

109TH CONGRESS
1ST SESSION

S. 1880

To amend the Public Health Service Act to enhance biodefense and pandemic preparedness activities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 17, 2005

Mr. KENNEDY (for himself, Mr. DODD, Mr. HARKIN, Ms. MIKULSKI, Mr. BINGAMAN, Mrs. CLINTON, Mr. SCHUMER, and Mr. OBAMA) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to enhance biodefense and pandemic preparedness activities, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “National Biodefense and Pandemic Preparedness Act of
6 2005”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—RESTRUCTURING THE NATIONAL BIODEFENSE
INITIATIVE

- Sec. 101. National Biodefense Trust.
- Sec. 102. Strategic Biodefense Initiative.
- Sec. 103. Collaboration and coordination.

TITLE II—ENSURING NATIONAL VACCINE MANUFACTURING
CAPACITY

- Sec. 201. Warm-based manufacturing for biological countermeasures.
- Sec. 202. Emergency manufacturing.
- Sec. 203. Construction of facilities.

TITLE III—IMPROVING PROJECT BIOSHIELD

- Sec. 301. Improving project BioShield.

TITLE IV—INCENTIVES FOR COUNTERMEASURE DEVELOPMENT

- Sec. 401. Prize payments for countermeasures development.
- Sec. 402. Providing for long-term sole-sourcing of countermeasures.

TITLE V—CROSSING THE VALLEY OF DEATH

- Sec. 501. Early support for countermeasure development.
- Sec. 502. Incentive payments.

TITLE VI—ACCELERATING THE APPROVAL OF
COUNTERMEASURES

- Sec. 601. Accelerating the approval of countermeasures.
- Sec. 602. Postmarketing studies for countermeasures.

TITLE VII—BIODEFENSE INJURY COMPENSATION PROGRAM

- Sec. 701. National Biodefense Injury Compensation Program.

TITLE VIII—INDEMNIFICATION FOR PRODUCERS OF
COUNTERMEASURES

- Sec. 801. Indemnification for manufacturers and health care professionals who administer medical products needed for biodefense.

TITLE IX—STRENGTHENING PUBLIC HEALTH READINESS FOR
PANDEMICS

Subtitle A—Improved Planning for Pandemic Influenza

- Sec. 901. Federal Pandemic Influenza Preparedness Plan.
- Sec. 902. Requirement to develop State pandemic influenza plans.
- Sec. 903. Use of CDC and HRSA funds for public health preparedness.

Subtitle B—Vaccine Supply

- Sec. 911. Buy-back program for flu vaccine.

Subtitle C—Enhancing the National Strategic Stockpile

- Sec. 921. Stockpiling of antivirals and other medications.

Sec. 922. Strategic plan for stockpile.

Subtitle D—Prohibiting Price Gouging on Needed Flu Medicines

Sec. 931. Unfair or deceptive acts or practices in commerce related to treatments for pandemic influenza.

Subtitle E—National Institute of Pathology

Sec. 941. National Institute of Pathology.

Sec. 942. Transfer of the Armed Forces Institute of Pathology.

Subtitle F—Increased Influenza Vaccine and Outbreak Surveillance Activities

Sec. 951. Tracking network and demonstration grants.

Sec. 952. Educational efforts and grants.

Subtitle G—Miscellaneous Provisions

Sec. 961. HRSA curriculum development and training programs.

Sec. 962. Using health information technology to enhance epidemic detection.

Sec. 963. Naturally occurring or deliberately introduced agents.

Sec. 964. Use of Federal facilities in emergencies.

Sec. 965. Advisory Committee on Vulnerable Populations.

Sec. 966. Emergency system for advance registration of health professions volunteers.

TITLE X—ENHANCING ANTIBIOTICS

Sec. 1001. Preserving the effectiveness of medically important antibiotics.

TITLE XI—IMPROVING RESEARCH ON BIODEFENSE
COUNTERMEASURES

Sec. 1101. Improving the ability of biodefense researchers to work with select agents.

1 **TITLE I—RESTRUCTURING THE**
2 **NATIONAL BIODEFENSE INI-**
3 **TIATIVE**

4 **SEC. 101. NATIONAL BIODEFENSE TRUST.**

5 (a) NATIONAL BIOVENTURE TRUST.—

6 (1) PURPOSE.—It is the purpose of this sub-
7 section to establish a Federal Government corpora-
8 tion for the purpose of—

9 (A) administering the Federal BioShield
10 program; and

1 (B) identifying and supporting the develop-
2 ment of promising technologies that could lead
3 to the development of qualified counter-
4 measures.

5 (2) ESTABLISHMENT OF TRUST.—There is es-
6 tablished a body corporate to be known as the “Na-
7 tional BioVenture Trust” (referred to in this section
8 as the “Trust”) which shall be in the Department of
9 Health and Human Services. The Trust shall have
10 succession until dissolved by Act of Congress. It
11 shall maintain its principal office in the District of
12 Columbia and shall be deemed, for purposes of
13 venue in civil actions, to be a resident thereof. Agen-
14 cies or offices may be established by the Trust in
15 such other place or places as it may deem necessary
16 or appropriate in the conduct of its business.

17 (3) CAPITALIZATION.—The Trust shall have
18 common stock, without par value, which shall be
19 vested with all voting rights, each share being enti-
20 tled to one vote with rights of cumulative voting at
21 all elections of directors. The Trust may eliminate
22 such rights of cumulative voting by a resolution
23 adopted by its board of directors and approved by
24 the holders of a majority of the shares of common
25 stock voting in person or by proxy at the annual

1 meeting, or other special meeting, at which such res-
2 olution is considered. The corporation may have pre-
3 ferred stock on such terms and conditions as the
4 board of directors shall prescribe. The free transfer-
5 ability of the stock at all times to any person, firm,
6 corporation, or other entity shall not be restricted
7 except that, as to the Trust, it shall be transferable
8 only on the books of the Trust. The Trust may issue
9 shares of common stock in return for appropriate
10 payments into capital or capital and surplus. Any
11 proceeds derived by the Trust under this paragraph
12 shall be reinvested for the develop of new technology.
13 Notwithstanding any other provision of law, the Sec-
14 retary of Health and Human Service shall ensure
15 that not less than 51 percent of the stock provided
16 for under this paragraph s held by the Department
17 of Health and Human Services.

18 (4) GENERAL MANAGEMENT.—There is hereby
19 established in the Department of Health and
20 Human Services the position of Chief Executive Of-
21 ficer, National BioVenture Trust, who shall be ap-
22 pointed by the President in consultation with the
23 Secretary, subject to the advice and consent of the
24 Senate. All the powers and duties of the Trust shall
25 be vested in the Chief Executive Officer. The Sec-

1 retary shall select and effect the appointment of
2 qualified persons to fill the offices of vice president,
3 and such other offices as may be provided for in the
4 bylaws of the Trust. Persons appointed under the
5 preceding sentence shall perform such executive
6 functions, powers, and duties as may be prescribed
7 by the bylaws or by the Secretary, and such persons
8 shall be executive officers of the Trust and shall dis-
9 charge all such executive functions, powers, and du-
10 ties. The Chief Executive Officer may participate in
11 meeting provided for under section 2(g) of the Clay-
12 ton Act (15 U.S.C. 13) (as added by section 103 of
13 this Act). In carrying out the activities under this
14 subsection, the Chief Executive Officer, in consulta-
15 tion with the National Advisory Committee on Vul-
16 nerable Populations and Terrorism, and the Vulner-
17 able Populations Working Group, and based on the
18 recommendations of the Secretary, shall give priority
19 to supporting and facilitating research and develop-
20 ment of countermeasures, and formulations of coun-
21 termeasures, that are likely to be safe and effective
22 for pediatric populations, pregnant women, and
23 other vulnerable populations.

24 (5) BOARD OF DIRECTORS.—

1 (A) IN GENERAL.—The Trust shall have a
2 board of directors, which shall consist of 18 in-
3 dividuals, 9 of whom shall be appointed annu-
4 ally by the Secretary, and the remainder of
5 whom shall be elected annually by the common
6 stockholders. The board shall at all times have
7 as members appointed by the Secretary at least
8 3 individuals from the biotechnology or pharma-
9 cology industry, at least 3 individuals with ex-
10 perience in chemical, nuclear, or biological
11 threats to the United States (including natu-
12 rally occurring biological threats), and at least
13 3 individuals who are representatives of
14 healthcare consumers or workers.

15 (B) TERMS AND VACANCIES.—Each mem-
16 ber of the board of directors shall be appointed
17 or elected for a term ending on the date of the
18 next annual meeting of the stockholders, except
19 that any such appointed member may be re-
20 moved from office by the Secretary for good
21 cause. Any elective seat on the board which be-
22 comes vacant after the annual election of the
23 directors shall be filled by the board, but only
24 for the unexpired portion of the term. Any ap-
25 pointive seat which becomes vacant shall be

1 filled by appointment of the Secretary, but only
2 for the unexpired portion of the term.

3 (C) POWERS.—Within the limitations of
4 law and regulation, the board shall determine
5 the general policies which shall govern the oper-
6 ations of the Trust, and shall have power to
7 adopt, amend, and repeal bylaws governing the
8 performance of the powers and duties granted
9 to or imposed upon it by law. The board of di-
10 rectors shall select and effect the appointment
11 of qualified persons to fill the offices of presi-
12 dent and vice president, and such other offices
13 as may be provided for in the bylaws. The
14 board shall make recommendations to the Chief
15 Executive Officer concerning the policies for ad-
16 ministering the Trust.

17 (D) COMPENSATION.—Any member of the
18 board who is a full-time officer or employee of
19 the Federal Government shall not, as such
20 member, receive compensation for his or her
21 services.

22 (6) GRANTS.—

23 (A) IN GENERAL.—The Trust shall award
24 grants to entities that have developed tech-
25 nologies that may (as determined by the Trust)

1 lead to the development of qualified counter-
2 measures. The Trust shall ensure that grant
3 funds are not provided under this section for
4 activities that will substantially occur outside of
5 the United States.

6 (B) POLICIES.—The Trust shall develop
7 policies and procedures for the awarding of
8 grants under subparagraph (A).

9 (C) REASONABLE PRICING.—To be eligible
10 to receive a grant under subparagraph (A), an
11 entity shall enter into an agreement with the
12 Trust under which—

13 (i) products developed using grant
14 funds will be made available at reasonable
15 prices to the Trust, the Federal Govern-
16 ment, and other consumers, except that in
17 lieu of such an agreement, a grantee may
18 provide the Trust with equity in return for
19 the receipt of grant funds;

20 (ii) product developed using grant
21 funds will be made available as provided
22 for under clause (i) at not more than the
23 market share price that exists on the com-
24 mercial market; and

1 (iii) the Trust is provided with the au-
2 thority to sell equity in products developed
3 using grant funds and obtained by the
4 Trust and to apply the proceeds from such
5 sales for the awarding of grants under sub-
6 paragraph (A).

7 (7) MISCELLANEOUS PROVISIONS.—

8 (A) IN GENERAL.—The Trust shall have
9 power to—

10 (i) adopt, alter, and use a corporate
11 seal, which shall be judicially noticed;

12 (ii) to enter into and perform con-
13 tracts, leases, cooperative agreements, or
14 other transactions, on such terms as it
15 may deem appropriate, with any agency or
16 instrumentality of the United States, or
17 with any State, Territory, or possession, or
18 the Commonwealth of Puerto Rico, or with
19 any political subdivision thereof, or with
20 any person, firm, association, or corpora-
21 tion; to execute, in accordance with its by-
22 laws, all instruments necessary or appro-
23 priate in the exercise of any of its powers;

24 (iii) in its corporate name, to sue and
25 to be sued, and to complain and to defend,

1 in any court of competent jurisdiction,
2 State or Federal, but no attachment, in-
3 junction, or other similar process, final,
4 shall be issued against the property of the
5 Trust or against the Trust with respect to
6 its property;

7 (iv) to conduct its business without re-
8 gard to any qualification or similar statute
9 in any State of the United States, includ-
10 ing the District of Columbia, the Common-
11 wealth of Puerto Rico, and the Territories
12 and possessions of the United States;

13 (v) to lease, purchase, or acquire any
14 property, real, personal, or mixed, or any
15 interest therein, to hold, rent, maintain,
16 modernize, use, and operate such property,
17 and to sell, for cash or credit, lease, or oth-
18 erwise dispose of the same, at such time
19 and in such manner as and to the extent
20 that it may deem necessary or appropriate;

21 (vi) to prescribe, repeal, and amend or
22 modify, rules, regulations, or requirements
23 governing the manner in which its general
24 business may be conducted; and

1 (vii) to do all things as are necessary
2 or incidental to the proper management of
3 its affairs and the proper conduct of its
4 business.

5 (B) DETERMINATION WITH RESPECT TO
6 OBLIGATIONS AND EXPENDITURES.—Except as
7 may be otherwise provided in this section, with
8 respect to chapter 91 of title 31, or in other
9 laws specifically applicable to Government cor-
10 porations, the Trust shall determine the neces-
11 sity for and the character and amount of its ob-
12 ligations and expenditures and the manner in
13 which they shall be incurred, allowed, paid, and
14 accounted for.

15 (C) EXEMPTION FROM TAXATION.—The
16 Trust, including its franchise, capital, reserves,
17 surplus, security holdings, and income shall be
18 exempt from all taxation now or hereafter im-
19 posed by the United States, by any territory,
20 dependency, or possession thereof, or by any
21 State, county, municipality, or local taxing au-
22 thority, except that any real property of the
23 Trust shall be subject to State, territorial,
24 county, municipal, or local taxation to the same

1 extent according to its value as other real prop-
2 erty is taxed.

3 (D) APPOINTMENT AND COMPENSATION
4 OF PERSONNEL; USE OF SERVICES OF OTHER
5 AGENCIES.—

6 (i) APPOINTMENT AND COMPENSA-
7 TION.—The Secretary shall have to power
8 to select and appoint or employ such offi-
9 cers, attorneys, employees, and agents of
10 the Trust, to vest them with such powers
11 and duties, and to fix and to cause the
12 Trust to pay such compensation to them
13 for their services, as he may determine,
14 subject to the civil service and classifica-
15 tion laws.

16 (ii) USE OF AGENCIES.—With the
17 consent of any Government corporation, or
18 of any board, commission, independent es-
19 tablishment, or executive department of
20 the Government, the Trust may avail itself
21 on a reimbursable basis of the use of infor-
22 mation, services, facilities, officers, and
23 employees thereof, including any field serv-
24 ice thereof, in carrying out the provisions
25 of the section.

1 (iii) COMPENSATION.—The board of
2 directors of the Trust shall have the power
3 to select and appoint or employ such offi-
4 cers, attorneys, employees, and agents, to
5 vest them with such powers and duties,
6 and to fix and to cause the Trust to pay
7 such compensation to them for their serv-
8 ices, as the board of directors determines
9 reasonable and comparable with compensa-
10 tion for employment in other similar busi-
11 nesses involving similar duties and respon-
12 sibilities, except that a significant portion
13 of potential compensation of all executive
14 officers of the Trust shall be based on the
15 performance of the Trust, and any such
16 action shall be without regard to the Fed-
17 eral civil service and classification laws.
18 Appointments, promotions, and separations
19 so made shall be based on merit and effi-
20 ciency, and no political tests or qualifica-
21 tions shall be permitted or given consider-
22 ation.

