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109TH CONGRESS
1ST SESSION

S. 975

To provide incentives to increase research by private sector entities to develop medical countermeasures to prevent, detect, identify, contain, and treat illnesses, including those associated with a biological, chemical, nuclear, or radiological weapons attack or an infectious disease outbreak, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 29 (legislative day, APRIL 28), 2005

Mr. LIEBERMAN (for himself, Mr. HATCH, and Mr. BROWNBACK) introduced the following bill; which was read the first time

MAY 9, 2005

Read the second time and placed on the calendar

A BILL

To provide incentives to increase research by private sector entities to develop medical countermeasures to prevent, detect, identify, contain, and treat illnesses, including those associated with a biological, chemical, nuclear, or radiological weapons attack or an infectious disease outbreak, 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,*

1 **SECTION 1. SHORT TITLE.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Project BioShield II Act of 2005”.

4 (b) **IN HONOR.**—This Act is enacted in honor of Rob-
5 ert Stevens, Thomas Morris, Jr., Joseph Curseen, Kathy
6 Nguyen, Otilie Lundgren, and Lisa J. Raines, victims of
7 terrorist attacks in the United States in 2001.

8 (c) **TABLE OF CONTENTS.**—The table of contents of
9 this Act is as follows:

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1 **TITLE I—AMENDMENTS TO THE**
2 **PROJECT BIOSHIELD ACT OF**
3 **2004 REGARDING TERROR**
4 **COUNTERMEASURES**

5 **SEC. 101. PROCUREMENT OF CERTAIN DRUGS, DETECTION**
6 **TECHNOLOGY, DIAGNOSTICS, AND RESEARCH**
7 **TOOLS.**

8 (a) IN GENERAL.—Part B of title III of the Public
9 Health Service Act (42 U.S.C. 243 et seq.) is amended—

10 (1) in section 319F–1(a)—

11 (A) by redesignating paragraphs (3), (4),
12 and (5) as paragraphs (4), (5), and (6), respec-
13 tively; and

14 (B) by inserting after paragraph (2) the
15 following:

16 “(3) INCLUSION.—The term ‘qualified counter-
17 measure’ includes detection technology, diagnostics,
18 and research tools, as those terms are defined in sec-
19 tion 319F–3.”; and

20 (2) in section 319F–2(c)(1)(B), in the matter
21 preceding clause (i), by striking “means a” and in-
22 serting “means detection technology, diagnostics,
23 and research tools, as those terms are defined in
24 319F–3, a”.

1 (b) PURCHASE FUNDS.—Title V of the Homeland Se-
2 curity Act of 2002 (6 U.S.C. 311 et seq.) is amended by
3 adding at the end the following:

4 **“SEC. 512. COUNTERMEASURE PURCHASE FUND AT THE**
5 **DEPARTMENT OF HOMELAND SECURITY.**

6 “(a) PURCHASE FUND.—

7 “(1) ESTABLISHMENT OF FUND.—There is es-
8 tablished in the Department a fund to be known as
9 the ‘Terrorism and Infectious Disease Counter-
10 measure Purchase Fund’ (referred to in this sub-
11 section as the ‘Fund’) consisting of amounts appro-
12 priated for expenditure by the Secretary under para-
13 graph (4). This fund shall be separate from the spe-
14 cial reserve fund established under section 510.

15 “(2) INVESTMENT OF FUND.—Amounts in the
16 Fund shall be invested in accordance with section
17 9702 of title 31, United States Code, and any inter-
18 est on, and proceeds from, any such investment shall
19 be credited to and become part of the Fund.

20 “(3) USE OF FUND.—

21 “(A) IN GENERAL.—The Secretary shall
22 expend amounts in the Fund—

23 “(i) for the purchase of counter-
24 measures; and

1 “(ii) to provide advance, partial,
2 progress or other payments, in accordance
3 with subparagraph (E), to manufacturers
4 of countermeasures.

5 “(B) PURCHASE.—Countermeasures shall
6 be purchased by the Fund at the price and
7 under the terms negotiated by the Secretary
8 and the manufacturer or at a commercial price,
9 if applicable.

10 “(C) COORDINATION WITH THE DEPART-
11 MENT OF HEALTH AND HUMAN SERVICES.—
12 The Secretary may delegate authority to the
13 Secretary of Health and Human Services to
14 purchase countermeasures using the Fund. Any
15 such purchases by the Secretary of Health and
16 Human Services shall be conducted as if made
17 by the Secretary under this section.

18 “(D) CONDITIONS FOR PURCHASE.—
19 “(i) IN GENERAL.—Payments for pur-
20 chases under subparagraph (A)(i) shall be
21 made under such terms and conditions as
22 are set forth in the contract between the
23 parties.

24 “(ii) DETERMINATIONS.—The deter-
25 minations required under section 319F—

1 2(c) of the Public Health Service Act shall
2 not be required with respect to a contract,
3 grant, or other transaction funded by the
4 Fund under this section.

5 “(E) ADVANCE, PARTIAL, PROGRESS, OR
6 OTHER PAYMENTS.—

7 “(i) IN GENERAL.—The Secretary
8 may make payments under subparagraph
9 (A)(ii) to manufacturers of counter-
10 measures prior to the final purchase of
11 such countermeasure.

12 “(ii) BASIS FOR PAYMENTS.—Pay-
13 ments under this subparagraph shall be
14 based on—

15 “(I) the performance of the man-
16 ufacturer involved as measured by the
17 Secretary using objective, quantifiable
18 methods (such as delivery of accept-
19 able items, work measurement, or sta-
20 tistical process controls) established
21 by the Secretary;

22 “(II) the accomplishment of
23 events or milestones as defined in a
24 program management plan that is de-

1 developed by the manufacturer and sub-
2 mitted to the Secretary; or

3 “(III) other quantifiable meas-
4 ures of results determined appropriate
5 by the Secretary.

6 “(iii) NUMBER, TIME, AND AMOUNT
7 OF PAYMENTS.—

8 “(I) IN GENERAL.—The Sec-
9 retary shall, with respect to a manu-
10 facturer of a countermeasure, deter-
11 mine the number of payments to be
12 made, the timing of such payments,
13 and subject to subclause (II), the
14 amount of each such payment.

15 “(II) LIMITATION.—The amount
16 of a partial payment made to a manu-
17 facturer under this subparagraph
18 shall not exceed the portion of the
19 total purchase price (described in sub-
20 paragraph (B)) for the counter-
21 measure that remains unpaid as of
22 the date of the payment involved.

23 “(iv) CONDITIONS FOR PAYMENT.—
24 The Secretary shall ensure that any pay-
25 ment to which this subparagraph applies is

1 commensurate with the actions taken by
2 the manufacturer and the progress made
3 in achieving the performance measures
4 under clause (ii)(I) through the time of
5 such payment. The manufacturer shall
6 provide such information and evidence as
7 such Secretary determines necessary to de-
8 termine compliance with the preceding sen-
9 tence.

10 “(v) INDEPENDENT RESEARCH AND
11 DEVELOPMENT COSTS.—The payment
12 amount under this subparagraph may in-
13 clude the costs associated with independent
14 research and development undertaken by
15 the manufacturer prior to entering into a
16 contract or other agreement with the Sec-
17 retary under this section.

18 “(4) AUTHORITY TO CONTRACT.—

19 “(A) IN GENERAL.—For purposes of a
20 procurement under this subsection, the Sec-
21 retary shall have responsibilities described in
22 subparagraphs (B) and (C).

23 “(B) PROCUREMENT.—

24 “(i) IN GENERAL.—The Secretary
25 shall be responsible for—

1 “(I) arranging for procurement
2 of a countermeasure, including negoti-
3 ating terms (including quantity, pro-
4 duction schedule, and price) of, and
5 entering into contracts, cooperative
6 agreements, or other transactions, and
7 for carrying out such other activities
8 as may reasonably be required; and

9 “(II) promulgating such regula-
10 tions as the Secretary determines nec-
11 essary to implement the provisions of
12 this subsection.

13 “(ii) OTHER TRANSACTION AUTHOR-
14 ITY, ADDITIONAL AUTHORITY FOR RE-
15 SEARCH PROJECTS.—The Secretary shall
16 have the authority to enter into trans-
17 actions (other than procurement contracts,
18 grants, and cooperative agreements), in-
19 cluding transactions for prototypes, to the
20 same extent as provided to the Secretary
21 of Defense under section 2371 of title 10,
22 United States Code, for purposes of car-
23 rying out the objectives of the Project Bio-
24 Shield II Act of 2005.

25 “(iii) CONTRACT TERMS.—

1 “(I) MANDATORY TERMS.—A
2 contract for procurement under this
3 subsection shall include the following
4 terms:

5 “(aa) CONTRACT DURA-
6 TION.—The contract shall be for
7 a period not to exceed 10 years,
8 except that, in first awarding the
9 contract, the Secretary may pro-
10 vide for a longer duration, not
11 exceeding a total of 18 years, if
12 the Secretary determines that
13 complexities or other difficulties
14 in performance under the con-
15 tract justify such an extended pe-
16 riod. The contract shall be renew-
17 able for additional periods, none
18 of which shall exceed 5 years.

19 “(bb) PRODUCT AP-
20 PROVAL.—The contract shall pro-
21 vide that the vendor seek ap-
22 proval, clearance, or licensing or
23 validating of the product from
24 the Secretary or other appro-
25 priate Federal agency and for a

1 timetable for the development of
2 data and other information to
3 support such approval, clearance,
4 or licensing, and that the Sec-
5 retary may waive part or all of
6 such contract term on request of
7 the vendor or on the initiative of
8 the Secretary.

9 “(II) STORAGE BY VENDOR.—A
10 contract for procurement under this
11 subsection may provide that the ven-
12 dor provide storage for stocks of a
13 product delivered to the ownership of
14 the Federal Government under the
15 contract, for such period and under
16 such terms and conditions as the Sec-
17 retary may specify, and in such case
18 amounts from the purchase fund
19 under subsection (a) shall be available
20 for costs of shipping, handling, stor-
21 age, and related costs for such prod-
22 uct.

23 “(III) WARM INDUSTRIAL BASE
24 FEE.—A contract for procurement
25 under this section may provide that

1 the vendor receive a fee for estab-
2 lishing and maintaining manufac-
3 turing capacity in excess of the initial
4 requirement of purchase of the coun-
5 termeasure, in order to ensure that
6 the Secretary has available a warm in-
7 dustrial base in the event of the need
8 to increase purchases of counter-
9 measures. To the extent practicable,
10 the Secretary shall modify contracts
11 in existence on the date of enactment
12 of this Act to have available a warm
13 industrial base. The cost of maintain-
14 ing a warm industrial base shall be an
15 allowable and allocable direct cost to
16 the contract.

17 “(IV) PURCHASE OF FDA LI-
18 CENSED PRODUCTS.—Nothing in this
19 section shall be construed to prevent
20 the Secretary from purchasing coun-
21 termeasures that are licensed by the
22 Food and Drug Administration for
23 the indicated use or, in the event of a
24 countermeasure that is established to
25 be safe and effective for uses other

1 than those indicated on the label of
2 such countermeasure, a use for which
3 the vendor may be approved under
4 emergency use authorities or approval
5 by the Food and Drug Administration
6 subsequent to purchase.

7 “(V) OTHER CONTRACT RE-
8 QUIREMENTS.—

9 “(aa) COST ACCOUNTING
10 STANDARD.—Notwithstanding
11 any other provision of law, the
12 cost accounting standards set
13 forth under chapter 99 of title
14 48, Code of Federal Regulations,
15 the cost principles set forth
16 under part 31 of title 48, Code of
17 Federal Regulations, and the re-
18 quirement for submission of cer-
19 tified cost and pricing data under
20 section 304A of the Federal
21 Property and Administrative
22 Services Act of 1949 (41 U.S.C.
23 254b) shall not apply to any con-
24 tract, grant, or cooperative agree-
25 ment entered into under the

1 Project BioShield Act of 2004
2 (or the amendments made to
3 such Act by the Project Bio-
4 Shield II Act of 2005.).

5 “(bb) SINGLE TRANS-
6 ACTION.—The Secretary shall, to
7 the extent practicable, enter into
8 a single transaction with each
9 contractor for the procurement of
10 countermeasures, even if addi-
11 tional research and development
12 of such countermeasures may be
13 required, so long as the Secretary
14 determines that sufficient and
15 satisfactory clinical experience or
16 research data supports a reason-
17 able conclusion that such security
18 countermeasures will qualify for
19 approval or licensing by the Food
20 and Drug Administration within
21 8 years from the date of entering
22 into the procurement transaction.

23 “(iv) PROCUREMENT OF MULTIPLE
24 PRODUCT AND TECHNOLOGIES.—Notwith-
25 standing any other provision of law, the

1 Secretary shall, to the maximum extent
2 practicable, enter into multiple trans-
3 actions for the procurement of multiple
4 technologies and products from multiple
5 manufacturers of countermeasures in order
6 to mitigate the risks associated with de-
7 pendence on a single supplier or tech-
8 nology.

9 “(v) SINGLE TRANSACTION.—The
10 Secretary shall, to the extent practicable,
11 enter into a single transaction for the pro-
12 curement of countermeasures, even if addi-
13 tional research and development of such
14 countermeasures may be required, so long
15 as the Secretary determines that sufficient
16 and satisfactory clinical experience or re-
17 search data supports a reasonable conclu-
18 sion that such security countermeasures
19 will qualify for approval or licensing by the
20 Food and Drug Administration within 8
21 years from the date of entering into the
22 procurement transaction. The fact that an
23 entity has not filed for investigational new
24 drug status with the Food and Drug Ad-
25 ministration, or has filed for such status

1 but has not yet been approved, shall not be
2 the sole basis for a determination by the
3 Secretary with respect to whether a coun-
4 termeasure qualifies for approval or licens-
5 ing by the Food and Drug Administration
6 not more than 8 years from the date of the
7 procurement transaction.

8 “(vi) AVAILABILITY OF SIMPLIFIED
9 ACQUISITION PROCEDURES.—

10 “(I) IN GENERAL.—If the Sec-
11 retary determines that there is a
12 pressing need for a procurement of a
13 specific countermeasure, the amount
14 of the procurement under this sub-
15 section shall be deemed to be below
16 the threshold amount specified in sec-
17 tion 4(11) of the Office of Federal
18 Procurement Policy Act (41 U.S.C.
19 403(11)), for purposes of application
20 to such procurement, pursuant to sec-
21 tion 302A(a) of the Federal Property
22 and Administrative Services Act of
23 1949 (41 U.S.C. 252a(a)), of—

24 “(aa) section 303(g)(1)(A)
25 of the Federal Property and Ad-

1 administrative Services Act of 1949
2 (41 U.S.C. 253(g)(1)(A)) and its
3 implementing regulations; and

4 “(bb) section 302A(b) of
5 such Act (41 U.S.C. 252a(b))
6 and its implementing regulations.

7 “(II) APPLICATION OF CERTAIN
8 PROVISIONS.—Notwithstanding sub-
9 clause (I) and the provisions of law
10 and regulations referred to in such
11 clause, each of the following provi-
12 sions shall apply to procurements de-
13 scribed in this clause to the same ex-
14 tent that such provisions would apply
15 to such procurements in the absence
16 of subclause (I):

17 “(aa) Chapter 37 of title 40,
18 United States Code (relating to
19 contract work hours and safety
20 standards).

21 “(bb) Subsections (a) and
22 (b) of section 7 of the Anti-Kick-
23 back Act of 1986 (41 U.S.C. 57
24 (a) and (b)).

1 “(cc) Section 304C of the
2 Federal Property and Adminis-
3 trative Services Act of 1949 (41
4 U.S.C. 254d) (relating to the ex-
5 amination of contractor records).

6 “(dd) Section 3131 of title
7 40, United States Code (relating
8 to bonds of contractors of public
9 buildings or works).

10 “(ee) Subsection (a) of sec-
11 tion 304 of the Federal Property
12 and Administrative Services Act
13 of 1949 (41 U.S.C. 254(a)) (re-
14 lating to contingent fees to mid-
15 dlemen).

16 “(ff) Section 6002 of the
17 Solid Waste Disposal Act (42
18 U.S.C. 6962).

19 “(gg) Section 1354 of title
20 31, United States Code (relating
21 to the limitation on the use of
22 appropriated funds for contracts
23 with entities not meeting vet-
24 erans employment reporting re-
25 quirements).

1 “(III) INTERNAL CONTROLS TO
2 BE ESTABLISHED.—The Secretary
3 shall establish appropriate internal
4 controls for procurements made under
5 this clause, including requirements
6 with respect to documentation of the
7 justification for the use of the author-
8 ity provided under this paragraph
9 with respect to the procurement in-
10 volved.

11 “(IV) AUTHORITY TO LIMIT COM-
12 PETITION.—In conducting a procure-
13 ment under this subparagraph, the
14 Secretary may not use the authority
15 provided for under subclause (I) to
16 conduct a procurement on a basis
17 other than full and open competition
18 unless the Secretary determines that
19 the mission of the BioShield Program
20 under the Project BioShield II Act of
21 2005 would be seriously impaired
22 without such a limitation.

23 “(vii) PROCEDURES OTHER THAN
24 FULL AND OPEN COMPETITION.—

1 “(I) IN GENERAL.—In using the
2 authority provided in section
3 303(c)(1) of the Federal Property and
4 Administrative Services Act of 1949
5 (41 U.S.C. 253(c)(1)) to use proce-
6 dures other than competitive proce-
7 dures in the case of a procurement
8 under this subsection, the phrase
9 ‘available from only one responsible
10 source’ in such section 303(c)(1) shall
11 be deemed to mean ‘available from
12 only one responsible source or only
13 from a limited number of responsible
14 sources’.

15 “(II) RELATION TO OTHER AU-
16 THORITIES.—The authority under
17 subclause (I) is in addition to any
18 other authority to use procedures
19 other than competitive procedures.

20 “(III) APPLICABLE GOVERNMENT
21 WIDE REGULATIONS.—The Secretary
22 shall implement this clause in accord-
23 ance with regulations implementing
24 such section 303(c)(1) (including re-
25 quirements that offers be solicited

1 from as many potential sources as is
2 practicable under the circumstances,
3 that required notices be published,
4 and that submitted offers be consid-
5 ered), as such regulations apply to
6 procurements for which an agency has
7 authority to use procedures other than
8 competitive procedures when the prop-
9 erty or services needed by the agency
10 are available from only one respon-
11 sible source or only from a limited
12 number of responsible sources and no
13 other type of property or services will
14 satisfy the needs of the agency.

15 “(viii) PREMIUM PROVISION IN MUL-
16 TIPLE AWARD CONTRACTS.—

17 “(I) IN GENERAL.—If, under this
18 subsection, the Secretary enters into
19 contracts with more than one vendor
20 to procure a countermeasure, such
21 Secretary may, notwithstanding any
22 other provision of law, include in each
23 of such contracts a provision that
24 identifies an increment of the total
25 quantity of countermeasure required,

1 whether by percentage or by numbers
2 of units.

3 “(II) DETERMINATION OF GOV-
4 ERNMENT’S REQUIREMENT NOT RE-
5 VIEWABLE.—If the Secretary includes
6 in each of a set of contracts a provi-
7 sion as described in subclause (I),
8 such Secretary’s determination of the
9 total quantity of countermeasures re-
10 quired, and any amendment of such
11 determination, is committed to agency
12 discretion.

13 “(ix) EXTENSION OF CLOSING DATE;
14 RECEIPT OF PROPOSALS NOT REVIEW-
15 ABLE.—A decision by the Secretary to ex-
16 tend the closing date for receipt of pro-
17 posals for a procurement under this sub-
18 section is committed to agency discretion.

19 “(x) LIMITING COMPETITION TO
20 SOURCES RESPONDING TO REQUEST FOR
21 INFORMATION.—In conducting a procure-
22 ment under this subsection, the Secretary
23 may exclude a source that has not re-
24 sponded to a request for information under
25 section 303A(a)(1)(B) of the Federal Prop-

1 erty and Administrative Services Act of
2 1949 (41 U.S.C. 253a(a)(1)(B)) if such re-
3 quest has given notice that the Secretary
4 may so exclude such a source.

5 “(C) COUNTERMEASURES PURCHASED.—
6 Any stockpiles of countermeasures purchased
7 under this section may be held in the strategic
8 national stockpile under section 319F–2 of the
9 Public Health Service Act (42 U.S.C. 247d–
10 6b).

11 “(5) REQUIREMENTS FOR MANUFACTURERS.—
12 The Secretary, or the Secretary of Health and
13 Human Services under delegated authority, shall
14 provide to manufacturers to the extent feasible the
15 logistical and operational requirements of counter-
16 measures prior to their development and acquisition.
17 The logistical and operational requirements will con-
18 sider public health needs as well as requirements for
19 storage, maintenance, security, rotation, and trans-
20 port of any countermeasures purchased through the
21 Countermeasure Purchase Fund.

22 “(6) COORDINATION.—Consistent with the pro-
23 visions of section 319F–2(e)(2)(B) of the Public
24 Health Service Act, the Secretary shall coordinate
25 with the Secretary of Health and Human Services to

1 store, maintain, secure, rotate, and transport any
2 materiel purchased through the Countermeasure
3 Purchase Fund and designated for use in the Stra-
4 tegic National Stockpile under such section 319F-2.

5 “(7) APPROPRIATION.—

6 “(A) IN GENERAL.—The total appropria-
7 tions made available for both the Fund under
8 section 512 and the special reserve fund under
9 section 510 may be used to provide funding for
10 activities conducted by the Secretary and, where
11 appropriate, the Secretary of Health and
12 Human Services, in accordance with the Project
13 BioShield Act of 2004 and the Project Bio-
14 Shield II Act of 2005 (and the amendments
15 made by such Acts).

16 “(B) USE OF FUNDS.—The Secretary, or
17 the Secretary of Health and Human Services
18 under delegated authority, may use the funds
19 under this section to cover the costs of storage,
20 maintenance, security, rotation, and transport
21 of any material purchased through the Counter-
22 measure Purchase Fund.”.

23 “(b) DEFINITION.—In this section, the term ‘coun-
24 termeasure’ has the meaning given such term in section
25 319F-3 of the Public Health Service Act.”.

1 **SEC. 102. ADDITIONAL AUTHORITY UNDER PROJECT BIO-**
2 **SHIELD.**

3 (a) ADDITIONAL AUTHORITY FOR RESEARCH
4 PROJECTS.—Section 319F–1 of the Public Health Service
5 Act (42 U.S.C. 247d–6a) is amended by—

6 (1) redesignating subsection (f) as subsection
7 (g); and

8 (2) inserting after subsection (e) the following:

9 “(f) OTHER TRANSACTION AUTHORITY.—The Sec-
10 retary shall have the authority to enter into transactions
11 (other than procurement contracts, grants, and coopera-
12 tive agreements), including transactions for prototypes, to
13 the same extent as provided to the Secretary of Defense
14 under section 2371 of title 10, United States Code, for
15 purposes of carrying out the objectives of the Project Bio-
16 Shield Act of 2004.”.

17 (b) ENCOURAGEMENT OF TECHNOLOGY TRANSFER
18 AND COMMERCIALIZATION.—Section 319F–2(c)(5)(B)(iii)
19 of the Public Health Service Act (42 U.S.C. 247d–
20 6b(c)(5)(B)(iii)) is amended to read as follows:

21 “(iii) Where there is a potential to
22 transfer the technology developed as a se-
23 curity countermeasure to the commercial
24 market, either as a countermeasure to be
25 sold in foreign markets or, if the counter-
26 measure has beneficial use and utility for

1 indications other than chemical, biological,
2 radiological, or nuclear protection, for use
3 as other than a countermeasure in com-
4 mercial markets thus meriting Federal
5 funding to stimulate and encourage such
6 commercialization and technology transfer,
7 and demonstrating a potential return on
8 such Federal investment.”.

9 (c) PROCUREMENT OF CERTAIN COUNTER-
10 MEASURES.—Section 319F–2 of the Public Health Service
11 Act (42 U.S.C. 247d–6b) is amended by—

12 (1) redesignating subsections (e) and (f) as sub-
13 sections (l) and (m), respectively; and

14 (2) by inserting after subsection (d) the fol-
15 lowing:

16 “(e) PROCUREMENT OF CERTAIN COUNTER-
17 MEASURES.—

18 “(1) IN GENERAL.—The Secretary shall, to the
19 extent practicable, enter into transactions for the
20 procurement of security countermeasures, even if ad-
21 ditional research and development of such security
22 countermeasures may be required, so long as the
23 Secretary determines that sufficient and satisfactory
24 clinical experience or research data supports a rea-
25 sonable conclusion that such security counter-

1 measures will qualify for approval or licensing by the
2 Food and Drug Administration within 8 years from
3 the date of entering into the procurement trans-
4 action.

5 “(2) BASIS FOR DETERMINATION.—The fact
6 that an entity has not filed for Investigational New
7 Drug status with the Food and Drug Administra-
8 tion, or has filed for such status but has not yet
9 been approved, shall not be the sole basis for a de-
10 termination by the Secretary with respect to whether
11 a security countermeasure qualifies for approval or
12 licensing by the Food and Drug Administration
13 within 8 years from the date of entering into the
14 procurement transaction.

15 “(f) EFFECT OF SECTION.—Notwithstanding any
16 other provision of law, the cost accounting standards set
17 forth under chapter 99 of title 48, Code of Federal Regu-
18 lations, the cost principles set forth under part 31 of title
19 48, Code of Federal Regulations, and the requirement of
20 the submission of certified cost and pricing information
21 under section 254b of title 41, United States Code, shall
22 not apply to any contract, grant, or cooperative agreement
23 entered into under the Project BioShield Act of 2004 (or
24 the amendments made to such Act by the Project Bio-
25 Shield II Act of 2005).

1 “(g) ACCELERATED APPROVAL.—An entity that en-
2 ters into an agreement under this section, section 319F–
3 1, or section 512 of the Homeland Security Act of 2002
4 shall be eligible for accelerated approval of a counter-
5 measure in accordance with section 573 of the Federal
6 Food, Drug, and Cosmetic Act.

7 “(h) PROCUREMENT OF MULTIPLE PRODUCT AND
8 TECHNOLOGIES.—Notwithstanding any other provision of
9 law, the Secretary shall, to the extent practicable, enter
10 into multiple transactions for the procurement of multiple
11 technologies and products from multiple manufacturers of
12 qualified and security countermeasures (as defined by this
13 section and section 319F–1) in order to mitigate the risks
14 associated with dependence on a single supplier or tech-
15 nology.

16 “(i) WARM INDUSTRIAL BASE FEE.—A contract for
17 procurement under this section may provide that the ven-
18 dor receive a fee for establishing and maintaining manu-
19 facturing capacity in excess of the initial requirement of
20 purchase of the countermeasure, in order to ensure that
21 the Secretary has available a warm industrial base in the
22 event of the need to increase purchases of counter-
23 measures. To the extent practicable, the Secretary shall
24 modify contracts in existence on the date of enactment of
25 this subsection to have available a warm industrial base.

1 The Secretary shall deem the cost of such fee allowable
2 and allocable as a direct cost to the contract.

3 “(j) PURCHASE OF FDA LICENSED PRODUCTS.—
4 Nothing in this section shall be construed to prevent the
5 Secretary from purchasing countermeasures that are li-
6 censed by the Food and Drug Administration for the indi-
7 cated use or, in the event of a countermeasure that is es-
8 tablished to be safe and effective for uses other than those
9 indicated on the label of such countermeasure, a use for
10 which the vendor may be approved under emergency use
11 authorities or approval by the Food and Drug Administra-
12 tion subsequent to purchase.”.

