on—

23 “(1) accepted animal models for diseases and
24 conditions associated with any biological (including
25 organisms that cause infectious diseases), chemical,

1 *radiological, or nuclear agent or toxin or potential*
2 *pandemic infectious disease;*

3 “(2) *strategies to accelerate animal model and*
4 *research tool development and validation; and*

5 “(3) *scientific issues raised in applications as re-*
6 *quested by the Secretary.*

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

9 “(e) *COMPENSATION; SUPPORT; FACA.—*

10 “(1) *COMPENSATION AND TRAVEL.—Members of*
11 *the Advisory Committee who are not officers or em-*
12 *ployees of the United States, while attending con-*
13 *ferences or meetings of the committee or otherwise en-*
14 *gaged in its business, shall be entitled to receive com-*
15 *pensation at rates to be fixed by the Secretary, which*
16 *may not exceed daily equivalent of the rate in effect*
17 *for level 4 of the Senior Executive Schedule under sec-*
18 *tion 5382 of title 5, United States Code, for each day*
19 *(including travel time) they are so engaged, and while*
20 *so serving away from their homes or regular places of*
21 *business each member may be allowed travel expenses,*
22 *including per diem in lieu of subsistence, as author-*
23 *ized by section 5703 of title 5, United States Code, for*
24 *persons in the Federal Government service employed*
25 *intermittently.*

1 “(2) ADMINISTRATIVE SUPPORT.—The Secretary
2 shall furnish the Advisory Committee clerical and
3 other assistance.

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

7 “(f) PROCEEDINGS.—The Advisory Committee shall
8 make and maintain a transcript of any proceeding of the
9 Committee. The Committee shall delete from any transcript
10 made under this subsection information, which is exempt
11 from disclosure under section 552(b) of title 5, United
12 States Code.”.

13 **SEC. 12. COLLABORATION AND COORDINATION.**

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

16 “(g) LIMITED ANTITRUST EXEMPTION.—

17 “(1) SECURITY COUNTERMEASURES, QUALIFIED
18 COUNTERMEASURES AND QUALIFIED PANDEMIC OR
19 EPIDEMIC PRODUCT DEVELOPMENT MEETINGS.—

20 “(A) COUNTERMEASURES AND PRODUCTS
21 DEVELOPMENT MEETINGS AND CONSULTA-
22 TIONS.—The Secretary of Health and Human
23 Services (referred to in this subsection as the
24 ‘Secretary’) or the Director of the Biomedical
25 Advanced Research and Development Agency (re-

1 *ferred to in this subsection as the ‘Director’), in*
2 *coordination with the Attorney General and the*
3 *Secretary of Homeland Security, may conduct*
4 *meetings and consultations with parties involved*
5 *in the development of security countermeasures*
6 *(as defined in section 319F–2 of the Public*
7 *Health Service Act) qualified countermeasures*
8 *(as defined in section 319F–1 of the Public*
9 *Health Service Act) or qualified pandemic or*
10 *epidemic products (as defined in section 319F–*
11 *3(c)(5) of the Public Health Service Act) (re-*
12 *ferred to in this section as “countermeasures or*
13 *products” for the purpose of the development,*
14 *manufacture, distribution, purchase, sale, or*
15 *storage of countermeasures or products consistent*
16 *with the purposes of this title. The Secretary or*
17 *Director may convene such meeting or consulta-*
18 *tion at the request of any person, the Secretary*
19 *of Homeland Security, the Attorney General, the*
20 *Chairperson of the Federal Trade Commission,*
21 *an industry representative or member, or upon*
22 *initiation by such Secretary. The Secretary or*
23 *Director shall give notice of such meetings and*
24 *consultations to the Chairperson of the Federal*

1 *Trade Commission (referred to in this subsection
2 as the ‘Chairperson’) and the Attorney General.*

3 “*(B) MEETING AND CONSULTATION CONDI-
4 TIONS.—A meeting or consultation conducted
5 under subparagraph (A) shall—*

6 “*(i) be chaired or, in the case of a con-
7 sultation, facilitated by the Secretary or Di-
8 rector;*

9 “*(ii) be open to parties involved in the
10 development, manufacture, distribution,
11 purchase, or sale of countermeasures or
12 products, as determined by the Secretary or
13 Director;*

14 “*(iii) be open to the Attorney General,
15 the Secretary of Homeland Security, and
16 the Chairperson;*

17 “*(iv) be limited to discussions involv-
18 ing the development, manufacture, distribu-
19 tion, or sale of countermeasures or products,
20 consistent with the purposes of this title;
21 and*

22 “*(v) be conducted in such manner as to
23 ensure that national security, confidential,
24 and proprietary information is not dis-
25 closed outside the meeting or consultation.*

1 “(C) *LIMITATION.*—The Secretary or Direc-
2 tor may not require the disclosure of confidential
3 commercial or proprietary information.