23 (E) PROHIBITION AGAINST USE OF NAMES;
24 INJUNCTION; DAMAGES.—No individual, asso-
25 ciation, partnership, or corporation, except the

1 Trust shall use the words “National BioVenture
2 Trust” as the name under which the individual,
3 association, partnership, or corporation shall do
4 business. Violations of the foregoing sentence
5 may be enjoined by any court of general juris-
6 diction at the suit of the proper body corporate.
7 In any such suit, the plaintiff may recover any
8 actual damages flowing from such violation,
9 and, in addition, shall be entitled to punitive
10 damages (regardless of the existence or non-
11 existence of actual damages) of not exceeding
12 \$100 for each day during which such violation
13 is committed or repeated.

14 (F) VULNERABLE POPULATIONS WORKING
15 GROUP.—The Trust shall establish and convene
16 a Vulnerable Populations Working Group com-
17 posed of experts on pediatric populations, preg-
18 nant women, and other vulnerable populations
19 to advise the Trust with respect to—

20 (i) supporting and facilitating re-
21 search and development of counter-
22 measures, and formulations of counter-
23 measures, that are safe and effective for
24 such populations; and

1 (ii) other activities of the Trust that
2 effect such populations.

3 (b) STUDY.—Not later than 120 days after the date
4 of enactment of this Act, the Government Accountability
5 Office shall conduct a study, and submit to the appro-
6 priate committees of Congress, a report on the efficient
7 organization of the administrative structure of the Federal
8 Government for responding to public health emergencies.
9 Such report shall contain the specific recommendations of
10 the Government Accountability Office on—

11 (1) whether the Assistant Secretary for Health
12 of the Department of Health and Human Services
13 and the Surgeon General positions should be held by
14 same individual; and

15 (2) the manner in which to improve coordina-
16 tion between the Assistant Secretary for Health, the
17 Surgeon General, the National Institutes of Health,
18 and the Centers for Disease Control and Prevention
19 with respect to biodefense preparedness.

20 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
21 authorized to be appropriate to carry out this section,
22 \$1,000,000,000 for fiscal year 2006, and such sums as
23 may be necessary for each subsequent fiscal year.

1 (d) CONFORMING AMENDMENTS.—Section 319F–
 2 2(c) of the Public Health Service Act (42 U.S.C. 247d–
 3 6b(c)) is amended—

4 (1) in paragraph (3), by striking “Secretary, in
 5 consultation with the Homeland Security Secretary,”
 6 and inserting “National BioVenture Trust (referred
 7 to in this section as the ‘Trust’)”;

8 (2) in paragraph (4)—

9 (A) in subparagraph (A)—

10 (i) by striking “Homeland Security
 11 Secretary and the Secretary make” and in-
 12 serting “Trust makes”; and

13 (ii) by striking “such Secretaries may
 14 jointly submit to the President a proposal
 15 to” and inserting “the Trust may”;

16 (B) in subparagraph (B), by striking
 17 “Homeland Security Secretary and the Sec-
 18 retary” and inserting “Trust”; and

19 (C) by striking subparagraph (C);

20 (3) in paragraph (5)—

21 (A) in subparagraph (A)—

22 (i) by striking “The Secretary” and
 23 inserting “The Trust”; and

24 (ii) by striking “Secretary determines,
 25 in consultation with the Homeland Secu-

1 rity Secretary,” and inserting “Trust de-
2 termines”; and

3 (B) in subparagraph (B), by striking “Sec-
4 retary” and inserting “Trust”;

5 (4) in paragraph (6)—

6 (A) by striking subparagraphs (A) and
7 (B);

8 (B) in subparagraph (C), by striking “Sec-
9 retary and the Homeland Security Secretary”
10 and inserting “Trust”; and

11 (C) by redesignating subparagraphs (C)
12 through (E), as subparagraphs (A) through
13 (C), respectively;

14 (5) in paragraph (7)—

15 (A) in subparagraph (B), by striking “the
16 Secretary” each place that such appears and in-
17 serting “the Trust”; and

18 (B) in subparagraph (C)—

19 (i) by striking “the Secretary” each
20 place that such appears and inserting “the
21 Trust”;

22 (ii) in clause (i), by striking “The
23 Secretary” and inserting “The Trust”;

24 (iii) in clause (ii)—

1 (I) in subclause (I), by striking
 2 “The Secretary’s” and inserting “The
 3 Trust’s”; and

4 (II) by adding at the end the fol-
 5 lowing:

6 “(VII) DELIVERY TO SEC-
 7 RETARY.—The contract shall provide
 8 that the products that are the subject
 9 of the contract shall be delivered to
 10 the Secretary (subject to the provi-
 11 sions of subclause (IV)) for inclusion
 12 in the National Strategic Stockpile.”;

13 (iv) in clause (iii), by striking “the
 14 Secretary” each place that such appears
 15 and inserting “the Trust”;

16 (v) in clause (iv), by striking “the
 17 Secretary” each place that such appears
 18 and inserting “the Trust”;

19 (vi) in clause (v)—

20 (I) by striking “the Secretary”
 21 each place that such appears and in-
 22 serting “the Trust”; and

23 (II) in subclause (II), by striking
 24 “The Secretary’s” and inserting “The
 25 Trust’s”;

1 (vii) in clause (vi), by striking “The
 2 Secretary” and inserting “The Trust”; and
 3 (viii) in clause (vii), by striking “The
 4 Secretary” and inserting “The Trust”;
 5 (6) by striking paragraph (8); and
 6 (7) by redesignating paragraphs (9) and (10)
 7 as paragraphs (8) and (9), respectively.

8 **SEC. 102. STRATEGIC BIODEFENSE INITIATIVE.**

9 (a) CALL FOR THE DEVELOPMENT OF COUNTER-
 10 MEASURES.—Section 319F–2(c)(4) of the Public Health
 11 Service Act (as added by Public Law 108–276) is amend-
 12 ed by adding at the end the following:

13 “(D) STATEMENT OF INTENT.—

14 “(i) IN GENERAL.—On any date that
 15 is subsequent to the date on which the
 16 Trust issues under subparagraph (B) a
 17 call for the development of a counter-
 18 measure, a person planning to develop the
 19 countermeasure that is the subject of such
 20 call may file with the Trust a statement of
 21 intent to develop such countermeasure.

22 “(ii) CONTENTS.—A statement of in-
 23 tent under clause (i) shall include a plan
 24 for the development of the countermeasure

1 that is the subject of the call approved
2 under subparagraph (C).

3 “(iii) ADVANCE PAYMENT.—The
4 Trust may make an advance payment de-
5 scribed in paragraph (7)(C)(ii)(I) only to a
6 person that has submitted a statement of
7 intent under this subparagraph.

8 “(E) EVALUATION OF STATEMENT OF IN-
9 TENT.—

10 “(i) NO FILING OF QUALIFIED STATE-
11 MENT.—If, by the date that is 120 days
12 after the date on which the Trust issues a
13 call for the development of a security coun-
14 termeasure under subparagraph (B) (and
15 subject to an extension of such period
16 under clause (iii)), the Trust finds that no
17 person has filed a statement of intent
18 under subparagraph (D) that includes a
19 plan for the development of such counter-
20 measure that, in the determination of the
21 Trust, is likely to lead to the development
22 of such countermeasure in a manner
23 that—

1 “(I) meets the specifications de-
 2 scribed under subparagraph (B) with
 3 respect to the countermeasure; and

4 “(II) satisfies the requirement of
 5 paragraph (5)(B)(ii);

6 then the Trust shall make the declaration
 7 of non-response described in subsection
 8 (d).

9 “(ii) EXTENSION OF TIME PERIOD—
 10 .—The 120-day period described in clause
 11 (i) shall be extended in the case of a grant
 12 awarded under subparagraph (F) for the
 13 duration of the grant period.”.

14 (b) ESTABLISHMENT OF INITIATIVE.—Section
 15 319F–2 of the Public Health Service Act (as added by
 16 Public Law 108–276) is amended—

17 (1) by redesignating subsections (d) through
 18 (f), as subsections (e) through (g), respectively; and

19 (2) by inserting after subsection (c), the fol-
 20 lowing:

21 “(d) STRATEGIC BIODEFENSE INITIATIVE.—

22 “(1) DECLARATION OF NON-RESPONSE.—If the
 23 Trust makes the finding described in subsection
 24 (c)(4)(E)(i), the Trust shall declare and commu-
 25 nicate promptly to the Secretary that no person has

1 responded adequately to the call for the development
2 of a security countermeasure under subsection
3 (c)(4). Such declaration shall specify the security
4 countermeasure with respect to which the declara-
5 tion applies.

6 “(2) REQUIREMENT FOR FEASIBILITY DETER-
7 MINATION.—

8 “(A) DETERMINATION OF FEASIBILITY.—

9 If the Trust makes a declaration described in
10 paragraph (1) with respect to a security coun-
11 termeasure, the Secretary shall determine
12 whether it is feasible to produce the counter-
13 measure at reasonable cost and within a reason-
14 able time through the procedures described in
15 paragraph (3).

16 “(B) FURTHER REVIEW REQUIRED.—If
17 the Secretary makes a negative determination
18 under subparagraph (A), the Secretary shall de-
19 termine whether it is feasible to produce such
20 countermeasure at reasonable cost and within a
21 reasonable period of time through the proce-
22 dures described in paragraph (4).

23 “(3) PRODUCTION OF COUNTERMEASURES
24 THROUGH CONTRACT.—

1 “(A) IN GENERAL.—This paragraph shall
2 apply only if the Secretary has made a positive
3 determination under paragraph (2)(A).

4 “(B) DEVELOPMENT OF PLAN.—Not later
5 than 120 days after making a positive deter-
6 mination under paragraph (2)(A), the Secretary
7 shall develop a plan for the production of the
8 countermeasure involved through the proce-
9 dures described in subparagraph (C).

10 “(C) OFFERS OF CONTRACT.—Following
11 the development of the plan under subpara-
12 graph (B), the Secretary shall issue an offer to
13 enter into contracts with any person for re-
14 search, development, testing, production, or any
15 other activity that, in the determination of the
16 Secretary, is likely to expedite the implementa-
17 tion of the plan under such subparagraph.

18 “(D) TERMS OF OFFER.—The offer de-
19 scribed in subparagraph (C) shall describe the
20 service or other activity for which the Secretary
21 desires to enter into the contract and shall in-
22 clude a description of the terms of the contract
23 as specified in subparagraph (E).

1 “(E) TERMS OF CONTRACT.—A contract
2 entered into pursuant to an offer under sub-
3 paragraph (C) shall provide that—

4 “(i) the Secretary will retain the intel-
5 lectual property rights to any product de-
6 veloped under the contract;

7 “(ii) the Secretary will own the prod-
8 uct developed under the contract;

9 “(iii) the product developed under the
10 contract will become a part of the national
11 stockpile under subsection (a); and

12 “(iv) the terms described in sub-
13 section (c)(7)(C)(ii) shall apply.

14 “(F) SATISFACTORY BIDS NOT RE-
15 CEIVED.—If, within 120 days of the issuance of
16 an offer described in subparagraph (C), the
17 Secretary has not received a bid or bids from
18 any person or persons to enter into a contract
19 or contracts for the services or other activities
20 described in such offer that, in the determina-
21 tion of the Secretary, will result in the produc-
22 tion of the specified countermeasure at reason-
23 able cost and within a reasonable time, the Sec-
24 retary shall issue a statement indicating that
25 satisfactory bids have not been received and

1 shall conduct the feasibility determination de-
2 scribed in paragraph (2)(B).

3 “(4) PRODUCTION OF COUNTERMEASURES BY
4 THE SECRETARY.—

5 “(A) IN GENERAL.—This paragraph shall
6 apply only if the Secretary has made a positive
7 determination under paragraph (2)(B) or if the
8 Secretary has issued a statement under para-
9 graph (3)(F).

10 “(B) PLAN REQUIRED.—Not later than
11 120 days after making a positive determination
12 under paragraph (2)(B) or issuing a statement
13 under paragraph (3)(F), the Secretary shall de-
14 velop a plan for producing the countermeasure
15 involved.

16 “(C) PRODUCTION OF COUNTER-
17 MEASURES.—Following the development of the
18 plan under subparagraph (B), the Secretary
19 shall conduct activities, subject to the avail-
20 ability of funds under paragraph (8), necessary
21 to implement the plan under subparagraph (B).
22 Such activities may include the production of
23 countermeasures at facilities owned or operated
24 by the Secretary or the expansion, enhancement
25 or improvement of such facilities.

1 “(5) APPLICATION OF PROVISIONS.—The provi-
 2 sions of clauses (iii) through (vii) of subsection
 3 (c)(7)(C) shall apply to the procurement of counter-
 4 measures under contracts under this subsection. The
 5 provisions of section 319F–1(f) shall apply to actions
 6 of the Secretary under paragraphs (1) through (4).

7 “(6) GUIDELINES.—The Secretary, pursuant to
 8 existing authority with respect to contracts with pri-
 9 vate sector entities, shall establish guidelines con-
 10 cerning the process of entering into contracts under
 11 this subsection, including the submission and review
 12 of bids by entities.

13 “(7) FUNDING.—

14 “(A) IN GENERAL.—To carry out this sub-
 15 section, the Secretary may use not to exceed 10
 16 percent of the amounts in the special reserve
 17 fund under subsection (c)(10) in each fiscal
 18 year.

19 “(B) AUTHORIZATION.—In addition to the
 20 amounts described in subparagraph (A), there
 21 are authorized to be appropriated such addi-
 22 tional funds as may be necessary for each of
 23 fiscal years 2005 through 2009 to carry out
 24 this subsection.”.

1 **SEC. 103. COLLABORATION AND COORDINATION.**

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

4 “(g) LIMITED ANTITRUST EXEMPTION.—

5 “(1) QUALIFIED COUNTERMEASURES AND
6 QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT DE-
7 VELOPMENT MEETINGS.—

8 “(A) COUNTERMEASURES AND PRODUCTS
9 DEVELOPMENT MEETINGS AND CONSULTA-
10 TIONS.—The Secretary of Health and Human
11 Services (referred to in this subsection as the
12 ‘Secretary’) or the Chief Executive Officer of
13 the National BioVenture Trust (referred to in
14 this subsection as the ‘CEO’), in coordination
15 with the Attorney General and the Secretary of
16 Homeland Security, may conduct meetings and
17 consultations with parties involved in the devel-
18 opment of qualified countermeasures (as de-
19 fined in section 319F–2 of the Public Health
20 Service Act) or qualified pandemic or epidemic
21 products (as defined in section 319F–3(c)(5) of
22 the Public Health Service Act) (referred to in
23 this section as “countermeasures or products”)
24 for the purpose of the development, manufac-
25 ture, distribution, purchase, sale, or storage of
26 countermeasures or products consistent with

1 the purposes of this title. The Secretary or
2 CEO may convene such meeting or consultation
3 at the request of any person, the Secretary of
4 Homeland Security, the Attorney General, the
5 Chairperson of the Federal Trade Commission,
6 an industry representative or member, or upon
7 initiation by such Secretary. The Secretary or
8 CEO shall give notice of such meetings and
9 consultations to the Chairperson of the Federal
10 Trade Commission (referred to in this sub-
11 section as the ‘Chairperson’).