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

16 (1) in the section heading, inserting “and Secu-
17 rity Countermeasure Procurements” after “Stock-
18 pile”; and

19 (2) in subsection (c)—

20 (A) in the heading, by deleting “bio-
21 medical”;

22 (B) in paragraph (5)—

23 (i) by amending subparagraph (A) to
24 read as follows:

1 “(A) IN GENERAL.—The Secretary, in ac-
2 cordance with the provisions of this paragraph,
3 shall identify specific security countermeasures
4 that the Secretary determines, in consultation
5 with the Homeland Security Secretary, to be
6 appropriate for inclusion in the stockpile under
7 subsection (a) or acquisition for other purposes
8 pursuant to procurements made with amounts
9 in the special reserve fund under paragraph
10 (10) (referred to in this subsection individually
11 as a “procurement under this subsection”).”;
12 and

13 (ii) in subparagraph (B)(ii), by delet-
14 ing the word “stockpile” and inserting
15 “government”;

16 (C) by amending paragraph (6)(D) to read
17 as follows:

18 “(D) Subsequent specific counter-
19 measures.—Procurement under this subsection
20 of a security countermeasure for a particular
21 purpose does not preclude the subsequent pro-
22 curement under this subsection of any other se-
23 curity countermeasure for such purpose if the
24 Secretary has determined under paragraph
25 (5)(A) that such countermeasure is appropriate

1 for inclusion in the stockpile or acquisition for
 2 other purposes and if, as determined by the
 3 Secretary, such countermeasure provides im-
 4 proved safety or effectiveness, or for other rea-
 5 sons enhances preparedness to respond to
 6 threats of use of a biological, chemical, radio-
 7 logical, or nuclear agent. Such a determination
 8 by the Secretary is committed to agency discre-
 9 tion.”; and

10 (D) in paragraph (8)—

11 (i) in subparagraph (A)—

12 (I) by striking “COOPERATION.—
 13 ” and all that follows through “out”
 14 and inserting “COOPERATION.—In
 15 carrying out”; and

16 (II) by striking “, subject to sub-
 17 paragraph (B),”; and

18 (ii) by striking subparagraph (B).

19 **SEC. 103. REQUEST OF AGENCY.**

20 Section 319F–2 of the Public Health Service Act (42
 21 U.S.C. 247d–6b) (as amended by section 102) is further
 22 amended by inserting after subsection (j) the following:

23 “(k) REQUEST OF AGENCY TO USE BIOSHIELD I
 24 AND BIOSHIELD II AUTHORITY AND INCENTIVES.—

1 “(1) IN GENERAL.—Upon request by a Federal
2 agency, the Secretary may establish interagency
3 agreements, under terms acceptable to the Sec-
4 retary, in which such agency may order counter-
5 measures under procurement contracts or procure-
6 ment pools established by the Secretary.

7 “(2) PROCESSING OF ORDERS.—The ordering
8 of a countermeasure under an agreement under
9 paragraph (1) (including transfers of appropriated
10 funds between an agency and the Department to pay
11 for such orders) may be conducted pursuant to sec-
12 tion 1535 of title 31, United States Code, if such
13 order is processed under the terms established—

14 “(A)(1) in the interagency agreement re-
15 quired by subsection (c)(7)(B), for orders of de-
16 tection technology and decontamination tech-
17 nology placed by the Department of Homeland
18 Security; or

19 “(2) by the Secretary in the interagency
20 agreement described under paragraph (1) for
21 all other orders; and

22 “(B) in the Project BioShield Act of 2004
23 and the Project BioShield II Act of 2005 (and
24 the amendments made by such Acts) with re-

1 spect to the procurement of countermeasures
2 under this section and section 319F–1.”.

3 **TITLE II—AMENDMENTS TO THE**
4 **PROJECT BIOSHIELD ACT OF**
5 **2004 REGARDING INFECTIOUS**
6 **DISEASE COUNTER-**
7 **MEASURES; ADDITIONAL PRO-**
8 **VISIONS**

9 **SEC. 201. AMENDMENTS TO THE PROJECT BIOSHIELD ACT**
10 **OF 2004 REGARDING INFECTIOUS DISEASE**
11 **COUNTERMEASURES.**

12 (a) COUNTERMEASURES TO DETECT, DIAGNOSE,
13 PREVENT, OR TREAT AN INFECTIOUS DISEASE.—

14 (1) PROCUREMENT AUTHORITY.—Section
15 319F–1(a)(2) of the Public Health Service Act (42
16 U.S.C. 247d–6a) is amended—

17 (A) in subparagraph (A), by striking “;
18 or” and inserting a semicolon;

19 (B) in subparagraph (B), by striking the
20 period and inserting “; or”; and

21 (C) by adding after subparagraph (B) the
22 following:

23 “(C) detect, diagnose, treat, or prevent an
24 infectious disease (as defined in section 319F–
25 3(a)(6)) adversely affecting public health.”.

1 (2) STRATEGIC NATIONAL STOCKPILE.—Section
2 319F–2(c)(1)(B) of the Public Health Service Act is
3 amended—

4 (A) in clause (i)(III)(bb), by striking “;
5 or” and inserting a semicolon;

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

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

9 “(iii) is intended to detect, diagnose,
10 prevent, or treat an infectious disease (as
11 defined in section 319–3(a)(6)).”.

12 **SEC. 202. PROCUREMENT POOLS; ADDITIONAL INCENTIVES**
13 **UNDER PROJECT BIOSHIELD.**

14 (a) IN GENERAL.—Part B of title III of the Public
15 Health Service Act (42 U.S.C. 243 et seq.), as amended
16 by section 101, is amended by inserting after section
17 319F–2 the following:

18 **“SEC. 319F–3. PROCUREMENT OF CERTAIN DRUGS, DETEC-**
19 **TION TECHNOLOGY, DIAGNOSTICS, AND RE-**
20 **SEARCH TOOLS.**

21 “(a) DEFINITIONS.—For purposes of this part:

22 “(1) BIOLOGICAL OR CHEMICAL AGENT; TOXIN;
23 NUCLEAR OR RADIOLOGICAL MATERIAL; TERROR
24 WEAPON.—The term—

1 “(A) ‘biological agent’, ‘biological toxin’, or
2 ‘chemical agent’, or any variation of any such
3 term, includes any microorganism, virus, infec-
4 tious substance, toxic biological product, or
5 toxic or poisonous chemical, that may be used
6 in a manner that may cause widespread death
7 or serious bodily injury, including biological
8 agents and toxins described in paragraphs (1)
9 and (2) of section 178 of title 18, United States
10 Code;

11 “(B) ‘nuclear or radiological material’
12 means any radioactive material that may be
13 used in a manner that may cause widespread
14 death or serious bodily injury; and

15 “(C) ‘terror weapon’ or ‘weapon of mass
16 destruction’ mean any matter described in sub-
17 paragraph (A) or (B) that may be used in a
18 manner that may cause widespread death or se-
19 rious bodily injury.

20 “(2) COUNTERMEASURE.—The term ‘counter-
21 measure’ means—

22 “(A) a vaccine and related delivery system,
23 anti-infective, antibiotic or combinations there-
24 of, therapy, microbicide, diagnostic technology,
25 drug, biological product, chemical, or other

1 technology that is subject to applicable provi-
2 sions of this Act, the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 301 et seq.), or the
4 Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.),
5 and that prevents infection with, or the spread
6 of, or the directly diagnose, treat, or prevent
7 the pathological effects of infection with, bodily
8 harm from, or the spread of, a biological or
9 chemical agent or toxin on the list described in
10 subsection (f), including treatments for address-
11 ing excessive bleeding and other trauma fol-
12 lowing a terrorist attack;

13 “(B) a therapy, diagnostic, or piece of
14 equipment that may be used to detect, treat, or
15 prevent bodily harm that may be caused by the
16 use of biological, chemical, nuclear, or radio-
17 logical material as a terror weapon or by an in-
18 fectious disease;

19 “(C) a qualified countermeasure, as de-
20 fined in section 319F-1; or

21 “(D) a security countermeasure, as defined
22 in section 319F-2.

23 “(3) DECONTAMINATION TECHNOLOGY.—The
24 term ‘decontamination technology’ means a product

1 or service used for the decontamination of property
2 following a terrorist attack.

3 “(4) DETECTION TECHNOLOGY.—The term ‘de-
4 tection technology’ means scientific instruments,
5 consumables (such as reagents or assays, including
6 reagents or assays using polymerase chain reaction
7 (PCR) or Real Time PCR), software, or services for
8 the detection of the presence, concentration, charac-
9 teristics, or identification of a biological, chemical,
10 nuclear, radiological agent, or infectious disease in
11 environmental or field samples.

12 “(5) DEVELOPMENT.—The term ‘development’
13 or ‘to develop’ includes research leading to the iden-
14 tification and isolation of suitable compounds or bio-
15 logical materials, the engineering, modification (in-
16 cluding research leading to the expanded use of cur-
17 rently approved drugs or biological products), eval-
18 uation, production, and formulation of such com-
19 pounds or materials, the conduct of preclinical and
20 clinical studies, the preparation of an application for
21 marketing approval, and preparation of test meth-
22 ods, with respect to countermeasures regulated by
23 the Food and Drug Administration, and other ac-
24 tions prior to approval of a countermeasure by the
25 Food and Drug Administration or when it is pro-

1 cured as an unlicensed countermeasure under sec-
2 tion 319F-2(e).

3 “(6) DIAGNOSTICS.—

4 “(A) IN GENERAL.—The term ‘diagnostics’
5 includes products, devices, and technologies to
6 detect, identify, or analyze the potential pres-
7 ence of, or exposure to, 1 or more biological,
8 nuclear, radiological, or chemical agent or toxin
9 in potentially exposed individuals through
10 means to enable effective medical intervention
11 through the administration of appropriate coun-
12 termeasures.

13 “(B) INCLUSION.—The term ‘diagnostics’
14 includes technologies that diagnose or screen
15 for the health and safety of potentially exposed
16 individuals and products that serve as
17 contraindicators for vaccines or drugs.

18 “(7) INFECTIOUS DISEASE.—

19 “(A) IN GENERAL.—The term ‘infectious
20 disease’ means a disease in humans caused
21 by—

22 “(i) a microbe (including a bacteria,
23 virus, fungus, or parasite) that is acquired
24 by a person and that reproduces in that
25 person;

1 “(ii) microbial products (such as botu-
2 linum toxin); or

3 “(iii) a prion.

4 “(B) INCLUSION.—The term ‘infectious
5 disease’ includes—

6 “(i) a disease in humans caused by a
7 microorganism, whether or not—

8 “(I) such microorganism is ac-
9 quired by an individual through
10 human-to-human contact; or

11 “(II) if the individual is initially
12 symptomatic of the disease; and

13 “(ii) zoonotic diseases that may find
14 hosts in animal and human populations.

15 “(8) MANUFACTURER.—

16 “(A) IN GENERAL.—The term ‘manufac-
17 turer’ means an entity responsible for research,
18 evaluation, development, or production of a
19 countermeasure and, except for a counter-
20 measure that is not subject to review and ap-
21 proval by the Food and Drug Administration
22 prior to marketing (such as research tools), the
23 potential or actual holder of the approved new
24 drug application, biologic license application, or

1 product license application or equivalent for
2 such countermeasure.

3 “(B) LIMITATION.—The term ‘manufac-
4 turer’ does not require that a manufacturer
5 conduct the actual research, evaluation, devel-
6 opment, or production in its own facilities, but
7 may enter into arrangements with third parties
8 for the research, evaluation, development, or
9 production of the countermeasure.

10 “(9) RESEARCH TOOL.—The term ‘research
11 tool’ includes the full range of tools and systems
12 that accelerate the discovery, development, and man-
13 ufacture of countermeasures, including animal dis-
14 ease models, cell lines, cell line cultures for the pro-
15 duction of biologics, de novo DNA synthesis,
16 monoclonal and polyclonal antibodies, reagents or
17 assays (such as those utilizing the polymerase chain
18 reaction (PCR) or Real Time PCR processes), drug
19 delivery technologies, vaccine adjuvants, antibiotic
20 sensitivity screens, laboratory animals, large animals
21 including nonhuman primates (and other such ani-
22 mals used or intended to be used for drug produc-
23 tion), growth factors, combinatorial chemistry and
24 DNA libraries, vaccine antigen libraries, clones and
25 cloning tools (such as PCR or Real Time PCR),

1 methods, laboratory equipment and machines, data-
2 bases, and other technologies that enable the rapid
3 and effective development of countermeasures, in-
4 cluding diagnostics, vaccines, drugs, antibiotics, non-
5 laboratory tools, and tools systems that directly as-
6 sist such countermeasure development efforts.

7 “(b) PROCUREMENT POOLS.—

8 “(1) IN GENERAL.—Notwithstanding any other
9 provision of law, the Secretary shall establish, and
10 make payments from, procurement pools with re-
11 spect to the procurement of a qualified counter-
12 measure under section 319F–1 or a security coun-
13 termeasure under section 319F–2.

14 “(2) ROLE OF OTHER ORGANIZATIONS.—In or-
15 ganizing the procurement pools under paragraph
16 (1), the Secretary may accept contributions and
17 guarantees from—

18 “(A) non-governmental organizations;

19 “(B) international health agencies;

20 “(C) the United Nations;

21 “(D) the Global Vaccine Acquisition Initia-
22 tive; and

23 “(E) private nonprofit organizations that
24 are organized to support international public
25 health research and programs.

1 “(3) CONSULTATION.—The Secretary shall—

2 “(A) consult with the organizations de-
3 scribed under paragraph (2) regarding the
4 terms and management of procurement con-
5 tracts that exceed \$25,000,000 in value under
6 this section and sections 319F–1 and 319F–2
7 that receive payment from the procurement pool
8 established under paragraph (1); and

9 “(B) provide information to such organiza-
10 tions regarding such procurement contracts.

11 “(4) LIMITATION.—Nothing in this part shall
12 be construed to prohibit the Secretary or the Sec-
13 retary of Homeland Security (with respect to pro-
14 curement agreements under section 512 of the
15 Homeland Security Act of 2002) from accepting
16 contributions and guarantees from organizations
17 that receive funding from the Federal Government.

18 “(5) CONTRIBUTION TO OTHER POOLS.—The
19 Secretary and the Secretary of Homeland Security
20 (with respect to procurement agreements under sec-
21 tion 512 of the Homeland Security Act of 2002)
22 may contribute funds to procurement pools orga-
23 nized by other entities, such as foreign governments,
24 the United Nations, or nonprofit or non-govern-

1 mental entities for procurement of qualified and se-
2 curity countermeasures.

3 “(c) ADVISORY COMMITTEE.—

4 “(1) ESTABLISHMENT.—The Secretary shall es-
5 tablish an advisory committee to be known as the
6 International Public Health Advisory Committee (re-
7 ferred to in this section as the ‘Advisory Com-
8 mittee’).

9 “(2) MEMBERSHIP.—

10 “(A) IN GENERAL.—The Advisory Com-
11 mittee shall be composed of representatives, to
12 be appointed by the Secretary, from organiza-
13 tions, including the Centers for Disease Control
14 and Prevention and the organizations described
15 in subparagraph (B), with expertise and re-
16 sources regarding the development and distribu-
17 tion of countermeasures against biological,
18 chemical, nuclear, or radiological agents or in-
19 fectious diseases.

20 “(B) ORGANIZATIONS DESCRIBED.—The
21 organizations described under this subpara-
22 graph are—

23 “(i) non-governmental organizations;

24 “(ii) international health agencies;

25 “(iii) the United Nations;

1 “(iv) the Global Vaccine Acquisition
2 Initiative; and

3 “(v) private nonprofit organizations
4 that are organized to support international
5 public health research and programs.

6 “(3) DUTIES OF ADVISORY COMMITTEE.—The
7 Advisory Committee, through a public process,
8 shall—

9 “(A) develop an international, multi-
10 faceted, and coordinated strategy, that, with re-
11 spect to countermeasures against biological,
12 chemical, radiological, and nuclear agents or in-
13 fectious disease—

14 “(i) develops strategies for estab-
15 lishing procurement pools;

16 “(ii) develops strategies to facilitate
17 partnerships between the government and
18 private sector;

19 “(iii) makes recommendations for
20 strengthening the infrastructure necessary
21 for researching, creating, and stockpiling
22 critical therapeutics;

23 “(iv) recommends ways in which the
24 countermeasure development process may
25 be shortened; and

1 “(v) makes recommendations for pri-
2 ority areas for developing research and dis-
3 covery programs necessary to develop
4 countermeasures;

5 “(B) develop criteria for determining which
6 countermeasures against biological, chemical,
7 nuclear, and radiological agents or infectious
8 disease should be developed and procured;

9 “(C) explore priority broad spectrum
10 therapeutics and ways in which the counter-
11 measure development process may be acceler-
12 ated to facilitate rapid development of new
13 drugs in the event of an attack with a pre-
14 viously unknown biological agent or pathogen;
15 and

16 “(D) recognize the importance and the
17 need for advancement in the field of
18 bioinformatics which will accelerate the dis-
19 covery or development of all types of counter-
20 measures by promoting the use of advanced
21 mathematical, computing, or image processing
22 technologies, including pattern recognition
23 methods, lossless digital data compression for
24 storage and transmission of biomedical images,
25 and the ability to analyze massive amounts of

1 data, in order to solve complex research and de-
2 velopment problems.

3 “(d) DIAGNOSTICS INCENTIVES.—

4 “(1) IDENTIFICATION.—Not later than 180
5 days after the date of enactment of the Project Bio-
6 Shield II Act of 2005, the Secretary shall develop
7 and make available to potential manufacturers, a list
8 of the diagnostics that need to be developed to pre-
9 pare the United States for a terrorist attack using
10 a biological or chemical agent, infectious disease,
11 toxin, or nuclear or radiological materials, or to
12 counter a naturally occurring infectious disease out-
13 break. The Secretary shall provide such information
14 as the Secretary determines to be necessary to en-
15 able such potential manufacturers to structure and
16 focus their research and development programs for
17 the development of such research tools.

18 “(2) REVISIONS.—The Secretary shall revise
19 the list developed under paragraph (1) not less often
20 than annually, and make such list available to poten-
21 tial manufacturers of diagnostics under terms and
22 conditions consistent with the security interests of
23 the United States.

24 “(3) DEVELOPMENT OF CERTAIN
25 DIAGNOSTICS.—

1 “(A) IN GENERAL.—The Secretary, acting
2 through the Assistant Secretary for Public
3 Health Countermeasure Development, shall de-
4 velop and implement, in consultation with State
5 and local public health officials and private sec-
6 tor entities, a strategy for the development of
7 infectious disease multiplexed molecular level di-
8 agnostic screening technologies and the building
9 of an integrated and standardized information
10 system linking the Federal, State, and local
11 public health systems for reporting automated
12 laboratory results for all toxicology and infec-
13 tious diseases. The strategy shall address the
14 integration, correlation, and analysis from lab-
15 oratory results with data generated from envi-
16 ronmental monitoring using detection tech-
17 nology.

18 “(B) STRATEGY.—The strategy developed
19 and implemented pursuant to subparagraph (A)
20 shall—

21 “(i) include the development of con-
22 firmatory laboratory tests to validate pre-
23 sumptive results available from initial
24 screening;

1 “(ii) complement the development of
2 therapeutics where appropriate; and

3 “(iii) promote the advancement of
4 bioinformatics through the use of incen-
5 tives, the procurement and rapid develop-
6 ment of new devices, and the development
7 of a robust and standardized information
8 infrastructure for carrying out medical
9 surveillance tasks.

10 “(C) TECHNOLOGY.—

11 “(i) IN GENERAL.—The specific
12 screening and diagnostics technology used
13 to implement the strategy described in sub-
14 paragraph (A) may consist of multiplexed
15 devices that screen for routinely encoun-
16 tered common infectious diseases and have
17 biothreat agent detection algorithms em-
18 bedded in the devices with automatic re-
19 porting features.

20 “(ii) DISSEMINATION AND EVALUA-
21 TION.—The Secretary shall develop—

22 “(I) the methods by which the re-
23 sults from such detection devices may
24 be rapidly disseminated to the appro-

1 priate domestic and international
2 health care systems; and

3 “(II) a system by which the util-
4 ity of such results, and the efficacy of
5 such dissemination system, may be
6 evaluated and improved, as necessary.

7 “(4) UTILIZATION OF DIAGNOSTICS BY HEALTH
8 CARE PROVIDERS.—

9 “(A) IN GENERAL.—The Secretary shall
10 develop and implement a strategy that recog-
11 nizes the need to provide the right incentives to
12 the health care industry, including the qualified
13 clinical countermeasures delivery centers under
14 the Project Bioshield II Act of 2005, to allow
15 the industry to utilize the new diagnostic tools
16 that will be made available through research
17 and allow for screening for infectious diseases
18 and other biological, chemical, nuclear, radio-
19 logical, and emerging terrorist threats.

20 “(B) REIMBURSEMENT.—The strategy
21 shall include appropriate incentives to allow for
22 reimbursement to State and local governments,
23 hospitals, clinics, and other providers who per-
24 form laboratory screening utilizing newer molec-
25 ular level tests that rapidly detect infectious

1 diseases and other biological, chemical, nuclear,
2 radiological, and emerging terrorist threats.

3 “(C) STRATEGIES.—The Secretary shall
4 establish similar strategies for States and local
5 governments to utilize to promote biological,
6 chemical, nuclear, radiological, and other
7 emerging terrorist threats and infectious dis-
8 eases screening, including testing for the rapid
9 identification of potential biothreat agents.

10 “(5) NO JUDICIAL REVIEW.—Notwithstanding
11 any other provision of law, there shall be no judicial
12 review of the list, or revised list, developed by the
13 Secretary under this subsection.

14 “(e) RESEARCH TOOLS INCENTIVES.—

15 “(1) IDENTIFICATION.—Not later than 180
16 days after the date of enactment of the Project Bio-
17 Shield II Act of 2005, the Secretary shall develop
18 and make available to potential entities and manu-
19 facturers, a list of the research tools and the sys-
20 tems to aid in the development of such tools that
21 need to be developed to prepare the United States
22 for a terrorist attack, with a biological or chemical
23 agent or toxin or nuclear or radiological materials,
24 or to counter a naturally occurring infectious disease
25 outbreak. The list developed by the Secretary shall

1 include research tools for which there is a need for
2 development in order to understand why certain
3 countermeasures may cause adverse events, how to
4 minimize such adverse events, and how to treat such
5 adverse events. The Secretary shall provide such in-
6 formation as the Secretary determines to be nec-
7 essary to enable such potential manufacturers to
8 structure and focus their research and development
9 programs for the development of research tools.

10 “(2) REVISIONS.—The Secretary shall revise
11 the list developed under paragraph (1) not less often
12 than annually, and make such list available to poten-
13 tial manufacturers of research tools under terms and
14 conditions consistent with the security interests of
15 the United States.

16 “(3) NO JUDICIAL REVIEW.—Notwithstanding
17 any other provision of law, there shall be no judicial
18 review of the list, or revised list, developed by the
19 Secretary under this subsection.

20 “(4) UTILIZATION AND AVAILABILITY.—

21 “(A) IN GENERAL.—Entities that enter
22 into a contract for procurement of a qualified
23 countermeasure under section 319F–1 or of a
24 security countermeasure under section 319F–2,
25 or under section 512 of the Homeland Security

1 Act of 2002 shall maximize the utilization of
2 the research tools involved for the development
3 of countermeasures. In addition, such entities
4 shall promote the advancement of
5 bioinformatics through the use of incentives for
6 the development and procurement of
7 bioinformatics research tools.

8 “(B) RULE OF CONSTRUCTION.—Nothing
9 in this section or chapter 18 of title 35, United
10 States Code, shall be construed to restrict the
11 right of an entity described in subparagraph
12 (A) to—

13 “(i) secure and enforce patents with
14 regard to research tools;

15 “(ii) enter into exclusive, revocable,
16 and nontransferable licenses of such re-
17 search tools; or

18 “(iii) impose limits on royalty- or
19 product-reach-through or downstream
20 rights or agreements on future counter-
21 measures or products, or option rights with
22 respect to a research tool.

23 “(f) INITIAL LIST.—Not later than 180 days after
24 the date of enactment of the Project BioShield II Act of
25 2005, the Secretary, in consultation with the Secretary of

1 Defense and the Secretary of Homeland Security, shall de-
2 velop, publish in the Federal Register, and make available
3 to potential manufacturers of terror weapons and infec-
4 tious disease countermeasures, except as provided in sub-
5 section (i), a list of biological and chemical agents, toxins,
6 and nuclear and radiological materials that may be used
7 as weapons of mass destruction or that are infectious dis-
8 eases with respect the which the Secretary finds that re-
9 search to develop new and improved countermeasures is
10 in the national interest of the United States. Such initial
11 list may, at the discretion of the Secretary, contain the
12 following:

13 “(1) Variola major (confluent, flat, and hemor-
14 rhagic smallpox).

15 “(2) Bacillus anthracis (anthrax) or near-neigh-
16 bor pathogenic Bacillus spp.

17 “(3) Clostridium botulinum (botulism) or botu-
18 lism toxins.

19 “(4) Francisella tularensis (tularemia).

20 “(5) Yersina pestis (Black Death: bubonic
21 plague, pneumonic plague).

22 “(6) Pathogenic Haemophilus spp.

23 “(7) Ebolavirus spp. (Ebola hemorrhagic fever).

24 “(8) Marburgvirus spp. (Marburg hemorrhagic
25 fever).

- 1 “(9) Arenavirus Lassa Virus (Lassa fever).
- 2 “(10) Arenavirus Junin Virus (Argentine
3 hemorrhagic fever).
- 4 “(11) Nairovirus Crimean-Congo hemorrhagic
5 fever virus (Crimean-Congo hemorrhagic fever).
- 6 “(12) Coxiella burnetti (Q fever).
- 7 “(13) Coccidioidomycosis immitis (Coccidioi-
8 domycosis, San Joaquin Valley, or desert fever).
- 9 “(14) Clostridium perfringens (gas gangrene,
10 necrotizing enteritis).
- 11 “(15) Treponema spp.
- 12 “(16) Borrelia spp.
- 13 “(17) Chlamydia psittaci (parrot fever).
- 14 “(18) Phlebovirus Rift Valley fever virus (Rift
15 Valley fever).
- 16 “(19) Rickettsia rickettsii (Rocky Mountain
17 Spotted Fever).
- 18 “(20) Brucella spp. (brucellosis).
- 19 “(21) Burkholderia mallei (glanders).
- 20 “(22) Alphavirus Venezuelan equine encephali-
21 litis virus (Venezuelan equine encephalomyelitis).
- 22 “(23) Alphavirus Eastern equine encephalitis
23 virus (Eastern equine encephalomyelitis) and
24 Alphavirus Western equine encephalitis virus (West-
25 ern equine encephalomyelitis).

- 1 “(24) Ricin toxin (castor bean toxin).
2 “(25) Trichothecene Mycotoxins.
3 “(26) Dinoflagellate neurotoxin (Paralytic
4 Shellfish Toxin).
5 “(27) Aflatoxins.
6 “(28) Epsilon toxin of clostridium perfringens.
7 “(29) Staphylococcus enterotoxin B (Staphy-
8 lococcus enterotoxin B intoxication).
9 “(30) Methicillin-resistant staphylococcus
10 aureus.
11 “(31) Influenza.
12 “(32) Avian influenza.
13 “(33) Pathogenic Salmonella spp. (gastro-
14 intestinal upset, enteric fever).
15 “(34) Salmonella Typhi (typhoid fever).
16 “(35) Shigella dysenteriae (dysentery, hemo-
17 lytic-uremic syndrome).
18 “(36) Escherichia coli 0157:H7 (severe diar-
19 rhea, hemolytic-uremic syndrome) and other Esch-
20 erichia coli pathotypes.
21 “(37) Vibrio species (cholera).
22 “(38) Toxoplasma gondii.
23 “(39) Cryptosporidium parvum.
24 “(40) Henipavirus Nipah virus (Nipa enceph-
25 litis).