4 “(D) *MINUTES.*—The Secretary or Director
5 shall maintain minutes of meetings and con-
6 sultations under this subsection, which shall not
7 be disclosed under section 552 of title 5, United
8 States Code, unless such Secretary or Director,
9 in consultation with the Attorney General, deter-
10 mines that disclosure would pose no threat to na-
11 tional security. Such determination shall not be
12 subject to judicial review.

13 “(E) *EXEMPTION.*—

14 “(i) *IN GENERAL.*—The antitrust laws
15 shall not apply to meetings and consulta-
16 tions under this paragraph.

17 “(ii) *LIMITATION.*—Clause (i) shall not
18 apply to any agreement or conduct that re-
19 sults from a meeting or consultation and
20 that does not receive an exemption pursuant
21 to this subsection.

22 “(2) *WRITTEN AGREEMENTS.*—The Secretary or
23 the Director shall file a written agreement regarding
24 covered activities, made pursuant to meetings or con-
25 sultations conducted under paragraph (1) and that is

1 *consistent with this paragraph, with the Attorney*
2 *General and the Chairperson for a determination of*
3 *the compliance of such agreement with antitrust laws.*

4 *In addition to the proposed agreement itself, any such*
5 *filing shall include—*

6 “(A) *an explanation of the intended purpose*
7 *of the agreement;*

8 “(B) *a specific statement of the substance of*
9 *the agreement;*

10 “(C) *a description of the methods that will*
11 *be utilized to achieve the objectives of the agree-*
12 *ment;*

13 “(D) *an explanation of the necessity of a co-*
14 *operative effort among the particular partici-*
15 *pating parties to achieve the objectives of the*
16 *agreement; and*

17 “(E) *any other relevant information deter-*
18 *mined necessary by the Secretary or Director in*
19 *consultation with the Attorney General and the*
20 *Chairperson.*

21 “(3) *DETERMINATION.—The Attorney General,*
22 *in consultation with the Chairperson, shall determine*
23 *whether an agreement regarding covered activities re-*
24 *ferred to in paragraph (2) would likely—*

1 “(A) be in compliance with the antitrust
2 laws, and so inform the Secretary or Director
3 and the participating parties; or

4 “(B) violate the antitrust laws, in which
5 case, the filing shall be deemed to be a request for
6 an exemption from the antitrust laws, limited to
7 the performance of the agreement consistent with
8 the purposes of this title.

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

10 “(A) IN GENERAL.—The Attorney General,
11 in consultation with the Chairperson, shall
12 grant, deny, grant in part and deny in part, or
13 propose modifications to a request for exemption
14 from the antitrust laws under paragraph (3)
15 within 15 business days of the receipt of such re-
16 quest.

17 “(B) EXTENSION.—The Attorney General
18 may extend the 15-day period referred to in sub-
19 paragraph (A) for an additional period of not to
20 exceed 10 business days. Such additional period
21 may be further extended only by the United
22 States district court, upon an application by the
23 Attorney General after notice to the Secretary or
24 Director and the parties involved.

1 “(C) DETERMINATION.—In granting an ex-
2 emption under this paragraph, the Attorney
3 General, in consultation with the Chairperson
4 and the Secretary or Director—

5 “(i) shall find—

6 “(I) that the agreement involved
7 is necessary to ensure the availability
8 of countermeasures or products;

9 “(II) that the exemption from the
10 antitrust laws would promote the pub-
11 lic interest; and

12 “(III) that there is no substantial
13 competitive impact to areas not di-
14 rectly related to the purposes of the
15 agreement; and

16 “(ii) may consider any other factors
17 determined relevant by the Attorney General
18 and the Chairperson.