12 “(B) MEETING AND CONSULTATION CON-
13 DITIONS.—A meeting or consultation conducted
14 under subparagraph (A) shall—

15 “(i) be chaired or, in the case of a
16 consultation, facilitated by the Secretary or
17 CEO;

18 “(ii) be open to parties involved in the
19 development, manufacture, distribution,
20 purchase, or sale of countermeasures or
21 products, as determined by the Secretary
22 or CEO;

23 “(iii) be open to the Attorney General,
24 the Secretary of Homeland Security, and
25 the Chairperson;

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

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

10 “(C) LIMITATION.—The Secretary or CEO
11 may not require the disclosure of confidential
12 commercial or proprietary information.

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

22 “(E) EXEMPTION.—

23 “(i) IN GENERAL.—The antitrust laws
24 shall not apply to meetings and consulta-
25 tions under this paragraph.

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

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

15 “(A) an explanation of the intended pur-
16 pose of the agreement;

17 “(B) a specific statement of the substance
18 of the agreement;

19 “(C) a description of the methods that will
20 be utilized to achieve the objectives of the
21 agreement;

22 “(D) an explanation of the necessity of a
23 cooperative effort among the particular partici-
24 pating parties to achieve the objectives of the
25 agreement; and

1 “(E) any other relevant information deter-
 2 mined necessary by the Secretary or CEO in
 3 consultation with the Attorney General and the
 4 Chairperson.

5 “(3) DETERMINATION.—The Attorney General,
 6 in consultation with the Chairperson, shall determine
 7 whether an agreement regarding covered activities
 8 referred to in paragraph (2) would likely—

9 “(A) be in compliance with the antitrust
 10 laws, and so inform the Secretary or CEO and
 11 the participating parties; or

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

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

18 “(A) IN GENERAL.—The Attorney General,
 19 in consultation with the Chairperson, shall
 20 grant, deny, grant in part and deny in part, or
 21 propose modifications to a request for exemp-
 22 tion from the antitrust laws under paragraph
 23 (3) within 15 days of the receipt of such re-
 24 quest.

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

9 “(C) DETERMINATION.—The Attorney
10 General, in consultation with the Chairperson
11 and the Secretary or CEO—

12 “(i) may not grant an exemption
13 under this paragraph unless the Attorney
14 General finds—

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

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

21 “(III) that there is no substantial
22 competitive impact to areas not di-
23 rectly related to the purposes of the
24 agreement; and

1 “(ii) may consider any other factors
2 determined relevant by the Attorney Gen-
3 eral or the Chairperson.

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

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

22 “(7) GUIDELINES.—The Attorney General and
23 the Chairperson may develop and issue guidelines to
24 implement this subsection.

1 “(8) REPORT.—Not later than 1 year after the
 2 date of enactment of this subsection, and annually
 3 thereafter, the Attorney General and the Chair-
 4 person shall report to Congress on the use and con-
 5 tinuing need for the exemption from the antitrust
 6 laws provided by this subsection.

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

17 “(h) DEFINITIONS.—In this section:

18 “(1) ANTITRUST LAWS.—The term ‘antitrust
 19 laws’—

20 “(A) has the meaning given such term in
 21 subsection (a) of the first section of the Clayton
 22 Act (15 U.S.C. 12(a)), except that such term
 23 includes the Act of June 19, 1936 (15 U.S.C.
 24 13 et seq.) commonly known as the Robinson-
 25 Patman Act), and section 5 of the Federal

1 Trade Commission Act (15 U.S.C. 45) to the
2 extent such section 5 applies to unfair methods
3 of competition; and

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

6 “(2) COVERED ACTIVITIES.—

7 “(A) IN GENERAL.—Except as provided in
8 subparagraph (B), the term ‘covered activities’
9 means any group of activities or conduct, in-
10 cluding attempting to make, making, or per-
11 forming a contract or agreement or engaging in
12 other conduct, for the purpose of—

13 “(i) theoretical analysis, experimen-
14 tation, or the systematic study of phe-
15 nomena or observable facts necessary to
16 the development of countermeasures or
17 products;

18 “(ii) the development or testing of
19 basic engineering techniques necessary to
20 the development of countermeasures or
21 products;

22 “(iii) the extension of investigative
23 findings or theory of a scientific or tech-
24 nical nature into practical application for
25 experimental and demonstration purposes,

1 including the experimental production and
2 testing of models, prototypes, equipment,
3 materials, and processes necessary to the
4 development of countermeasures or prod-
5 ucts;

6 “(iv) the production, distribution, or
7 marketing of a product, process, or service
8 that is a countermeasures or products;

9 “(v) the testing in connection with the
10 production of a product, process, or serv-
11 ices necessary to the development of coun-
12 termeasures or products;

13 “(vi) the collection, exchange, and
14 analysis of research or production informa-
15 tion necessary to the development of coun-
16 termeasures or products; or

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

19 and such term may include the establishment
20 and operation of facilities for the conduct of
21 covered activities described in clauses (i)
22 through (vi), the conduct of such covered activi-
23 ties on a protracted and proprietary basis, and
24 the processing of applications for patents and

1 the granting of licenses for the results of such
2 covered activities.

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

6 “(i) Exchanging information among
7 competitors relating to costs, sales, profit-
8 ability, prices, marketing, or distribution of
9 any product, process, or service if such in-
10 formation is not reasonably necessary to
11 carry out the purposes of covered activi-
12 ties.

13 “(ii) Entering into any agreement or
14 engaging in any other conduct—

15 “(I) to restrict or require the
16 sale, licensing, or sharing of inven-
17 tions, developments, products, proc-
18 esses, or services not developed
19 through, produced by, or distributed
20 or sold through such covered activi-
21 ties; or

22 “(II) to restrict or require par-
23 ticipation by any person who is a
24 party to such covered activities in
25 other research and development activi-

1 ties, that is not reasonably necessary
2 to prevent the misappropriation of
3 proprietary information contributed
4 by any person who is a party to such
5 covered activities or of the results of
6 such covered activities.

7 “(iii) Entering into any agreement or
8 engaging in any other conduct allocating a
9 market with a competitor that is not ex-
10 pressly exempted from the antitrust laws
11 by a determination under subsection
12 (g)(4).

13 “(iv) Exchanging information among
14 competitors relating to production (other
15 than production by such covered activities)
16 of a product, process, or service if such in-
17 formation is not reasonably necessary to
18 carry out the purpose of such covered ac-
19 tivities.

20 “(v) Entering into any agreement or
21 engaging in any other conduct restricting,
22 requiring, or otherwise involving the pro-
23 duction of a product, process, or service
24 that is not so expressly exempted from the

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

3 “(vi) Except as otherwise provided in
4 this subsection, entering into any agree-
5 ment or engaging in any other conduct to
6 restrict or require participation by any per-
7 son who is a party to such activities, in
8 any unilateral or joint activity that is not
9 reasonably necessary to carry out the pur-
10 pose of such covered activities.

11 “(4) DEVELOPMENT.—The term ‘development’
12 includes the identification of suitable compounds or
13 biological materials, the conduct of preclinical and
14 clinical studies, the preparation of an application for
15 marketing approval, and any other actions related to
16 preparation of a countermeasure or products.”.

17 (b) TERMINATION OF AUTHORITY.—The authority
18 provided for in the amendment made by subsection (a)
19 shall terminate on the date that is 5 years after the date
20 of enactment of this Act.

21 (c) REPORT.—Not later than 4 years after the date
22 of enactment of this Act, the Government Accountability
23 Office shall submit to the appropriate committees of Con-
24 gress a report on the activities conducted under the au-

1 thority provided under the amendment made by subsection
 2 (a).

3 **TITLE II—ENSURING NATIONAL** 4 **VACCINE MANUFACTURING** 5 **CAPACITY**

6 **SEC. 201. WARM-BASED MANUFACTURING FOR BIOLOGICAL** 7 **COUNTERMEASURES.**

8 Section 319F–2(c)(7)(C)(ii) of the Public Health
 9 Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)), as amended
 10 by section 101(d), is further amended by adding at the
 11 end the following:

12 “(VIII) WARM-BASED MANUFAC-
 13 TURING.—The contract shall, if the
 14 product is a biological product, pro-
 15 vide for annual payments after the
 16 initial delivery of the product to meet
 17 the needs of the stockpile to pay the
 18 cost of maintaining domestic manu-
 19 facturing capacity for, and providing
 20 additional units of, the product to the
 21 stockpile sufficient to allow the Sec-
 22 retary in an emergency or other time
 23 of need to promptly acquire additional
 24 units of the product for the stock-
 25 pile.”.

1 **SEC. 202. EMERGENCY MANUFACTURING.**

2 Section 319F–2(c)(7)(C)(ii) of the Public Health
3 Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)), as amended
4 by section 201, is further amended by adding at the end
5 the following:

6 “(IX) EMERGENCY MANUFAC-
7 TURING.—The contract shall, if the
8 product is not a biological product,
9 provide for domestic manufacturing
10 capacity, including through alternate
11 domestic manufacturing arrangements
12 such as through licensing to another
13 manufacturer and preapproval of such
14 manufacturer’s product by the Food
15 and Drug Administration, sufficient
16 to allow the Trust in an emergency or
17 other time of need to promptly ac-
18 quire additional units of the product
19 for the stockpile. Such contract shall
20 ensure that the intellectual property
21 resulting from such contract become
22 the property of the Federal Govern-
23 ment.”.

1 **SEC. 203. CONSTRUCTION OF FACILITIES.**

2 Section 319F of the Public Health Service Act (42
3 U.S.C. 247d–6) is amended by adding at the end the fol-
4 lowing:

5 “(k) LOANS FOR CONSTRUCTION.—

6 “(1) IN GENERAL.—The Secretary shall estab-
7 lish a program under which the Secretary may make
8 loans to eligible entities to enable such entities to
9 provide for the construction of countermeasure man-
10 ufacturing facilities.

11 “(2) ELIGIBILITY.—To be eligible to receive a
12 loan under paragraph (1), an entity shall submit an
13 application to the Secretary at such time, in such
14 manner, and containing such information as the Sec-
15 retary may require.

16 “(3) FORGIVENESS OF LOAN AMOUNTS.—The
17 Secretary may forgive up to 25 percent of the
18 amount of a loan if the entity involved enters into
19 an agreement with the Secretary to permit the facili-
20 ties constructed using loan amounts to be made
21 available to produce any countermeasure product
22 specified by the Secretary upon the declaration of a
23 public health emergency under section 319.

24 “(4) LABOR STANDARDS.—All laborers and me-
25 chanics employed by contractors or subcontractors
26 on projects assisted by the Secretary of Health and

1 Human Services under this Act (or an amendment
2 made by this Act) shall be paid wages at rates not
3 less than those prevailing on similar construction in
4 the locality involved, as determined by the Secretary
5 of Labor, in accordance with sections 3141 through
6 3144, 3146, and 3147 of title 40, United States
7 Code. The Secretary of Health and Human Services
8 shall not award any contract, grant, cooperative
9 agreement, or other transaction under this Act (or
10 amendments) for such a project without first obtain-
11 ing adequate assurance that the labor standards pro-
12 vided for in this subsection will be maintained upon
13 the construction project. The Secretary of Labor
14 shall have, with respect to the labor standards speci-
15 fied in this subsection, the authority and functions
16 set forth in Reorganization Plan Numbered 14 of
17 1950 (15 F.R. 3176; 64 Stat. 1267), and section
18 3145 of title 40, United States Code.

19 “(5) AUTHORIZATION OF APPROPRIATIONS.—
20 There is authorized to be appropriated, such sums
21 as may be necessary to carry out this section.”.

1 **TITLE III—IMPROVING PROJECT**
2 **BIOSHIELD**

3 **SEC. 301. IMPROVING PROJECT BIOSHIELD.**

4 (a) STATEMENT OF CONGRESSIONAL INTENT.—Sec-
5 tion 319F–2(c) of the Public Health Service Act (42
6 U.S.C. 247d–6b(c)) is amended—

7 (1) by redesignating paragraphs (1) through
8 (9) as paragraphs (2) through (10), respectively;
9 and

10 (2) by inserting before paragraph (2), as so re-
11 designated, the following:

12 “(1) STATEMENT OF CONGRESSIONAL IN-
13 TENT.—

14 “(A) IN GENERAL.—The intent of Con-
15 gress in establishing Project BioShield (under
16 the Project BioShield Act of 2004 (Public law
17 108–276)) is—

18 “(i) that the Project provide a guar-
19 anteed market for products for which the
20 incentives of the commercial market are in-
21 adequate to induce their development and
22 which meet important national needs in
23 preparing for material threats to the
24 health of the American public;

1 “(ii) that the Project is not intended
 2 simply to procure products that are in ad-
 3 vanced stages of development; and

4 “(iii) that the Project should identify
 5 national needs in preparing for material
 6 threats to the health of the American pub-
 7 lic and accelerate the development of coun-
 8 termeasures to meet those needs.

9 “(B) REQUIREMENT TO FOLLOW IN-
 10 TENT.—Activities conducted under this sub-
 11 section shall be consistent with the statement of
 12 intent described in subparagraph (A).”.

13 (b) AMENDMENTS.—Section 319F–2(c) of the Public
 14 Health Service Act (42 U.S.C. 247d–6b(c)), as amended
 15 by subsection (a), is further amended—

16 (1) in paragraph (2)(B)—

17 (A) in clause (i)—

18 (i) in subclause (I), by striking “(con-
 19 sistent with sections 302(2) and 304(a) of
 20 the Homeland Security Act of 2002)”;

21 (ii) in subclause (III)(bb), by striking
 22 “within eight years” and inserting “within
 23 8 years or such additional time as the
 24 Trust determines to be reasonable”; and

1 (iii) by striking “or” at the end there-
2 of;

3 (B) in clause (ii), by striking the period
4 and inserting “; or”; and

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

6 “(iii) is a vaccine or microbicide used
7 to treat or prevent AIDS, tuberculosis,
8 Malaria, or a strain of influenza that may
9 (in the determination of the Secretary)
10 contribute to a pandemic.”;

11 (2) in paragraph (3)—

12 (A) by redesignating subparagraphs (C)
13 and (D) as subparagraphs (D) and (E), respec-
14 tively;

15 (B) by inserting after subparagraph (B),
16 the following:

17 “(C) REQUESTS FOR DETERMINATIONS.—

18 The Secretary may request the Homeland Secu-
19 rity Secretary to make a determination with re-
20 spect to a specific chemical, biological, radio-
21 logical, or nuclear agent. The Homeland Secu-
22 rity Secretary shall respond to such request
23 within 90 days of such request.”; and

1 (C) in subparagraph (D) (as so redesign-
2 nated), by striking “or (B)” and inserting “,
3 (B), or (C)”; and
4 (3) in paragraph (6)(B)—

5 (A) in clause (ii), by striking “within eight
6 years” and inserting “within 8 years or such
7 additional time as the Trust determines to be
8 reasonable”; and

9 (B) by striking clause (iii) and inserting
10 the following:

11 “(iii) Whether the commercial market
12 for the product is sufficient to ensure the
13 continued development of the product. If
14 the determination under this clause is that
15 the commercial market for the product is
16 sufficient, funds available under this sub-
17 section may not be provided for such prod-
18 uct.”.