- 1 “(41) Hantavirus spp. (Hantavirus Pulmonary
2 Syndrome).
- 3 “(42) Tickborne hemorrhagic fever viruses.
- 4 “(43) Tickborne encephalitis virus.
- 5 “(44) Flavivirus Yellow Fever virus (Yellow
6 fever, West Nile virus, Dengue).
- 7 “(45) Human Immunodeficiency Virus (HIV),
8 Acquired Immune Deficiency Syndrome (AIDS)
- 9 “(46) Plasmodium falciparum, P. ovale, P.
10 vivax, P. malariae (Malaria).
- 11 “(47) Rickettsia typhi (typhus).
- 12 “(48) Antibiotic-resistant Mycobacterium tuber-
13 culosis.
- 14 “(49) Entamoeba histolytica (amebiasis).
- 15 “(50) Pathogenic Shigella spp. (bacillary dys-
16 entery, Shigellosis).
- 17 “(51) Giardia lamblia (giardiasis).
- 18 “(52) Orthopox virus spp. (monkey pox infec-
19 tion).
- 20 “(53) Trypanosoma brucei gambiense or
21 rhodesiense (trypanosomiasis, sleeping sickness).
- 22 “(54) Leishmania donovane (visceral leishmani-
23 asis, black fever, Kala Azar).
- 24 “(55) Schistosoma mansoni, S. haematobium,
25 S. japonicum (schistosomiasis or bilharzia).

- 1 “(56) *Necator Americanus* and *Ancylostoma*
2 *duodenale* (hookworm).
- 3 “(57) *Ascaris lumbricoides* (roundworm).
- 4 “(58) *Trichuris trichiura* (whipworm).
- 5 “(59) *Onchocerca volvulus* (river blindness).
- 6 “(60) *Drancunculus medianensis* (guinea
7 worm).
- 8 “(61) *Wuchereria bancrofti* and *Brugia malayi*
9 (lymphatic filariasis or elephantiasis).
- 10 “(62) *Mycobacterium ulcerans* (Burulu Ulcer).
- 11 “(63) *Mycobacterium leprea* (leprosy).
- 12 “(64) *Chlamydia trachomatis* (Trachoma).
- 13 “(65) Pathogenic *Streptococcus* spp.
- 14 “(66) Nerve agents (including Tabun, Sarin,
15 Soman, GF, VX, V-gas, third generation nerve
16 agents organophosphate pesticides and carbamate
17 insecticides).
- 18 “(67) Blood agents (including hydrogen cyanide
19 and cyanogen chloride).
- 20 “(68) Blister agents (including Lewisite, nitro-
21 gen and sulfur mustards).
- 22 “(69) Heavy metals (including arsenic, lead,
23 and mercury).
- 24 “(70) Volatile toxins (including benzene, chloro-
25 form, and trihalomethanes).

1 “(71) Pulmonary agents (including phosgene
2 and chlorine vinyl chloride).

3 “(72) Incapacitating agents (including BZ).

4 “(73) Nuclear and radiological materials.

5 “(74) Exotic agents including hybrid orga-
6 nisms, genetically modified organisms, antibiotic-in-
7 duced toxins, autoimmune peptides, immune mim-
8 icry agents, binary bioweapons, stealth viruses, and
9 bioregulators and biomodulators.

10 “(75) Innovative treatments and measures to
11 address trauma, including excessive bleeding, result-
12 ing from an act of terrorism.

13 “(76) Any other new and emerging natural in-
14 fectious disease threats.

15 “(g) REVISIONS.—The Secretary shall revise the list
16 developed under subsection (f) on at least an annual basis,
17 and make such list available, under the terms and limita-
18 tions described in this section, to potential manufacturers
19 of terror weapons countermeasures, infectious disease
20 countermeasures, or weapons of mass destruction counter-
21 measures, or to holders of approved certifications. Such
22 terms and conditions shall be consistent with the security
23 interests of the United States.

24 “(h) NO JUDICIAL REVIEW.—Notwithstanding any
25 other provision of law, there shall be no judicial review

1 of the Secretary's determinations regarding which agents,
2 toxins, or materials to include on the list, or revised list,
3 developed under this section or of a determination to ex-
4 empt information from public distribution under this sec-
5 tion.

6 “(i) EXEMPTION.—

7 “(1) IN GENERAL.—The Secretary may exempt
8 certain information concerning weapons of mass de-
9 struction from publication if the Secretary deter-
10 mines that such publication would be detrimental to
11 the security of the United States. In providing an
12 exemption under the preceding sentence, the Sec-
13 retary shall develop procedures for making such list
14 or information available on a confidential basis to
15 potential manufacturers of countermeasures.

16 “(2) SUFFICIENCY OF INFORMATION.—In devel-
17 oping the procedures described in paragraph (1), the
18 Secretary shall ensure that the information provided
19 to potential manufacturers of countermeasures is
20 sufficient to enable the Federal Government and the
21 manufacturer to determine when such a manufac-
22 turer has successfully developed a countermeasure
23 and therefore becomes entitled to the procurement,
24 intellectual property, and liability provisions of title

1 III of the Project BioShield II Act of 2005 (and the
2 amendments made by such title).”.

3 (b) DETECTION TECHNOLOGY INCENTIVES.—Section
4 512 of the Homeland Security Act of 2002 (as added by
5 section 101), is amended by—

6 (1) redesignating subsection (b) as subsection
7 (d); and

8 (2) inserting after subsection (a) the following:

9 “(b) DETECTORS TECHNOLOGY INCENTIVES.—

10 “(1) IDENTIFICATION.—

11 “(A) IN GENERAL.—Not later than 180
12 days after the date of enactment of the Project
13 BioShield II Act of 2005, the Secretary shall
14 develop and make available to potential manu-
15 facturers, a list of the infectious disease, bio-
16 logical, chemical, radiological, or nuclear agents
17 to be detected as well as the name and seller of
18 the detection technology furnished to the Gov-
19 ernment and whether the Secretary has cer-
20 tified such detection technology under section
21 301(b)(4) of the Project BioShield II Act of
22 2005. The detection targets shall include chem-
23 ical or biological agents or toxins or nuclear or
24 radiological materials.

1 “(B) AVAILABILITY OF INFORMATION.—
2 The Secretary shall provide such information as
3 the Secretary determines to be necessary to en-
4 able the potential manufacturers of terror
5 weapons and infectious disease detection tech-
6 nology to structure and focus their research and
7 development programs for the development of
8 such technology.

9 “(C) REVISIONS.—The Secretary shall re-
10 vise the list developed under subparagraph (A)
11 not less often than annually, and make such list
12 available to potential manufacturers of terror
13 weapons and infectious disease detections equip-
14 ment under terms and conditions consistent
15 with the security interests of the United States.

16 “(D) NO JUDICIAL REVIEW.—Notwith-
17 standing any other provision of law, there shall
18 be no judicial review of the determinations by
19 the Secretary regarding which agents, toxins, or
20 materials are to be included on the list, or re-
21 vised list, developed under this subsection.

22 “(E) CONSULTATION.—In developing and
23 revising the list described under subparagraph
24 (A), the Secretary shall consult with the Sec-

1 retary of Health and Human Services and the
2 Secretary of Defense.

3 “(F) EXEMPTION.—

4 “(i) IN GENERAL.—The Secretary
5 may exempt certain information concerning
6 weapons of mass destruction from publica-
7 tion under this subsection if the Secretary
8 determines that such publication would be
9 detrimental to the security of the United
10 States. In providing an exemption under
11 the preceding sentence, the Secretary shall
12 develop procedures for making such list or
13 information available on a confidential
14 basis to potential manufacturers of coun-
15 termeasures.

16 “(ii) SUFFICIENCY OF INFORMA-
17 TION.—In developing the procedures de-
18 scribed in clause (i), the Secretary shall
19 ensure that the information provided to po-
20 tential manufacturers of countermeasures
21 is sufficient to enable the Federal Govern-
22 ment and the manufacturer to determine
23 when such a manufacturer has successfully
24 developed a countermeasure and therefore
25 becomes entitled to the procurement, intel-

1 lectual property, and liability provisions of
2 title III of the Project BioShield II Act of
3 2005 (and the amendments made by such
4 title).

5 “(2) OTHER DETECTION TECHNOLOGY INCEN-
6 TIVES.—

7 “(A) IN GENERAL.—In furnishing the list
8 to potential vendors of detection technology, the
9 Secretary shall promote the advancement of
10 bioinformatics through the use of incentives for
11 bioinformatics research tools to develop detec-
12 tion technology.

13 “(B) COOPERATION.—The Secretary shall
14 cooperate with the Secretary of the Department
15 of Homeland Security and in consultation with
16 the appropriate Advisory Committees, in the
17 course of DHS certification of detection tech-
18 nology countermeasures, to generate perform-
19 ance measures or performance standards (such
20 as ‘time to result’, ‘sensitivity’, or ‘specificity’
21 with respect to a target pathogen) for such de-
22 tection technology countermeasures.

23 “(c) DECONTAMINATION TECHNOLOGY INCEN-
24 TIVES.—

25 “(1) IDENTIFICATION.—

1 “(A) IN GENERAL.—Not later than 180
2 days after the date of enactment of the Project
3 BioShield II Act of 2005, the Secretary shall
4 develop and make available to potential manu-
5 facturers, a list of the infectious disease, bio-
6 logical, chemical, radiological, or nuclear agents
7 for which decontamination technology is nec-
8 essary as well as the name and seller of the de-
9 contamination technology furnished to the Gov-
10 ernment and whether the Secretary has cer-
11 tified such decontamination technology under
12 section 301(b)(4) of the Project BioShield II
13 Act of 2005. The decontamination targets shall
14 include chemical or biological agents or toxins
15 or nuclear or radiological materials.

16 “(B) AVAILABILITY OF INFORMATION.—
17 The Secretary shall provide such information as
18 the Secretary determines to be necessary to en-
19 able the potential manufacturers of terror
20 weapons and infectious disease decontamination
21 technology to structure and focus their research
22 and development programs for the development
23 of such technology.

24 “(C) REVISIONS.—The Secretary shall re-
25 vise the list developed under subparagraph (A)

1 not less often than annually, and make such list
2 available to potential manufacturers of terror
3 weapons and infectious disease decontamination
4 equipment under terms and conditions con-
5 sistent with the security interests of the United
6 States.

7 “(D) NO JUDICIAL REVIEW.—Notwith-
8 standing any other provision of law, there shall
9 be no judicial review of the determinations by
10 the Secretary regarding which agents, toxins, or
11 materials are to be included on the list, or re-
12 vised list, developed under this subsection.

13 “(E) CONSULTATION.—In developing and
14 revising the list described under subparagraph
15 (A), the Secretary shall consult with the Sec-
16 retary of Health and Human Services and the
17 Secretary of Defense.

18 “(F) EXEMPTION.—

19 “(i) IN GENERAL.—The Secretary
20 may exempt certain information concerning
21 weapons of mass destruction from publica-
22 tion under this subsection if the Secretary
23 determines that such publication would be
24 detrimental to the security of the United
25 States. In providing an exemption under

1 the preceding sentence, the Secretary shall
2 develop procedures for making such list or
3 information available on a confidential
4 basis to potential manufacturers of coun-
5 termeasures.

6 “(ii) SUFFICIENCY OF INFORMA-
7 TION.—In developing the procedures de-
8 scribed in clause (i), the Secretary shall
9 ensure that the information provided to po-
10 tential manufacturers of countermeasures
11 is sufficient to enable the Federal Govern-
12 ment and the manufacturer to determine
13 when such a manufacturer has successfully
14 developed a countermeasure and therefore
15 becomes entitled to the procurement, intel-
16 lectual property, and liability provisions of
17 title III of the Project BioShield II Act of
18 2005 (and the amendments made by such
19 title).”.

20 (d) NEGOTIATIONS WITH FOREIGN GOVERN-
21 MENTS.—The Secretary of Homeland Security shall enter
22 into negotiations with foreign governments and organiza-
23 tions to secure coordination and reciprocity among the ap-
24 plicable regulatory agencies responsible for approving and
25 licensing countermeasures, including diagnostics, vaccines,

1 and drugs to prevent, treat, detect, or identify, an infec-
2 tious disease.

3 **SEC. 203. ANNUAL REPORT.**

4 Part B of title III of the Public Health Service Act
5 (42 U.S.C. 243 et seq.) (as amended by sections 202,
6 1401, 1631, 1901, 2101, and 2102) is amended by insert-
7 ing after section 319F–8 (as added by section 1631) the
8 following:

9 **“SEC. 319F–9. ANNUAL REPORT.**

10 “(a) IN GENERAL.—

11 “(1) SUBMISSION OF REPORT.—Not later than
12 January 1, 2006, and each January 1 thereafter,
13 the Secretary shall submit to the appropriate com-
14 mittees of Congress, and make available to the pub-
15 lic, a report concerning the implementation of sec-
16 tions 319F–4 through 319F–8 and the amendments
17 made by title III of the Project BioShield II Act of
18 2005.

19 “(2) CONTENT OF REPORT.—Reports under
20 paragraph (1) shall include—

21 “(A) an assessment of whether the incen-
22 tives provided for under sections 319F–4
23 through 319F–8 and such amendments are suf-
24 ficient, as determined by the Secretary, to in-
25 duce the biotechnology, pharmaceutical, device,

1 and research tool industries to modify their on-
2 going research priorities and devote manage-
3 ment and scientific talent to researching the de-
4 velopment of priority countermeasures, detec-
5 tions equipment, diagnostics, research tools, or
6 drugs intended to directly prevent or treat the
7 pathological and physiological effects of expo-
8 sures to biological, chemical, nuclear, radio-
9 logical, and other emerging bioterrorist threats
10 and infectious diseases;

11 “(B) an assessment of whether such incen-
12 tives are sufficient, as determined by the Sec-
13 retary, to address the sensitivity of such indus-
14 tries to the possibility of challenges to their
15 prices and patents and the terms of sales that
16 may arise when the Federal Government is an
17 oligopoly or monopoly purchaser;

18 “(C) an assessment of whether such incen-
19 tives are likely to lead to the development of
20 countermeasures and implementation through
21 the qualified clinical countermeasures delivery
22 centers to prepare the United States in the
23 event of the use by terrorists and others of bio-
24 logical, chemical, nuclear, or radiological weap-
25 ons against military or intelligence, Govern-

1 ment, and civilian population of the United
2 States;

3 “(D) an assessment of whether such incen-
4 tives will lead to the development of research
5 tools;

6 “(E) an assessment of whether such provi-
7 sions are achieving the goal of securing the
8 United States from bioterror attacks and infec-
9 tious disease outbreaks;

10 “(F) an assessment of whether the
11 incentives of the Project BioShield II Act of
12 2005 are being abused by sponsors seeking ex-
13 panded market protection for non-counter-
14 measure products based on the development of
15 countermeasures that are marginally useful or
16 that require minimal research and development
17 efforts;

18 “(G) an accounting of the additional
19 healthcare costs to consumers, healthcare pro-
20 viders, and government payors due to the appli-
21 cation of the marketing protection incentives of
22 such Act;

23 “(H) a description of how such incentives
24 for private sector research relate to the provi-

1 sion of public funding for the development of
2 countermeasures; and

3 “(I) recommendations to increase or de-
4 crease the effectiveness of such incentives.

5 “(b) LIMITATION ON PUBLICATION.—The Secretary
6 may exempt information from disclosure to the public
7 under subsection (a) if the Secretary determines that such
8 publication may be detrimental to the security of the
9 United States. Such determinations by the Secretary shall
10 not be subject to judicial review.”.

11 **SEC. 204. USE OF FUNDS; REQUIREMENTS OF MANUFAC-**
12 **TURERS.**

13 (a) IN GENERAL.—The Secretary of Health and
14 Human Services may use funds appropriated for the Stra-
15 tegic National Stockpile under section 319F-2 of the Pub-
16 lic Health Service Act (42 U.S.C. 247d-6b) or under any
17 other provision of law for the storage, maintenance, secu-
18 rity, rotation, and transport of any material purchased for
19 such stockpile.

20 (b) REQUIREMENTS OF MANUFACTURERS.—The Sec-
21 retary of Health and Humans Services shall provide to
22 manufacturers, to the extent practicable, the logistical and
23 operational requirements of countermeasures prior to their
24 development and acquisition. The logistical and oper-
25 ational requirements shall consider public health needs as

1 well as requirements for storage, maintenance, security,
2 rotation, and transport of any countermeasures purchased
3 under the authority of the Project BioShield Act of 2004.

4 **TITLE III—AMENDMENTS TO**
5 **THE PROJECT BIOSHIELD**
6 **ACT OF 2004 REGARDING IN-**
7 **CENTIVES TO ESTABLISH BIO-**
8 **DEFENSE, INFECTIOUS DIS-**
9 **EASE, VACCINE, AND RE-**
10 **SEARCH TOOL INDUSTRIES**
11 **Subtitle A—Certification of**
12 **Successful Development**

13 **SEC. 301. CERTIFICATION OF SUCCESSFUL DEVELOPMENT.**

14 (a) DEFINITIONS.—For purposes of this title, the
15 term “countermeasure” has the meaning given that term
16 in section 319F–3 of the Public Health Service Act (as
17 added by section 101), and the terms “countermeasure
18 product”, “eligible patent” and “designated product” have
19 the meanings given such terms in section 156(a) of title
20 35, United States Code (as added by section 331).

21 (b) CERTIFICATION REQUIREMENTS.—

22 (1) IN GENERAL.—An entity described in para-
23 graph (2) may submit to the Secretary of Health
24 and Human Services (referred to in this subtitle as
25 the “Secretary”) with respect to agreements for pro-

1 curement entered into under section 319F–1 or
2 319F–2 of the Public Health Service Act (42 U.S.C.
3 247d–6a or 247d–6b), or to the Secretary of Home-
4 land Security with respect to agreements for pro-
5 curement entered into under section 512 of the
6 Homeland Security Act of 2002 (as added by section
7 202), an application for certification that—

8 (A) the entity may receive a patent term
9 extension under the provisions of section 158 of
10 title 35, United States Code (as added by sec-
11 tion 331), and the duration of any such exten-
12 sion; and

13 (B) the entity has successfully developed a
14 countermeasure under an agreement described
15 in paragraph (2)(C).

16 (2) ENTITY DESCRIBED.—An entity described
17 under this paragraph is an entity that—

18 (A) operates a private sector establish-
19 ment;

20 (B) is engaged in the conduct of research
21 to develop a countermeasure; and

22 (C) enters into an agreement for procure-
23 ment with the Secretary under the authority
24 provided in section 319F–1 or 319F–2 of the
25 Public Health Service Act (42 U.S.C. 247d–6a

1 or 247d–6b), or with the Secretary of Home-
2 land Security under section 512 of the Home-
3 land Security Act of 2002 (as added by section
4 101).

5 (3) SUCCESSFUL DEVELOPMENT OF A COUN-
6 TERMEASURE.—For the purposes of this section, an
7 entity shall be deemed to have successfully developed
8 a countermeasure if, after the date the entity enters
9 into an agreement for procurement with the Sec-
10 retary under the authority provided in section
11 319F–1 or 319F–2 of the Public Health Service Act
12 (42 U.S.C. 247d–6a or 247d–6b), or with the Sec-
13 retary of Homeland Security under section 512 of
14 the Homeland Security Act of 2002 as added by sec-
15 tion 101, either—

16 (A) the entity has met the requirements
17 specified in the contract for procurement under
18 section 319F–1 or 319F–2 of the Public Health
19 Service Act (42 U.S.C. 247d–6a or 247d–6b))
20 or under section 512 of the Homeland Security
21 Act of 2002; or

22 (B) the countermeasure has been approved
23 under sections 505 or 513 of the Federal Food
24 Drug and Cosmetic Act (21 U.S.C. 355) or sec-

1 tion 351 of the Public Health Service Act; (42
2 U.S.C. 262), as appropriate.

3 (4) CERTIFICATIONS BY SECRETARY.—

4 (A) CERTIFICATION AS TO ELIGIBILITY
5 FOR SPECIAL PATENT TERM EXTENSION.—

6 (i) IN GENERAL.—An entity, prior to
7 the date it has successfully developed a
8 countermeasure product, may request that
9 the Secretary determine if the entity is en-
10 titled to receive an extension of the term of
11 an eligible patent under section 158 of title
12 35, United States Code (as added by sec-
13 tion 331), and the duration of any such ex-
14 tension.

15 (ii) FACTORS CONSIDERED.—The Sec-
16 retary shall consider the following factors
17 in making the determinations specified in
18 clause (i)—

19 (I) the nature of the terror
20 threats to be countered and the im-
21 portance of developing the counter-
22 measures in question to respond to
23 such threat;

1 (II) the difficulty, risk, and ex-
2 pense likely to be associated with the
3 development of such countermeasure;

4 (III) the existence or non-exist-
5 ence of practical alternatives to the
6 countermeasure to be developed;

7 (IV) whether review of the safety
8 and effectiveness of the counter-
9 measure product will require reports
10 from clinical investigations of the
11 countermeasure product; and

12 (V) the impact of the patent ex-
13 tension on consumers and healthcare
14 providers.

15 (iii) LIMITATION.—The Secretary may
16 determine that an extension under this sec-
17 tion is available only if the countermeasure
18 product involved—

19 (I) contains an active ingredient
20 (including any ester or salt of the ac-
21 tive ingredient) which has not been
22 approved in another application under
23 section 505(b) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C.
25 355(b)); and

1 (II) is superior to a previously
2 available drug, antibiotic drug, bio-
3 logical product, device, detection tech-
4 nology, or research tool.

5 (iv) LIMITATION ON EXTENSIONS.—
6 Any extension authorized by the Secretary
7 shall not exceed 2 years, and shall not be
8 less than 6 months, in duration.

9 (v) WRITTEN DETERMINATION.—The
10 Secretary shall provide an entity that re-
11 quests a determination under clause (i)
12 with a written determination on the eligi-
13 bility of that entity for a patent term ex-
14 tension under section 158 of title 35,
15 United States Code (as added by section
16 331), and the duration of any such exten-
17 sion.

18 (vi) EFFECT OF SECTION.—The Sec-
19 retary shall promulgate regulations to give
20 effect to this section.

21 (B) WRITTEN NOTICE OF ENTITY DEVEL-
22 OPING COUNTERMEASURE.—

23 (i) IN GENERAL.—Not later than 180
24 days after entering a contract with the
25 Secretary of Health and Human Services

1 under section 319F–1 or 319F–2 of the
2 Public Health Service Act (42 U.S.C.
3 247d–6a or 247d–6b) or with the Sec-
4 retary of Homeland Security under section
5 512 of the Homeland Security Act of 2002
6 (as added by section 101) for the procure-
7 ment of a countermeasure for which the
8 Secretary of Health and Human Services
9 or the Secretary of Homeland Security, as
10 appropriate, has determined that a patent
11 extension is available under section 158 of
12 title 35, United States Code (as added by
13 section 331), the entity that enters such
14 contract shall notify such appropriate Sec-
15 retary of the patent that would be ex-
16 tended if such entity received a certifi-
17 cation under section 301(b)(4)(A).

18 (ii) PUBLICATION OF INFORMATION.—

19 The Secretary of Health and Human Serv-
20 ices, with respect to a contract under such
21 section 319F–1 or 319F–2 of the Public
22 Health Service Act, or the Secretary of
23 Homeland Security, with respect to a con-
24 tract under such section 512 of the Home-
25 land Security Act of 2002, shall publish in

1 the Federal Register the information pro-
2 vided in a notification received under
3 clause (i).

4 (iii) IRREVOCABLE ELECTION.—An
5 submission of a notification by an entity
6 under clause (i) shall constitute an irrev-
7 ocable election of the patent extended
8 under section 158 of title 35, United
9 States Code, except that such entity may
10 elect to restore the term of the eligible pat-
11 ent under section 156a of title 35, United
12 States Code, instead of extending the term
13 of the patent under such section 158 on
14 the basis of the successful development of
15 the countermeasure.

16 (C) CERTIFICATION AS TO SUCCESSFUL
17 DEVELOPMENT.—With respect to an application
18 for certification submitted by an entity in ac-
19 cordance with the terms of the agreement for
20 procurement described under paragraph (2)(C),
21 the Secretary or the Secretary of Homeland Se-
22 curity, as appropriate, shall—

23 (i) determine if the entity has success-
24 fully developed the countermeasure in-
25 volved;

1 (ii) provide the notice required under
2 subparagraph (B);

3 (iii) approve or deny the application
4 for certification; and

5 (iv) notify such entity of and publish
6 such approval or denial, and the reasons
7 therefore.

8 (D) EFFECTS OF CERTIFICATION.—If the
9 Secretary or Secretary of Homeland Security
10 certifies the application of an entity under para-
11 graph (3)(A), such entity—

12 (i) shall receive payment under the
13 contract described in paragraph (2)(C);

14 (ii) may utilize the patent restoration
15 and extension protection under section
16 156a and 158 of title 35, United States
17 Code (as added by section 331);

18 (iii) may utilize the marketing exclu-
19 sivity provisions of section 505(c)(3)(E)
20 and 505(j)(5)(F) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C.
22 355(c)(3)(E) and 21 U.S.C. 355(j)(5)(E));
23 and

1 (iv) may utilize the liability protec-
2 tions described under this title (and the
3 amendments made by this title).

4 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
5 tion shall be construed to restrict the authority of the Sec-
6 retary (with respect to procurement agreements under sec-
7 tion 319F–1 or 319F–2 of the Public Health Service Act
8 (42 U.S.C. 247d–6a or 247d–6b)) or the Secretary of
9 Homeland Security (with respect to procurement agree-
10 ments under section 512 of the Homeland Security Act
11 of 2002 (as added by section 101) to permit an entity to
12 utilize the liability protections described under this title
13 (and the amendments made by this title) or to receive pay-
14 ment under the agreement described in subsection
15 (b)(2)(C) prior to the approval of the application for cer-
16 tification submitted by the entity pursuant to the terms
17 of such agreement.

18 (d) JUDICIAL REVIEW.—A determination by the Sec-
19 retary or the Secretary of Homeland Security, as appro-
20 priate, under subsection (b) shall constitute final agency
21 action subject to judicial review. A prevailing plaintiff in
22 an action challenging an adverse determination by the
23 Secretary or Secretary of Homeland Security under such
24 subsection may be awarded reasonable attorneys fees
25 under section 2412 of title 28, United States Code.

1 **Subtitle B—Federal Tax Incentives**

2 **SEC. 311. GENERAL PROVISIONS.**

3 (a) IN GENERAL.—Any entity which enters into a
4 contract for procurement with the Secretary under the au-
5 thority provided in section 319F–1 or 319F–2 of the Pub-
6 lic Health Service Act (42 U.S.C. 247d–6a or 247d–6b)
7 or under section 512 of the Homeland Security Act of
8 2002 (as added by section 101) may irrevocably elect 1
9 of the following Federal tax incentives to fund research
10 with respect to each contract to develop countermeasures
11 (as that term is defined in section 319F–3 of the Public
12 Health Service Act (as added by section 202)):

13 (1) RESEARCH AND DEVELOPMENT LIMITED
14 PARTNERSHIPS TO FUND COUNTERMEASURE RE-
15 SEARCH.—The entity may establish a limited part-
16 nership for the countermeasures, but only if such en-
17 tity is a qualified small business as determined
18 under section 1202(d) of the Internal Revenue Code
19 of 1986, by substituting “\$750,000,000” for
20 “\$50,000,000” each place it appears. For purposes
21 of the Internal Revenue Code of 1986, section 469
22 of such Code shall not apply with respect to a lim-
23 ited partnership established under this paragraph.