19 “(5) LIMITATION ON AND RENEWAL OF EXEMP-
20 TIONS.—An exemption granted under paragraph (4)
21 shall be limited to covered activities, and shall be re-
22 newed (with modifications, as appropriate) on the
23 date that is 3 years after the date on which the ex-
24 emption becomes effective (and at 3-year intervals
25 thereafter, if renewed) unless the Attorney General in

1 *consultation with the Chairperson determines that the*
2 *exemption should not be renewed (with modifications,*
3 *as appropriate) considering the factors described in*
4 *paragraph (4).*

5 “(6) *LIMITATION ON PARTIES.*—*The use of any*
6 *information acquired under an exempted agreement*
7 *by the parties to such an agreement for any purposes*
8 *other than those specified in the antitrust exemption*
9 *granted by the Attorney General shall be subject to the*
10 *antitrust laws and any other applicable laws.*

11 “(7) *GUIDELINES.*—*The Attorney General and*
12 *the Chairperson may develop and issue guidelines to*
13 *implement this subsection.*

14 “(8) *REPORT.*—*Not later than 1 year after the*
15 *date of enactment of the Biodefense and Pandemic*
16 *Vaccine and Drug Development Act of 2005, and an-*
17 *nually thereafter, the Attorney General and the*
18 *Chairperson shall report to Congress on the use and*
19 *continuing need for the exemption from the antitrust*
20 *laws provided by this subsection.*

21 “(9) *STATUS OF MEMORANDUMS.*—*Minutes*
22 *maintained by the Secretary or Director pursuant to*
23 *paragraph (1)(D) shall not be disclosed under section*
24 *552 of title 5, United States Code, if the exemption*
25 *is not renewed under paragraph (5), or if meetings*

1 *are no longer conducted, unless the Secretary or Di-*
2 *rector, in consultation with the Attorney General, de-*
3 *termines that the disclosure would pose no threat to*
4 *national security. Such determination shall not be*
5 *subject to judicial review.*

6 “(h) SUNSET.—*The authority of the Attorney General*
7 *to grant or renew a limited antitrust exemption under this*
8 *section shall expire at the end of the 6-year period that be-*
9 *gins on the date of enactment of the Biodefense and Pan-*
10 *demic Vaccine and Drug Development Act of 2005.*

11 “(i) DEFINITIONS.—*In this section:*

12 “(1) ANTITRUST LAWS.—*The term ‘antitrust*
13 *laws’—*

14 “(A) *has the meaning given such term in*
15 *subsection (a) of the first section of this Act, ex-*
16 *cept that such term includes the Act of June 19,*
17 *1936 (15 U.S.C. 13 et seq.) (commonly known as*
18 *the Robinson-Patman Act), and section 5 of the*
19 *Federal Trade Commission Act (15 U.S.C. 45) to*
20 *the extent such section 5 applies to unfair meth-*
21 *ods of competition; and*

22 “(B) *includes any State law similar to the*
23 *laws referred to in subparagraph (A).*

24 “(2) COVERED ACTIVITIES.—

1 “(A) *IN GENERAL.*—Except as provided in
2 *subparagraph (B), the term ‘covered activities’*
3 *means any group of activities or conduct, includ-*
4 *ing attempting to make, making, or performing*
5 *a contract or agreement or engaging in other*
6 *conduct, for the purpose of—*

7 “(i) *theoretical analysis, experimen-*
8 *tation, or the systematic study of phe-*
9 *nomena or observable facts necessary to the*
10 *development of countermeasures or products;*

11 “(ii) *the development or testing of*
12 *basic engineering techniques necessary to*
13 *the development of countermeasures or prod-*
14 *ucts;*

15 “(iii) *the extension of investigative*
16 *findings or theory of a scientific or tech-*
17 *nical nature into practical application for*
18 *experimental and demonstration purposes,*
19 *including the experimental production and*
20 *testing of models, prototypes, equipment,*
21 *materials, and processes necessary to the de-*
22 *velopment of countermeasures or products;*

23 “(iv) *the production, distribution, or*
24 *marketing of a product, process, or service*
25 *that is a countermeasures or products;*

1 “(v) the testing in connection with the
2 production of a product, process, or services
3 necessary to the development of counter-
4 measures or products;

5 “(vi) the collection, exchange, and
6 analysis of research or production informa-
7 tion necessary to the development of coun-
8 termeasures or products; or

9 “(vii) any combination of the purposes
10 described in clauses (i) through (vi);
11 and such term may include the establishment
12 and operation of facilities for the conduct of cov-
13 ered activities described in clauses (i) through
14 (vi), the conduct of such covered activities on a
15 protracted and proprietary basis, and the proc-
16 essing of applications for patents and the grant-
17 ing of licenses for the results of such covered ac-
18 tivities.