1 **TITLE IV—INCENTIVES FOR**
2 **COUNTERMEASURE DEVELOP-**
3 **MENT**

4 **SEC. 401. PRIZE PAYMENTS FOR COUNTERMEASURES DE-**
5 **VELOPMENT.**

6 Section 319F–2(f) of the Public Health Service Act
7 (42 U.S.C. 247d–6b(f)) is amended by adding at the end
8 the following:

9 “(3) PRIZE PAYMENT FOR COUNTERMEASURE
10 DEVELOPMENT AND PRODUCTION.—

11 “(A) IN GENERAL.—If the Secretary deter-
12 mines that it is necessary to engage a bio-
13 technology or pharmaceutical company to en-
14 sure the development and production of a coun-
15 termeasure, and that procurement under sub-
16 section (c)(7) will not engage such a company,
17 the Secretary may recommend that the Presi-
18 dent request that Congress appropriate a prize
19 payment, in a sum that shall not exceed
20 \$1,000,000,000, to be made to such company
21 upon the delivery of the total number of units
22 of the countermeasure contracted for.

23 “(B) REQUIREMENTS.—If the Secretary
24 makes a recommendation under subparagraph
25 (A), the President shall promptly—

1 “(i) request that Congress appropriate
2 such a sum for a prize payment for such
3 countermeasure; or

4 “(ii) report to Congress concerning
5 why such recommendation is inappropriate.

6 “(C) REASONABLE PRICING.—To be eligi-
7 ble to receive a payment under this paragraph,
8 a manufacturer shall provide assurances that
9 the countermeasure with respect to which the
10 payment is to be made will be made available—

11 “(i) to the Federal Government at the
12 lowest of —

13 “(I) the price paid for that prod-
14 uct by the Department of Veterans
15 Affairs;

16 “(II) the Federal ceiling price; or

17 “(III) the Federal supply sched-
18 ule price; and

19 “(ii) to the general public at a reason-
20 able price determined by the Secretary
21 through negotiations with the recipient,
22 but in no case shall such price be higher
23 than the average price paid for the coun-
24 termeasure in the G–8 nations.

1 “(D) LICENSE.—To be eligible to receive a
 2 payment under this paragraph, a manufacturer
 3 shall provide assurances that a license for the
 4 countermeasure with respect to which the pay-
 5 ment is to be made will be made shall be grant-
 6 ed to produce the product at low cost in the de-
 7 veloping world (as determined by the Sec-
 8 retary).

9 “(E) PREFERENCE.—In making payments
 10 under this paragraph, the Secretary shall give
 11 preference to any vaccine or microbicide for
 12 AIDS, Tuberculosis, malaria, or a strain of in-
 13 fluenza that (in the determination of the Sec-
 14 retary) contribute to a pandemic that is likely
 15 to significantly reduce global mortality from
 16 these diseases.

17 “(F) FUNDING.—

18 “(i) AUTHORIZATION OF APPROPRIA-
 19 TIONS.—For purposes of this paragraph,
 20 there are authorized to be appropriated
 21 \$3,000,000,000 for fiscal year 2006, and
 22 such sums as may be necessary in each fis-
 23 cal year thereafter, to be used as a prize
 24 payment to be made to the vendor involved
 25 in the fiscal year in which the vendor deliv-

ers the total number of units contracted for. Amounts appropriated under this subparagraph shall remain available until expended.

“(ii) ACCEPTANCE OF DONATIONS.—
Notwithstanding any other provision of law, the Secretary may accept donations from foreign governments and other entities for the purpose of awarding prizes under this paragraph. The Secretary may use amounts received under this clause to increase the amount of prizes under this paragraph.”.

**SEC. 402. PROVIDING FOR LONG-TERM SOLE-SOURCING OF
COUNTERMEASURES.**

Section 319F–2(c)(8)(C)(ii) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)), as amended by section 202, is further amended by adding at the end the following:

“(X) SOLE SOURCING.—

“(aa) IN GENERAL.—The contract shall provide that the vendor shall be the sole source for the countermeasure for the stockpile under subsection (a) for

1 a period of 20 years from the
2 first date of delivery of the prod-
3 uct to the Secretary under the
4 contract, except that the contract
5 shall provide that the Secretary
6 may purchase the counter-
7 measure from another source to
8 the extent to which the vendor is
9 unable or unwilling to deliver the
10 product in the quantity or time-
11 frame required by the Secretary
12 or if the vendor permits purchase
13 from another source.

14 “(bb) RULE OF CONSTRUC-
15 TION.—Nothing in item (aa)
16 shall be construed to prevent the
17 Secretary from purchasing a
18 countermeasure from a source
19 other than the source described
20 in such item.”.

TITLE V—CROSSING THE VALLEY OF DEATH

SEC. 501. EARLY SUPPORT FOR COUNTERMEASURE DEVELOPMENT.

Section 319F–2(c)(4) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(4)), as amended by section 102, is further amended by adding at the end the following:

“(F) SUPPORT FOR CALL FOR COUNTERMEASURE.—The Secretary may provide grants to one or more of the persons to whom a call for a countermeasure is made known under subparagraph (C) to support the cost of screening, research, development, testing, and initial manufacture of potential candidates for such countermeasure.”.

SEC. 502. INCENTIVE PAYMENTS.

Section 319F–2(c)(7)(C)(ii)(I) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)(I)) is amended by adding at the end the following: “In addition to the advance payments described in the preceding sentences, the contract may provide for not more than 3 incentive payments to be made, each in an amount that does not exceed 5 percent of the contract amount, for the achievement by the manufacturer of specific milestones. Any such

1 incentive payments shall not be required to be repaid for
 2 failure to perform.”.

3 **TITLE VI—ACCELERATING THE** 4 **APPROVAL OF COUNTER-** 5 **MEASURES**

6 **SEC. 601. ACCELERATING THE APPROVAL OF COUNTER-** 7 **MEASURES.**

8 The Secretary of Health and Human Services, acting
 9 through the Commissioner of Food and Drugs, shall facili-
 10 tate the prompt development, review, and approval of se-
 11 curity countermeasures that, pursuant to section 319F–
 12 2(c)(6) of the Public Health Service Act, the Secretary
 13 has identified for inclusion in the stockpile under section
 14 319F–2(a) of such Act, including, as appropriate, by—

15 (1) working with such Directors or Administra-
 16 tors as may be appropriate, to facilitate the identi-
 17 fication and development of animal models necessary
 18 to assess the effectiveness of such countermeasures,
 19 if applicable;

20 (2) meeting and otherwise interacting with the
 21 sponsor of an application under the Federal Food,
 22 Drug, and Cosmetic Act or under section 351 of the
 23 Public Health Service Act for approval of such coun-
 24 termeasure to facilitate the development and clinical

1 testing of the product necessary for preparation and
 2 review of such application;

3 (3) considering such an application to be a pri-
 4 ority, subject to the performance goals established
 5 by the Commissioner of Food and Drugs for priority
 6 drugs or devices; or

7 (3) reviewing such an application in reviewable
 8 unites, as provided by the Commissioner of Food
 9 and Drugs in a pilot for fast-track products under
 10 the performance goals established by the Commis-
 11 sioner of Food and Drugs, or providing a modular
 12 review, under section 515(c)(3) of the Federal Food,
 13 Drug, and Cosmetic Act.

14 **SEC. 602. POSTMARKETING STUDIES FOR COUNTER-**
 15 **MEASURES.**

16 (a) NEW DRUGS.—Section 505(k) of the Federal
 17 Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)) is
 18 amended by adding at the end the following:

19 “(3) POSTMARKETING STUDIES FOR DRUGS AP-
 20 PROVED USING ANIMAL DATA.—

21 “(A) IN GENERAL.—The sponsor of a drug
 22 approved or licensed pursuant to the regula-
 23 tions under subpart I of part 314 or under sub-
 24 part H of part 601 of title 21, Code of Federal
 25 Regulations (as in effect on the date of enact-

1 ment of the National Biodefense Act of 2005),
2 shall—

3 “(i) when feasible and ethical, conduct
4 postmarketing studies, according to the
5 plan approved by the Secretary under sub-
6 paragraph (D), to—

7 “(I) verify and describe the clin-
8 ical benefit of the drug when used as
9 indicated; and

10 “(II) assess the safety of the
11 drug when used as indicated; and

12 “(ii) immediately submit reports of all
13 data from such studies to the Secretary
14 (excluding names and any other informa-
15 tion that identifies a patient or provider).

16 “(B) FEASIBILITY.—Postmarketing stud-
17 ies under subparagraph (A) shall not be consid-
18 ered feasible until an exigency requiring use of
19 the drug arises.

20 “(C) DUE DILIGENCE.—When post-
21 marketing studies are feasible, the sponsor shall
22 conduct such studies with due diligence.

23 “(D) PLAN SUBMISSION AND APPROVAL.—
24 A sponsor shall include, as part of an applica-
25 tion under subsection (b) or section 351 of the

1 Public Health Service Act for which approval is
2 sought under the regulations described in sub-
3 paragraph (A), a plan for postmarketing study
4 commitments in the event such studies become
5 ethical and feasible. The Secretary shall ap-
6 prove such a plan with modifications deemed
7 necessary by the Secretary.

8 “(E) PLAN REQUIREMENTS.—Studies re-
9 quired under a plan approved under subpara-
10 graph (D) shall include—

11 “(i) short-term field studies, to be
12 completed after the first, second, and
13 fourth weeks of initial administration of
14 the drug;

15 “(ii) long-term tracking studies;

16 “(iii) civilian and military populations;

17 and

18 “(iv) major population subgroups such
19 as men, women (including pregnant and
20 lactating women), children, the elderly,
21 persons with multiple chronic conditions,
22 and different racial and ethnic subgroups.

23 “(F) REPORTS ON STUDIES.—The Sec-
24 retary shall make available—

“(i) to the public, not later than 1 week after submission of data from a study required under subparagraph (A), a summary of the data from such study, including data for the major population subgroups identified in clauses (iii) and (iv) of subparagraph (E); and

“(ii) to any physician or expert in public health, as soon as practicable but in no case later than 30 days after submission, the raw data from such a study.”.

(b) AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.—Section 564(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3(e)) is amended—

(1) in paragraph (1)(A), by—

(A) redesignating clauses (iii) and (iv) as clauses (iv) and (v), respectively; and

(B) inserting after clause (ii), the following:

“(iii)(I) Appropriate postmarketing studies, conducted with due diligence, including short-term field studies (to be completed after the first, second, and fourth weeks of initial administration of the prod-

uct) and long-term tracking studies, civilian and military populations (as appropriate to the declaration under subsection (b)), and major populations subgroups such as men, women (including pregnant and lactating women), children, the elderly, persons with multiple chronic conditions, and different racial and ethnic subgroups, to—

“(aa) verify and describe the clinical benefit of the product when used as indicated; and

“(bb) assess the safety of the product when used as indicated.

“(II) Immediate submission of reports of all data from such studies to the Secretary (excluding names and any other information that identifies a patient or provider).”;

(2) in paragraph (2)(A), by striking “clauses (i) and (ii) of paragraph (1)(A), and may establish conditions described in clauses (iii) and (iv)” and inserting “clauses (i), (ii), and (iii) of paragraph (1)(A), and may establish conditions described in clauses (iv) and (v)”;

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

2 “(5) REPORTS ON STUDIES.—The Secretary
3 shall make available—

4 “(A) to the public, not later than 1 week
5 after submission of data from a study required
6 under paragraph (1)(A)(iii) or (2)(A), a sum-
7 mary of the data from such study, including
8 data for the major population subgroups identi-
9 fied in paragraph (1)(A)(iii); and

10 “(B) to any physician or expert in public
11 health, as soon as practicable but in no case
12 later than 30 days after submission, the raw
13 data from such a study.”.

14 (c) STUDIES REQUIRED.—The Secretary of Health
15 and Human Services shall conduct the postmarketing
16 studies required by the amendments made by subsection
17 (a) and (b) for any countermeasure that—

18 (1) is the subject of a declaration under section
19 224(p)(2) of the Public Health Service Act; and

20 (2) is not subject to the amendments made by
21 subsection (a) or subsection (b).

22 (d) COORDINATED SURVEILLANCE.—The Secretary
23 of Health and Human Services, the Secretary of Defense,
24 and the Secretary of Veterans Affairs shall coordinate ef-
25 forts to collect information on adverse events associated

1 with the use of vaccines and other countermeasures
 2 through both active and passive surveillance, including
 3 through the Clinical Immunization Safety Assessment net-
 4 work, the Vaccine Healthcare Centers, and State and local
 5 health departments.

6 **TITLE VII—BIODEFENSE INJURY** 7 **COMPENSATION PROGRAM**

8 **SEC. 701. NATIONAL BIODEFENSE INJURY COMPENSATION** 9 **PROGRAM.**

10 (a) ESTABLISHMENT.—Section 224 of the Public
 11 Health Service Act (42 U.S.C. 233) is amended by adding
 12 at the end the following:

13 “(q) BIODEFENSE INJURY COMPENSATION PRO-
 14 GRAM.—

15 “(1) ESTABLISHMENT.—There is established
 16 the Biodefense Injury Compensation Program (re-
 17 ferred to in this subsection as the ‘Compensation
 18 Program’) under which compensation may be paid
 19 for death or any injury, illness, disability, or condi-
 20 tion that is likely (based on best available evidence)
 21 to have been caused by the administration of a cov-
 22 ered countermeasure to an individual pursuant to a
 23 declaration under subsection (p)(2).

24 “(2) ADMINISTRATION AND INTERPRETA-
 25 TION.—The statutory provisions governing the Com-

1 pensation Program shall be administered and inter-
 2 preted in consideration of the program goals de-
 3 scribed in paragraph (4)(B)(iii).

4 “(3) PROCEDURES AND STANDARDS.—The Sec-
 5 retary shall by regulation establish procedures and
 6 standards applicable to the Compensation Program
 7 that follow the procedures and standards applicable
 8 under the National Vaccine Injury Compensation
 9 Program established under section 2110, except that
 10 the regulations promulgated under this paragraph
 11 shall permit a person claiming injury or death re-
 12 lated to the administration of any covered counter-
 13 measure to file either—

14 “(A) a civil action for relief under sub-
 15 section (p); or

16 “(B) a petition for compensation under
 17 this subsection.

18 “(4) INJURY TABLE.—

19 “(A) INCLUSION.—For purposes of receiv-
 20 ing compensation under the Compensation Pro-
 21 gram with respect to a countermeasure that is
 22 the subject of a declaration under subsection
 23 (p)(2), the Vaccine Injury Table under section
 24 2114 shall be deemed to include death and the
 25 injuries, disabilities, illnesses, and conditions

1 specified by the Secretary under subparagraph
2 (B)(ii).