24 (2) CAPITAL GAINS EXCLUSION FOR INVESTORS
25 TO FUND COUNTERMEASURE RESEARCH.—The enti-

1 ty may issue a class of stock for the counter-
2 measures under section 1202 of the Internal Rev-
3 enue Code of 1986 with the following modifications:

4 (A) INCREASED EXCLUSION FOR NONCOR-
5 PORATE TAXPAYERS.—Subsection (a) of section
6 1202 of such Code shall be applied by sub-
7 stituting “100 percent” for “50 percent”.

8 (B) APPLICATION TO CORPORATE TAX-
9 PAYERS.—Subsection (a) of section 1202 of
10 such Code shall be applied without regard to
11 the phrase “other than a corporation”.

12 (C) STOCK OF LARGER BUSINESSES ELIGI-
13 BLE FOR EXCLUSION.—Paragraph (1) of sec-
14 tion 1202(d) of such Code (defining qualified
15 small business) shall be applied by substituting
16 “\$750,000,000” for “\$50,000,000” each place
17 it appears.

18 (D) REDUCTION IN HOLDING PERIOD.—
19 Subsection (a) of section 1202 of such Code
20 shall be applied by substituting “3 years” for
21 “5 years”.

22 (E) NONAPPLICATION OF PER-ISSUER LIM-
23 ITATION.—Section 1202 of such Code shall be
24 applied without regard to subsection (b) (relat-

1 ing to per-issuer limitations on taxpayer’s eligi-
2 ble gain).

3 (F) MODIFICATION OF WORKING CAPITAL
4 LIMITATION.—Section 1202(e)(6) of such Code
5 shall be applied—

6 (i) in subparagraph (B), by sub-
7 stituting “5 years” for “2 years”, and

8 (ii) without regard to the last sen-
9 tence.

10 (G) NONAPPLICATION OF MINIMUM TAX
11 PREFERENCE.—Section 57(a) of such Code
12 shall be applied without regard to paragraph
13 (7).

14 (3) TAX CREDITS TO FUND COUNTERMEASURE
15 RESEARCH.—The entity may be eligible for the tax
16 credits provided for in section 312.

17 (b) REPORTING; RECAPTURE.—

18 (1) REPORTING.—Each entity described in sub-
19 section (a) shall submit to the Secretary and the
20 Secretary of the Treasury such information regard-
21 ing its election of any tax incentive under this sec-
22 tion with respect to any contract described in sub-
23 section (a) as the Director of the National Institutes
24 of Health and the Secretary of Health and Human
25 Services determine necessary to carry out the en-

1 enforcement provisions prescribed under paragraph
2 (2).

3 (2) RECAPTURE.—The Secretary of the Treas-
4 ury, in consultation with the Director of the Na-
5 tional Institutes of Health and the Secretary of
6 Health and Human Services, shall provide for the
7 recapture of any tax benefits resulting from any
8 elected tax incentive under this section if the result-
9 ing research is for a purpose other than that speci-
10 fied in such contract.

11 (c) EFFECTIVE DATE.—The provisions of this section
12 shall apply to taxable years beginning after December 31,
13 2004.

14 **SEC. 312. TAX CREDITS.**

15 (a) AMENDMENTS TO THE INTERNAL REVENUE
16 CODE.—

17 (1) TAX CREDIT TO FUND COUNTERMEASURE
18 RESEARCH.—

19 (A) IN GENERAL.—Subpart D of part IV
20 of subchapter A of chapter 1 of the Internal
21 Revenue Code of 1986 (relating to business-re-
22 lated credits) is amended by adding at the end
23 the following new section:

1 **“SEC. 45J. CREDIT FOR MEDICAL RESEARCH RELATED TO**
2 **DEVELOPING COUNTERMEASURES.**

3 “(a) GENERAL RULE.—For purposes of section 38,
4 in the case of any entity described in section 311(a) of
5 the Project BioShield II Act of 2005 which makes an elec-
6 tion under such section to apply this section, the counter-
7 measures research credit determined under this section for
8 the taxable year is an amount equal to 35 percent of the
9 eligible countermeasures research expenses for the taxable
10 year.

11 “(b) ELIGIBLE COUNTERMEASURES RESEARCH EX-
12 PENSES.—For purposes of this section—

13 “(1) ELIGIBLE COUNTERMEASURES RESEARCH
14 EXPENSES.—

15 “(A) IN GENERAL.—Except as otherwise
16 provided in this paragraph, the term ‘eligible
17 countermeasures research expenses’ means the
18 amounts which are paid or incurred by the tax-
19 payer during the taxable year with respect to
20 any contract described in section 311(a) of the
21 Project BioShield II Act of 2005 which would
22 be described in subsection (b) of section 41 if
23 such subsection were applied with the modifica-
24 tions set forth in subparagraph (B).

25 “(B) MODIFICATIONS; INCREASED INCEN-
26 TIVE FOR CONTRACT RESEARCH PAYMENTS.—

1 For purposes of subparagraph (A), subsection
2 (b) of section 41 shall be applied—

3 “(i) by substituting ‘eligible counter-
4 measures research’ for ‘qualified research’
5 each place it appears in paragraphs (2)
6 and (3) of such subsection, and

7 “(ii) by substituting ‘100 percent’ for
8 ‘65 percent’ in paragraph (3)(A) of such
9 subsection.

10 “(C) EXCLUSION FOR AMOUNTS FUNDED
11 BY GRANTS, ETC.—The term ‘eligible counter-
12 measures research expenses’ shall not include
13 any amount to the extent such amount is fund-
14 ed by any grant, contract, or otherwise by an-
15 other person (or any governmental entity).

16 “(2) COUNTERMEASURES RESEARCH.—The
17 term ‘countermeasures research’ means research
18 conducted by an entity with respect to the develop-
19 ment of countermeasures (as defined in section
20 319F–3 of the Public Health Service Act).

21 “(c) COORDINATION WITH CREDIT FOR INCREASING
22 RESEARCH EXPENDITURES.—

23 “(1) IN GENERAL.—Except as provided in para-
24 graph (2), any eligible countermeasures research ex-
25 penses for a taxable year to which an election under

1 this section applies shall not be taken into account
2 for purposes of determining the credit allowable
3 under section 41 for such taxable year.

4 “(2) EXPENSES INCLUDED IN DETERMINING
5 BASE PERIOD RESEARCH EXPENSES.—Any eligible
6 countermeasures research expenses for any taxable
7 year which are qualified research expenses (within
8 the meaning of section 41(b)) shall be taken into ac-
9 count in determining base period research expenses
10 for purposes of applying section 41 to subsequent
11 taxable years.

12 “(d) COORDINATION WITH CREDIT FOR CLINICAL
13 TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE
14 DISEASES.—Any eligible countermeasures research ex-
15 pense for a taxable year shall not be taken into account
16 for purposes of determining the credit allowable under sec-
17 tion 45C for such taxable year.

18 “(e) SPECIAL RULES.—

19 “(1) PRE-CLINICAL RESEARCH.—No credit shall
20 be allowed under this section for pre-clinical re-
21 search unless such research is pursuant to a re-
22 search plan an abstract of which has been filed with
23 the Food and Drug Administration before the begin-
24 ning of such year. This paragraph shall be waived
25 for any research that is pursuant to a research plan

1 or abstract that has been filed with the Food and
 2 Drug Administration not later than 270 days after
 3 the date of enactment of this section. The Secretary
 4 of Health and Human Services shall prescribe regu-
 5 lations specifying the requirements for such plans
 6 and procedures for filing under this paragraph.

7 “(2) CERTAIN RULES MADE APPLICABLE.—
 8 Rules similar to the rules of paragraphs (1) and (2)
 9 of section 41(f) shall apply for purposes of this sec-
 10 tion.”.

11 (B) INCLUSION IN GENERAL BUSINESS
 12 CREDIT.—Section 38(b) of such Code is amend-
 13 ed by striking “plus” at the end of paragraph
 14 (18), by striking the period at the end of para-
 15 graph (19) and inserting “, plus”, and by add-
 16 ing at the end the following new paragraph:

17 “(20) the countermeasures research credit de-
 18 termined under section 45J.”.

19 (C) DENIAL OF DOUBLE BENEFIT.—Sec-
 20 tion 280C of such Code is amended by adding
 21 at the end the following new subsection:

22 “(e) CREDIT FOR ELIGIBLE COUNTERMEASURES RE-
 23 SEARCH EXPENSES.—

24 “(1) IN GENERAL.—No deduction shall be al-
 25 lowed for that portion of the eligible counter-

1 measures research expenses (as defined in section
2 45J(b)) otherwise allowable as a deduction for the
3 taxable year which is equal to the amount of the
4 credit determined for such taxable year under sec-
5 tion 45J(a).

6 “(2) CERTAIN RULES TO APPLY.—Rules similar
7 to the rules of paragraphs (2), (3), and (4) of sub-
8 section (c) shall apply for purposes of this sub-
9 section.”.

10 (D) DEDUCTION FOR UNUSED PORTION OF
11 CREDIT.—Section 196(c) of such Code (defining
12 qualified business credits) is amended by strik-
13 ing “and” at the end of paragraph (11), by
14 striking the period at the end of paragraph (12)
15 and inserting “, and”, and by adding at the end
16 the following new paragraph:

17 “(13) the countermeasures research credit de-
18 termined under section 45J(a) (other than such
19 credit determined under the rules of section
20 280C(e)(2)).”.

21 (E) TECHNICAL AMENDMENT.—The table
22 of sections for subpart D of part IV of sub-
23 chapter A of chapter 1 of such Code is amended
24 by adding at the end the following new item:

“Sec. 45J. Credit for medical research related to developing coun-
termeasures.”.

1 (2) TAX CREDIT TO FUND COUNTERMEASURE
2 RESEARCH AT CERTAIN QUALIFIED NON-PROFIT AND
3 ACADEMIC INSTITUTIONS INCLUDING TEACHING
4 HOSPITALS.—

5 (A) IN GENERAL.—Subpart D of part IV
6 of subchapter A of chapter 1 of the Internal
7 Revenue Code of 1986 (relating to business re-
8 lated credits) is amended by inserting after sec-
9 tion 41 the following:

10 **“SEC. 41A. CREDIT FOR COUNTERMEASURES RESEARCH**
11 **EXPENSES.**

12 “(a) GENERAL RULE.—For purposes of section 38,
13 in the case of any entity described in section 311(a) of
14 the Project BioShield II Act of 2005 which makes an elec-
15 tion under such section to apply this section, the counter-
16 measures research credit determined under this section for
17 the taxable year shall be an amount equal to 35 percent
18 of the excess (if any) of—

19 “(1) the eligible countermeasures research ex-
20 penses for the taxable year, over

21 “(2) the countermeasures base period amount.

22 “(b) ELIGIBLE COUNTERMEASURES RESEARCH EX-
23 PENSES.—For purposes of this section—

24 “(1) IN GENERAL.—The term ‘eligible counter-
25 measures research expenses’ means the amounts

1 which are paid or incurred by the taxpayer during
2 the taxable year directly or indirectly to any quali-
3 fied nonprofit or academic institution for counter-
4 measures research activities with respect to any con-
5 tract described in section 311(a) of the Project Bio-
6 Shield II Act of 2005.

7 “(2) COUNTERMEASURES RESEARCH ACTIVI-
8 TIES.—

9 “(A) IN GENERAL.—The term ‘counter-
10 measures research activities’ means research
11 conducted by an entity with respect to the de-
12 velopment of countermeasures (as defined in
13 section 319F–3 of the Public Health Service
14 Act), conducted at any qualified nonprofit or
15 academic institution in the development of any
16 product, which occurs before—

17 “(i) the date on which an application
18 with respect to such product is approved
19 under section 505(b), 506, or 507 of the
20 Federal Food, Drug, and Cosmetic Act,

21 “(ii) the date on which a license for
22 such product is issued under section 351 of
23 the Public Health Service Act, or

24 “(iii) the date classification or ap-
25 proval of such product which is a device in-

1 tended for human use is given under sec-
2 tion 513, 514, or 515 of the Federal Food,
3 Drug, and Cosmetic Act.

4 “(B) PRODUCT.—The term ‘product’
5 means any drug, biologic, medical device, or re-
6 search tool.

7 “(3) QUALIFIED NONPROFIT OR ACADEMIC IN-
8 STITUTION.—The term ‘qualified nonprofit or aca-
9 demic institution’ means any of the following institu-
10 tions:

11 “(A) EDUCATIONAL INSTITUTION.—A
12 qualified organization described in section
13 170(b)(1)(A)(iii) which is owned or affiliated
14 with an institution of higher education as de-
15 scribed in section 3304(f).

16 “(B) TEACHING HOSPITAL.—A teaching
17 hospital which—

18 “(i) is publicly supported or owned by
19 an organization described in section
20 501(e)(3), and

21 “(ii) is affiliated with an organization
22 meeting the requirements of subparagraph
23 (A).

24 “(C) FOUNDATION.—A medical research
25 organization described in section 501(e)(3)

1 (other than a private foundation) which is affli-
 2 ated with, or owned by—

3 “(i) an organization meeting the re-
 4 quirements of subparagraph (A), or

5 “(ii) a teaching hospital meeting the
 6 requirements of subparagraph (B).

7 “(D) CHARITABLE RESEARCH HOS-
 8 PITAL.—A hospital that is designated as a can-
 9 cer center by the National Cancer Institute.

10 “(E) OTHER INSTITUTIONS.—A qualified
 11 organization (as defined in section 41(e)(6)).

12 “(4) EXCLUSION FOR AMOUNTS FUNDED BY
 13 GRANTS, ETC.—The term ‘eligible countermeasures
 14 research expenses’ shall not include any amount to
 15 the extent such amount is funded by any grant, con-
 16 tract, or otherwise by another person (or any gov-
 17 ernmental entity).

18 “(c) COUNTERMEASURES RESEARCH BASE PERIOD
 19 AMOUNT.—For purposes of this section, the term ‘coun-
 20 termeasures research base period amount’ means the aver-
 21 age annual eligible countermeasures research expenses
 22 paid by the taxpayer during the 3-taxable year period end-
 23 ing with the taxable year immediately preceding the first
 24 taxable year of the taxpayer beginning after December 31,
 25 2004.

1 “(d) SPECIAL RULES.—

2 “(1) CERTAIN RULES MADE APPLICABLE.—

3 Rules similar to the rules of subsections (f) and (g)
4 of section 41 shall apply for purposes of this section.

5 “(2) COORDINATION WITH CREDIT FOR IN-

6 CREATING RESEARCH EXPENDITURES AND WITH

7 CREDIT FOR CLINICAL TESTING EXPENSES FOR CER-

8 TAIN DRUGS FOR RARE DISEASES.—Any eligible

9 countermeasures research expense for a taxable year

10 shall not be taken into account for purposes of de-

11 termining the credit allowable under section 41 or

12 45C for such taxable year.

13 “(3) ELIGIBLE COUNTERMEASURES RESEARCH

14 EXPENSES NOT TREATED AS UNRELATED BUSINESS

15 TAXABLE INCOME.—For purposes of section 511, el-

16 igible countermeasures research expenses paid or in-

17 curred by the taxpayer directly or indirectly to any

18 qualified non-profit or academic institution shall not

19 be considered unrelated business taxable income of

20 such institution.”.

21 (B) CREDIT TO BE PART OF GENERAL

22 BUSINESS CREDIT.—Section 38(b) of such Code

23 (relating to current year business credits), as

24 amended by this section, is amended by striking

25 “plus” at the end of paragraph (19), by strik-

1 ing the period at the end of paragraph (20) and
2 inserting “, plus”, and by adding at the end the
3 following:

4 “(21) the countermeasures research credit de-
5 termined under section 41A(a).”.

6 (C) DENIAL OF DOUBLE BENEFIT.—Sec-
7 tion 280C of such Code, as amended by this
8 section, is amended by adding at the end the
9 following new subsection:

10 “(f) CREDIT FOR COUNTERMEASURES RESEARCH
11 EXPENSES.—

12 “(1) IN GENERAL.—No deduction shall be al-
13 lowed for that portion of the eligible counter-
14 measures research expenses (as defined in section
15 41A(b)) otherwise allowable as a deduction for the
16 taxable year which is equal to the amount of the
17 credit determined for such taxable year under sec-
18 tion 41A(a).

19 “(2) CERTAIN RULES TO APPLY.—Rules similar
20 to the rules of paragraphs (2), (3), and (4) of sub-
21 section (c) shall apply for purposes of this sub-
22 section.”.

23 (D) DEDUCTION FOR UNUSED PORTION OF
24 CREDIT.—Section 196(c) of such Code (defining
25 qualified business credits), as amended by this

1 section, is amended by striking “and” at the
2 end of paragraph (12), by striking the period at
3 the end of paragraph (13) and inserting “,
4 and”, and by adding at the end the following
5 new paragraph:

6 “(14) the countermeasures research expenses
7 credit determined under section 41A(a) (other than
8 such credit determined under the rules of section
9 280C(f)(2)),”.

10 (E) CLERICAL AMENDMENT.—The table of
11 sections for subpart D of part IV of subchapter
12 A of chapter 1 of such Code is amended by
13 adding after the item relating to section 41 the
14 following:

“Sec. 41A. Credit for countermeasures research expenses.”.

15 (3) COUNTERMEASURES EQUITY TAX CREDIT.—

16 (A) IN GENERAL.—Subpart D of part IV
17 of subchapter A of chapter 1 of the Internal
18 Revenue Code of 1986 (relating to business-re-
19 lated credits), as amended by this section, is
20 amended by adding at the end the following
21 new section:

22 **“SEC. 45K. COUNTERMEASURES EQUITY TAX CREDIT.**

23 “(a) ALLOWANCE OF CREDIT.—

24 “(1) GENERAL RULE.—For purposes of section
25 38, in the case of a taxpayer who holds a qualified

1 countermeasures equity investment on a credit allow-
2 ance date of such investment which occurs during
3 the taxable year, the countermeasures equity tax
4 credit determined under this section for such taxable
5 year is an amount equal to the applicable percentage
6 of the amount paid to the qualified countermeasures
7 company solely in exchange for its stock at original
8 issue.

9 “(2) APPLICABLE PERCENTAGE.—For purposes
10 of paragraph (1), the applicable percentage is 40
11 percent.

12 “(3) CREDIT ALLOWANCE DATE.—For purposes
13 of paragraph (1), the term ‘credit allowance date’
14 means, with respect to any qualified counter-
15 measures equity investment—

16 “(A) the date on which such investment is
17 initially made, and

18 “(B) each of the 3 anniversary dates of
19 such date thereafter.

20 “(b) QUALIFIED COUNTERMEASURES EQUITY IN-
21 VESTMENT.—For purposes of this section—

22 “(1) IN GENERAL.—The term ‘qualified coun-
23 termeasures equity investment’ means any equity in-
24 vestment in a qualified countermeasures company
25 if—

1 “(A) such investment is acquired by the
2 taxpayer at its original issue (directly or
3 through an underwriter) solely in exchange for
4 cash,

5 “(B) not less than $\frac{1}{2}$ of such cash is used
6 by the qualified countermeasures company with
7 respect to any contract described in section
8 311(a) of the Project BioShield II Act of 2005
9 or efforts reasonably leading to such contract
10 (such as generation of preliminary data or pro-
11 totype development), and

12 “(C) such investment is designated for
13 purposes of this section by the qualified coun-
14 termeasures company.

15 Such term shall not include any equity investment
16 issued by a qualified countermeasures company more
17 than 5 years after the date that such company re-
18 ceives an allocation under subsection (d). Any alloca-
19 tion not used within such 5-year period may be re-
20 allocated by the Secretary under subsection (d).

21 “(2) LIMITATION.—The maximum amount of
22 equity investments issued by a qualified counter-
23 measures company which may be designated under
24 paragraph (1)(C) by such company shall not exceed

1 the portion of the limitation amount allocated under
2 subsection (f) to such company.

3 “(3) TREATMENT OF SUBSEQUENT PUR-
4 CHASERS.—The term ‘qualified equity investment’
5 includes any equity investment which would (but for
6 paragraph (1)(A)) be a qualified equity investment
7 in the hands of the taxpayer if such investment was
8 a qualified equity investment in the hands of a prior
9 holder.

10 “(4) REDEMPTIONS.—A rule similar to the rule
11 of section 1202(e)(3) shall apply for purposes of this
12 subsection.

13 “(5) EQUITY INVESTMENT.—The term ‘equity
14 investment’ means any stock (other than non-
15 qualified preferred stock as defined in section
16 351(g)(2)) in an entity which is a corporation.

17 “(c) QUALIFIED COUNTERMEASURES COMPANY.—
18 For purposes of this section the term ‘qualified counter-
19 measures company’ means any domestic corporation sub-
20 ject to tax under subchapter C of this chapter if such com-
21 pany has entered into a procurement contract with the
22 Secretary of Health and Human Services under section
23 319F–1 or 319F–2 of the Public Health Service Act (42
24 U.S.C. 247d–6a or 247d–6b) or with the Secretary of

1 Homeland Security under section 512 of the Homeland
2 Security Act of 2002.

3 “(d) NATIONAL LIMITATION ON AMOUNT OF INVEST-
4 MENTS DESIGNATED.—

5 “(1) IN GENERAL.—There is a qualified coun-
6 termeasures equity tax credit limitation for each cal-
7 endar year. Such limitation is \$100,000,000 for each
8 calendar year 2005 through 2009.

9 “(2) ALLOCATION OF LIMITATION.—The limita-
10 tion under paragraph (1) shall be allocated by the
11 Secretary among qualified countermeasures compa-
12 nies selected by the Secretary. In making allocations
13 under the preceding sentence, the Secretary shall
14 give priority to the extent to which it is reasonably
15 anticipated that a qualified countermeasures com-
16 pany would have insufficient taxable income and tax
17 liability to utilize research tax credits and other tax
18 incentives provided by sections 311 and 312 of the
19 Project BioShield II Act of 2005.

20 “(3) CARRYOVER OF UNUSED LIMITATION.—If
21 the qualified countermeasures equity tax credit limi-
22 tation for any calendar year exceeds the aggregate
23 amount allocated under paragraph (2) for such year,
24 such limitation for the succeeding calendar year
25 shall be increased by the amount of such excess. No

1 amount may be carried under the preceding sentence
2 to any calendar year after 2014.

3 “(e) RECAPTURE OF CREDIT IN CERTAIN CASES.—

4 “(1) IN GENERAL.—If, at any time during the
5 4-year period beginning on the date of the original
6 issue of a qualified countermeasures equity invest-
7 ment in a qualified countermeasures company, there
8 is a recapture event with respect to such investment,
9 then the tax imposed by this chapter for the taxable
10 year in which such event occurs shall be increased
11 by the credit recapture amount.

12 “(2) CREDIT RECAPTURE AMOUNT.—For pur-
13 poses of paragraph (1), the credit recapture amount
14 is an amount equal to the sum of—

15 “(A) the aggregate decrease in the credits
16 allowed to the taxpayer under section 38 for all
17 prior taxable years which would have resulted if
18 no credit had been determined under this sec-
19 tion with respect to such investment, plus

20 “(B) interest at the underpayment rate es-
21 tablished under section 6621 on the amount de-
22 termined under subparagraph (A) for each
23 prior taxable year for the period beginning on
24 the due date for filing the return for the prior
25 taxable year involved.

1 No deduction shall be allowed under this chapter for
2 interest described in subparagraph (B).

3 “(3) RECAPTURE EVENT.—For purposes of
4 paragraph (1), there is a recapture event with re-
5 spect to a qualified countermeasures equity invest-
6 ment in a qualified countermeasures company if—

7 “(A) such company ceases to be a qualified
8 countermeasures company, or

9 “(B) such investment is redeemed by such
10 company.

11 “(4) SPECIAL RULES.—

12 “(A) TAX BENEFIT RULE.—The tax for
13 the taxable year shall be increased under para-
14 graph (1) only with respect to credits allowed
15 by reason of this section which were used to re-
16 duce tax liability. In the case of credits not so
17 used to reduce tax liability, the carryforwards
18 and carrybacks under section 39 shall be appro-
19 priately adjusted.

20 “(B) NO CREDITS AGAINST TAX.—Any in-
21 crease in tax under this subsection shall not be
22 treated as a tax imposed by this chapter for
23 purposes of determining the amount of any
24 credit under this chapter or for purposes of sec-
25 tion 55.

1 “(f) BASIS REDUCTION.—The basis of any qualified
2 countermeasures equity investment shall be reduced by the
3 amount of any credit determined under this section with
4 respect to such investment. This subsection shall not apply
5 for purposes of sections 1202, 1400B, and 1400F.

6 “(g) REGULATIONS.—The Secretary shall prescribe
7 such regulations as may be appropriate to carry out this
8 section, including regulations which—

9 “(1) prevent the abuse of the purposes of this
10 section,

11 “(2) impose appropriate reporting require-
12 ments, and

13 “(3) apply the provisions of this section to
14 newly formed entities.”.

15 (B) CREDIT TO BE PART OF GENERAL
16 BUSINESS CREDIT.—Section 38(b) of such Code
17 (relating to current year business credits), as
18 amended by this section, is amended by striking
19 “plus” at the end of paragraph (20), by strik-
20 ing the period at the end of paragraph (21) and
21 inserting “, plus”, and by adding at the end the
22 following:

23 “(22) the countermeasures equity investment
24 credit determined under section 45K(a).”.

1 (C) DEDUCTION FOR UNUSED PORTION OF
 2 CREDIT.—Section 196(c) of such Code (defining
 3 qualified business credits), as amended by this
 4 section, is amended by striking “and” at the
 5 end of paragraph (13), by striking the period at
 6 the end of paragraph (14) and inserting “,
 7 and”, and by adding at the end the following
 8 new paragraph:

9 “(15) the countermeasures equity investment
 10 credit determined under section 45K(a),”.

11 (D) CLERICAL AMENDMENT.—The table of
 12 sections for subpart D of part IV of subchapter
 13 A of chapter 1 of such Code is amended by
 14 adding after the item relating to section 41 the
 15 following:

“Sec. 45K. Countermeasures equity tax credit.”.

16 (b) EFFECTIVE DATE.—The amendments made by
 17 this section shall apply to taxable years beginning after
 18 December 31, 2004.

19 **Subtitle C—Patent Protections**

20 **SEC. 331. PATENT TERM RESTORATION AND EXTENSION** 21 **AND EXCLUSIVE MARKETING.**

22 (a) LIMITATION.—A private entity may utilize the
 23 patent term restoration and extension and exclusive mar-
 24 keting provisions described in this subtitle if such private
 25 entity—

1 (1) is an entity described under section
2 301(b)(2);

3 (2) has had an application for certification ap-
4 proved by the Secretary of Health and Human Serv-
5 ices or the Secretary of Homeland Security, as ap-
6 propriate, under section 301(b)(4)(C); and

7 (3)(A) has received approval of the counter-
8 measure by the Food and Drug Administration; or

9 (B) section 319F-2(e) applies.