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

22 “(i) Exchanging information among
23 competitors relating to costs, profitability,
24 marketing, or distribution of any product,
25 process, or service if such information is not

1 *reasonably necessary to carry out the pur-*
2 *poses of covered activities.*

3 “(ii) *Entering into any agreement or*
4 *engaging in any other conduct—*

5 “(I) *to restrict or require the sale,*
6 *licensing, or sharing of inventions, de-*
7 *velopments, products, processes, or*
8 *services not developed through, pro-*
9 *duced by, or distributed or sold*
10 *through such covered activities; or*

11 “(II) *to restrict or require partici-*
12 *pation by any person who is a party*
13 *to such covered activities in other re-*
14 *search and development activities, that*
15 *is not reasonably necessary to prevent*
16 *the misappropriation of proprietary*
17 *information contributed by any person*
18 *who is a party to such covered activi-*
19 *ties or of the results of such covered ac-*
20 *tivities.*

21 “(iii) *Entering into any agreement or*
22 *engaging in any other conduct allocating a*
23 *market with a competitor that is not ex-*
24 *pressly exempted from the antitrust laws by*
25 *a determination under subsection (g)(4).*

1 “(iv) Exchanging information among
2 competitors relating to production (other
3 than production by such covered activities)
4 of a product, process, or service if such in-
5 formation is not reasonably necessary to
6 carry out the purpose of such covered activi-
7 ties.

8 “(v) Entering into any agreement or
9 engaging in any other conduct restricting,
10 requiring, or otherwise involving the pro-
11 duction of a product, process, or service that
12 is not so expressly exempted from the anti-
13 trust laws by a determination under sub-
14 section (g)(4).

15 “(vi) Except as otherwise provided in
16 this subsection, entering into any agreement
17 or engaging in any other conduct to restrict
18 or require participation by any person who
19 is a party to such activities, in any unilat-
20 eral or joint activity that is not reasonably
21 necessary to carry out the purpose of such
22 covered activities.

23 “(vii) Entering into any agreement or
24 engaging in any other conduct restricting or

1 *setting the price at which a product is of-*
2 *fered for sale, whether by bid or otherwise.*

3 “(4) **DEVELOPMENT**.—The term ‘development’
4 *includes the identification of suitable compounds or*
5 *biological materials, the conduct of preclinical and*
6 *clinical studies, the preparation of an application for*
7 *marketing approval, and any other actions related to*
8 *preparation of a countermeasure or product.”.*

9 **SEC. 13. PROCUREMENT.**

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

12 (1) *in the section heading, by inserting “**AND***
13 **SECURITY COUNTERMEASURE PROCUREMENT**
14 *MENTS” before the period; and*

15 (2) *in subsection (c)—*

16 (A) *in the subsection heading, by striking*
17 *“BIOMEDICAL”;*

18 (B) *in paragraph (5)(B)(i), by striking “to*
19 *meet the needs of the stockpile” and inserting “to*
20 *meet the stockpile needs”;*

21 (C) *in paragraph (7)(C)(ii)—*

22 (i) *by amending clause (I) to read as*
23 *follows:*

24 “(I) **PAYMENT CONDITIONED ON**
25 **DELIVERY**.—The contract shall provide

1 *that no payment may be made until*
2 *delivery of a portion, acceptable to the*
3 *Secretary, of the total number of units*
4 *contracted for, except that, notwithstanding*
5 *any other provision of law,*
6 *the contract may provide that, if the*
7 *Secretary determines (as the Sec-*
8 *retary's discretion) that an advance*
9 *payment, partial payment for signifi-*
10 *cant milestones, or payment to increase*
11 *manufacturing capacity is necessary to*
12 *ensure success of a project, the Sec-*
13 *retary shall pay an amount, not to ex-*
14 *ceed 10 percent of the contract amount,*
15 *in advance of delivery. The contract*
16 *shall provide that such advance pay-*
17 *ment is required to be repaid if there*
18 *is a failure to perform by the vendor*
19 *under the contract. The contract may*
20 *also provide for up to 3 additional ad-*
21 *vance payments of 5 percent each for*
22 *meeting the milestones specified in*
23 *such contract. Provided that the speci-*
24 *fied milestones are reached, these ad-*
25 *vanced payments of 5 percent shall not*