3 “(B) INJURIES, DISABILITIES, ILLNESSES,
4 AND CONDITIONS.—

5 “(i) INSTITUTE OF MEDICINE.—Not
6 later than 30 days after making a declara-
7 tion described in subsection (p)(2), the
8 Secretary shall enter into a contract with
9 the Institute of Medicine, under which the
10 Institute shall, within 180 days of the date
11 on which the contract is entered into, and
12 periodically thereafter as new information,
13 including information derived from the
14 monitoring of those who were administered
15 the countermeasure, becomes available,
16 provide its expert recommendations on the
17 injuries, disabilities, illnesses, and condi-
18 tions whose occurrence in one or more in-
19 dividuals are likely (based on best available
20 evidence) to have been caused by the ad-
21 ministration of a countermeasure that is
22 the subject of the declaration.

23 “(ii) SPECIFICATION BY SEC-
24 RETARY.—Not later than 30 days after the
25 receipt of the expert recommendations de-

1 scribed in clause (i), the Secretary shall,
2 based on such recommendations, specify
3 those injuries, disabilities, illnesses, and
4 conditions deemed to be included in the
5 Vaccine Injury Table under section 2114
6 for the purposes described in subparagraph
7 (A).

8 “(iii) PROGRAM GOALS.—The Insti-
9 tute of Medicine, under the contract under
10 clause (i), shall make such recommenda-
11 tions, the Secretary shall specify, under
12 clause (ii), such injuries, disabilities, ill-
13 nesses, and conditions, and claims under
14 the Compensation Program under this sub-
15 section shall be processed and decided tak-
16 ing into account the following goals of such
17 program:

18 “(I) To encourage persons to de-
19 velop, manufacture, and distribute
20 countermeasures, and to administer
21 covered countermeasures to individ-
22 uals, by limiting such persons’ liability
23 for damages related to death and such
24 injuries, disabilities, illnesses, and
25 conditions.

1 “(II) To encourage individuals to
2 consent to the administration of a
3 covered countermeasure by providing
4 adequate and just compensation for
5 damages related to death and such in-
6 juries, disabilities, illnesses, or condi-
7 tions.

8 “(III) To provide individuals
9 seeking compensation for damages re-
10 lated to the administration of a coun-
11 termeasure with a non-adversarial ad-
12 ministrative process for obtaining ade-
13 quate and just compensation.

14 “(iv) USE OF BEST AVAILABLE EVI-
15 DENCE.—The Institute of Medicine, under
16 the contract under clause (i), shall make
17 such recommendations, the Secretary shall
18 specify, under clause (ii), such injuries,
19 disabilities, illnesses, and conditions, and
20 claims under the Compensation Program
21 under this subsection shall be processed
22 and decided using the best available evi-
23 dence, including information from adverse
24 event reporting or other monitoring of
25 those individuals who were administered

1 the countermeasure, whether evidence from
 2 clinical trials or other scientific studies in
 3 humans is available.

4 “(v) APPLICATION OF SECTION
 5 2116.—Section 2116(b) shall apply to in-
 6 juries, disabilities, illnesses, and conditions
 7 initially specified or revised by the Sec-
 8 retary under clause (ii), except that the ex-
 9 ceptions contained in paragraphs (1) and
 10 (2) of such section shall not apply.

11 “(C) RULE OF CONSTRUCTION.—Section
 12 13632 (a)(3) of Public Law 103–66 (107 Stat.
 13 646) (making revisions by Secretary to the Vac-
 14 cine Injury Table effective on the effective date
 15 of a corresponding tax) shall not be construed
 16 to apply to any revision to the Vaccine Injury
 17 Table made under regulations under this para-
 18 graph.

19 “(5) APPLICATION.—The Compensation Pro-
 20 gram applies to any death or injury, illness, dis-
 21 ability, or condition that is likely (based on best
 22 available evidence) to have been caused by the ad-
 23 ministration of a covered countermeasure to an indi-
 24 vidual pursuant to a declaration under subsection
 25 (p)(2).

1 “(6) SPECIAL MASTERS.—

2 “(A) HIRING.—In accordance with section
3 2112, the judges of the United States Claims
4 Court shall appoint a sufficient number of spe-
5 cial masters to address claims for compensation
6 under this subsection.

7 “(B) BUDGET AUTHORITY.—There are ap-
8 propriated to carry out this paragraph such
9 sums as may be necessary for fiscal year 2005
10 and each fiscal year thereafter. This subpara-
11 graph constitutes budget authority in advance
12 of appropriations and represents the obligation
13 of the Federal Government.

14 “(7) COVERED COUNTERMEASURE.—For pur-
15 poses of this subsection, the term ‘covered counter-
16 measure’ has the meaning given to such term in sub-
17 section (p)(7)(A).

18 “(8) FUNDING.—Compensation made under the
19 Compensation Program shall be made from the same
20 source of funds as payments made under subsection
21 (p).”.

22 (b) EFFECTIVE DATE.—This section shall take effect
23 as of November 25, 2002 (the date of enactment of the
24 Homeland Security Act of 2002 (Public Law 107–296;
25 116 Stat. 2135)).

1 **TITLE VIII—INDEMNIFICATION**
 2 **FOR PRODUCERS OF COUN-**
 3 **TERMEASURES**

4 **SEC. 801. INDEMNIFICATION FOR MANUFACTURERS AND**
 5 **HEALTH CARE PROFESSIONALS WHO ADMIN-**
 6 **ISTER MEDICAL PRODUCTS NEEDED FOR**
 7 **BIODEFENSE.**

8 Section 224(p) of the Public Health Service Act (42
 9 U.S.C. 233(p)) is amended—

10 (1) in the subsection heading by striking
 11 “SMALLPOX”;

12 (2) in paragraph (1), by striking “against
 13 smallpox”;

14 (3) in paragraph (2)—

15 (A) in the paragraph heading, by striking
 16 “AGAINST SMALLPOX”; and

17 (B) in subparagraph (B), by striking
 18 clause (ii);

19 (4) by striking paragraph (3) and inserting the
 20 following:

21 “(3) EXCLUSIVITY; OFFSET.—

22 “(A) EXCLUSIVITY.—With respect to an
 23 individual to which this subsection applies, such
 24 individual may bring a claim for relief under—

25 “(i) this subsection;

1 “(ii) subsection (q); or

2 “(iii) part C.

3 “(B) ELECTION OF ALTERNATIVES.—An
4 individual may only pursue one remedy under
5 subparagraph (A) at any one time based on the
6 same incident or series of incidents. Nothing in
7 the preceding sentence shall be construed to
8 prevent an individual from pursuing a remedy
9 under subparagraph (A) after such individual
10 has elected to decline to pursue another remedy.

11 “(C) STATUTE OF LIMITATIONS.—For pur-
12 poses of determining how much time has lapsed
13 when applying statute of limitations require-
14 ments relating to remedies under subparagraph
15 (A), any limitation of time for commencing an
16 action, or filing an application, petition, or
17 claim for such remedies, shall be deemed to
18 have been suspended for the periods during
19 which an individual pursues a remedy under
20 such subparagraph.

21 “(D) OFFSET.—The value of all compensa-
22 tion and benefits provided under part C of this
23 title for an incident or series of incidents shall
24 be offset against the amount of an award, com-
25 promise, or settlement of money damages in a

claim or suit under this subsection based on the same incident or series of incidents.”;

(5) in paragraph (6)—

(A) in subparagraph (A), by inserting “or under subsection (q)” after “under this subsection”; and

(B) by redesignating subparagraph (B) as subparagraph (C);

(C) by inserting after subparagraph (A), the following:

“(B) GROSSLY NEGLIGENT, RECKLESS, OR ILLEGAL CONDUCT AND WILLFUL MISCONDUCT.—For purposes of subparagraph (A), grossly negligent, reckless, or illegal conduct or willful misconduct shall include the administration by a qualified person of a covered countermeasure to an individual who was not within a category of individuals covered by a declaration under subsection (p)(2) with respect to such countermeasure where the qualified person fails to have had reasonable grounds to believe such individual was within such a category.”; and

(D) by adding at the end the following:

“(D) LIABILITY OF THE UNITED STATES.—The United States shall be liable

1 under this subsection with respect to a claim
2 arising out of the manufacture, distribution, or
3 administration of a covered countermeasure re-
4 gardless of whether—

5 “(i) the cause of action seeking com-
6 pensation is alleged as negligence, strict li-
7 ability, breach of warranty, failure to warn,
8 or other action; or

9 “(ii) the covered countermeasure is
10 designated as a qualified anti-terrorism
11 technology under the SAFETY Act (6
12 U.S.C. 441 et seq.).

13 “(E) GOVERNING LAW.—Notwithstanding
14 the provisions of section 1346(b)(1) and chap-
15 ter 171 of title 28, United States Code, as they
16 relate to governing law, the liability of the
17 United States as provided in this subsection
18 shall be in accordance with the law of the place
19 of injury.

20 “(F) MILITARY PERSONNEL AND UNITED
21 STATES CITIZENS OVERSEAS.—

22 “(i) MILITARY PERSONNEL.—The li-
23 ability of the United States as provided in
24 this subsection shall extend to claims

1 brought by United States military per-
2 sonnel.

3 “(ii) CLAIMS ARISING IN A FOREIGN
4 COUNTRY.—Notwithstanding the provisions
5 of section 2680(k) of title 28, United
6 States Code, the liability of the United
7 States as provided for in the subsection
8 shall extend to claims based on injuries
9 arising in a foreign country where the in-
10 jured party is a member of the United
11 States military, is the spouse or child of a
12 member of the United States military, or is
13 a United States citizen.

14 “(iii) GOVERNING LAW.—With regard
15 to all claims brought under clause (ii), and
16 notwithstanding the provisions of section
17 1346(b)(1) and chapter 171 of title 28,
18 United States Code, and of subparagraph
19 (C), as they relate to governing law, the li-
20 ability of the United States as provided in
21 this subsection shall be in accordance with
22 the law of the claimant’s domicile in the
23 United States or most recent domicile with
24 the United States.”; and

25 (6) in paragraph (7)—

1 (A) by striking subparagraph (A) and in-
2 serting the following:

3 “(A) COVERED COUNTERMEASURE.—The
4 term ‘covered countermeasure’, means—

5 “(i) a substance that is—

6 “(I)(aa) used to prevent or treat
7 smallpox (including the vaccinia or
8 another vaccine); or

9 “(bb) vaccinia immune globulin
10 used to control or treat the adverse
11 effects of vaccinia inoculation; and

12 “(II) specified in a declaration
13 under paragraph (2); or

14 “(ii) a drug (as such term is defined
15 in section 201(g)(1) of the Federal Food,
16 Drug, and Cosmetic Act), biological prod-
17 uct (as such term is defined in section
18 351(i) of this Act), or device (as such term
19 is defined in section 201(h) of the Federal
20 Food, Drug, and Cosmetic Act) that—

21 “(I) the Secretary determines to
22 be a priority (consistent with sections
23 302(2) and 304(a) of the Homeland
24 Security Act of 2002) to treat, iden-
25 tify, or prevent harm from any bio-

1 logical, chemical, radiological, or nu-
2 clear agent identified as a material
3 threat under section 319F-
4 2(c)(2)(A)(ii), or to treat, identify, or
5 prevent harm from a condition that
6 may result in adverse health con-
7 sequences or death and may be caused
8 by administering a drug, biological
9 product, or device against such an
10 agent;

11 “(II) is—

12 “(aa) authorized for emer-
13 gency use under section 564 of
14 the Federal Food, Drug, and
15 Cosmetic Act, so long as the
16 manufacturer of such drug, bio-
17 logical product, or device has—

18 “(AA) made all reason-
19 able efforts to obtain applicable
20 approval, clearance, or licensure;
21 and

22 “(BB) cooperated fully
23 with the requirements of the Sec-
24 retary under such section 564; or

1 “(bb) approved or licensed
 2 solely pursuant to the regulations
 3 under subpart I of part 314 or
 4 under subpart H of part 601 of
 5 title 21, Code of Federal Regula-
 6 tions (as in effect on the date of
 7 enactment of the National Bio-
 8 defense Act of 2005); and

9 “(III) is specified in a declaration
 10 under paragraph (2).”; and

11 (B) in subparagraph (B)—

12 (i) by striking clause (ii), and insert-
 13 ing the following:

14 “(ii) a health care entity, a State, or
 15 a political subdivision of a State under
 16 whose auspices such countermeasure was
 17 administered;” and

18 (vi) in clause (viii), by inserting before
 19 the period “if such individual performs a
 20 function for which a person described in
 21 clause (i), (ii), or (iv) is a covered person”.

1 **TITLE IX—STRENGTHENING**
 2 **PUBLIC HEALTH READINESS**
 3 **FOR PANDEMICS**

4 **Subtitle A—Improved Planning for**
 5 **Pandemic Influenza**

6 **SEC. 901. FEDERAL PANDEMIC INFLUENZA PREPAREDNESS**
 7 **PLAN.**

8 Not later than 10 days after the date of enactment
 9 of this Act, the Secretary of Health and Human Services
 10 shall issue in final form a Pandemic Influenza Prepared-
 11 ness Plan to provide for a coordinated Federal, State, and
 12 local preparation and response to an influenza pandemic.

13 **SEC. 902. REQUIREMENT TO DEVELOP STATE PANDEMIC**
 14 **INFLUENZA PLANS.**

15 (a) IN GENERAL.—In fiscal years after the fiscal year
 16 in which the Secretary issues the Plan described in section
 17 901, the Secretary shall withhold from a State that has
 18 not submitted to the Secretary an acceptable State pan-
 19 demic influenza plan (as determined by the Secretary) the
 20 amounts described in subsection (b) for each fiscal year
 21 for which such a plan is not submitted. The Secretary
 22 shall develop criteria for what constitutes an acceptable
 23 State plan based on the Plan described in section 901.

24 (b) AMOUNTS DESCRIBED.—The amounts described
 25 in this subsection with respect to a State described in sub-

1 section (a) are the following amounts that are payable to
2 a State for a fiscal year under section 319C, 319C–1, or
3 319C–2 of the Public Health Service Act or from the Pub-
4 lic Health and Social Services Emergency Fund (or any
5 successor to such Fund):

6 (1) For the first fiscal year after the initial year
7 in which the Secretary of Health and Human Serv-
8 ices issues the Plan described in section 901, an
9 amount equal to 10 percent of the amount the State
10 was eligible to receive for such fiscal year.

11 (2) For the second such fiscal year, an amount
12 equal to 15 percent of the amount the State was eli-
13 gible to receive for such fiscal year.

14 (3) For the third such fiscal year, an amount
15 equal to 20 percent of the amount the State was eli-
16 gible to receive for such fiscal year.

17 (4) For the fourth and each subsequent fiscal
18 years, an amount equal to 25 percent of the amount
19 the State was eligible to receive for such fiscal year.

20 (c) DISTRIBUTION.—The Secretary shall redistribute
21 amounts withheld under this section to compliant States
22 in proportion to the populations of such States.

23 (d) PLANNING GRANTS.—The Secretary shall award
24 planning grants to States to assist such States in pre-
25 paring or enhancing the plans described in subsection (a).

1 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this section,
3 such sums as may be necessary for each of fiscal years
4 2006 through 2010.