10 (b) RESTORATION OF PATENT TERMS RELATING TO
11 COUNTERMEASURES.—

12 (1) IN GENERAL.—Chapter 14 of title 35,
13 United States Code, is amended by inserting after
14 section 156 the following:

15 **“§ 156a. Restoration of patent terms relating to coun-
16 termeasure products**

17 **“(a) DEFINITIONS.—**In this section, the term—

18 **“(1) ‘countermeasure product’** means a counter-
19 measure, as that term is defined in section 319F-
20 3(a)(2) of the Public Health Service Act, that is a—

21 **“(A) new drug, antibiotic drug, or device,**
22 **as those terms are defined in section 201 of the**
23 **Federal Food, Drug, and Cosmetic Act (21**
24 **U.S.C. 321); or**

1 “(B) biological product, as such term is
2 defined in section 351 of the Public Health
3 Service Act (42 U.S.C. 262);

4 “(2) ‘regulatory review period’ means the period
5 of time that—

6 “(A) starts on the date that is the later
7 of—

8 “(i) the date that an eligible patent
9 sought to be extended under this section is
10 filed;

11 “(ii) if the countermeasure product is
12 a drug, antibiotic drug, or biological prod-
13 uct, the date that an exemption under sec-
14 tion 505(i) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355(i)) became
16 effective for the product; or

17 “(iii) if the countermeasure product is
18 a device, the date that an investigational
19 device exception is approved under section
20 520(g) of the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 360j(g)) became
22 effective for the product; and

23 “(B) ends on the date that is—

24 “(i) in the case of a drug or antibiotic
25 drug, the date on which an application

1 submitted for the drug or antibiotic drug
2 under section 505(b)(1) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(b)(1)) is approved;

5 “(ii) in the case of a biological prod-
6 uct, the date on which an application sub-
7 mitted for the biological product under sec-
8 tion 351 of the Public Health Service Act
9 (42 U.S.C. 262) is approved;

10 “(iii) in the case of a device, the date
11 on which an application submitted for the
12 device under section 513 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C.
14 360c) is approved; or

15 “(iv) if an application is submitted
16 under subsection (c)(3) prior to any of the
17 dates specified in clauses (i) through (iii),
18 the date that the countermeasure product
19 became eligible for purchase under a con-
20 tract for procurement under section 319F-
21 1 or 319F-2 of the Public Health Service
22 Act (42 U.S.C. 247d-6a or 247d-6b)) or
23 under section 512 of the Homeland Secu-
24 rity Act of 2002;

25 “(3) ‘eligible patent’ means a patent that—

1 “(A) claims a countermeasure product that
2 has been successfully developed as specified in
3 section 301(b)(3) of the Research Act, or an ac-
4 tive ingredient of such product, or a process of
5 making or method of using such product or the
6 active ingredient of such product for the coun-
7 termeasure use that has been approved by the
8 Food and Drug Administration; and

9 “(B) is owned by, or licensed to, an entity
10 that has been certified as having successfully
11 developed the countermeasure section
12 301(b)(4)(C) of the Research Act; and

13 “(4) ‘Research Act’ means the Project Bio-
14 Shield II Act of 2005.

15 “(b) PATENT TERM RESTORATION.—The term of an
16 eligible patent shall be restored by a period equal to the
17 number of days in the regulatory review period if, with
18 respect to the patent that is the basis of the application—

19 “(1) an application under subsection (c) is sub-
20 mitted to the Director by either the owner of record
21 of the patent, or its agent, on or before the later
22 of—

23 “(A) the date specified in subsection
24 (c)(3); or

1 “(B) 45 days after the date of issuance of
2 the patent;

3 “(2) the patent has not been previously restored
4 under this section, or extended under section 156 or
5 158;

6 “(3) the term of the patent has not expired be-
7 fore the date that the application is submitted to the
8 Director; and

9 “(4) the regulatory review period for the coun-
10 termeasure product—

11 “(A) has not been relied upon to support
12 an application to extend the term of another
13 patent under this section or under section 156;
14 and

15 “(B) did not commence before the date of
16 enactment of the Research Act.

17 “(c) ADMINISTRATIVE PROVISIONS.—

18 “(1) IN GENERAL.—To obtain a restoration of
19 the term of a patent under this section, the owner
20 of record of the patent or the agent of the owner
21 shall submit an application to the Director.

22 “(2) CONTENT.—The application shall con-
23 tain—

1 “(A) a description of the approved counter-
2 measure product and the Federal statute under
3 which regulatory review occurred;

4 “(B) the identity of the patent for which
5 a restoration is sought; and

6 “(C) such other information as the Direc-
7 tor may require.

8 “(3) SUBMISSION OF APPLICATION.—An appli-
9 cation under this section shall be submitted to the
10 Director not later than 60 days after the last of the
11 following dates:

12 “(A) The date that the product became eli-
13 gible for purchase under a contract for procure-
14 ment under section 319F-1 or 319F-2 of the
15 Public Health Service Act (42 U.S.C. 247d-6a
16 or 247d-6b)) or under section 512 of the
17 Homeland Security Act of 2002.

18 “(B) The date that an application under
19 section 505 of the Federal Food Drug and Cos-
20 metic Act was approved for the drug or anti-
21 biotic drug.

22 “(C) The date that an application under
23 section 351 of the Public Health Service Act
24 was approved for the biological product.

1 “(D) The date that an application under
2 section 513 of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 360e) was approved
4 for the device.

5 “(4) PUBLICATION OF APPLICATIONS BY THE
6 SECRETARY.—Immediately under receipt of an appli-
7 cation for patent restoration under this subsection,
8 the Director shall publish the application and pro-
9 vide a reasonable period of time for interested par-
10 ties to submit comments with respect to the applica-
11 tion.

12 “(5) IRREVOCABLE ELECTION.—The submis-
13 sion of an application under this section is an irrev-
14 ocable election of the application of this section to
15 the patent that is the basis of the application. A pat-
16 ent that has been the basis of an application made
17 under this section may not be the subject of an ap-
18 plication made under section 156 or 158.

19 “(d) LIMITATIONS.—A patent that is the subject of
20 an application filed under subsection (c) may not be re-
21 stored under this section if—

22 “(1) the regulatory review period for the coun-
23 termeasure product was commenced before the date
24 of enactment of the Research Act;

1 “(2) the patent that is the basis of the applica-
2 tion under this section expired before the date of en-
3 actment of the Research Act; or

4 “(3) a patent which has been extended under
5 section 156 of this title prior to the date of enact-
6 ment of the Research Act claims the countermeasure
7 product, an active ingredient of the countermeasure
8 product, a method of using the countermeasure
9 product, a method of using an active ingredient of
10 the countermeasure product, or making the counter-
11 measure.”.

12 (2) TECHNICAL AND CONFORMING AMEND-
13 MENT.—The table of sections for chapter 14 of title
14 35, United States Code, is amended by inserting
15 after the item relating to section 156 the following:
16 “156a. Restoration of patent terms relating to countermeasure products.”.

17 (c) EXTENSION OF PATENT TERMS RELATING TO
18 COUNTERMEASURE PRODUCTS.—

19 (1) IN GENERAL.—Chapter 14 of title 35,
20 United States Code, is amended by adding at the
21 end the following:

22 “§ 158. Extension of patent terms relating to counter-
23 measure products

 “(a) DEFINITIONS.—In this section, the term—

1 “(1) ‘countermeasure product’ means a counter-
2 measure, as that term is defined in 319F-3(a)(2) of
3 the Public Health Service Act, that is a—

4 “(A) new drug or antibiotic drug, as those
5 terms are defined in section 201 in the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C.
7 321), containing an active ingredient (including
8 any ester or salt of the active ingredient) which
9 has not been approved in another application
10 under section 505(b) of that Act (21 U.S.C.
11 355(b));

12 “(B) device, as that term is defined in sec-
13 tion 201 in the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 321); or

15 “(C) biological product, as that term is de-
16 fined in section 351 of the Public Health Serv-
17 ice Act (42 U.S.C. 262);

18 “(2) ‘designated product’ means a drug, anti-
19 biotic drug, or device, as those terms are defined in
20 section 201 of the Federal Food, Drug and Cosmetic
21 Act (21 U.S.C. 321), or a biological product, as that
22 term is defined in section 351 of the Public Health
23 Service Act;

24 “(3) ‘eligible patent’ means a patent that at the
25 time the eligible entity entered into the contract to

1 develop such countermeasure product, was owned by
2 or licensed to that eligible entity, and claims a des-
3 ignated product, an active ingredient of a designated
4 product, a method of making or using a designated
5 product or a method of making or using an active
6 ingredient of a designated product;

7 “(4) ‘eligible entity’ means a natural or legal
8 person that has—

9 “(A) successfully developed a counter-
10 measure product;

11 “(B) been certified as being eligible to re-
12 ceive a patent term extension under this section
13 by section 301(b)(4)(A)(i) of the Research Act;

14 “(C) been certified as having successfully
15 developed a countermeasure under section
16 301(b)(4)(C) of the Research Act; and

17 “(D) entered into a contract for the sale of
18 the countermeasure product under section
19 319F–1 or 319F–2 of the Public Health Serv-
20 ice Act (42 U.S.C. 247d–6a or 247d–6b) or sec-
21 tion 512 of the Homeland Security Act of 2002;
22 and

23 “(5) ‘Research Act’ means the Project Bio-
24 Shield II Act of 2005.

1 “(b) PATENT TERM EXTENSION.—The term of an el-
2 eligible patent shall be extended for the period determined
3 by the Secretary of Health and Human Services in a cer-
4 tification under section 301(b)(4)(A)(i) of the Research
5 Act, in addition to the term which would otherwise apply
6 except for this section, if—

7 “(1) an application under subsection (c) is sub-
8 mitted to the Director by either the owner of record
9 of the patent or its agent on or before the date spec-
10 ified in subsection (c)(3);

11 “(2) the patent has not been previously ex-
12 tended under this section, or under section 156 or
13 156a;

14 “(3) the applicant has provided written notice
15 and the Secretary has published such information as
16 required under section 301(b)(4)(B) of the Project
17 BioShield II Act of 2005;

18 “(4) the patent has not expired before the date
19 that the application is submitted;

20 “(5) the term of no other patent has been ex-
21 tended based on the certification being relied upon
22 by the eligible entity to request extension of the pat-
23 ent; and

24 “(6) no other patent that claims the designated
25 product, an active ingredient of the designated prod-

1 uct, a method of making or using a designated prod-
2 uct or a method of making or using an active ingre-
3 dient of a designated product has been extended
4 under this section or under section 156a.

5 “(c) ADMINISTRATIVE PROVISIONS.—

6 “(1) IN GENERAL.—To obtain an extension of
7 the term of a patent under this section, the owner
8 of record of the patent or the agent of the owner
9 shall submit an application to the Director.

10 “(2) CONTENT.—An application filed under this
11 section shall contain—

12 “(A) a description of the approved counter-
13 measure product and the Federal statute under
14 which regulatory review occurred;

15 “(B) the identity of the eligible patent for
16 which an extension is sought under this section;

17 “(C) the identity of the eligible entity and
18 the applicant (if different from the eligible enti-
19 ty);

20 “(D) the identity of the designated product
21 to which the eligible patent relates;

22 “(E) information concerning the certifi-
23 cation specified in section 301(b)(4)(A)(i) of the
24 Research Act being relied upon as the basis of
25 the extension being requested;

1 “(F) information indicating that the entity
2 owned or licensed the eligible patent at the time
3 it entered into the contract to develop the
4 countermeasure product; and

5 “(G) such other information as the Direc-
6 tor may require including to establish that the
7 applicant meets the requirements of this sec-
8 tion.

9 “(3) SUBMISSION OF APPLICATION.—An appli-
10 cation under this section shall be submitted to the
11 Director within 60 days after the date of the certifi-
12 cation specified in section 301(b)(4)(C) of the Re-
13 search Act that is being relied upon to request ex-
14 tension of the patent that is the subject of the appli-
15 cation.

16 “(d) IRREVOCABLE ELECTION.—The submission of
17 an application under this section is an irrevocable election
18 of the application of this section to the patent that is the
19 basis of the application. A patent that has been the basis
20 of an application made under this section may not be the
21 subject of an application made under sections 156 or
22 156a.”.

23 (2) TECHNICAL AND CONFORMING AMEND-
24 MENT.—The table of sections for chapter 14 of title

1 35, United States Code, is amended by adding at
2 the end the following:

“158. Extension of patent terms relating to countermeasure products.”.

3 (d) DISCRETIONARY WAIVER OF MARCH-IN RIGHTS
4 AND EXCLUSIVE LICENSING.—

5 (1) DISCRETION TO WAIVE MARCH-IN
6 RIGHTS.—

7 (A) IN GENERAL.—The owner of a patent
8 over which the Government has rights under
9 chapter 18 of title 35, United States Code, may
10 request that a Federal agency under whose
11 funding a subject invention was made may
12 waive rights the Government has under sections
13 200, 203, and 209 of title 35, United States
14 Code, if—

15 (i) such entity holds a certification
16 under section 301(b)(4)(C) of the Research
17 Act; and

18 (ii) the subject invention is related to
19 or will be used to discover, evaluate,
20 produce, manufacture or use the counter-
21 measure, detection equipment, diagnostic,
22 research tool, drug, antibiotic drug, biological
23 product or a device that is the subject
24 of the certification.

1 (B) REQUESTS.—If a request under sub-
2 paragraph (A) is made within 90 days after the
3 date of the certification under section
4 301(b)(4)(C) of the Research Act or the date
5 that the entity obtained title to the patent, the
6 Federal agency shall grant the request.

7 (2) FEDERALLY OWNED INVENTIONS.—Section
8 209 of title 35, United States Code, is amended—

9 (A) by redesignating subsections (e) and
10 (f) as subsections (f) and (g), respectively; and

11 (B) by inserting after subsection (d) the
12 following:

13 “(e) TERMS AND CONDITIONS OF EXCLUSIVE LI-
14 CENSE.—Each exclusive license granted under section
15 207(a)(2) shall include a provision that, at the discretion
16 of the licensee, the licensee may act as the agent for the
17 licensor with respect to any patent for the licensed inven-
18 tion for purposes of extending a patent under section 156a
19 or 158.”.

20 (3) COOPERATIVE RESEARCH AND DEVELOP-
21 MENT AGREEMENTS.—Section 12(b) of the Steven-
22 son-Wydler Technology Innovation Act of 1980 (15
23 U.S.C. 3710a(b)) is amended by adding at the end
24 the following:

1 “(7) Each exclusive license for a patent granted
2 under an agreement entered into under subsection
3 (a)(1) shall include a provision that, at the discre-
4 tion of the licensee, the licensee may act as the
5 agent for the licensor with respect to that patent for
6 purposes of extending a patent under section 156a
7 or 158 of title 35, United States Code.”.

8 (4) **APPLICABLE LICENSES.**—The amendments
9 made by paragraphs (2) and (3) shall apply only to
10 exclusive licenses granted after 60 days after the
11 date of enactment of this Act.

12 (e) **EXCLUSIVE MARKETING.**—Subchapter A of chap-
13 ter V of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 351 et seq.) is amended by inserting after section
15 505B, the following:

16 **“SEC. 505C. MARKET EXCLUSIVITY FOR COUNTERMEASURE**
17 **PRODUCTS.**

18 “(a) **IN GENERAL.**—Subsection (b) shall apply if the
19 Secretary determines that a new drug is a countermeasure
20 product, as that term is defined in section 156a(a)(1) of
21 title 35, United States Code, that has been successfully
22 developed by an entity that has been certified under sec-
23 tion 301(b)(4)(A) of the Project BioShield II Act of 2005.

24 “(b) **EXCLUSIVITY.**—With respect to a new drug de-
25 scribed in subsection (a)—

1 “(1)(A)(i) the period referred to in subsection
2 (c)(3)(E)(ii) of section 505, and in subsection
3 (j)(5)(F)(ii) of such section, shall be 10 years in-
4 stead of 5 years, and the periods of 4 years, to 48
5 months, and to 7 and one-half years referred to in
6 subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such
7 section shall be 9 years, 108 months, and 9 years,
8 respectively; or

9 “(ii) the period referred to in clauses (iii) and
10 (iv) of subsection (c)(3)(E) of such section, and in
11 clauses (iii) and (iv) of subsection (j)(5)(F) of such
12 section, shall be 6 years instead of 3 years; and

13 “(B) if the drug is designated under section
14 526 for a rare disease or condition, the period re-
15 ferred to in section 527(a) shall be 10 years instead
16 of 7 years.

17 “(c) SPECIAL RULE FOR UNEXPLOITED COUNTER-
18 MEASURES.—If, as of the date that is 45 days before the
19 date on which the periods specified in paragraph (1) or
20 (2) of section 505B expire, there has been no substantial
21 commercial exploitation of the drug, including insubstan-
22 tial sales of the drug following its approval for marketing,
23 the periods specified in such sections shall be extended by
24 a period of 3 years.”.

1 **SEC. 332. INTERNATIONAL PROTECTION FOR BIOSHIELD**
2 **INTELLECTUAL PROPERTY.**

3 The Secretary of Commerce, the United States Trade
4 Representative, and the Commissioner of Patents shall en-
5 sure in international, bilateral, and multilateral negotia-
6 tions and agreements, and proceedings before agencies of
7 the World Trade Organization, that—

8 (1) intellectual property for which restoration of
9 a patent term is granted under section 156a of title
10 35, United States Code (as added by section 331),
11 or for which an extension of a patent term is grant-
12 ed under section 158 of title 35, United States Code,
13 (as added by section 331) under this Act is not im-
14 paired;

15 (2) substantially similar intellectual property
16 rights granted to the same or related entities as
17 those that qualify for restoration or an extension
18 under such sections are not impaired; and

19 (3) vigorous enforcement actions and sanctions
20 are taken and imposed with respect to infringement
21 of such intellectual property.

1 **Subtitle D—Liability Protections**

2 **SEC. 341. LIABILITY AND COMPENSATION FOR INJURED**
3 **PARTIES.**

4 (a) THE PUBLIC HEALTH SERVICE ACT AMEND-
5 MENTS.—Section 224 of the Public Health Service Act
6 (42 U.S.C. 233) is amended—

7 (1) in subsection (a), by inserting “or the man-
8 ufacture or distribution of a covered countermeasure
9 as defined in subsection (p)” after “including the
10 conduct of clinical studies or investigation”;

11 (2) in the heading of subsection (p), by striking
12 “ADMINISTRATION OF SMALLPOX COUNTER-
13 MEASURES BY HEALTH PROFESSIONALS” and in-
14 serting “MANUFACTURE, DISTRIBUTION, AND AD-
15 MINISTRATION OF COVERED COUNTERMEASURES”;

16 (3) in subsection (p)(1)—

17 (A) by inserting “manufacture, distribu-
18 tion, or” after “liability arising out of”;

19 (B) by striking “against smallpox to an in-
20 dividual”; and

21 (C) by inserting before the period at the
22 end “notwithstanding the applicability of the
23 SAFETY Act (6 U.S.C. 441 et seq.)”;

24 (4) in subsection (p)(2)—

1 (A) in the heading, by striking “COUNTER-
2 MEASURE AGAINST SMALLPOX” and inserting
3 “COVERED COUNTERMEASURES”;

4 (B) in subparagraph (A)(i)—

5 (i) by inserting “(I)” after “makes
6 advisable”; and

7 (ii) by inserting before the period at
8 the end “; or (II) the manufacture or dis-
9 tribution of a covered countermeasure for
10 possible future administration to a cat-
11 egory or categories of individuals”;

12 (C) in subparagraph (A)(ii) by inserting—

13 (i) “, or product or products” after
14 “or substances”; and

15 (ii) before the period at the end “and
16 any conditions governing the manufacture
17 or distribution of such covered counter-
18 measures”;

19 (D) in subparagraph (A)(iv), by adding at
20 the end before the period “. Notwithstanding
21 clause (iii), such declaration or amendment
22 shall take effect immediately upon publication
23 and shall not be subject to the provisions of sec-
24 tion 553 of title 5, United States code, con-

1 cerning prior notice and opportunity for com-
2 ment”.

3 (E) in subparagraph (A), by adding at the
4 end the following:

5 “(v) RECOMMENDED DECLARATION.—Any
6 person may recommend to the Secretary at any
7 time the declaration of a countermeasure under
8 this paragraph and may provide data and infor-
9 mation to support such recommendation.”;

10 (F) in subparagraph (B)(i), by striking “,
11 for a purpose stated in paragraph (7)(A)(i),”;
12 and

13 (G) by adding at the end the following:

14 “(E) LIABILITY OF THE UNITED
15 STATES.—The United States shall be liable
16 under this subsection with respect to a claim
17 arising out of the manufacture, distribution, or
18 administration of a covered countermeasure re-
19 gardless of whether—

20 “(i) the cause of action seeking com-
21 pensation for harm caused by such coun-
22 termeasure is alleged as negligence, strict
23 liability, breach of warranty, failure to
24 warn, or other action; or

1 “(ii) the covered countermeasure is
2 designated or certified as a qualified anti-
3 terrorism technology under the SAFETY
4 Act (6 U.S.C. 441 et seq.).

5 The United States shall be liable under this
6 subsection for claims for injury or loss arising
7 out of administration of a covered
8 countermeasre during a human clinical inves-
9 tigation on a covered countermeasure whether
10 or not the certification for successful develop-
11 ment of the countermeasre is made under sec-
12 tion 301(b)(3) of the Project BioShield II Act
13 of 2005.

14 “(F) LIABILITY OF THE UNITED STATES
15 FOR MANUFACTURE OR DISTRIBUTION WITHIN
16 THE SCOPE OF DECLARATION.—

17 “(i) IN GENERAL.—Except as pro-
18 vided in paragraph (5)(B)(ii), the United
19 States shall be liable under this subsection
20 with respect to a claim arising out of the
21 manufacture or distribution of a covered
22 countermeasure if—

23 “(I) the manufacturer was cov-
24 ered by a declaration by the Secretary

1 under subparagraph (A) with respect
2 to such countermeasure; and

3 “(II) the countermeasure was
4 manufactured and distributed in ac-
5 cordance with, and during, the rel-
6 evant period of such declaration.

7 “(ii) EFFECT OF SECTION.—For pur-
8 poses of this section, any activity reason-
9 ably related to the manufacture, distribu-
10 tion, or administration of a covered coun-
11 termeasure shall be considered to be a
12 medical, surgical, dental, or related func-
13 tion within the scope of the covered per-
14 son’s employment by the Public Health
15 Service.”;

16 (5) in subsection (p)(4)(A), by inserting “man-
17 ufacture, distribution, or” after “arising out of the”;
18 and

19 (6) in subsection (p)(7)—

20 (A) by striking subparagraph (A) and in-
21 serting the following:

22 “(A) COVERED COUNTERMEASURE.—

23 “(i) BEFORE PUBLICATION OF
24 LIST.—Until the date that the Secretary
25 publishes the list described under section

1 319F–3(f), the term “covered counter-
2 measure” means a substance or product
3 that is specified in a declaration under
4 paragraph (2).

5 “(ii) After publication of list. After
6 the date that the Secretary publishes the
7 list described under section 319F–3(f), the
8 term “covered countermeasure” means a
9 substance or product that is—

10 “(I) specified in a declaration
11 under paragraph (2); and

12 “(II)(aa) a countermeasure, as
13 such term is defined in section 319F–
14 3; or

15 “(bb) designed, developed, modi-
16 fied, used, or procured for the purpose
17 of preventing, detecting, identifying,
18 or treating pandemic influenza or lim-
19 iting the harm such influenza might
20 otherwise cause.”;

21 (B) in subparagraph (B)—

22 (i) in the matter preceding clause (i),
23 by inserting “manufacture, distribution,
24 or” after “with respect to the”; and

1 (ii) in clause (iv), by inserting “or dis-
2 tribution” after “with respect to adminis-
3 tration”; and

4 (C) in subparagraph (D)—

5 (i) in the heading, by inserting “MAN-
6 UFACTURE, DISTRIBUTION, OR” after
7 “ARISING OUT OF”;

8 (ii) in the matter preceding clause (i)
9 by—

10 (I) striking “administration of a
11 covered countermeasure”; and

12 (II) by inserting “relating to the
13 manufacture, distribution, or adminis-
14 tration of a covered countermeasure”
15 after “with respect to a claim or li-
16 ability”;

17 (iii) in clause (iii), by striking “; or”
18 and inserting a semicolon;

19 (iv) in clause (iv) by striking the pe-
20 riod and inserting “; or”; and

21 (v) by adding at the end the following:

22 “(v) the manufacture or distribution
23 of a covered countermeasure and adminis-
24 tration of a covered countermeasure in the
25 course of a human clinical investigation.

1 For purposes of this subsection, the term
2 ‘administration’ includes administration in
3 the course of a human clinical investiga-
4 tion.”.

5 (b) AMENDMENTS TO THE SAFETY ACT.—The
6 SAFETY Act (6 U.S.C. 441 et seq.) is amended—

7 (1) in section 863, in subsections (a)(1), (a)(2),
8 (d)(1), and (d)(2), by inserting “, or potential threat
9 of such act,” after “from such act”;

10 (2) in section 864—

11 (A) in subsections (a)(1), (b), and (c), by
12 inserting “or potential threat of such act” after
13 “from such act”; and

14 (B) in subsection (a)(3), by inserting “or
15 potential threat of such act” after “act of ter-
16 rorism”; and

17 (3) in section 865(1)—

18 (A) by inserting “(including a vaccine,
19 therapeutic or other biological product, drug,
20 antimicrobial or combination thereof, detection
21 technology, or device)” after “product”;

22 (B) by inserting “, biotechnology, detection
23 technology, or a pharmacological product” after
24 “information technology”; and

1 (C) by inserting “treating,” after “pre-
2 venting,”.

3 (c) LIMITATION.—A private entity may utilize the li-
4 ability protections described in this section (and the
5 amendments made by this section) if such entity—

6 (1)(A) is described under section 301(b)(2);
7 and

8 (B) has been certified by the Secretary of
9 Health and Human Services or the Secretary of
10 Homeland Security, as appropriate, under section
11 301(b)(4); or

12 (2) without regard to the requirements of sec-
13 tions 301(b)(2) and 301(b)(4), has developed a
14 product (including a drug, vaccine, or other bio-
15 logic), equipment, service (including support service),
16 device, or technology (including information tech-
17 nology) designed, developed, modified, used, or pro-
18 cured for the specific purpose of preventing, detect-
19 ing, identifying, or treating pandemic influenza or
20 limiting the harm such pandemic might cause.

21 (d) EFFECT OF SECTION.—Notwithstanding any
22 other provision of law, an entity shall not be required to
23 apply for and receive designation or certification by the
24 Secretary of Homeland Security of a product or service
25 as a Qualified Anti-Terror Technology under the SAFE-

1 TY Act (6 U.S.C. 441 et seq.) in order to receive indem-
2 nification under Public Law 85–804.

3 (e) EFFECT ON PENDING ACTIONS.—Nothing in this
4 Act (or the amendments made by this Act) shall be con-
5 strued to apply to a legal action pending or filed on or
6 before the date of enactment of this Act against a manu-
7 facturer or other entity with respect to a diagnostic, thera-
8 peutic, detection technology, or research that was not con-
9 ducted pursuant to a contract under the amendments
10 made by this Act or the Project BioShield Act of 2004
11 (Public Law 108–276).

12 **TITLE IV—VALLEY OF DEATH** 13 **FOR SMALL COMPANIES**

14 **SEC. 401. PURPOSE.**

15 It is the purpose of this title to enable small compa-
16 nies to fund the initial research and development nec-
17 essary so that such small companies may be able to par-
18 ticipate in the procurement process for countermeasures,
19 and become part of a national biodefense, infectious dis-
20 ease, and research tool industry.

21 **SEC. 402. VALLEY OF DEATH FOR SMALL COMPANIES.**

22 Section 319F–2 of the Public Health Service Act (42
23 U.S.C. 247d–6b), as amended by section 103, is amended
24 by—

1 (1) redesignating subsections (l) and (m) as
2 subsections (r) and (s), respectively; and

3 (2) inserting after subsection (k) the following:

4 “(l) REIMBURSEMENT.—The Secretary may reim-
5 burse an entity for costs associated with improvement, in-
6 crease, or production of a countermeasure necessary for
7 testing (including a clinical trial) conducted on humans
8 or animals from funds appropriated to fund the Project
9 BioShield Act of 2004 and the Project BioShield II Act
10 of 2005.

11 “(m) GRANTS TO CERTAIN ENTITIES.—The Sec-
12 retary may award grants to State or local government
13 agencies, small businesses, university technology partner-
14 ship offices, and other entities to conduct preliminary
15 screening of compounds and to develop of business plans
16 related to such preliminary screenings.