1 *be required to be repaid. Nothing in*
2 *this subclause shall be construed as af-*
3 *flecting the rights of vendors under pro-*
4 *visions of law or regulation (including*
5 *the Federal Acquisition Regulation) re-*
6 *lating to the termination of contracts*
7 *for the convenience of the Govern-*
8 *ment.”; and*

9 *(ii) by adding at the end the following:*

10 *“(VII) SALES EXCLUSIVITY.—The*
11 *contract may provide that the vendor*
12 *is the sole and exclusive supplier of the*
13 *product to the Federal Government for*
14 *a specified period of time, not to exceed*
15 *15 years, on the condition that the ven-*
16 *dor is able to satisfy the needs of the*
17 *Government. During the agreed period*
18 *of sales exclusivity, the vendor shall not*
19 *assign its rights of sales exclusivity to*
20 *another entity or entities without ap-*
21 *proval by the Secretary.*

22 *“(VIII) SURGE CAPACITY.—The*
23 *contract may provide that the vendor*
24 *establish domestic manufacturing ca-*
25 *pacity of the product to ensure that ad-*

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

14 “*(IX) CONTRACT TERMS.—The*
15 *Secretary, in any contract for procure-*
16 *ment under this section, may specify—*

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

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

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

22 **SEC. 14. NATIONAL PATHOLOGY CENTER.**

23 (a) *IN GENERAL.*—Title IV of the Public Health Serv-
24 ice Act (42 U.S.C. 281 et seq.) is amended—

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

3 “(H) The National Pathology Center.”; and

4 (2) by adding at the end of part E (42 U.S.C.
5 287 et seq.) the following:

6 **“Subpart 7—National Pathology Center**

7 **“SEC. 485A. ESTABLISHMENT OF NATIONAL PATHOLOGY**

8 **CENTER.**

9 “In order to provide pathology consultation for civil-
10 ian and military health professionals (including Depart-
11 ment of Veterans Affairs health professionals) there is estab-
12 lished the National Pathology Center (in this subpart re-
13 ferred to as the ‘Center’). The Center shall be headed by
14 a director, who shall be appointed by the Secretary. The
15 Director of the Center shall report directly to the Director
16 of NIH.

17 **“SEC. 485B. PURPOSES AND FUNCTIONS OF THE CENTER.**

18 “(a) PURPOSES OF THE CENTER.—The general pur-
19 poses of the Center are to—

20 “(1) conduct and support research, education,
21 training, and other programs with respect to the
22 science and clinical practice of pathology;

23 “(2) maintain and improve a pathology tissue
24 repository; and

25 “(3) provide pathology consultation services.

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

4 “(1) shall—

5 “(A) maintain and improve a comprehensive
6 repository of pathological specimens;

7 “(B) provide consultations on request regarding clinical cases;

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

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

10 “(E) conduct and support research on pathology; and

11 “(2) may—

12 “(A) collect reasonable and appropriate fees for the activities described in paragraph (1)(B);
13 and

14 “(B) conduct such other activities as the Director of the Center determines appropriate to carry out the purposes described in subsection (a).

1 “(c) *AUTHORITY FOR EXPERT OPINIONS.*—The Direc-
2 tor 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 Board
12 of Regents of the Center (in this subpart referred to
13 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 the
7 Board described in subparagraphs (A) through (E) of
8 paragraph (1) shall serve as *ex officio* members of the
9 Board.

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

14 “(b) *DUTIES OF THE BOARD*.—It shall be the duty of
15 the Board to advise, consult with, and make recommenda-
16 tions to the Director of NIH on important matters of policy
17 in regard to the Center, including such matters as the scope,
18 content and organization of the research, education and
19 consultative services provided by the Center. The Board
20 shall make recommendations to the Director of NIH regard-
21 ing the rules under which specimens from the tissue reposi-
22 tory will be used and under which publications, facilities
23 and services of the Center will be made available to various
24 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 predecessor
5 of such member was appointed shall be appointed for the
6 remainder of such term. None of the appointed members
7 shall be eligible for reappointment within 1 year after the
8 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 and
19 administration of gifts made for the benefit of the Center
20 or for carrying out any of its functions.