5 **SEC. 903. USE OF CDC AND HRSA FUNDS FOR PUBLIC**
6 **HEALTH PREPAREDNESS.**

7 (a) APPLICABILITY OF PRIORITY STATEMENT TO
8 CDC PREPAREDNESS PROGRAMS.—

9 (1) IN GENERAL.—The statement of priorities
10 described in section 319C–1(e) of the Public Health
11 Service Act shall apply to awards made by the Cen-
12 ters for Disease Control and Prevention—

13 (A) from amounts under the Public Health
14 and Social Services Emergency Fund (or any
15 successor to such Fund); and

16 (B) under the Public Health Preparedness
17 and Response for Bioterrorism program or any
18 successor to such program.

19 (2) LIMITATION.—No State that receives as
20 award under a program described in paragraph (1)
21 may deny funding or impose any other sanction
22 against an entity that uses funds received under
23 such program to enhance preparedness for naturally
24 occurring outbreaks of infectious disease.

1 (2) APPLICABILITY OF PRIORITY STATEMENT
2 TO HRSA PREPAREDNESS PROGRAMS.—

3 (1) IN GENERAL.—The statement of priorities
4 described in section 319C–2(g) of the Public Health
5 Service Act shall apply to awards made by the
6 Health Resources and Service Administration—

7 (A) from amounts under the Public Health
8 and Social Services Emergency Fund (or any
9 successor to such Fund); and

10 (B) under the National Bioterrorism Hos-
11 pital Preparedness Program or any successor to
12 such program.

13 (2) LIMITATION.—No State that receives as
14 award under a program described in paragraph (1)
15 may deny funding or impose any other sanction
16 against an entity that uses funds received under
17 such program to enhance preparedness for naturally
18 occurring outbreaks of infectious disease.

19 **Subtitle B—Vaccine Supply**

20 **SEC. 911. BUY-BACK PROGRAM FOR FLU VACCINE.**

21 (a) REQUESTS FOR MORE DOSES.—

22 (1) IN GENERAL.—Not later than March 15 of
23 each year, the Secretary of Health and Human Serv-
24 ices shall enter into contracts with manufacturers to

1 produce such additional doses of the influenza vac-
 2 cine as determined necessary by the Secretary.

3 (2) CONTENT OF CONTRACT.—A contract for
 4 additional doses shall provide that the manufacturer
 5 will be compensated by the Secretary at an equitable
 6 rate negotiated by the Secretary and the manufac-
 7 turer for any doses that—

8 (A) were not sold by the manufacturer
 9 through routine market mechanisms at the end
 10 of the influenza season for that year; and

11 (B) were requested by the Secretary to be
 12 produced by such manufacturer.

13 (3) WHEN SUCH VACCINE PURCHASES SHOULD
 14 TAKE PLACE.—The Secretary of Health and Human
 15 Services may purchase from the manufacturer the
 16 doses for which it has contracted at any time after
 17 which it is determined by the Secretary, in consulta-
 18 tion with the manufacturer, that the doses will likely
 19 not be absorbed by the private market.

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

**Subtitle C—Enhancing the
National Strategic Stockpile**

SEC. 921. STOCKPILING OF ANTIVIRALS AND OTHER MEDICATIONS.

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

(1) by striking the subsection heading and inserting the following: “STOCKPILING NATIONAL PRIORITY COUNTERMEASURES”; and

(2) by adding at the end the following:

“(3) MEDICATION FOR PANDEMIC INFLUENZA.—

“(A) IN GENERAL.—The Secretary shall ensure that the stockpile described in subsection (a) includes an amount of antiviral medication sufficient to provide for the emergency health security of the United States (including the emergency health security of children and other vulnerable populations) with respect to strains of influenza that may (in the determination of the Secretary) contribute to a pandemic.

“(B) AMOUNT AND TYPE.—In determining the types and amounts of the antivirals and other medications to be placed in the stockpile under subparagraph (A), the Secretary shall

1 take into account the recommendations of the
 2 World Health Organization and of professional
 3 societies with expertise in infectious diseases.

4 “(C) AUTHORIZATION OF APPROPRIA-
 5 TIONS.—

6 “(i) IN GENERAL.—There is author-
 7 ized to be appropriated to carry out sub-
 8 paragraph (A), \$3,080,000,000 for fiscal
 9 year 2006. Amounts appropriated under
 10 this paragraph shall remain available until
 11 expended.

12 “(ii) REALLOCATION OF UNEXPENDED
 13 AMOUNTS.—The Secretary shall reallocate
 14 amounts appropriated under clause (i) that
 15 are not utilized by the Secretary for the
 16 purchase of antivirals under such clause,
 17 for activities under sections 319C–1 and
 18 319C–2 of the Public Health Service Act
 19 (42 U.S.C. 247d–3a and 247d–3b). Such
 20 amounts shall be reallocated equally be-
 21 tween such sections.”.

22 (b) TECHNICAL AMENDMENT.—Section 319F–
 23 2(a)(1) of the Public Health Service Act (42 U.S.C. 247d–
 24 6b(a)(1)) is amended by inserting “(including drugs, bio-
 25 logics, and devices to address acute exacerbation of chron-

1 ic illness and mental health disorders)” after “other sup-
2 plies”.

3 **SEC. 922. STRATEGIC PLAN FOR STOCKPILE.**

4 (a) IN GENERAL.—Not later than 1 year after the
5 date of enactment of this Act, the Secretary of Health and
6 Human Services shall develop a comprehensive plan for
7 the use of each medical intervention contained in the na-
8 tional stockpile under section 121 of the Public Health
9 Security and Bioterrorism Preparedness and Response
10 Act of 2002 (42 U.S.C. 300hh–12).

11 (b) REQUIREMENTS OF PLAN.—The plan developed
12 under subsection (a) shall—

13 (1) cover all relevant Federal, State, and local
14 agencies as well as necessary members of the private
15 sector;

16 (2) with respect to all products in the stockpile,
17 provide for the coordination of activation, distribu-
18 tion, and dissemination of such products to the pop-
19 ulation at large and to specific high-risk groups such
20 as health care professionals;

21 (3) with respect to new medicines or vaccines
22 that are added to the stockpile, provide, within a
23 reasonable period of time, for the coordination of ac-
24 tivation, distribution, and dissemination of the prod-

1 uct to the population at large and specific high-risk
2 groups such as health care professionals; and

3 (4) include procedures for triage or other meth-
4 ods to prioritize the distribution of materials from
5 the stockpile in the event of multiple transit attacks
6 or other public health emergencies occurring simul-
7 taneously in different areas of the nation.

8 (c) PERIODIC UPDATING.—The plan developed under
9 subsection (a) shall be periodically reviewed and updated
10 to ensure the consideration of the needs of the changing
11 nature of threats, the State of medical practice, and the
12 capacities of the agencies and organizations involved.

13 **Subtitle D—Prohibiting Price** 14 **Gouging on Needed Flu Medicines**

15 **SEC. 931. UNFAIR OR DECEPTIVE ACTS OR PRACTICES IN** 16 **COMMERCE RELATED TO TREATMENTS FOR** 17 **PANDEMIC INFLUENZA.**

18 Section 319F–2 of the Public Health Service Act (42
19 U.S.C. 247d–6b) is amended by adding at the end the fol-
20 lowing:

21 “(g) UNFAIR OR DECEPTIVE ACTS OR PRACTICES IN
22 COMMERCE RELATED TO TREATMENTS FOR PANDEMIC
23 INFLUENZA.—

24 “(1) SALES TO CONSUMERS AT UNCONSCION-
25 ABLE PRICE.—

“(A) IN GENERAL.—During any public health emergency declared by the Secretary under section 319 related to pandemic influenza, it shall be unlawful for any person to sell any drug (including an anti-viral drug), device, or biologic for the prevention or treatment of influenza in, or for use in, the area to which that declaration applies at a price that—

“(i) is unconscionably excessive (as determined by the Secretary); or

“(ii) indicates the seller is taking unfair advantage of the circumstances to increase prices unreasonably.

“(B) FACTORS TO BE CONSIDERED.—In determining whether a violation of paragraph (1) has occurred, a court shall take into account, among other factors, whether—

“(i) the amount charged represents a gross disparity between the price of a drug, device, or biologic for the prevention or treatment of influenza and the price at which the drug, device, or biologic was offered for sale in the usual course of the seller’s business immediately prior to the public health emergency; or

1 “(ii) the amount charged grossly ex-
2 ceeds the price at which the same or simi-
3 lar drug, device, or biologic for the preven-
4 tion or treatment of influenza was readily
5 obtainable by other purchasers in the area
6 in which the declaration applies.

7 “(C) MITIGATING FACTORS.—In deter-
8 mining whether a violation of subparagraph (A)
9 has occurred, the court shall also take into ac-
10 count, among other factors, the price that
11 would reasonably equate supply and demand in
12 a competitive and freely functioning market and
13 whether the price at which the drug, device, or
14 biologic for the prevention or treatment of influ-
15 enza was sold reasonably reflects additional
16 costs, not within the control of the seller, that
17 were paid or incurred by the seller.

18 “(2) FALSE PRICING INFORMATION.—It shall
19 be unlawful for any person to report information re-
20 lated to the wholesale price of any drug, device, or
21 biologic for the prevention or treatment of influenza
22 to the Secretary if—

23 “(A) that person knew, or reasonably
24 should have known, the information to be false
25 or misleading;

1 “(B) the information was required by law
2 to be reported; and

3 “(C) the person intended the false or mis-
4 leading data to affect data compiled by the de-
5 partment or agency involved for statistical or
6 analytical purposes with respect to the market
7 for drugs, devices, or biologics for the preven-
8 tion or treatment of influenza.

9 “(3) MARKET MANIPULATION.—It shall be un-
10 lawful for any person, directly or indirectly, to use
11 or employ, in connection with the purchase or sale
12 of drugs, devices, or biologics for the prevention or
13 treatment of influenza at wholesale, any manipula-
14 tive or deceptive device or contrivance, in contraven-
15 tion of such rules and regulations as the Secretary
16 may prescribe as necessary or appropriate in the
17 public interest or for the protection of United States
18 citizens.”.

19 **Subtitle E—National Institute of** 20 **Pathology**

21 **SEC. 941. NATIONAL INSTITUTE OF PATHOLOGY.**

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

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

1 “(H) The National Institute of Pathology.”;

2 and

3 (2) by adding at the end of part E (42 U.S.C.

4 287 et seq.) the following:

5 **“Subpart 7—National Institute of Pathology**

6 **“SEC. 485A. ESTABLISHMENT OF NATIONAL INSTITUTE OF**

7 **PATHOLOGY.**

8 “In order to provide pathology consultation for civil-
 9 ian and military health professionals (including Depart-
 10 ment of Veterans Affairs health professionals) there is es-
 11 tablished the National Institute of Pathology (in this sub-
 12 part referred to as the ‘Institute’). The Institute shall be
 13 headed by a director, who shall be appointed by the Sec-
 14 retary. The Director of the Institute shall report directly
 15 to the Director of NIH.

16 **“SEC. 485B. PURPOSES AND FUNCTIONS OF THE INSTITUTE.**

17 “(a) PURPOSES OF THE INSTITUTE.—The general
 18 purposes of the Institute are to—

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

22 “(2) maintain and improve a pathology tissue
 23 repository; and

24 “(3) provide pathology consultation services.

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

4 “(1) shall—

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

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

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

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

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

17 “(2) may—

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

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

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

9 **“SEC. 485C. BOARD OF REGENTS.**

10 “(a) MEMBERSHIP.—

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

14 “(A) the Surgeons General of—

15 “(i) the Public Health Service;

16 “(ii) the Army;

17 “(iii) the Navy; and

18 “(iv) the Air Force;

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

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

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

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

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

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

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

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

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

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

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

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

21 **“SEC. 485E. INSTITUTE FACILITIES.**

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

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

12 **SEC. 942. TRANSFER OF THE ARMED FORCES INSTITUTE OF**
 13 **PATHOLOGY.**

14 (a) IN GENERAL.—

15 (1) IN GENERAL.—Except as provided in para-
 16 graph (2), there are transferred to the National In-
 17 stitute of Pathology established under subpart 7 of
 18 part E of title IV of the Public Health Service Act
 19 all functions, duties, personnel, assets, liabilities,
 20 contracts, property, records, and unexpended bal-
 21 ances of appropriations of the Armed Forces Insti-
 22 tute of Pathology. The preceding sentence shall not
 23 affect any proceedings, pending applications, suits,
 24 or other actions pending on the date of enactment
 25 of this Act.

1 (2) EXCEPTIONS.—The following components of
2 the Armed Forces Institute of Pathology shall not be
3 transferred from the Department of Defense pursu-
4 ant to paragraph (1):

5 (A) The Armed Forces Medical Examiner.

6 (B) The Department of Defense DNA reg-
7 istry.

8 (C) Accident Investigation Program.

9 (D) The histopathology training program.

10 (E) The patient safety center.

11 (F) Department of Legal Medicine.

12 (G) Center for Clinical Laboratory Medi-
13 cine.

14 (H) Drug Testing and Quality Assurance
15 Program.

16 (I) Subject to the discretion of the Sec-
17 retary of Defense, medical research programs
18 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 re-
24 lated to pathology as the Secretary of De-
25 fense shall choose to conduct.

(b) REFERENCES.—Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or relating to the Armed Forces Institute of Pathology shall be deemed to be a reference to the National Institute of Pathology established under subpart 7 of part E of title IV of the Public Health Service Act.

Subtitle F—Increased Influenza Vaccine and Outbreak Surveillance Activities

SEC. 951. TRACKING NETWORK AND DEMONSTRATION GRANTS.

Title III of the Public Health Service Act is amended by inserting after section 319B (42 U.S.C. 247d–2) the following:

“SEC. 319B-1. TRACKING NETWORK AND DEMONSTRATION GRANTS.

“(a) TRACKING SYSTEM.—

“(1) ESTABLISHMENT.—Not later than 2 years after the date of enactment of this section, the Director of the Centers for Disease Control and Prevention, in conjunction with State and local public health officials, shall establish an electronic tracking system through which the Director and such officials can determine the amount of influenza vaccine that

1 is available for distribution to patients, as well as
2 the need for such vaccine on a county-by-county
3 basis, and the progress of vaccine delivery and dis-
4 tribution efforts at the State and local level.

5 “(2) ESTIMATES.—The tracking system estab-
6 lished under paragraph (1) shall collect estimates of
7 the size of high priority populations (as defined by
8 the Advisory Committee on Immunization Practices
9 and the Centers for Disease Control and Prevention)
10 (referred to in this section as ‘high priority popu-
11 lations’) in each county in the United States, so as
12 to better determine where influenza vaccine re-
13 sources may need to be directed in the case of an
14 emergency.

15 “(3) PROVISION OF INFORMATION.—To be eli-
16 gible to participate in the program under section
17 911 the vaccine manufacturer shall provide informa-
18 tion to the tracking system as the Director of the
19 Centers for Disease Control and Prevention deter-
20 mines appropriate in accordance with subtitle 3 of
21 title XXI.

22 “(4) DATABASE.—In consultation with manu-
23 facturers, distributors, wholesalers, and State and
24 local health departments, the Secretary shall develop
25 guidelines for the development and use of a database

1 in order to maintain confidentiality and ensure that
 2 none of the information provided under paragraph
 3 (3) and contained in the database can be used to
 4 provide a proprietary advantage within the vaccine
 5 market while allowing State and local health officials
 6 such information to maximize the delivery and avail-
 7 ability of vaccines to high priority populations.