17 “(n) SECURITY FUNDING.—The Secretary shall pro-
18 vide funding for an entity that enters into an agreement
19 under the amendments made by the Project BioShield Act
20 of 2004 or the Project BioShield II Act of 2005 (and the
21 amendments made by such Act) to provide security for
22 the personnel and facilities of such entity that develop,
23 produce, distribute, or store countermeasures under sec-
24 tion 319K.

1 “(o) PRIORITY ACCESS TO CERTAIN RESEARCH RE-
2 SULTS.—An entity that enters into an agreement under
3 this section, section 319F–2, or section 512 of the Home-
4 land Security Act of 2002 shall be given priority access
5 to the results of research related to the epidemiology and
6 pathogenesis of agents, the genomes and other DNA anal-
7 ysis, or other comparative analysis of agents relevant to
8 research conducted under subparagraphs (A), (B), and
9 (C) of section 319F(h)(1).

10 “(p) TRANSLATIONAL DEVELOPMENT FOR BIO-
11 DEFENSE DRUG AND VACCINE CANDIDATES.—

12 “(1) IN GENERAL.—An entity that enters into
13 an agreement under this section, section 319F–2, or
14 section 512 of the Homeland Security Act of 2002
15 shall be eligible for translational development for
16 biodefense drug and infectious disease counter-
17 measure candidates. For purposes of this section,
18 such entities may include universities, small busi-
19 nesses, for-profit, and nonprofit entities.

20 “(2) TRANSLATIONAL DEVELOPMENT.—In this
21 subsection, the term ‘translational development’
22 shall include the following:

23 “(A) Triage screening of applications for
24 promising drug and biological candidates.

1 “(B) Plans to outline the tasks, timelines,
2 and costs required to complete the development
3 process for promising drug and biological can-
4 didates.

5 “(C) Implementation of the recommended
6 development steps for key therapeutics.

7 “(D) Project management to implement
8 the recommended development steps.

9 “(E) Regulatory consultants to interface
10 with the Food and Drug Administration and
11 the entity to devise a plan that rapidly brings
12 new biodefense candidates to approval and
13 stockpiling.

14 “(q) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to limit the authority of the Sec-
16 retary or the Secretary of Homeland Security to distribute
17 countermeasures from the Strategic National Stockpile to
18 foreign countries or foreign entities if it is determined by
19 such Secretaries that such a deployment would protect the
20 interests and safety of citizens of the United States, living
21 in the United States or abroad, from the event of a bioter-
22 rorist attack or other public health emergency.”.

1 **TITLE V—BIOSHIELD ANTITRUST**
2 **EXEMPTION**

3 **SEC. 501. LIMITED ANTITRUST EXEMPTION.**

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

6 “(g) LIMITED ANTITRUST EXEMPTION.—

7 “(1) COUNTERMEASURES DEVELOPMENT MEET-
8 INGS.—

9 “(A) COUNTERMEASURES DEVELOPMENT
10 MEETINGS AND CONSULTATIONS.—The Sec-
11 retary may conduct meetings and consultations
12 with parties involved in the development of
13 countermeasures for the purpose of the develop-
14 ment, manufacture, distribution, purchase, or
15 sale of countermeasures consistent with the
16 purposes of this title. The Secretary shall give
17 notice of such meetings and consultations to the
18 Attorney General and the Chairperson of the
19 Federal Trade Commission (referred to in this
20 subsection as the ‘Chairperson’).

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

24 “(i) be chaired or, in the case of a
25 consultation, facilitated by the Secretary;

1 “(ii) be open to parties involved in the
2 development, manufacture, distribution,
3 purchase, or sale of countermeasures, as
4 determined by the Secretary;

5 “(iii) be open to the Attorney General
6 and the Chairperson;

7 “(iv) be limited to discussions involv-
8 ing the development, manufacture, dis-
9 tribution, or sale of countermeasures, con-
10 sistent with the purposes of this title; and

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

15 “(C) MINUTES.—The Secretary shall
16 maintain minutes of meetings and consultations
17 under this subsection, which shall not be dis-
18 closed under section 552 of title 5, United
19 States Code.

20 “(D) EXEMPTION.—The antitrust laws
21 shall not apply to meetings and consultations
22 under this paragraph, except that any agree-
23 ment or conduct that results from a meeting or
24 consultation and that does not receive an ex-

1 emption pursuant to this subsection shall be
2 subject to the antitrust laws.

3 “(2) WRITTEN AGREEMENTS.—The Secretary
4 shall file a written agreement regarding covered ac-
5 tivities, made pursuant to meetings or consultations
6 conducted under paragraph (1) and that is con-
7 sistent with this paragraph, with the Attorney Gen-
8 eral and the Chairperson for a determination of the
9 compliance of such agreement with antitrust laws.
10 In addition to the proposed agreement itself, any
11 such filing shall include—

12 “(A) an explanation of the intended pur-
13 pose of the agreement;

14 “(B) a specific statement of the substance
15 of the agreement;

16 “(C) a description of the methods that will
17 be utilized to achieve the objectives of the
18 agreement;

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

23 “(E) any other relevant information deter-
24 mined necessary by the Secretary in consulta-

1 tion with the Attorney General and the Chair-
2 person.

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

7 “(A) be in compliance with the antitrust
8 laws, and so inform the Secretary and the par-
9 ticipating parties; or

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

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

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

23 “(B) EXTENSION.—The Attorney General
24 may extend the 15-day period referred to in
25 subparagraph (A) for an additional period of

1 not to exceed 10 days. Such additional period
2 may be further extended only by the United
3 States district court, upon an application by the
4 Attorney General after notice to the Secretary
5 and the parties involved.

6 “(C) DETERMINATION.—In granting an
7 exemption under this paragraph, the Attorney
8 General, in consultation with the Chairperson
9 and the Secretary—

10 “(i) must find—

11 “(I) that the agreement involved
12 is necessary to ensure the availability
13 of countermeasures;

14 “(II) that the exemption from
15 the antitrust laws would promote the
16 public interest; and

17 “(III) that there is no substantial
18 competitive impact to areas not di-
19 rectly related to the purposes of the
20 agreement; and

21 “(ii) may consider any other factors
22 determined relevant by the Attorney Gen-
23 eral and the Chairperson.

24 “(5) LIMITATION ON AND RENEWAL OF EXEMP-
25 TIONS.—An exemption granted under paragraph (4)

1 shall be limited to covered activities, and shall expire
2 on the date that is 3 years after the date on which
3 the exemption becomes effective (and at 3-year in-
4 tervals thereafter, if renewed) unless the Attorney
5 General in consultation with the Chairperson deter-
6 mines that the exemption should be renewed (with
7 modifications, as appropriate) considering the fac-
8 tors described in paragraph (4).

9 “(6) LIMITATION ON PARTIES.—The use of any
10 information acquired under an exempted agreement
11 by the parties to such an agreement for any pur-
12 poses other than those specified in the antitrust ex-
13 emption granted by the Attorney General shall be
14 subject to the antitrust laws and any other applica-
15 ble laws.

16 “(7) GUIDELINES.—The Attorney General and
17 the Chairperson may develop and issue guidelines to
18 implement this subsection.

19 “(8) REPORT.—Not later than 1 year after the
20 date of enactment of the Project BioShield II Act of
21 2005, and annually thereafter, the Attorney General
22 and the Chairperson shall report to Congress on the
23 use and continuing need for the exemption from the
24 antitrust laws provided by this subsection.

1 “(9) SUNSET.—The authority of the Attorney
2 General to grant or renew a limited antitrust exemp-
3 tion under this subsection shall expire at the end of
4 the 10-year period that begins on the date of enact-
5 ment of the Project BioShield II Act of 2005.

6 “(h) DEFINITIONS.—In this section:

7 “(1) ANTITRUST LAWS.—The term ‘antitrust
8 laws’—

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

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

20 “(2) COUNTERMEASURE.—The term ‘counter-
21 measure’ has the meaning given that term in section
22 319F–3 of the Public Health Service Act.

23 “(3) COVERED ACTIVITIES.—

24 “(A) IN GENERAL.—Except as provided in
25 subparagraph (B), the term ‘covered activities’

1 means any group of activities or conduct, in-
2 cluding attempting to make, making, or per-
3 forming a contract or agreement or engaging in
4 other conduct, for the purpose of—

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

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

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

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

23 “(v) the testing in connection with the
24 production of a product, process, or serv-

1 ices necessary to the development of coun-
2 termeasures;

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

7 “*(vii)* any combination of the purposes
8 described in clauses *(i)* through *(vi)*;

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

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

20 “(i) Exchanging information among
21 competitors relating to costs, sales, profit-
22 ability, prices, marketing, or distribution of
23 any product, process, or service if such in-
24 formation is not reasonably necessary to

1 carry out the purposes of covered activi-
2 ties.

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

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

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

22 “(iii) Entering into any agreement or
23 engaging in any other conduct allocating a
24 market with a competitor that is not ex-

1 expressly exempted from the antitrust laws
2 by a determination under subsection (i)(4).

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

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

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

1 “(4) DEVELOPMENT.—The term ‘development’
2 includes the identification of suitable compounds or
3 biological materials, the conduct of preclinical and
4 clinical studies, the preparation of an application for
5 marketing approval, and any other actions related to
6 preparation of a countermeasure.

7 “(5) PERSON.—The term ‘person’ has the
8 meaning given such term in subsection (a) of the
9 first section of this Act.

10 “(6) SECRETARY.—The term ‘Secretary’ means
11 the Secretary of Health and Human Services.”.

12 **TITLE VI—BIOSHIELD**
13 **IMMIGRATION PRIORITY**

14 **SEC. 601. H1B VISA EXEMPTION.**

15 Section 214(g) of the Immigration and Nationality
16 Act (8 U.S.C. 1184(g)) is amended by adding at the end
17 the following new paragraph:

18 “(9)(A) The numerical limitations contained in para-
19 graph (1)(A) shall not apply to any nonimmigrant alien
20 issued a visa or otherwise provided status under section
21 101(a)(15)(H)(i)(b) who—

22 “(i) is employed by a person that has entered
23 into a contract for procurement with the Secretary
24 of Health and Human Services under the authority
25 provided in section 319F–1 or 319F–2 of the Public

1 Health Service Act (42 U.S.C. 247d–6a and 247d–
2 6b) or with the Secretary of Homeland Security
3 under section 512 of the Homeland Security Act of
4 2002; and

5 “(ii) provides services related to the research,
6 development, or production of a qualified counter-
7 measure or a security countermeasure under such
8 contract.

9 “(B) In this paragraph:

10 “(i) The term ‘qualified countermeasure’ has
11 the meaning given that term in section 319F–1 of
12 the Public Health Service Act.

13 “(ii) The term ‘security countermeasure’ has
14 the meaning given that term in section 319F–2 of
15 the Public Health Service Act.”.

16 **SEC. 602. VISA PROCESSING.**

17 (a) REQUIREMENT TO EXPEDITE.—The Secretary of
18 Homeland Security and the Secretary of State shall expe-
19 dite the processing of an application of an alien seeking
20 a visa under section 101(a)(15)(H)(i)(b) of the Immigra-
21 tion and Nationality Act (8 U.S.C. 1101(a)(15)(H)(i)(b))
22 if such alien—

23 (1) is employed by a person that has entered
24 into a contract for procurement with the Secretary
25 of Health and Human Services under the authority

1 provided in section 319F–1 or 319F–2 of the Public
2 Health Service Act (42 U.S.C. 247d–6a and 247d–
3 6b) or with the Secretary of Homeland Security
4 under section 512 of the Homeland Security Act of
5 2002; and

6 (2) provides services related to the research, de-
7 velopment, or production of a qualified counter-
8 measure or a security countermeasure under such
9 contract.

10 (b) DEFINITIONS.—In this section:

11 (1) QUALIFIED COUNTERMEASURE.—The term
12 “qualified countermeasure” has the meaning given
13 that term in section 319F–1 of the Public Health
14 Service Act.

15 (2) SECURITY COUNTERMEASURE.—The term
16 “security countermeasure” has the meaning given
17 that term in section 319F–2 of the Public Health
18 Service Act.

19 **TITLE VII—BIOSHIELD EXPORT** 20 **PRIORITY**

21 **SEC. 701. SHORT TITLE.**

22 This title may be cited as the “Bioshield Export Pri-
23 ority Act”.

1 **SEC. 702. REQUIREMENT TO EXPEDITE EXPORT APPLICA-**
2 **TIONS.**

3 (a) IN GENERAL.—The Secretary of Commerce or
4 the Secretary of Health and Human Services, whichever
5 is applicable, shall expedite the processing of a request to
6 export a drug, medical device, diagnostic test, etiological
7 agent, biological product, or any item the export of which
8 is restricted pursuant to section 5 or 6 of the Export Ad-
9 ministration Act of 1979 (as in effect pursuant to the
10 International Emergency Economic Powers Act; 50 U.S.C.
11 1701 et seq.), if the export of that drug, medical device,
12 diagnostic test, etiological agent, biological product, or
13 other item is necessary to carry out a procurement con-
14 tract entered into by the Secretary of Health and Human
15 Services under the authority provided in section 319F–
16 1 or section 319F–2 of the Public Health Service Act (42
17 U.S.C. 247d–6a and 247d–6b), or by the Secretary of
18 Homeland Security under section 512 of the Homeland
19 Security Act of 2002, with respect to a qualified counter-
20 measure or security countermeasure under such contract.

21 (b) QUALIFIED AND SECURITY COUNTERMEASURES
22 DEFINED.—In this section:

23 (1) the term “qualified countermeasure” has
24 the meaning given that term in section 319F–1 of
25 the Public Health Service Act (42 U.S.C. 247d–6a);
26 and

1 (2) the term “security countermeasure” has the
2 meaning given that term in section 319F–2 of the
3 Public Health Service Act (42 U.S.C. 247d–6b).

4 **SEC. 703. PRESERVATION OF FOREIGN SALES MARKETS**
5 **FOR QUALIFIED AND SECURITY COUNTER-**
6 **MEASURES.**

7 Notwithstanding any other provision of law, no Fed-
8 eral agency shall sell, barter, trade, or transfer a qualified
9 countermeasure or a security countermeasure to a foreign
10 government, or to any other foreign entity or purchaser
11 outside the United States where an entity that has suc-
12 cessfully developed a countermeasure under this Act or the
13 Project BioShield Act of 2004 (Public Law 108–276) (and
14 the amendments made by such Acts) is able to sell, barter,
15 trade, or transfer such countermeasure to such foreign
16 government or entity, unless the President makes a deter-
17 mination that such sale, barter, trade, or transfer is nec-
18 essary for protecting the national security or national de-
19 fense of the United States.

1 **TITLE VIII—OFFICE OF PUBLIC**
2 **HEALTH COUNTERMEASURE**
3 **DEVELOPMENT**

4 **SEC. 801. OFFICE OF PUBLIC HEALTH COUNTERMEASURE**
5 **DEVELOPMENT.**

6 Section 2811(a) of the Public Health Service Act (42
7 U.S.C. 300hh–11(a)) is amended to read as follows:

8 “(a) ASSISTANT SECRETARY FOR PUBLIC HEALTH
9 COUNTERMEASURE DEVELOPMENT.—

10 “(1) IN GENERAL.—There is established within
11 the Department of Health and Human Services the
12 Office of Public Health Countermeasure Develop-
13 ment (referred to in this subsection as the ‘Office’).
14 Such Office shall be headed by an Assistant Sec-
15 retary for Public Health Countermeasure Develop-
16 ment, who shall be appointed by the President and
17 shall report to the Secretary.

18 “(2) DEPUTY DIRECTOR.—There is established
19 within the Department of Health and Human Serv-
20 ices the position of Deputy Director for Medical
21 Countermeasure Development.

22 “(3) DUTIES.—The Assistant Secretary for
23 Public Health Countermeasure Development shall
24 ensure that research supported by the Department
25 of Health and Human Services—

1 “(A) is consistent with the national pre-
2 paredness plan developed under section 2812
3 with respect to—

4 “(i) identifying priorities, goals, objec-
5 tives, and policies for identifying, devel-
6 oping, delivering, and evaluating medical
7 and other countermeasures to biological,
8 chemical, radiological, nuclear, and other
9 emerging natural and terrorists threats
10 and infectious diseases and research tools
11 and countermeasures should include con-
12 tainment and decontamination strategies
13 for human and animal remains; and

14 “(ii) coordinating the civilian efforts
15 of the Federal Government to identify and
16 rapidly develop such countermeasures; and

17 “(B) is conducted pursuant to a com-
18 prehensive, research-based strategy for—

19 “(i) the conduct of basic and applied
20 research;

21 “(ii) the development of the counter-
22 measures described under subparagraph
23 (A)(i); and

1 “(iii) the development of standards by
2 which the goals of such strategy may be
3 accomplished and evaluated.”.

4 **SEC. 802. BIOTERROR, CHEMICAL, NUCLEAR, RADIO-**
5 **LOGICAL, AND INFECTIOUS DISEASE COUN-**
6 **TERMEASURE DEVELOPMENT STRATEGY.**

7 Subtitle B of title XXVIII of the Public Health Serv-
8 ice Act (42 U.S.C. 300hh–11 et seq.) is amended by add-
9 ing at the end the following:

10 **“SEC. 2812. BIOTERROR, CHEMICAL, NUCLEAR, RADIO-**
11 **LOGICAL, AND INFECTIOUS DISEASE COUN-**
12 **TERMEASURE DEVELOPMENT STRATEGY.**

13 “(a) PLAN FOR COUNTERMEASURE RESEARCH.—

14 “(1) IN GENERAL.—The Secretary, in consulta-
15 tion with the Secretary of Defense and the Secretary
16 of Homeland Security, shall develop a comprehen-
17 sive, long-term plan for engaging State and local
18 public health officials, medical examiners, and other
19 non-Federal entities, including private for-profit en-
20 tities, in the research, development, production, de-
21 livery, and evaluation of countermeasures for biologi-
22 cal, chemical, radiological, and nuclear weapons and
23 infectious diseases.

24 “(2) CONTENTS.—The plan described under
25 paragraph (1) shall include a plan for the develop-

1 ment of countermeasures for exotic pathogens (in-
2 cluding vaccine resistant bacterial or viral strains,
3 antibiotic resistant organisms, genetically modified
4 organisms, hybrid organisms, synthetic organisms,
5 autoimmune peptides, antibiotic-induced toxins, eth-
6 nic and racial specific pathogens, and bioregulators
7 and biomodulators) and measures for containment
8 and safe handling of contaminated human and ani-
9 mal remains.

10 “(3) OTHER DUTIES.—The Secretary, in con-
11 sultation with the Secretary of Defense and the Sec-
12 retary of Homeland Security, shall—

13 “(A) develop a plan and strategy for en-
14 gaging pharmaceutical and biotechnology com-
15 panies, universities, small businesses, and non-
16 profit institutions, including entities that are
17 under-resourced and not able to advance beyond
18 preclinical development to clinical trials, in
19 order to create a multi-dimensional biodefense,
20 infectious disease, vaccine, and research tool in-
21 dustry; and

22 “(B) provide joint oversight of
23 translational development for biodefense drug
24 and vaccine candidates, as provided in section
25 319F-2(o).

1 “(4) COORDINATION; PURPOSE.—In developing
2 the plan described under paragraph (1), the Sec-
3 retary, in consultation with the Secretary of Defense
4 and the Secretary of Homeland Security, shall—

5 “(A) consult with—

6 “(i) other Federal agencies with ex-
7 pertise in research, development, and pro-
8 duction of the countermeasures described
9 under paragraph (1);

10 “(ii) private, for-profit entities, State
11 and local public health officials, medical
12 examiners, and entrepreneurs with exper-
13 tise and technology with respect to such
14 countermeasures, research tools, and the
15 systems for developing such research tools;

16 “(iii) investors that fund the entities
17 described under clause (ii);

18 “(iv) nonprofit research universities
19 and institutions;

20 “(v) professional organizations rep-
21 resenting infectious disease physicians and
22 scientists;

23 “(vi) local public health and hospital
24 organizations; and

1 “(vii) national and international
2 healthcare delivery and public health enti-
3 ties, and other interested private and pub-
4 lic entities;

5 “(B) evaluate proposals to ensure that—

6 “(i) Federal efforts assist and
7 incentivize private sector development of
8 systems to facilitate and expedite the de-
9 velopment and diffusion of research tools,
10 and research tool systems, to aid in the de-
11 velopment and deployment of counter-
12 measures;

13 “(ii) research and development of
14 such countermeasures by non-Federal enti-
15 ties is likely to yield countermeasures that
16 may be procured and deployed with respect
17 to the homeland security in the United
18 States and against an infectious diseases;

19 “(iii) ample investor capital is avail-
20 able to fund such research and develop-
21 ment, and non-Federal entities are not de-
22 pendent on grants from the Federal Gov-
23 ernment;

24 “(iv) the terms of procurement of
25 such countermeasures are defined in ad-

1 vance so that entities may accurately and
2 reliably assess—

3 “(I) the potential counter-
4 measures market;

5 “(II) the potential rate of return;

6 and

7 “(III) that the terms of the pro-
8 curement are comparable to the pro-
9 curement of other medicines and bio-
10 logical products from other markets;

11 “(v) appropriate intellectual property,
12 risk protection, and Government approval
13 standards are applicable to such counter-
14 measures;

15 “(vi) federally funded research is con-
16 ducted and prioritized to address the high-
17 est priority countermeasure detection tools
18 and transfer or license those technologies,
19 as appropriate, to non-Federal entities for
20 production; and

21 “(vii) universities, State and local gov-
22 ernment laboratories, and research institu-
23 tions play a vital role as partners in re-
24 search, development, and technology trans-
25 fer, with appropriate progress benchmarks

1 for such activities, with for-profit entities;
2 and

3 “(C) provide the private sector with suffi-
4 cient advance notice of the procurement prior-
5 ities of the Federal Government with respect to
6 countermeasures.

7 “(5) PLAN DETAILS.—

8 “(A) IN GENERAL.—The plan described
9 under paragraph (1) shall, on an annual
10 basis—

11 “(i) designate, in 5 year increments,
12 specific countermeasures for which con-
13 tracts under the Project BioShield Act of
14 2004 and the Project BioShield II Act of
15 2005 will be awarded;

16 “(ii) estimate the date on which re-
17 quest for proposals will be published;

18 “(iii) provide information regarding
19 the qualifications of the entities with which
20 it may enter into an agreement; and

21 “(iv) list the projected schedule for
22 the completion of the development of such
23 countermeasures.

24 “(B) DESIGNATION OF COUNTER-
25 MEASURES.—

1 “(i) IN GENERAL.—The plan de-
2 scribed in paragraph (1) shall, on an an-
3 nual basis, designate specific counter-
4 measures to be developed against terror
5 weapons or weapons of mass destruction.

6 “(ii) INFECTIOUS DISEASE COUNTER-
7 MEASURES IN THE UNITED STATES.—For
8 every 5 such countermeasures designated
9 under clause (i), not less than 2 additional
10 countermeasures shall be designated for
11 development against an infectious disease
12 that—

13 “(I) is not a terror weapon or
14 weapon of mass destruction; and

15 “(II) has or may have substantial
16 incidence in the United States.

17 “(iii) GLOBAL INFECTIOUS DISEASE
18 COUNTERMEASURES IN DEVELOPING
19 COUNTRIES.—For every 5 such counter-
20 measures designated under clause (i), not
21 less than 2 additional countermeasures
22 shall be designated for development
23 against an infectious disease that—

24 “(I) is not a terror weapon or
25 weapon of mass destruction; and

1 “(II) has or may have substantial
2 incidence largely in developing coun-
3 tries.

4 “(C) DESIGNATION OF RESEARCH TOOLS;
5 PURCHASE POOLS; ESTIMATION.—The plan de-
6 scribed in paragraph (1) shall—

7 “(i) designate research tools, includ-
8 ing research tool systems, to be developed;

9 “(ii) identify purchase pools with
10 which the Secretary shall seek to negotiate
11 for the development of countermeasures;
12 and

13 “(iii) estimate the amount of appro-
14 priations necessary to procure the develop-
15 ment of such countermeasures and re-
16 search tools.

17 “(D) PUBLIC AVAILABILITY.—The plan de-
18 scribed in paragraph (1) shall be published in
19 the Federal Register.

20 “(6) PERFORMANCE MEASURE SYSTEM.—

21 “(A) IN GENERAL.—Not later than 180
22 days after the development of the plan de-
23 scribed in paragraph (1), the Secretary shall
24 implement a performance measure system to
25 evaluate the progress toward the goals of the

1 Project BioShield II Act of 2005, which shall
2 include a list of clear, measurable benchmarks
3 by which progress may be evaluated, includ-
4 ing—

5 “(i) a list of threats for which coun-
6 termeasures are necessary;

7 “(ii) a list of research and research
8 tool systems necessary for the development
9 of countermeasures;

10 “(iii) systems to develop and deliver
11 countermeasures for at-risk populations;

12 “(iv) an annual accounting of the
13 number of outbreaks, including incidence
14 numbers and case fatality rates, in the
15 United States of influenza and other such
16 diseases that such Act addresses;

17 “(v) a list of any new threats that ei-
18 ther emerged from nature, or that were en-
19 gineered and released during the previous
20 year; and

21 “(vi) an accounting of the time that it
22 took to detect, analyze, and respond to any
23 instance of a threat.

24 “(B) EVALUATION.—Not later than 1 year
25 after the publication of the benchmarks de-

1 scribed in subparagraph (A), and on annual
2 basis thereafter, the Secretary shall publish and
3 submit to Congress an evaluation of the
4 progress made with respect to such benchmarks
5 during the preceding year.

6 “(7) SUBMISSION OF PLAN; REPORTING.—

7 “(A) SUBMISSION OF PLAN.—Not later
8 than 270 days after the date of enactment of
9 the Project BioShield II Act of 2005, the Sec-
10 retary shall submit to Congress the plan devel-
11 oped under paragraph (1) and recommenda-
12 tions for the enactment of supporting or ena-
13 bling legislation with respect to such plan. The
14 Secretary shall submit to Congress an updated
15 version of such plan and such recommendations
16 on an annual basis.

17 “(B) REPORTING.—The Secretary shall re-
18 port periodically to Congress on the status of
19 the countermeasure research, development, and
20 production of non-Federal entities, and submit
21 recommendations for legislation as determined
22 necessary by the Secretary.

23 “(b) ADVISORY COMMITTEE.—

24 “(1) ESTABLISHMENT OF COMMITTEE.—The
25 Secretary, in consultation with the Secretary of De-

1 fense and the Secretary of Homeland Security, shall
2 establish an advisory committee to be known as the
3 Public Health Countermeasure Development Advi-
4 sory Committee (referred to in this section as the
5 ‘Advisory Committee’).

6 “(2) DUTIES.—The Advisory Committee shall
7 advise the Secretary, the Secretary of Defense, and
8 the Secretary of Homeland Security with respect to
9 the establishment of a biodefense, an infectious dis-
10 ease, vaccine, and a research tool industry to supply
11 the Federal Government and other public entities
12 with the medical countermeasures necessary to pro-
13 tect the public from biological, chemical, radiological,
14 and nuclear attacks, or infectious diseases.

15 “(3) MEMBERSHIP.—The Secretary, Secretary
16 of Defense, and the Secretary of Homeland Security
17 shall appoint the members of the Advisory Com-
18 mittee, which shall be composed of—

19 “(A) representatives of the for-profit and
20 nonprofit research sectors, and State and local
21 governments, including representatives of the
22 small business industry and infectious disease
23 medical, research, biotechnology, and pharma-
24 ceutical communities; and

1 “(B) experts on the terms and impact of
2 the incentives provided under the Project Bio-
3 Shield Act of 2004 or the Project BioShield II
4 Act of 2005 (and the amendments made by
5 such Acts).