21 **“SEC. 485E. CENTER FACILITIES.**

22 “There are authorized to be appropriated amounts suf-
23 ficient for the erection and equipment of suitable and ade-
24 quate buildings and facilities for use of the Center. The Ad-
25 ministrator of General Services may acquire, by purchase,

1 condemnation, donation, or otherwise, a suitable site or
2 sites, selected by the Secretary in accordance with the direc-
3 tion of the Board, for such buildings and facilities and to
4 erect thereon, furnish, and equip such buildings and facili-
5 ties. The amounts authorized to be appropriated by this sec-
6 tion include the cost of preparation of drawings and speci-
7 fications, supervision of construction, and other adminis-
8 trative expenses incident to the work. The Administrator
9 of General Services shall prepare the plans and specifica-
10 tions, make all necessary contracts, and supervise construc-
11 tion.”.

12 (b) REPORT.—Not later than 1 year after the date of
13 enactment of this Act, the Secretary of Health and Human
14 Services shall submit a report to the appropriate commit-
15 tees of Congress that contains—

16 (1) a review of all functions and duties of the
17 National Pathology Center under subpart 7 of part E
18 of title IV of the Public Health Service Act, as estab-
19 lished 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 modi-
24 fications to the National Pathology Center.

1 (c) TRANSFER OF THE ARMED FORCES INSTITUTE OF

2 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 sub-
7 part 7 of part E of title IV of the Public Health
8 Service Act all functions, duties, personnel, as-
9 sets, liabilities, contracts, property, records, and
10 unexpended balances of appropriations of the
11 Armed Forces Institute of Pathology. The pre-
12 ceding sentence shall not affect any proceedings,
13 pending applications, suits, or other actions
14 pending on the date of enactment of this Act.

15 (B) EXCEPTIONS.—The following compo-
16 nents of the Armed Forces Institute of Pathology
17 shall not be transferred from the Department of
18 Defense pursuant to subparagraph (A):

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

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

23 (iii) Accident Investigation Program.

24 (iv) The histopathology training pro-
25 gram.

- 1 (v) *The patient safety center.*
- 2 (vi) *Department of Legal Medicine.*
- 3 (vii) *Center for Clinical Laboratory*
- 4 *Medicine.*
- 5 (viii) *Drug Testing and Quality Assur-*
- 6 *ance Program.*
- 7 (ix) *Subject to the discretion of the*
- 8 *Secretary of Defense, medical research pro-*
- 9 *grams on the following:*
- 10 (I) *Body armor.*
- 11 (II) *Environmental sarcoidosis.*
- 12 (III) *Depleted uranium.*
- 13 (IV) *Military working dogs.*
- 14 (V) *Such other areas of research*
- 15 *related to pathology as the Secretary of*
- 16 *Defense shall choose to conduct.*
- 17 (2) *REFERENCES.—Any reference in any Federal*
- 18 *law, Executive order, rule, regulation, or delegation of*
- 19 *authority, or any document of or relating to the*
- 20 *Armed Forces Institute of Pathology shall be deemed*
- 21 *to be a reference to the National Pathology Center es-*
- 22 *tablished under subpart 7 of part E of title IV of the*
- 23 *Public Health Service Act.*

1 **SEC. 15. RULE OF CONSTRUCTION.**

2 *Nothing in this Act, or any amendment made by this
3 Act, shall be construed to affect any law that applies to
4 the National Vaccine Injury Compensation Program under
5 title XXI of the Public Health Service Act (42 U.S.C.
6 300aa-1 et seq.), including such laws regarding—*

- 7 *(1) whether claims may be filed or compensation
8 may be paid for a vaccine-related injury or death
9 under such Program;*
- 10 *(2) claims pending under such Program; and*
- 11 *(3) any petitions, cases, or other proceedings be-
12 fore the United States Court of Federal Claims pursu-
13 ant to such title.*

Calendar No. 257

109TH CONGRESS
1ST SESSION
S. 1873

A BILL

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

OCTOBER 24, 2005

Reported with an amendment