8 “(b) EXPANSION OF CURRENT SYSTEMS AND ACTIVI-
 9 TIES.—

10 “(1) SURVEILLANCE SYSTEM.—Not later than
 11 4 years after the date of enactment of this section,
 12 the Director of the Centers for Disease Control and
 13 Prevention shall upgrade the influenza surveillance
 14 system of the Centers for Disease Control and Pre-
 15 vention to report influenza data from State and local
 16 health departments into the tracking system estab-
 17 lished under subsection (a)(1).

18 “(2) EDUCATIONAL MATERIALS.—The tracking
 19 system shall contain information to assist users in
 20 accessing influenza education, outreach, and commu-
 21 nications tools.

22 “(3) EMERGENCY PROVIDER DATABASE.—The
 23 Director of the Centers for Disease Control and Pre-
 24 vention shall coordinate access to, in conjunction
 25 with State and local health departments and State

1 licensing boards for health professionals, a database
2 registry of medical personnel who can provide serv-
3 ices in the event of a health emergency, including
4 pandemic influenza or an influenza vaccine shortage.
5 Such information shall be made available through
6 the tracking network.

7 “(c) DEMONSTRATION GRANTS.—

8 “(1) IN GENERAL.—The Director of the Cen-
9 ters for Disease Control and Prevention shall award
10 demonstration grants to State and local health de-
11 partments to enable such departments to enter into
12 contract with hospitals, community health centers,
13 long-term care facilities, physicians’ offices, and
14 health care facilities operated or funded by such de-
15 partments to assist such entities in upgrading their
16 information technology, and workforce in a manner
17 that will allow such entities to improve their ability
18 to report and track influenza vaccine dissemination.

19 “(2) PRIORITY.—In awarding grants under
20 paragraph (1), priority shall be given to entities that
21 serve high priority populations in medically under-
22 served areas.

23 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated—

1 “(1) to carry out subsection (a), \$100,000,000
 2 for each of fiscal years 2007 through 2011, of which
 3 \$500,000 for each fiscal year shall be made available
 4 to implement subsection (b)(3); and
 5 “(2) to carry out subsection (c), \$100,000,000
 6 for each of fiscal years 2007 through 2011.”.

7 **SEC. 952. EDUCATIONAL EFFORTS AND GRANTS.**

8 Title III of the Public Health Service Act is amended
 9 by inserting after section 319B–1 (as added by section
 10 951) the following:

11 **“SEC. 319B–2. IMMUNIZATION EDUCATIONAL EFFORTS AND**
 12 **GRANTS.**

13 “(a) IN GENERAL.—The Director of the Centers for
 14 Disease Control and Prevention, in conjunction with State
 15 and local health departments, shall revise and expand the
 16 influenza-related educational materials to the Centers for
 17 Disease Control and Prevention, and facilitate the use of
 18 such materials by health care providers and patients. The
 19 Director is authorized to coordinate such educational ef-
 20 forts with nonprofit provider and patient advocacy groups.

21 “(b) INFLUENZA VACCINE EDUCATION AND OUT-
 22 REACH.—

23 “(1) IN GENERAL.—In order to achieve an opti-
 24 mal balance in the influenza vaccine market, and to
 25 ensure that the recommendations of the Advisory

1 Committee on Immunization Practices to the Cen-
2 ters for Disease Control and Prevention for vaccine
3 administration are carried out to the maximum ex-
4 tent possible, the Director of the Centers for Disease
5 Control and Prevention, in conjunction with State
6 and local health departments, shall carry out influ-
7 enza immunization education and outreach activities
8 that target physicians and other health care pro-
9 viders, health insurance providers, health care insti-
10 tutions and patients, particularly those in high pri-
11 ority populations (as defined by the Advisory Com-
12 mittee on Immunization Practices and the Centers
13 for Disease Control and Prevention) (referred to in
14 this section as ‘high priority populations’).

15 “(2) TYPES OF ACTIVITIES.—The education
16 and outreach activities under paragraph (1) shall in-
17 clude—

18 “(A) activities to encourage voluntary par-
19 ticipation in influenza vaccination programs,
20 with the goal of increasing overall influenza
21 vaccination rates in the United States, achiev-
22 ing full influenza vaccination of all high priority
23 populations, and full use of each season’s influ-
24 enza vaccine supply;

1 “(B) the provision of information on influ-
2 enza prevention;

3 “(C) activities to increase the number of
4 healthcare providers who receive influenza vac-
5 cines each year; and

6 “(D) other influenza educational efforts
7 determined appropriate by the Director.

8 “(c) GRANTS.—The Director of the Centers for Dis-
9 ease Control and Prevention may award grants to State
10 and local health departments to carry out activities to en-
11 courage individuals, particularly those from high priority
12 populations, to seek out influenza vaccinations.

13 “(d) COLLABORATION.—State and local health de-
14 partments that receive grants under subsection (b) are en-
15 couraged to collaborate on projects with physicians and
16 other health care providers, health insurance providers,
17 health care institutions, and groups representing high pri-
18 ority populations.

19 “(e) AUTHORIZATION OF APPROPRIATIONS.—In ad-
20 dition to any amounts otherwise available through the Sec-
21 retary for influenza outreach and education, there is au-
22 thorized to be appropriated to carry out this section,
23 \$10,000,000 for each of fiscal years 2007 through 2011.”.

Subtitle G—Miscellaneous Provisions

SEC. 961. HRSA CURRICULUM DEVELOPMENT AND TRAIN- ING PROGRAMS.

In carrying out activities under section 319F(g) of the Public Health Service Act and any related activities on the development of training program for health professionals in the recognition of the signs and symptoms of exposure to a potential bioweapon and other agents that may create a public health emergency (including the Bio-terrorism Training and Curriculum Development program of the Health Resources and Services Administration), the Secretary of Health and Human Services shall, to the maximum extent practicable, provide awards to a single entity or a small number of entities that have the capacity to provide consistent training nationwide. In carrying out the requirement of the preceding sentence, the Secretary may not, except if there is no practicable alternative, provide awards to any single entity that is less than 20 per cent of the total awards made for any fiscal year.

SEC. 962. USING HEALTH INFORMATION TECHNOLOGY TO ENHANCE EPIDEMIC DETECTION.

Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended by adding at the end the following:

1 “(k) USING HEALTH INFORMATION TECHNOLOGY
2 TO ENHANCE EPIDEMIC DETECTION.—

3 “(1) IN GENERAL.—The Secretary may award
4 demonstration grants to eligible entities to enable
5 such entities to establish or enhance information
6 technology systems for the rapid detection of infec-
7 tious disease outbreaks.

8 “(2) ELIGIBILITY.—To be eligible to receive a
9 grant under paragraph (1), an entity shall—

10 “(A) be a State or local government or
11 nonprofit entity; and

12 “(B) submit to the Secretary an applica-
13 tion at such time, in such manner, and con-
14 taining such information as the Secretary may
15 require, including and assurance that the entity
16 will submit to the Secretary a report on the ef-
17 fective of the systems funded under the grant.

18 “(3) EVALUATION OF SYSTEMS.—Not later
19 than 1 year after the date of enactment of this sub-
20 section, and annually thereafter, the Director of the
21 Centers for Disease Control and Prevention shall
22 conduct an evaluation of the systems implemented
23 under grants under this subsection to determine
24 which systems are most effective. The Director shall

1 issue recommendations on best practices for such
2 systems.

3 “(4) INDEPENDENT EVALUATION.—Not later
4 than 4 years after the date of enactment of this sub-
5 section, the Government Accountability Office shall
6 conduct an independent evaluation, and submit to
7 the Secretary and the appropriate committees of
8 Congress a report, concerning the activities con-
9 ducted under this subsection.

10 “(5) AUTHORIZATION OF APPROPRIATIONS.—
11 There are authorized to be appropriated to carry out
12 this subsection, \$50,000,000 for each of fiscal years
13 2006 through 2010.”.

14 **SEC. 963. NATURALLY OCCURRING OR DELIBERATELY IN-**
15 **TRODUCED AGENTS.**

16 Section 319C–1(d)(7)(A) of the Public Health Serv-
17 ice Act (42 U.S.C. 247d–3a(d)(7)(A)) is amended by in-
18 serting “(where such biological agent may be naturally oc-
19 ccurring or deliberately introduced)” after “agent”.

20 **SEC. 964. USE OF FEDERAL FACILITIES IN EMERGENCIES.**

21 (a) IDENTIFICATION.—Not later than 90 days after
22 the date of enactment of this Act, the Secretary of Health
23 and Human Services shall identify Federal facilities that
24 are capable of being used to provide health care as surge

1 capacity hospitals during a public health emergency under
2 section 319 of the Public Health Service Act.

3 (b) MEMORANDUM OF UNDERSTANDING.—The Sec-
4 retary of Health and Human Services may enter into a
5 memorandum of understanding with the heads of appro-
6 priate Federal agencies and other workforce groups to uti-
7 lize the facilities identified under subsection (a) during a
8 public health emergency under section 319 of the Public
9 Health Service Act.

10 **SEC. 965. ADVISORY COMMITTEE ON VULNERABLE POPU-**
11 **LATIONS.**

12 (a) IN GENERAL.—Section 319F(b)(2) of the Public
13 Health Service Act (42 U.S.C. 247d–6(b)(2)) is amended
14 to read as follows:

15 “(2) NATIONAL ADVISORY COMMITTEE ON VUL-
16 NERABLE POPULATIONS AND TERRORISM.—

17 “(A) IN GENERAL.—For purposes of para-
18 graph (1), the Secretary shall establish an advi-
19 sory committee to be known as the National
20 Advisory Committee on Vulnerable Populations
21 and Terrorism (referred to in this paragraph as
22 the ‘Advisory Committee’).

23 “(B) DUTIES.—The Advisory Committee
24 shall—

1 “(i) provide recommendations regard-
2 ing—

3 “(I) the preparedness of the
4 health care (including mental health
5 care) system to respond to bioter-
6 rorism as it relates to children, preg-
7 nant women, and other vulnerable
8 populations;

9 “(II) needed changes to the
10 health care and emergency medical
11 service systems and emergency med-
12 ical services protocols to meet the spe-
13 cial needs of children, pregnant
14 women, and other vulnerable popu-
15 lations; and

16 “(III) changes, if necessary, to
17 the national stockpile under section
18 121 of the Public Health Security and
19 Bioterrorism Preparedness and Re-
20 sponse Act of 2002 to meet the emer-
21 gency health security of children,
22 pregnant women, and other vulnerable
23 populations; and

24 “(ii) advise the National BioVenture
25 Trust with respect to granting priority to

1 supporting and facilitating research and
2 development of countermeasures, and for-
3 mulations of countermeasures, that are
4 likely to be safe and effective for children,
5 pregnant women, and other vulnerable
6 populations.

7 “(C) COMPOSITION.—The Advisory Com-
8 mittee shall be composed of such Federal offi-
9 cials as may be appropriate to address the spe-
10 cial needs of the diverse population groups of
11 children, pregnant women, and other popu-
12 lations and health experts on infectious disease,
13 environmental health, toxicology, and other rel-
14 evant professional disciplines.”.

15 (b) ANNUAL REVIEW OF STRATEGIC NATIONAL
16 STOCKPILE.—

17 (1) IN GENERAL.—The Secretary, in consulta-
18 tion with the National Advisory Committee on Vul-
19 nerable Populations and Terrorism and other ex-
20 perts as determined appropriate by the Secretary,
21 shall annually conduct a review of—

22 (A) the capacity of the Strategic National
23 Stockpile under section 319F–2 of the Public
24 Health Service Act (42 U.S.C. 247d–6b) to ad-
25 dress the emergency health needs of pediatric

1 populations, pregnant women, and other vulner-
 2 able populations; and

3 (B) any formulary additions or modifica-
 4 tions with respect to the contents of such
 5 Stockpile to ensure that the needs of such pop-
 6 ulations are met.

7 (2) RECOMMENDATIONS.—Based on the review
 8 under paragraph (1), the Secretary shall—

9 (A) determine and prioritize recommenda-
 10 tions of formulary additions to the Strategic
 11 National Stockpile with respect to pediatric
 12 populations, pregnant women, and other vulner-
 13 able populations; and

14 (B) submit such recommendations to Con-
 15 gress.

16 **SEC. 966. EMERGENCY SYSTEM FOR ADVANCE REGISTRA-**
 17 **TION OF HEALTH PROFESSIONS VOLUN-**
 18 **TEERS.**

19 Section 319I(a) of the Public Health Service Act (42
 20 U.S.C. 247d–7b(a)) is amended by striking “maintain a
 21 system” and inserting “maintain a single system”.

TITLE X—ENHANCING ANTIBIOTICS

SEC. 1001. PRESERVING THE EFFECTIVENESS OF MEDICALLY IMPORTANT ANTIBIOTICS.

(a) PROOF OF SAFETY OF CRITICAL ANTIMICROBIAL ANIMAL DRUGS.—

(1) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

“(nn) CRITICAL ANTIMICROBIAL ANIMAL DRUG.—The term ‘critical antimicrobial animal drug’ means a drug that—

“(1) is intended for use in food-producing animals; and

“(2) is composed wholly or partly of—

“(A) any kind of penicillin, tetracycline, bacitracin, macrolide, lincomycin, streptogramin, aminoglycoside, sulfonamide; or

“(B) any other drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection caused by microorganisms.

“(oo) NONTHERAPEUTIC USE.—The term ‘nonthera-
peutic use’, with respect to a critical antimicrobial animal drug, means any use of the drug as a feed or water addi-

1 tive for an animal in the absence of any clinical sign of
2 disease in the animal for growth promotion, feed effi-
3 ciency, weight gain, routine disease prevention, or other
4 routine purpose.”.

5 (2) NONTHERAPEUTIC USE.—Section 512(d)(1)
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 360b(d)(1)) is amended—

8 (A) in the first sentence—

9 (i) in subparagraph (H), by striking
10 “or” at the end;

11 (ii) by redesignating subparagraph (I)
12 as subparagraph (J); and

13 (iii) by inserting after subparagraph
14 (H) the following:

15 “(I) with respect to a critical antimicrobial
16 animal drug or a drug of the same chemical
17 class as a critical antimicrobial animal drug,
18 the applicant has failed to demonstrate that
19 there is a reasonable certainty of no harm to
20 human health due to the development of anti-
21 microbial resistance that is attributable, in
22 whole or in part, to the nontherapeutic use of
23 the drug; or”; and

1 (B) in the second sentence, by striking
 2 “(A) through (I)” and inserting “(A) through
 3 (J)”.