6 “(4) VACANCIES.—Any vacancy in the Advisory
7 Committee shall not affect its powers, but shall be
8 filled in the same manner as the original appoint-
9 ment.

10 “(5) MEETINGS.—The Advisory Committee
11 shall meet at the call of the co-chairpersons.

12 “(6) CO-CHAIRPERSONS.—The Secretary, the
13 Secretary of Defense, and the Secretary of Health
14 and Human Services shall serve as the co-chair-
15 persons of the Advisory Committee.

16 “(7) POWERS.—

17 “(A) HEARINGS.—The Advisory Com-
18 mittee may hold such hearings, sit and act at
19 such times and places, take such testimony, and
20 receive such evidence as the Advisory Com-
21 mittee considers advisable to carry out this sec-
22 tion.

23 “(B) INFORMATION FROM FEDERAL AGEN-
24 CIES.—

1 “(i) IN GENERAL.—The Advisory
2 Committee may secure directly from any
3 Federal department or agency such infor-
4 mation as the Advisory Committee con-
5 siders necessary to carry out the provisions
6 of this section. Upon request of the Advi-
7 sory Committee, the head of such depart-
8 ment or agency shall furnish such informa-
9 tion to the Advisory Committee.

10 “(ii) LIMITATION.—Nothing in this
11 subsection shall be construed to allow the
12 Advisory Committee to secure information
13 that is exempt from disclosure under sec-
14 tion 552 of title 5, United States Code
15 (commonly referred to as the Freedom of
16 Information Act).

17 “(C) POSTAL SERVICES.—The Advisory
18 Committee may use the United States mails in
19 the same manner and under the same condi-
20 tions as other departments and agencies of the
21 Federal Government.

22 “(8) PERSONNEL.—

23 “(A) TRAVEL EXPENSES.—The members
24 of the Advisory Committee shall not receive
25 compensation for the performance of services

1 for the Advisory Committee, but shall be al-
2 lowed travel expenses, including per diem in lieu
3 of subsistence, at rates authorized for employ-
4 ees of agencies under subchapter I of chapter
5 57 of title 5, United States Code, while away
6 from their homes or regular places of business
7 in the performance of services for the Advisory
8 Committee. Notwithstanding section 1342 of
9 title 31, United States Code, the Secretary may
10 accept the voluntary and uncompensated serv-
11 ices of members of the Advisory Committee.

12 “(B) DETAIL OF GOVERNMENT EMPLOY-
13 EES.—Any Federal Government employee may
14 be detailed to the Advisory Committee without
15 reimbursement, and such detail shall be without
16 interruption or loss of civil service status or
17 privilege.”.

1 **TITLE IX—OFFICE OF MEDICAL**
2 **READINESS AND RESPONSE**
3 **OF THE DEPARTMENT OF**
4 **HOMELAND SECURITY**

5 **SEC. 901. OFFICE OF MEDICAL READINESS AND RESPONSE**
6 **OF THE DEPARTMENT OF HOMELAND SECUR-**
7 **RITY.**

8 (a) IN GENERAL.—Title VIII of the Homeland Secu-
9 rity Act of 2002 (6 U.S.C. 361 et seq.) is amended by
10 inserting after section 879 the following:

11 **“SEC. 879A. OFFICE OF MEDICAL READINESS AND RE-**
12 **SPONSE.**

13 “(a) ESTABLISHMENT.—There is established within
14 the Office of the Secretary an Office of Medical Readiness
15 and Response.

16 “(b) ASSISTANT SECRETARY.—The Office estab-
17 lished under subsection (a) shall be headed by an Assist-
18 ant Secretary for Medical Readiness and Response, who
19 shall be appointed by the President by and with the advice
20 and consent of the Senate.

21 “(c) DUTIES OF THE ASSISTANT SECRETARY.—The
22 Assistant Secretary for Medical Readiness and Response
23 shall—

1 “(1) serve as the principal advisor to the Sec-
2 retary on all matters related to emergency medical
3 preparedness and response;

4 “(2) develop Federal strategy, training (includ-
5 ing exercises), coordination, funding, and implemen-
6 tation of emergency medical response to mass cas-
7 ualty events for Federal, State, and local public
8 health agencies and private sector entities in support
9 of homeland security;

10 “(3) serve as the primary Federal official with
11 respect to overseeing the identification and develop-
12 ment, in consultation with nonprofit health and pub-
13 lic health departments and medical centers, of med-
14 ical preparedness centers and deployable medical
15 care units designed to meet the demands of a ter-
16 rorist event or other incident requiring mass cas-
17 ualty care and containment of infectious disease;

18 “(4) serve as the primary official of the Depart-
19 ment relating to and overseeing medical emer-
20 gencies, including emergencies incident to a terrorist
21 attack or naturally occurring infectious disease out-
22 break;

23 “(5) in coordination with the Secretary of
24 Health and Human Services, have the authority to

1 deploy the Strategic National Stockpile and the
2 Commissioned Corps of the Public Health Service;

3 “(6) report directly to the Secretary; and

4 “(7) evaluate and report to Congress on the
5 preparedness of Federal, State, and local agencies to
6 respond to major medical disaster.

7 “(d) FUNCTIONS.—There shall be transferred to the
8 Office of Medical Readiness and Response the following
9 functions, personnel, assets, and liabilities of the following:

10 “(1) The National Disaster Medical System
11 (transferred to the Department pursuant to section
12 503(5)).

13 “(2) The Metropolitan Medical Response Sys-
14 tem (transferred to the Department pursuant to sec-
15 tion 503(5)).

16 “(3) The emergency medical response functions
17 of the Office of Emergency Preparedness (trans-
18 ferred to the Department pursuant to section
19 503(5)).

20 “(4) Other resources and offices of the Depart-
21 ment as designated by the Secretary.”

22 (b) CONFORMING AMENDMENTS.—Section 502(3) of
23 the Homeland Security Act of 2002 (6 U.S.C. 312(3)) is
24 amended—

25 (1) in subparagraph (B)—

1 (A) by striking “, the National Disaster
2 Medical System,”; and

3 (B) by striking the semicolon and inserting
4 “; and”;

5 (2) by striking subparagraph (C); and

6 (3) by redesignating subparagraph (D) as sub-
7 paragraph (C).

8 **TITLE X—NATIONAL EMER-**
9 **GENCY MEDICAL READINESS**
10 **AND RESPONSE BOARD**

11 **SEC. 1001. NATIONAL EMERGENCY MEDICAL READINESS**
12 **AND RESPONSE BOARD.**

13 (a) IN GENERAL.—Title VIII of the Homeland Secu-
14 rity Act of 2002 (6 U.S.C. 361 et seq.), as amended by
15 section 901, is further amended by inserting after section
16 879A (as added by section 901) the following:

17 **“SEC. 879B. NATIONAL EMERGENCY MEDICAL READINESS**
18 **AND RESPONSE BOARD.**

19 “(a) ESTABLISHMENT OF BOARD.—

20 “(1) IN GENERAL.—There is established in the
21 Department the National Emergency Medical Read-
22 iness and Response Board (referred to in this section
23 as the ‘Board’).

1 “(2) CHAIRPERSON.—The Assistant Secretary
2 for Medical Readiness and Response shall serve as
3 the chairperson of the Board.

4 “(3) COMPOSITION.—The Board shall be com-
5 posed of the following members (or their designees):

6 “(A) The Assistant Secretary for Medical
7 Readiness and Response.

8 “(B) The United States Surgeon General.

9 “(C) The Assistant Secretary for Public
10 Health Countermeasure Development.

11 “(D) The Director of the National Insti-
12 tutes of Health.

13 “(E) The Director of the Centers for Dis-
14 ease Control and Prevention.

15 “(F) The Director of National Bioter-
16 rorism and Hospital Readiness of the Health
17 Resources and Services Administration.

18 “(G) The Deputy Assistant to the Sec-
19 retary of Defense for Chemical and Biological
20 Defense.

21 “(H) The Commanding General, Army
22 Medical Research and Materiel Command.

23 “(I) The Assistant Secretary for Health of
24 the Department of Veterans Affairs.

1 “(J) The Deputy Commander, United
2 States Northern Command.

3 “(K) The Commissioner of Food and
4 Drugs.

5 “(L) The Secretary of Agriculture.

6 “(M) The Postmaster General.

7 “(N) Any other individual appointed by the
8 President to the Board.

9 “(4) MEETINGS.—The Board shall meet at the
10 call of the chairperson.

11 “(b) DUTIES AND POWERS.—

12 “(1) DUTIES.—The Board shall oversee the fol-
13 lowing activities:

14 “(A) The development, assessment, and
15 validation of national, interagency, emergency
16 medical response plans, in coordination with
17 State and local public health officials, for bio-
18 terrorism (including agroterrorism), chemical
19 attack, radiological attack, nuclear attack, in-
20 fectionous disease, and high explosives attack.

21 “(B) In cooperation with State and local
22 public health agencies, the development, testing,
23 and implementation of a plan for the necessary
24 training related to, and the assessment and

1 evaluation of, the Federal emergency medical
2 response plans described in subparagraph (A).

3 “(C) The coordination of the Federal
4 emergency medical response plans described in
5 subparagraph (A) among all the Federal de-
6 partments and agencies represented on the
7 Board through joint exercises that shall be ob-
8 served and evaluated by the members of the
9 Board (or their designees).

10 “(D) Defining, and determining when and
11 how to implement, national level emergency
12 medical response plans to medical disasters.

13 “(2) POWERS.—The Board may secure directly
14 from any Federal department or agency such infor-
15 mation as the Board considers necessary to carry
16 out this subsection. Upon request of the chairperson
17 of the Board, the head of such department or agency
18 shall furnish such information to the Board.

19 “(c) BOARD PERSONNEL MATTERS.—

20 “(1) DETAIL OF GOVERNMENT EMPLOYEES.—
21 Any Federal Government employee may be detailed
22 to the Board without reimbursement, and such de-
23 tail shall be without interruption or loss of civil serv-
24 ice status or privilege.

1 “(2) PROCUREMENT OF TEMPORARY AND
2 INTERMITTENT SERVICES.—The chairperson of the
3 Board may procure temporary and intermittent serv-
4 ices under section 3109(b) of title 5, United States
5 Code, at rates for individuals which do not exceed
6 the daily equivalent of the annual rate of basic pay
7 prescribed for level V of the Executive Schedule
8 under section 5316 of such title.

9 “(d) ADVISORY COMMITTEE.—

10 “(1) ESTABLISHMENT.—Not later than 180
11 days after the date of enactment of the Project Bio-
12 Shield II Act of 2005, the Assistant Secretary for
13 Medical Readiness and Response shall establish an
14 advisory committee that shall provide assistance and
15 oversight to the Board and to the Assistant Sec-
16 retary for Medical Readiness and Response.

17 “(2) COMPOSITION.—The advisory committee
18 established pursuant to paragraph (1) shall consist
19 of representatives, appointed by the Assistant Sec-
20 retary for Medical Readiness and Response, of—

21 “(A) designees of State and local public
22 health and emergency management agencies;

23 “(B) State and local emergency managers
24 or adjutant generals and State emergency med-
25 ical services directors;

- 1 “(C) physicians and first responders (in-
- 2 cluding nurses, police, and paramedics);
- 3 “(D) academic medical research institu-
- 4 tions;
- 5 “(E) the World Health Organization;
- 6 “(F) the International Committee of the
- 7 Red Cross;
- 8 “(G) the International Federation of Red
- 9 Cross and Red Crescent Societies;
- 10 “(H) the American Red Cross;
- 11 “(I) the Infectious Disease Society of
- 12 America;
- 13 “(J) professional medical and clinical soci-
- 14 eties, as appropriate;
- 15 “(K) local hospitals and hospital districts;
- 16 “(L) medical care delivery facilities (hos-
- 17 pital outpatient centers);
- 18 “(M) pharmacies;
- 19 “(N) accredited schools of public health;
- 20 “(O) pathologists, coroners, and chief med-
- 21 ical examiners; and
- 22 “(P) other individuals and representatives
- 23 of entities appointed by the Assistant Secretary
- 24 for Medical Readiness and Response to the ad-
- 25 visory committee.”.

1 (b) CONFORMING AMENDMENTS.—The table of con-
 2 tents in section 1(b) of the Homeland Security Act of
 3 2002 (6 U.S.C. 101 note) is amended by—

4 (1) inserting after the item relating to section
 5 511 the following:

“Sec. 510. Countermeasure Purchase Fund at the Department of Homeland
 Security.”;

6 and

7 (2) inserting after the item relating to section
 8 879 the following:

“Sec. 879A. Office of Medical Readiness and Response.

“Sec. 879B. National Emergency Medical Readiness and Response Board.”.

9 **TITLE XI—ENCOURAGING**
 10 **GREATER COORDINATION**
 11 **WITH FORMER SOVIET SCI-**
 12 **ENTISTS AND TRANSFER OF**
 13 **COUNTERMEASURES**

14 **SEC. 1101. PURPOSE; REPORT TO CONGRESS.**

15 (a) PURPOSE.—The purpose of this section is to di-
 16 rect the Department of State and the Department of Com-
 17 merce to develop and implement a program to secure the
 18 access to, and transfer of, compounds, culture collections,
 19 devices, scientific methods, and research tools to the
 20 United States to further the protection of the United
 21 States and its allies against biological, chemical, nuclear,
 22 and radiological agents or infectious diseases. Such an ef-

1 fort must address the state of intellectual property of such
2 items and ensure the security of such intellectual property
3 to allow for and encourage commercialization.

4 (b) REPORT.—

5 (1) IN GENERAL.—Not later than 180 days
6 after the date of enactment of the Project BioShield
7 II Act of 2005, the Secretary of State, in coopera-
8 tion with the Secretary of Homeland Security and
9 Secretary of Commerce, shall report to the Com-
10 mittee on Foreign Relations of the Senate and the
11 Committee on International Relations of the House
12 of Representatives on the existence and adequacy of
13 all United States Government-sponsored programs
14 or organizations responsible for encouraging com-
15 mercialization of countermeasures developed by
16 former-Soviet scientists and current scientists work-
17 ing within the Commonwealth of Independent States
18 (referred to in this section as “CIS”).

19 (2) CONTENT OF REPORT.—The report de-
20 scribed under paragraph (1) shall identify any
21 known legal prohibitions and practical challenges in
22 the United States or CIS to the purposes of this sec-
23 tion, including laws governing intellectual property,
24 export controls, and classification of information re-
25 stricting or inhibiting private-sector exchange and

1 development of such countermeasures. The Secretary
 2 of State shall provide such information as the Sec-
 3 retary determines to be necessary to enable such po-
 4 tential commercialization and cooperation.

5 **TITLE XII—EMERGENCY CON-**
 6 **TINUITY OF NATIONAL**
 7 **HEALTHCARE; REIMBURSE-**
 8 **MENT OF INFECTIOUS DIS-**
 9 **EASE PHYSICIANS FOR COM-**
 10 **MUNITY EMERGENCY PRE-**
 11 **PAREDNESS ACTIVITIES;**
 12 **MEDICAL LICENSE RECI-**
 13 **PROCITY**

14 **SEC. 1201. CONTINUITY OF NATIONAL HEALTHCARE SYS-**
 15 **TEM IN AN EMERGENCY.**

16 Section 319 of the Public Health Service Act (42
 17 U.S.C. 247d) is amended by adding at the end the fol-
 18 lowing:

19 “(e) CONTINUITY OF NATIONAL HEALTHCARE SYS-
 20 TEM IN AN EMERGENCY.—

21 “(1) EMERGENCY HEALTH INSURANCE REIM-
 22 BURSEMENT.—In the event of a public health emer-
 23 gency determined pursuant to subsection (a), the
 24 Secretary may guarantee reimbursement to public
 25 and private healthcare providers (which shall include

1 nurses and non-clinical staff) for care related to the
2 public health emergency provided to individuals by
3 such providers to the extent that the public or pri-
4 vate health insurance reimbursement (as the case
5 may be) to such providers is not applicable because
6 of war or terrorism coverage exclusions at one of the
7 following rates:

8 “(A) The applicable rates under the Medi-
9 care and Medicaid programs.

10 “(B) A per diem rate determined by the
11 Secretary.

12 “(2) GUARANTEE OF PAYMENTS.—During a
13 closure of the United States mails due to a public
14 health emergency determined pursuant to subsection
15 (a), the Secretary may provide a guarantee of pay-
16 ment to private healthcare providers to enable such
17 providers to maintain services and continuity in re-
18 sponse to such emergency.”.

19 **SEC. 1202. REIMBURSEMENT OF INFECTIOUS DISEASE PHY-**
20 **SICIANS FOR COMMUNITY EMERGENCY PRE-**
21 **PAREDNESS ACTIVITIES.**

22 Section 319 of the Public Health Service Act (as
23 amended by section 1201) is further amended by adding
24 at the end the following:

1 “(f) REIMBURSEMENT OF INFECTIOUS DISEASE
2 PHYSICIANS FOR COMMUNITY EMERGENCY PREPARED-
3 NESS ACTIVITIES.—The Secretary shall reimburse board-
4 certified infectious disease and public health specialists for
5 services provided during a public health emergency under
6 subsection (a) at applicable rates under the Medicare pro-
7 gram, to the extent that such services are not otherwise
8 wholly reimbursed by other public or private insurance.”.

9 **SEC. 1203. MEDICAL LICENSE RECIPROCITY.**

10 Section 319 of the Public Health Service Act (42
11 U.S.C. 247d) (as amended by section 1202) is further
12 amended by adding at the end the following:

13 “(g) MEDICAL LICENSE RECIPROCITY.—The Sec-
14 retary may issue regulations requiring the establishment
15 of reciprocity of medical licensing and certification be-
16 tween or among States during a national or local public
17 health emergency determined pursuant to subsection (a).

18 “(h) MINIMUM STANDARDS.—Medical licensing for
19 the purposes of subsection (g) shall include the licensing
20 of allopathic and osteopathic physicians, registered nurses,
21 nurse practitioners, physician assistants, pharmacists,
22 paramedics, respiratory therapists, and other first re-
23 sponders or allied health professionals.

24 “(i) PSA.—The Secretary may issue regulations re-
25 quiring or providing appropriate liability and workman’s

1 compensation coverage for healthcare professionals and
 2 others responding to a public health emergency, as deter-
 3 mined under subsection (a).”.

4 **SEC. 1204. LIABILITY PROTECTION FOR HEALTHCARE VOL-**
 5 **UNTEERS AND HOSPITALS.**

6 Part B of title III of the Public Health Service Act
 7 (42 U.S.C. 243 et seq.) (as amended by sections 202,
 8 1402, 1631, 1901, 2101, 2102, and 1631) is amended by
 9 inserting after section 319F–9 (as added by section 203)
 10 the following:

11 **“SEC. 319F–10. LIABILITY PROTECTION FOR HEALTHCARE**
 12 **VOLUNTEERS AND HOSPITALS LITIGATION**
 13 **MANAGEMENT.**

14 “(a) FEDERAL CAUSE OF ACTION.—

15 “(1) IN GENERAL.—There shall exist an exclu-
 16 sive Federal cause of action for claims arising out
 17 of, related to, or resulting from care delivered by any
 18 person or entity at any location in the United States
 19 if the governor of that State has declared a state of
 20 emergency, or the Secretary of Health and Human
 21 Services declares that a public health emergency is
 22 in effect in that State, or the President signs a dis-
 23 aster declaration for that State. Such Federal cause
 24 of action shall be brought in the United States dis-
 25 trict court for the District of Columbia and shall be

1 only for injuries that are caused by willful or wanton
2 misconduct.

3 “(2) LIMITATIONS.—Healthcare personnel, vol-
4 unteers, and other workers providing emergency
5 medical or triage care in field settings, alternative
6 treatment facilities, and in vaccination or medication
7 distribution settings shall be immune from claim for
8 loss of property (including business interruption or
9 other types of indirect losses), personal injury, or
10 death.

11 “(b) SPECIAL RULES.—

12 “(1) IN GENERAL.—When a hospital is pro-
13 viding care under emergency conditions as described
14 in this section and such care is not administered for
15 or in expectation of compensation, then the max-
16 imum liability to the Federal Government on behalf
17 of the hospital (or its employees, volunteers, officers,
18 and directors) is \$250,000 for each claimant.

19 “(2) PUNITIVE DAMAGES.—No punitive dam-
20 ages intended to punish or deter, exemplary dam-
21 ages, or other damages not intended to compensate
22 a plaintiff for actual medical expenses or lost wages
23 may be awarded in an action under this section, nor
24 shall any party in such action be liable for interest
25 prior to the judgment.

1 “(3) NONECONOMIC DAMAGES.—No non-
2 economic damages may be awarded for claims under
3 this section.

4 “(4) LIMITATIONS.—Hospitals and other health
5 care organizations shall be immune from vicarious li-
6 ability for the actions of volunteers providing care
7 under emergency conditions described in this section,
8 even if the hospital or health care organization is
9 considered the employer for worker’ compensation
10 purposes.

11 “(5) ATTORNEY FEES.—Attorney fees in an ac-
12 tion under this section shall be calculated on a rea-
13 sonable amount of work performed on behalf of the
14 plaintiff.”.

15 **TITLE XIII—ADEQUACY OF**
16 **EMERGENCY MEDICAL RE-**
17 **SPONSE ASSETS FOR HOME-**
18 **LAND SECURITY MISSIONS**

19 **SEC. 1301. ADEQUACY OF EMERGENCY MEDICAL RESPONSE**
20 **ASSETS FOR HOMELAND SECURITY MIS-**
21 **SIONS.**

22 (a) STUDY.—The Assistant Secretary for Medical
23 Readiness and Response of the Department of Homeland
24 Security shall perform a study and prepare a report as-
25 sessing the state of medical and health readiness and re-

1 sponse capability to respond to large-scale medical emer-
2 gencies, such as terrorist actions. The study will evaluate
3 the following aspects of medical and health readiness and
4 response:

5 (1) The nature and extent of emergency med-
6 ical and health resources needed to respond to and
7 mitigate a biological, chemical, radiological, or nu-
8 clear attack or an infectious disease outbreak.

9 (2) The assets and resources currently available
10 from the Federal, State, and local governments, pri-
11 vate sector entities, industry, hospitals, and aca-
12 demia to meet the homeland security mission.

13 (3) The deficiencies in assets and resources
14 needed to respond to such an attack or outbreak.

15 (4) Recommendations regarding the types and
16 extent of assets and resources needed to be secured
17 to respond to such an attack or outbreak, including
18 those requested from State and local public health
19 agencies and their volunteer responders.

20 (b) CONTENT.—The report described in subsection
21 (a) shall assess and make recommendations with regard
22 to—

23 (1) the appropriate roles and responsibilities in
24 responding to a medical emergency of—

25 (A) full-time government employees;

1 (B) part-time personnel; and

2 (C) volunteer personnel;

3 (2) the appropriate skills and skilled workers
4 needed, including physicians (including infectious
5 diseases specialists), other health care personnel,
6 and first responders;

7 (3) the appropriate planning and training need-
8 ed prior to an attack or outbreak;

9 (4) the appropriate contingency plans for re-
10 sponding to a novel or catastrophic incident; and

11 (5) mechanisms to—

12 (A) develop and pilot test strategies to be
13 used to reduce disease transmission in a bioter-
14 rorism incident, a public health emergency, or
15 an epidemic or pandemic;

16 (B) develop and validate meaningful na-
17 tional standards for Federal, State, and local
18 public health agencies and for nongovernmental
19 healthcare delivery institutions in preparedness
20 for and response to epidemics, pandemics, and
21 mass casualty incidents;

22 (C) test these methods in State, local, and
23 multi-State proof-of-concept tests; and

1 (D) develop public risk communication
2 tools that support the widespread use of such
3 activities.

4 (c) CONSULTATION.—In preparing this report, the
5 Assistant Secretary for Medical Readiness and Response
6 of the Department of Homeland Security shall consult
7 with the members of the National Emergency Prepared-
8 ness and Response Board.

9 (d) SUBMISSION DATE.—The report shall be sub-
10 mitted to Congress not later than 1 year after the date
11 of enactment of this Act.

12 **TITLE XIV—CONSTRUCTION OF**
13 **SPECIALIZED RESEARCH FA-**
14 **CILITIES FOR THE DEVELOP-**
15 **MENT OF COUNTER-**
16 **MEASURES**

17 **SEC. 1401. CONSTRUCTION OF SPECIALIZED RESEARCH FA-**
18 **CILITIES FOR THE DEVELOPMENT OF COUN-**
19 **TERMEASURES.**

20 (a) IN GENERAL.—Part B of title III of the Public
21 Health Service Act (42 U.S.C. 243 et seq.) (as amended
22 by sections 202, 1901, 2101, and 2102) is amended by
23 inserting after section 319F–6 (as added by section 2102)
24 the following:

1 **“SEC. 319F-7. CONSTRUCTION OF BIOSAFETY LEVEL 3-4 RE-**
2 **SEARCH FACILITIES.**

3 “(a) FINDINGS.—Congress finds that—

4 “(1) research to develop countermeasures re-
5 quires the use of special facilities where biological
6 and chemical agents can be handled safely both for
7 laboratory research and efficacy testing in animal
8 models;

9 “(2) very few companies and very few State and
10 local public health laboratories have sufficient funds
11 for the construction of these special facilities; and

12 “(3) the Federal Government can facilitate re-
13 search and development of countermeasures by fi-
14 nancing the construction of these special facilities.

15 “(b) GRANTS AUTHORIZED.—

16 “(1) IN GENERAL.—The Secretary is authorized
17 to award grants and contracts to grantees to con-
18 struct, maintain, and manage (including funding for
19 staff and staff training) biosafety level 3-4 facilities.

20 “(2) REQUIREMENTS.—To be eligible for a
21 grant under paragraph (1) an entity shall—

22 “(A) allow use of the facility involved by
23 only those researchers who meet qualifications
24 set by the Secretary;

25 “(B) give priority for the use of the facility
26 involved to those entities that have been reg-

1 istered and certified by the Secretary to develop
2 countermeasures; and

3 “(C) allow the National Institutes of
4 Health and the Centers for Disease Control and
5 Prevention to inspect the facility involved at
6 any time.

7 “(3) NUMBER OF GRANTS.—The Secretary of
8 Homeland Security shall determine the number of
9 facilities that need to be constructed under this sec-
10 tion, not to exceed 10 such facilities nationwide, and
11 the Secretary shall award grants based on such de-
12 termination.

13 “(c) APPLICATION.—

14 “(1) IN GENERAL.—To be eligible to receive a
15 grant under this section, an entity shall submit to
16 the Secretary an application at such time, in such
17 form, and containing such information as the Sec-
18 retary may require.

19 “(2) CONTENTS.—Each application submitted
20 pursuant to paragraph (1) shall—

21 “(A) provide detailed information on the
22 technical specifications of proposed facilities;

23 “(B) propose a design that includes offices
24 for personnel, visiting researchers, and facilities
25 for research and laboratory materials; and

1 “(C) provide assurances that—

2 “(i) the facilities shall be available on
3 a fee-for-service or other basis to compa-
4 nies and academic researchers;

5 “(ii) such services offered to compa-
6 nies and academic researchers shall include
7 testing and validation studies for all types
8 of countermeasures, including detection
9 technology;

10 “(iii) such facilities shall utilize the
11 research tools identified by the Secretary
12 in section 319F–3 of this Act or certified
13 under section 301(b)(4) of the Project Bio-
14 Shield II Act of 2005; and

15 “(iv) that the facilities will be con-
16 structed as secure facilities.