4 (3) PHASED ELIMINATION OF NONTHERA-
 5 PEUTIC USE IN ANIMALS OF CRITICAL ANTI-
 6 MICROBIAL ANIMAL DRUGS IMPORTANT FOR HUMAN
 7 HEALTH.—Section 512 of the Federal Food, Drug,
 8 and Cosmetic Act (21 U.S.C. 360b) is amended by
 9 adding at the end the following:

10 “(q) PHASED ELIMINATION OF NONTHERAPEUTIC
 11 USE IN ANIMALS OF CRITICAL ANTIMICROBIAL ANIMAL
 12 DRUGS IMPORTANT FOR HUMAN HEALTH.—

13 “(1) APPLICABILITY.—This subsection applies
 14 to the nontherapeutic use in a food-producing ani-
 15 mal of—

16 “(A)(i) a drug that is a critical anti-
 17 microbial animal drug; or

18 “(ii) a drug that is of the same chemical
 19 class as a critical antimicrobial animal drug;
 20 and

21 “(B) a drug—

22 “(i) for which, as of the day before
 23 the date of enactment of this subsection,
 24 there was in effect an approval of an appli-

1 cation filed under subsection (b) or (j) of
2 section 505; or

3 “(ii) that was otherwise marketed for
4 use.

5 “(2) WITHDRAWAL.—The Secretary shall with-
6 draw the approval of a nontherapeutic use in food-
7 producing animals described in paragraph (1) on the
8 date that is 2 years after the date of enactment of
9 this subsection unless—

10 “(A) before the date that is 2 years after
11 that date of enactment, the Secretary makes a
12 written determination that the holder of the ap-
13 proved application has demonstrated that there
14 is a reasonable certainty of no harm to human
15 health due to the development of antimicrobial
16 resistance that is attributable in whole or in
17 part to the nontherapeutic use of the drug; or

18 “(B) before the date specified in subpara-
19 graph (A), the Secretary makes a final written
20 determination under this subsection, with re-
21 spect to a risk analysis of the drug conducted
22 by the Secretary and other relevant informa-
23 tion, that there is a reasonable certainty of no
24 harm to human health due to the development
25 of antimicrobial resistance that is attributable

1 in whole or in part to the nontherapeutic use of
2 the drug.

3 “(3) EXEMPTIONS.—Except as provided in
4 paragraph (5), if the Secretary grants an exemption
5 under section 505(i) for a drug that is a critical
6 antimicrobial animal drug, the Secretary shall re-
7 scind each approval of a nontherapeutic use in a
8 food-producing animal of the critical antimicrobial
9 animal drug, or of a drug in the same chemical class
10 as the critical antimicrobial animal drug, as of the
11 date that is 2 years after the date on which the Sec-
12 retary grants the exemption.

13 “(4) APPROVALS.—If an application for a drug
14 that is critical antimicrobial animal drug is sub-
15 mitted to the Secretary under section 505(b), the
16 Secretary shall rescind each approval of a nonthera-
17 peutic use in a food-producing animal of the critical
18 antimicrobial animal drug, or of a drug in the same
19 chemical class as the critical antimicrobial animal
20 drug, as of the date that is 2 years after the date
21 on which the application is submitted to the Sec-
22 retary.

23 “(5) EXCEPTION.—Paragraph (3) or (4), as the
24 case may be, shall not apply if, before the date on
25 which approval would be rescinded under that sub-

1 paragraph, the Secretary determines that the holder
 2 of the approved application has demonstrated that
 3 there is a reasonable certainty of no harm to human
 4 health due to the development of antimicrobial re-
 5 sistance that is attributable, in whole or in part, to
 6 the nontherapeutic use in the food-producing animal
 7 of the critical antimicrobial animal drug.”.

8 (b) ASSISTANCE TO DEFRAY EXPENSES OF LIVE-
 9 STOCK OR POULTRY PRODUCERS IN PHASING OUT NON-
 10 THERAPEUTIC USE OF CRITICAL ANTIMICROBIAL ANIMAL
 11 DRUGS.—

12 (1) DEFINITIONS.—In this subsection, the
 13 terms “critical antimicrobial animal drug” and
 14 “nontherapeutic use” have the meanings given the
 15 terms in section 201 of the Federal Food, Drug, and
 16 Cosmetic Act (21 U.S.C. 321).

17 (2) PAYMENTS.—The Secretary of Agriculture
 18 may make payments to producers of livestock or
 19 poultry that the Secretary determines are substan-
 20 tially reducing, or have substantially reduced, the
 21 nontherapeutic use of critical antimicrobial animal
 22 drugs in livestock or poultry in order to defray the
 23 costs of such reduction.

24 (3) PRIORITY FOR FAMILY FARMERS AND
 25 SMALL FARMS.—In awarding payments under para-

1 graph (2), the Secretary of Agriculture shall give
 2 priority to family-owned and family-operated farms
 3 or ranches and to small farms or ranches, as deter-
 4 mined by the Secretary.

5 (4) AUTHORIZATION OF APPROPRIATIONS.—

6 There are authorized to be appropriated such sums
 7 as are necessary to carry out this subsection for fis-
 8 cal year 2005 and for each subsequent fiscal year.

9 (c) RESEARCH AND DEMONSTRATION PROGRAMS.—

10 Subtitle D of title VII of the Farm Security and Rural
 11 Investment Act of 2002 (116 Stat. 455) is amended by
 12 adding at the end the following:

13 **“SEC. 7413. PHASING OUT OF NONTHERAPEUTIC USE OF**
 14 **CRITICAL ANTIMICROBIAL ANIMAL DRUGS.**

15 “(a) DEFINITIONS.—In this section, the terms ‘crit-
 16 ical antimicrobial animal drug’ and ‘nontherapeutic use’
 17 have the meanings given the terms in section 201 of the
 18 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

19 “(b) GRANTS.—The Secretary, in consultation with
 20 the Secretary of Health and Human Services, shall award
 21 grants to colleges and universities to establish research
 22 and demonstration programs for—

23 “(1) phasing out the nontherapeutic use of crit-
 24 ical antimicrobial animal drugs in livestock or poul-
 25 try; and

12 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated such sums as are nec-
14 essary to carry out this section for fiscal years 2004
15 through 2007.”.

(1) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 512 (21 U.S.C. 360b) the following:

23 “(a) IN GENERAL.—Not later than July 1 of each
24 year, a manufacturer of a critical antimicrobial animal
25 drug or an animal feed for food-producing animals bearing

1 or containing a critical antimicrobial animal drug shall
2 submit to the Secretary a report, in such form as the Sec-
3 retary shall require, containing information on the sales
4 during the previous calendar year of the critical anti-
5 microbial animal drug or animal feed.

6 “(b) INFORMATION TO BE INCLUDED.—A report
7 under subsection (a) shall—

8 “(1) state separately the quantity of the critical
9 antimicrobial animal drug, including in animal feed
10 bearing or containing the critical antimicrobial ani-
11 mal drug, sold for each kind of food-producing ani-
12 mal;

13 “(2) describe the claimed purpose of use for
14 each kind of food-producing animal as being for
15 growth promotion, weight gain, feed efficiency, dis-
16 ease prevention, disease control, disease treatment,
17 or another purpose; and

18 “(3) describe the dosage form of the drug.

19 “(c) PUBLICATION.—

20 “(1) IN GENERAL.—The Secretary shall—

21 “(A) make the information submitted
22 under subsection (a) available to the public; and

23 “(B) publish the information at least an-
24 nually.

1 “(2) PROTECTION OF CONFIDENTIALITY.—The
2 Secretary shall aggregate information, if necessary,
3 to avoid disclosure under paragraph (1) of confiden-
4 tial business information.”.

5 (2) PROHIBITED ACTS.—Section 301(e) of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 331(e)) is amended by striking “515(f)” and insert-
8 ing “512A, 515(f),”.

9 (3) EFFECTIVE DATE.—The amendments made
10 by this subsection take effect on January 1, 2005.

11 (e) LIMITATION ON ANTIBIOTIC USES.—If a counter-
12 measure that is developed using assistance provided under
13 the Project BioShield Program (under the Project Bio-
14 Shield Act of 2004, and the amendments made by such
15 Act) is an antibiotic (as defined for purposes of the Fed-
16 eral Food, Drug, and Cosmetic Act)—

17 (1) such countermeasure may not be used for
18 nontherapeutic uses (as defined in section 201(o) of
19 the Federal Food, Drug, and Cosmetic Act (as
20 added by subsection (a)) in animals; and

21 (2) the Secretary of Health and Human Serv-
22 ices shall transfer from the BioShield fund an
23 amount equal to 10 percent of the funds provided to
24 the programs authorized under section 319E of the

1 Public Health Service Act (42 U.S.C. 247d–5) for
2 purposes of funding the countermeasure.

3 **TITLE XI—IMPROVING RE-**
4 **SEARCH ON BIODEFENSE**
5 **COUNTERMEASURES**

6 **SEC. 1101. IMPROVING THE ABILITY OF BIODEFENSE RE-**
7 **SEARCHERS TO WORK WITH SELECT AGENTS.**

8 Section 351A of the Public Health Service Act (42
9 U.S.C. 262a) is amended—

10 (1) in subsection (a)—

11 (A) in paragraph (1)(B)(ii), by inserting “,
12 and with the Advisory Committee established
13 under subsection (m) in the manner described
14 in paragraph (3) of such subsection” before the
15 period; and

16 (B) by striking paragraph (2), and insert-
17 ing the following:

18 “(2) BIENNIAL REVIEW.—

19 “(A) IN GENERAL.—The Secretary shall,
20 on a biennial or more frequent basis as deter-
21 mined appropriate, review and republish the list
22 established under paragraph (1), and by regula-
23 tion revise such list as necessary in accordance
24 with such paragraph.

1 “(B) CONSULTATION.—In carrying out the
 2 activities described in subparagraph (A), the
 3 Secretary shall consult with the Advisory Com-
 4 mittee established under subsection (m) in the
 5 manner described in paragraph (3) of such sub-
 6 section.”;

7 (2) in subsection (e)(3), by adding at the end
 8 the following:

9 “(D) PRESUMPTION OF ALLOWED AC-
 10 CESS.—

11 “(i) IN GENERAL.—If an individual
 12 described in subclause (I) or (II) of clause
 13 (iii) transfers employment or professional
 14 affiliation from one registered person (re-
 15 ferred to in this subparagraph as the
 16 ‘sender’) to another registered person (re-
 17 ferred to in this subparagraph as the ‘re-
 18 cipient’), and the recipient determines that
 19 such individual is an individual described
 20 in paragraph (2)(A), the recipient shall
 21 take the actions described in paragraph (2)
 22 with respect to such individual.

23 “(ii) TREATMENT DURING ATTORNEY
 24 GENERAL REVIEW.—During the period in
 25 which the Attorney General is conducting a

1 review pursuant to this paragraph with re-
 2 spect to an individual described in clause
 3 (i), such individual shall be presumed not
 4 to be an individual described in clauses (i)
 5 or (ii) of subparagraph (B).

6 “(iii) INDIVIDUAL DESCRIBED.—An
 7 individual described in this clause is—

8 “(I) an individual the name of
 9 whom the sender has submitted to the
 10 Secretary and the Attorney General
 11 under paragraph (2)(B) and whom
 12 the Attorney General has determined
 13 is not described in clause (i) or (ii) of
 14 subparagraph (B); or

15 “(II) an individual who is a reg-
 16 istered person under paragraph
 17 (6)(A).

18 “(iv) Not later than 180 days after
 19 the date of enactment of this subpara-
 20 graph, the Secretary shall promulgate reg-
 21 ulations to implement this subparagraph.”;

22 (3) by redesignating subsection (m) as sub-
 23 section (p); and

24 (4) by inserting after subsection (l), the fol-
 25 lowing:

1 “(m) SELECT AGENT SCIENTIFIC ADVISORY COM-
2 MITTEE.—

3 “(1) ESTABLISHMENT.—The Secretary shall es-
4 tablish a Select Agent Advisory Committee (referred
5 to in this section as the ‘Advisory Committee’) to
6 consult with, and provide expert advice to, the Sec-
7 retary and the Secretary of Agriculture in the man-
8 ner described in paragraph (3).

9 “(2) MEMBERSHIP.—

10 “(A) IN GENERAL.—The Advisory Com-
11 mittee shall be composed of individuals, to be
12 appointed by the Secretary, having expertise in
13 scientific research with select agents or other
14 microbial or viral pathogens.

15 “(B) TERMS.—An individual appointed
16 under subparagraph (A) shall serve for a 2-year
17 term. The terms of the initial members ap-
18 pointed under such subparagraph shall be stag-
19 gered as determined by the Secretary,

20 “(3) CONSULTATION AND RESPONSE.—

21 “(A) IN GENERAL.—Except during a pub-
22 lic health emergency, the Secretary shall, not
23 later than 90 days prior to promulgating a reg-
24 ulation under this section, transmit a draft of
25 such regulation to the Advisory Committee.

1 “(B) COMMENTS AND RECOMMENDA-
 2 TIONS.—The Advisory Committee may submit
 3 to the Secretary comments and recommenda-
 4 tions regarding a draft regulation submitted by
 5 the Secretary under subparagraph (A).

6 “(C) With respect to any recommendations
 7 submitted by the Advisory Committee under
 8 subparagraph (B) relating to a draft regulation
 9 during the 60-day period beginning on the date
 10 on which such draft regulation was transmitted
 11 to the Advisory Committee, the Secretary shall,
 12 prior to promulgating such regulation—

13 “(i) modify the draft regulation to in-
 14 corporate the recommendations of the Ad-
 15 visory Committee; or

16 “(ii) publish an explanation of why
 17 the recommendation has not been adopted.

18 “(n) REPORT BY COMPTROLLER GENERAL.—Not
 19 later than 1 year after the date of enactment of this sub-
 20 section, the Comptroller shall submit to the appropriate
 21 committees of Congress a report that—

22 “(1) describes the length of time required to
 23 complete the security checks and other procedures
 24 required for an institution to become a registered
 25 person;

1 “(2) makes recommendations on ways to reduce
2 the length of time described in paragraph (1) with-
3 out compromising security;

4 “(3) describes the ongoing costs for a registered
5 person to comply with the requirements of regula-
6 tions promulgated under this section;

7 “(4) makes recommendations on ways to reduce
8 the costs described in paragraph (3) without com-
9 promising security; and

10 “(5) describes the degree to which registered
11 persons that are nonprofit institutions are able to
12 recoup the costs described in paragraph (3) from
13 Federal agencies that provide financial support for
14 research conducted at such institutions; and

15 “(6) describes the source or sources of funding
16 used by registered persons that are nonprofit institu-
17 tions to comply with the requirements of regulations
18 promulgated under this section.

19 “(o) CLARIFICATION OF CERTAIN TERMS.—

20 “(1) FINDINGS.—Congress finds that—

21 “(A) certainty and predictability are essen-
22 tial for registered persons to be able to comply
23 properly with the requirements of the regula-
24 tions promulgated under this section;

1 “(B) the terms ‘access’ and ‘incident’ are
2 of central importance in the requirements of
3 such regulations; and

4 “(C) it is essential for there to be a clear
5 definition in such regulations of such terms.

6 “(2) REQUIREMENT TO PUBLISH.—

7 “(A) IN GENERAL.—Not later than 180
8 days after the date of enactment of this sub-
9 section, the Secretary shall by regulation pro-
10 mulgate a definition of the terms ‘access’ and
11 ‘incident’ as such terms are used in regulations
12 promulgated pursuant to this section.

13 “(B) CONSULTATION.—In carrying out
14 subparagraph (A), the Secretary shall consult
15 with the Advisory Committee established under
16 subsection (m) in the manner paragraph (3) of
17 such subsection.”.

○