17 “(d) DEFINITIONS.—For the purposes of this sec-
18 tion—

19 “(1) unless otherwise specifically identified, the
20 term ‘Director’ means the Director of the National
21 Institutes of Health;

22 “(2) the term ‘biosafety level 3 facility’ means
23 a facility described in section 627.15 of title 32,
24 Code of Federal Regulations (or any successor regu-
25 lation); and

1 “(3) the term ‘biosafety level 4 facility’ means
2 a facility described in section 627.16 of title 32,
3 Code of Federal Regulation (or any successor regu-
4 lation).

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

8 (b) NEEDS ASSESSMENT.—The Secretary of Health
9 and Human Services shall conduct a study of regional and
10 national laboratory capacities with respect to the labora-
11 tories described in section 319F–7 of the Public Health
12 Service Act (as added by this title) before implementing
13 such section.

14 **TITLE XV—BIODEFENSE AND IN-**
15 **FECTIONOUS DISEASE RE-**
16 **SEARCH AND SCIENTIFIC AND**
17 **TECHNICAL PERSONNEL**

18 **SEC. 1501. ESTABLISHMENT OF GRANT PROGRAM.**

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

22 **“SEC. 409J. GRANTS FOR BIODEFENSE AND INFECTIOUS**
23 **DISEASE RESEARCH.**

24 “(a) IN GENERAL.—The Director of the Centers for
25 Disease Control and Prevention (referred in this section

1 as the ‘Director’), in consultation with the Assistant Sec-
2 retary for Medical Readiness and Response of the Depart-
3 ment of Homeland Security, and the Secretary of Defense
4 shall establish a program to award grants and scholar-
5 ships to eligible entities to ensure that sufficient scientific
6 and technical personnel are available to conduct biodefense
7 and infectious disease research.

8 “(b) ELIGIBILITY.—To be eligible to receive a grant
9 or scholarship under subsection (a), an entity shall—

10 “(1) be—

11 “(A) an individual who desires to acquire
12 a scientific or technical skill identified and list-
13 ed by the Director under subsection (c)(1)(A);

14 or

15 “(B) a facility or institution that is des-
16 igned as a scientific or technical skills facility
17 under subsection (c)(1)(B); and

18 “(2) submit to the Director an application, at
19 such time, in such manner, and containing such in-
20 formation as the Director may require.

21 “(c) IDENTIFICATION OF SCIENTIFIC AND TECH-
22 NICAL SKILLS SHORTAGES.—

23 “(1) ASSESSMENT AND DESIGNATION.—

24 “(A) IN GENERAL.—Not later than 1 year
25 after the date of enactment of this section, and

1 annually thereafter, the Director shall, for pur-
2 poses of this section, assess the science and
3 technical skills that are needed for the develop-
4 ment of medical countermeasures to biological,
5 chemical, nuclear, radiological, and other
6 emerging natural and terrorists threats and in-
7 fectionous diseases, including the expertise needed
8 concerning the identification of drugs, detection
9 equipment, diagnostics, and research tools with
10 respect to such countermeasures. Upon comple-
11 tion of such assessment, the Director shall pub-
12 lish a list of the scientific and technical skills so
13 identified and for which there exists a shortage
14 of qualified individuals.

15 “(B) FACILITIES.—Not later than 1 year
16 after the date of enactment of this section, and
17 annually thereafter, the Director shall designate
18 public or nonprofit private facilities or institu-
19 tions that the Director determines provides edu-
20 cation or training with respect to a scientific or
21 technical skill identified and published on the
22 list under subparagraph (A).

23 “(2) LIMITATION ON REMOVAL FROM LIST OR
24 DESIGNATION.—The Director shall not remove a
25 skill from the list under paragraph (1)(A) or a des-

1 ignation with respect to a facility or institution
2 under paragraph (1)(B) unless the Director has af-
3 forded interested persons and groups an opportunity
4 to provide data and information in support of the
5 listing or designation involved, and has made a de-
6 termination on the basis of the data and information
7 submitted by such persons and groups and other
8 data and information available to the Director.

9 “(3) CRITERIA.—The Director shall establish
10 by regulation criteria for the listing of skills or des-
11 ignation of facilities and institutions under para-
12 graph (1).

13 “(4) NOTICE.—The Director shall give written
14 notice of the listing of a skill or designation of a fa-
15 cility or institution not later than 60 days from the
16 date of such designation, to—

17 “(A) the Governor of each State and offi-
18 cial of each local city or town in which the facil-
19 ity or institution so designated is in whole or
20 part located; and

21 “(B) appropriate public or nonprofit pri-
22 vate entities which provide education or train-
23 ing in the skills so listed.

24 “(5) RECOMMENDED DESIGNATION.—Any per-
25 son may recommend to the Director the listing or a

1 skill or designation of a facility or other institution
2 under paragraph (1).

3 “(6) DISSEMINATION OF CRITERIA.—The Di-
4 rector shall disseminate information concerning the
5 criteria described in paragraph (3) to—

6 “(A) the Governor of each State;

7 “(B) the representative of any facility se-
8 lected by any such Governor to receive such in-
9 formation;

10 “(C) the representative of any facility that
11 requests such information; and

12 “(D) the representative of any facility de-
13 termined by the Director to be likely to meet
14 such criteria.

15 “(d) USE OF FUNDS.—

16 “(1) SCHOLARSHIPS.—

17 “(A) IN GENERAL.—Amounts provided to
18 an individual under a scholarship under sub-
19 section (a) shall be used to obtain education
20 leading to a degree or postdoctoral training at
21 a nonprofit institution determined appropriate
22 by the Secretary to further the development of
23 medical countermeasures to biological, chemical,
24 nuclear, radiological, and other emerging terror-
25 ists threats and infectious diseases, including

1 the expertise needed concerning the identifica-
2 tion and development of drugs, detection equip-
3 ment, human and animal remains handling and
4 containment equipment and methods,
5 diagnostics, and research tools with respect to
6 such countermeasures.

7 “(B) AGREEMENT TO SERVE.—To be eligi-
8 ble to receive a scholarship described in sub-
9 paragraph (A), an individual shall agree to
10 enter into contract with the Director for obli-
11 gated service as provided for in subparagraph
12 (C).

13 “(C) OBLIGATED SERVICE.—An individual
14 who has entered into a written contract with
15 the Director under subparagraph (B) shall con-
16 duct countermeasures research on a full-time
17 basis in an area determined appropriate by the
18 Director for the period of obligated service pro-
19 vided for in such contract.

20 “(D) PERIOD OF SERVICE.—The period of
21 obligated service under a contract under sub-
22 paragraph (B) shall be equal to the greater
23 of—

1 “(i) 1 year for each school year for
2 which the individual was provided a schol-
3 arship under subsection (a); or

4 “(ii) 2 years.

5 “(E) BREACH OF CONTRACT.—The provi-
6 sions of section 338E shall apply to a breach of
7 contract under this paragraph to the same ex-
8 tent that such provisions apply to a breach of
9 a scholarship contract under such section.

10 “(2) TRANSITION TO WORKFORCE.—The Direc-
11 tor is authorized to provide assistance to Federal
12 agencies to incorporate the individuals who receive a
13 grant under this section into the Federal workforce,
14 including non-tenured positions that could transition
15 into permanent positions at the end of the payback
16 period.

17 “(3) GRANTS.—Amounts awarded under a
18 grant under subsection (a) shall be used for activi-
19 ties that facilitate the conduct of countermeasures
20 research.

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

1 **TITLE XVI—NATIONAL**
 2 **INSTITUTES OF HEALTH**
 3 **Subtitle A—National Center for**
 4 **Healthcare Technology Develop-**
 5 **ment**

6 **SEC. 1601. PURPOSE.**

7 The purpose of this subtitle is to enhance the licens-
 8 ing of research, and protect the value of intellectual prop-
 9 erty, funded by the National Institutes of Health to com-
 10 panies to develop healthcare technologies for the benefit
 11 of patients.

12 **SEC. 1602. NATIONAL CENTER FOR HEALTHCARE TECH-**
 13 **NOLOGY DEVELOPMENT.**

14 (a) IN GENERAL.—Part E of title IV of the Public
 15 Health Service Act (42 U.S.C. 287 et seq.) is amended
 16 by adding at the end the following:

17 “SUBPART 7—NATIONAL CENTER FOR HEALTHCARE
 18 TECHNOLOGY DEVELOPMENT

19 **“SEC. 485K. NATIONAL CENTER FOR HEALTH CARE TECH-**
 20 **NOLOGY DEVELOPMENT.**

21 “(a) DEFINITION.—In this subpart, the term
 22 ‘healthcare technology development program’ means a pro-
 23 gram designed to—

24 “(1) maximize the technology development op-
 25 portunities and the return on the investment of the

1 Federal Government in research related to the devel-
2 opment of human diagnostics, therapeutics, anti-
3 microbials, vaccines, and research tools so that this
4 investment provides clinical benefits to individuals;

5 “(2) ensure that research supported by the
6 Federal Government is complimentary to, and not
7 duplicative of or competitive with, private sector re-
8 search;

9 “(3) speed the development of biomedical re-
10 search enabling human diagnostics, therapeutics,
11 vaccines, and research tools; and

12 “(4) reduce the time and cost necessary for the
13 development of human diagnostics, therapeutics, vac-
14 cines, and research tools.

15 “(b) ESTABLISHMENT; PURPOSE.—

16 “(1) ESTABLISHMENT.—There is established
17 within the National Institutes of Health a National
18 Center for Healthcare Technology Development (re-
19 ferred to in this subpart as the ‘Center’).

20 “(2) PURPOSE.—The purpose of the Center is
21 to increase and support healthcare technology devel-
22 opment, which includes—

23 “(A) maximizing the technology develop-
24 ment opportunities and the return on the in-
25 vestment of the Federal Government in re-

1 search related to the development of human
2 diagnostics, therapeutics, vaccines, and research
3 tools so that this investment provides clinical
4 benefits to individuals;

5 “(B) ensuring that research supported by
6 the Federal Government is complimentary to,
7 and not duplicative of or competitive with, pri-
8 vate sector research;

9 “(C) speeding the development of bio-
10 medical research enabling human diagnostics,
11 therapeutics, vaccines, and research tools; and

12 “(D) reducing the cost and time necessary
13 for the development of human diagnostics,
14 therapeutics, vaccines, and research tools.

15 “(c) DIRECTOR.—

16 “(1) IN GENERAL.—The Center shall be headed
17 by a Center Director (referred to in this section as
18 the ‘Center Director’) appointed by the President by
19 and with the advice and consent of the Senate.

20 “(2) COMPENSATION.—The Center Director
21 shall be compensated at a rate that is the greater
22 of—

23 “(A) the average total compensation of the
24 directors of the national research institutes; or

25 “(B) level IV of the Executive Schedule.

1 “(3) DUTIES OF THE CENTER DIRECTOR.—The
2 Center Director shall perform functions as described
3 under this subpart and as the Secretary and the Di-
4 rector of NIH determine appropriate.

5 “(d) ASSOCIATE DIRECTOR.—

6 “(1) IN GENERAL.—There shall be in the Cen-
7 ter an Associate Director for Biological, Chemical,
8 Radiological, and Infectious Disease Countermeasure
9 Development (referred to in this section as the ‘As-
10 sociate Director’), who shall be appointed by the
11 Center Director.

12 “(2) DUTIES OF THE ASSOCIATE DIRECTOR.—
13 The Associate Director shall—

14 “(A) serve as a liaison between the Depart-
15 ment of Health and Human Services, the Na-
16 tional Institutes of Health, the Department of
17 Homeland Security, and the Department of De-
18 fense on matters relating to the development of
19 biomedical technologies that enable effective
20 countermeasures to bioterror, chemical, and ra-
21 diological agents and infectious diseases;

22 “(B) ensure that the National Institutes of
23 Health supports research that is consistent
24 with, and supportive of, the joint strategy for
25 the development of countermeasures for bio-

1 terror, chemical, and radiological agents and in-
2 fectious diseases of the Department of Home-
3 land Security, the Department of Health and
4 Human Services, and the Department of De-
5 fense; and

6 “(C) annually review the effectiveness of
7 the technology transfer policies and practices of
8 the National Institutes of Health with respect
9 to the development of countermeasures for bio-
10 terror, chemical, and radiological agents and in-
11 fectious diseases to ensure that the policies and
12 practices are consistent with the joint counter-
13 measure development strategy of the Depart-
14 ment of Homeland Security, the Department of
15 Health and Human Services, and the Depart-
16 ment of Defense.

17 “(e) DUTIES OF THE CENTER.—The Center shall—

18 “(1) manage the technology transfer, partner-
19 ship, and healthcare technology development pro-
20 grams at the National Institutes of Health;

21 “(2) oversee the healthcare technology develop-
22 ment programs of the grantees of the National Insti-
23 tutes of Health;

1 “(3) secure and license intellectual property for
2 research performed at the National Institutes of
3 Health;

4 “(4) prepare, on an annual basis, the National
5 Healthcare Technology Development Strategy re-
6 garding the technology transfer, partnership, and
7 healthcare technology development programs of the
8 National Institutes of Health and the grantees of
9 the National Institutes of Health;

10 “(5) with regard to the Healthcare Technology
11 Development Opportunities Assessments under sec-
12 tion 492A—

13 “(A) establish criteria for the contents of
14 the assessments;

15 “(B) assist National Institutes of Health
16 applicants in preparing the assessments;

17 “(C) assist the Directors of the national
18 research institutes in reviewing the assess-
19 ments;

20 “(D) prepare periodic analyses of the con-
21 tents of the assessments; and

22 “(E) prepare periodic analyses of the ex-
23 tent to which the opportunities were realized;

24 “(6) in consultation with the Directors of the
25 national research institutes, the National Advisory

1 Council under subsection (f) and the Institute Advi-
2 sory Councils under subsection (g), prepare a re-
3 search agenda for the National Institutes of Health,
4 and for each national research institute, that de-
5 scribes—

6 “(A) the technology development opportu-
7 nities and the research that would be most ben-
8 efitial to enhancing the return on the invest-
9 ment of the Federal Government in developing
10 human diagnostics, therapeutics, vaccines, and
11 research tools, so that this investment provides
12 clinical benefits to individuals;

13 “(B) the research supported by the Fed-
14 eral Government that is complimentary to, and
15 not duplicative of or competitive with, private
16 sector research;

17 “(C) proposed measures designed to speed
18 the development of human diagnostics, thera-
19 peutics, vaccines, and research tools; and

20 “(D) proposed measures designed to re-
21 duce the cost and time necessary to develop
22 human diagnostics, therapeutics, vaccines, and
23 research tools;

24 “(7) publish a technology transfer, partnership,
25 and healthcare technology development manual that

1 describes the most effective healthcare technology
2 development policies and practices for the National
3 Institutes of Health and its grantees that maximize
4 the technology development opportunities and the re-
5 turn on the investment of the Federal Government
6 in research to the development of healthcare tech-
7 nology;

8 “(8) collect and analyze comprehensive data re-
9 garding the effectiveness of the technology transfer,
10 partnerships, and healthcare technology development
11 programs of the National Institutes of Health and
12 its grantees that maximize the technology develop-
13 ment opportunities and the return on the investment
14 of the Federal Government in research to the devel-
15 opment of healthcare technology, including data re-
16 garding—

17 “(A) intellectual property;

18 “(B) licensing and commercialization of in-
19 ventions sponsored by the National Institutes of
20 Health;

21 “(C) cooperative research and development
22 agreements; and

23 “(D) technology development opportunities
24 assessments under section 492A(a);

1 “(9) develop guidelines that enable the National
2 Institutes of Health to accept and divest economic
3 interests in commercial entities that enter into tech-
4 nology transfer, licensing, and partnership relation-
5 ships with the National Institutes of Health;

6 “(10) accept payment for services, use of equip-
7 ment, materials, or laboratory personnel, and retain
8 or transfer those funds to the appropriate labora-
9 tories;

10 “(11) ensure that Small Business Innovative
11 Research (SBIR) and Small Business Technology
12 Transfer Program (STTR) grants under section 9 of
13 the Small Business Act (15 U.S.C. 638) are award-
14 ed to entities that have the greatest capacity to de-
15 velop healthcare technology that provides clinical
16 benefits to individuals;

17 “(12) oversee the review of SBIR and STTR
18 grants;

19 “(13) annually award the ‘Birch Bayh and
20 Robert Dole Award for Healthcare Partnerships’ to
21 the individual and to the organization that has made
22 the most significant contribution with regard to—

23 “(A) maximizing the technology develop-
24 ment opportunities and the return on the in-
25 vestment of the Federal Government in re-

1 search related to the development of human
2 diagnostics, therapeutics, vaccines, and research
3 tools so that this investment provides clinical
4 benefits to individuals;

5 “(B) ensuring that research supported by
6 the Federal Government is complimentary to,
7 and not duplicative of or competitive with, pri-
8 vate sector research;

9 “(C) speeding the development of bio-
10 medical research enabling human diagnostics,
11 therapeutics, vaccines, and research tools; and

12 “(D) reducing the time and cost necessary
13 to develop human diagnostics, therapeutics, vac-
14 cines, and research tools;

15 “(14) annually award the ‘Ronald Reagan and
16 Morris Udall Award for Healthcare Technology De-
17 velopment’ to the individual scientist supported by
18 the National Institutes of Health that has made the
19 most significant contribution to the development of
20 healthcare technology that provides clinical benefits
21 to individuals;

22 “(15) provide grants to private organizations
23 with expertise in technology transfer, partnerships,
24 and healthcare technology development programs;

1 “(16) manage an education program for Na-
2 tional Institutes of Health and private sector entity
3 employees and grantees on the role of the National
4 Institutes of Health concerning the development of
5 healthcare technology; and

6 “(17) manage the advisory councils under sub-
7 sections (f) and (g).

8 “(f) NATIONAL ADVISORY COUNCIL.—

9 “(1) ESTABLISHMENT.—The Secretary shall es-
10 tablish in the Center an advisory council to be
11 known as the National Healthcare Technology De-
12 velopment Advisory Council (referred to in this sub-
13 section as the ‘National Advisory Council’).

14 “(2) COMPOSITION.—

15 “(A) IN GENERAL.—The National Advi-
16 sory Council shall be composed of 13 members
17 to be appointed in accordance with subpara-
18 graph (B) and subject to subparagraphs (C),
19 (D), (E), and (F).

20 “(B) APPOINTMENT; BACKGROUND.—

21 “(i) APPOINTMENT.—Not later than
22 180 days after the effective date of the
23 Project BioShield II Act of 2005, the Di-
24 rector of NIH shall appoint the members
25 of the National Advisory Council.

1 “(ii) BACKGROUND.—Of the members
2 appointed under clause (i)—

3 “(I) not less than 9 members
4 shall be executive officers of bio-
5 technology, pharmaceutical, diag-
6 nostic, and research tool companies
7 that are currently developing or com-
8 mercializing healthcare technology;

9 “(II) not less than 3 members
10 shall be executive offices of small busi-
11 ness interests; and

12 “(III) the remaining members
13 may include investors and investment
14 company executives, securities ana-
15 lysts, experts in the economics of bio-
16 medical research and development, ex-
17 perts in intellectual property and tech-
18 nology transfer, Food and Drug Ad-
19 ministration regulations, licenses,
20 partnerships, and technology transfer
21 officers of grantees of the National
22 Institutes of Health.

23 “(C) INSTITUTE ADVISORY COUNCILS.—A
24 member of the National Advisory Council shall

1 not serve as a member of an Institute Advisory
2 Council under subsection (g).

3 “(D) EX OFFICIO MEMBERS.—

4 “(i) IN GENERAL.—The Secretary of
5 Commerce, the Director of the National
6 Science Foundation, and the Director of
7 the National Institute of Standards and
8 Technology shall serve as ex officio mem-
9 bers of the National Advisory Council.

10 “(ii) DESIGNEES.—The officers listed
11 in clause (i) may appoint a designee to
12 perform their functions on the National
13 Advisory Council.

14 “(E) CHAIRPERSON.—The Director of
15 NIH shall appoint a chairperson of the Na-
16 tional Advisory Council from among the council
17 members.

18 “(F) VACANCY.—Any vacancy in the Na-
19 tional Advisory Council shall not affect the pow-
20 ers of the Council and shall be filled in the
21 same manner as the original appointment.

22 “(3) DUTIES OF THE NATIONAL ADVISORY
23 COUNCIL.—The National Advisory Council shall ad-
24 vise the Center Director regarding policies and pro-
25 cedures that will—

1 “(A) maximize the technology development
2 opportunities and the return on the investment
3 of the Federal Government in research related
4 to the development of human diagnostics, thera-
5 peutics, vaccines, and research tools so that this
6 investment provides clinical benefits to individ-
7 uals;

8 “(B) ensure that research supported by the
9 Federal Government is complimentary to, and
10 not duplicative of or competitive with, private
11 sector research;

12 “(C) speed the development of biomedical
13 research into effective human diagnostics,
14 therapeutics, vaccines, and research tools; and

15 “(D) reduce the cost and time needed for
16 the development of human diagnostics, thera-
17 peutics, vaccines, and research tools.

18 “(4) POWERS.—

19 “(A) HEARINGS.—The National Advisory
20 Council may hold such hearings, sit and act at
21 such times and places, take such testimony, and
22 receive such evidence as the National Advisory
23 Council considers advisable to carry out this
24 section.

1 “(B) INFORMATION FROM FEDERAL AGEN-
2 CIES.—The National Advisory Council may se-
3 cure directly from any Federal department or
4 agency such information as the National Advi-
5 sory Council considers necessary to carry out
6 the provisions of this section. Upon request of
7 the National Advisory Council, the head of such
8 department or agency shall furnish such infor-
9 mation to the National Advisory Council.

10 “(C) POSTAL SERVICES.—The National
11 Advisory Council may use the United States
12 mails in the same manner and under the same
13 conditions as other departments and agencies of
14 the Federal Government.

15 “(5) PERSONNEL.—

16 “(A) TRAVEL EXPENSES.—The members
17 of the National Advisory Council shall not re-
18 ceive compensation for the performance of serv-
19 ices for the National Advisory Council, but shall
20 be allowed travel expenses, including per diem
21 in lieu of subsistence, at rates authorized for
22 employees of agencies under subchapter I of
23 chapter 57 of title 5, United States Code, while
24 away from their homes or regular places of
25 business in the performance of services for the

1 National Advisory Council. Notwithstanding
2 section 1342 of title 31, United States Code,
3 the Secretary may accept the voluntary and un-
4 compensated services of members of the Na-
5 tional Advisory Council.

6 “(B) DETAIL OF GOVERNMENT EMPLOY-
7 EES.—Any Federal Government employee may
8 be detailed to the National Advisory Council
9 without reimbursement, and such detail shall be
10 without interruption or loss of civil service sta-
11 tus or privilege.

12 “(g) INSTITUTE ADVISORY COUNCILS.—

13 “(1) ESTABLISHMENT.—The Secretary shall es-
14 tablish in the Center the National Center for
15 Healthcare Technology Development Institute Advi-
16 sory Councils (referred to in this subsection as the
17 ‘Institute Advisory Councils’).

18 “(2) COMPOSITION.—

19 “(A) IN GENERAL.—Each Institute Advi-
20 sory Council shall be composed of 13 members
21 appointed in accordance with subparagraph (B)
22 and subject to subparagraphs (C), (D), (E),
23 and (F).

24 “(B) APPOINTMENT; BACKGROUND.—

1 “(i) APPOINTMENT.—Not later than
2 180 days after the effective date of the
3 Project BioShield II Act of 2005, the ap-
4 propriate Institute Director shall appoint
5 the members of the respective Institute
6 Advisory Council.

7 “(ii) BACKGROUND.—Of the members
8 appointed under clause (i)—

9 “(I) at least 9 members shall be
10 executive officers of biotechnology,
11 pharmaceutical, diagnostic, and re-
12 search tool companies that are cur-
13 rently developing or commercializing
14 healthcare technology; and

15 “(II) the remaining members
16 shall include investors and investment
17 company executives, securities ana-
18 lysts, experts in the economics of bio-
19 medical research and development, ex-
20 perts in intellectual property and tech-
21 nology transfer, Food and Drug Ad-
22 ministration regulations, licenses,
23 partnerships, and technology transfer
24 officers of grantees of the National
25 Institutes of Health.

1 “(C) NATIONAL ADVISORY COUNCIL.—A
2 member of an Institute Advisory Council shall
3 not serve as a member of the National Advisory
4 Council under subsection (f).

5 “(D) EX OFFICIO MEMBER.—The Center
6 Director, or his or her designee, shall serve as
7 an ex officio member of the Institute Advisory
8 Councils.

9 “(E) CHAIRPERSON.—The appropriate In-
10 stitute Director shall appoint a chairperson of
11 the respective Institute Advisory Council from
12 among the council members.

13 “(F) VACANCIES.—Any vacancy in an In-
14 stitute Advisory Council shall not affect the
15 powers of the Council and shall be filled in the
16 same manner as the original appointment.

17 “(3) DUTIES OF THE INSTITUTE ADVISORY
18 COUNCIL.—The Institute Advisory Councils shall ad-
19 vise the Center Director regarding policies and pro-
20 cedures that will—

21 “(A) maximize the technology development
22 opportunities and the return on the investment
23 of the Federal Government in research related
24 to the development of human diagnostics, thera-
25 peutics, vaccines, and research tools so that this

1 investment provides clinical benefits to individ-
2 uals;

3 “(B) ensure that research supported by the
4 Federal Government is complimentary to, and
5 not duplicative of or competitive with, private
6 sector research;

7 “(C) speed the development of biomedical
8 research into human diagnostics, therapeutics,
9 vaccines, and research tools; and

10 “(D) reduce the cost and time needed for
11 the development of human diagnostics, thera-
12apeutics, vaccines, and research tools.

13 “(4) POWERS.—

14 “(A) HEARINGS.—The Institute Advisory
15 Councils may hold such hearings, sit and act at
16 such times and places, take such testimony, and
17 receive such evidence as the Institute Advisory
18 Council considers advisable to carry out this
19 section.

20 “(B) INFORMATION FROM FEDERAL AGEN-
21CIES.—The Institute Advisory Councils may se-
22cure directly from any Federal department or
23agency such information as the Institute Advi-
24sory Council considers necessary to carry out
25the provisions of this section. Upon request of

1 an Institute Advisory Council, the head of such
2 department or agency shall furnish such infor-
3 mation to the Institute Advisory Council.

4 “(C) POSTAL SERVICES.—The Institute
5 Advisory Councils may use the United States
6 mails in the same manner and under the same
7 conditions as other departments and agencies of
8 the Federal Government.

9 “(5) PERSONNEL.—

10 “(A) TRAVEL EXPENSES.—The members
11 of the Institute Advisory Councils shall not re-
12 ceive compensation for the performance of serv-
13 ices for the Institute Advisory Councils, but
14 shall be allowed travel expenses, including per
15 diem in lieu of subsistence, at rates authorized
16 for employees of agencies under subchapter I of
17 chapter 57 of title 5, United States Code, while
18 away from their homes or regular places of
19 business in the performance of services for the
20 Institute Advisory Councils. Notwithstanding
21 section 1342 of title 31, United States Code,
22 the Secretary may accept the voluntary and un-
23 compensated services of members of the Insti-
24 tute Advisory Council.

1 “(B) DETAIL OF GOVERNMENT EMPLOY-
2 EES.—Any Federal Government employee may
3 be detailed to an Institute Advisory Council
4 without reimbursement, and such detail shall be
5 without interruption or loss of civil service sta-
6 tus or privilege.

7 “(h) TRAINEESHIPS; FELLOWSHIPS.—

8 “(1) IN GENERAL.—The Secretary, acting
9 through the Center Director, may—

10 “(A) provide research training and instruc-
11 tion in technology transfer and healthcare com-
12 mercialization transfer, licenses, partnerships,
13 and healthcare technology development; and

14 “(B) establish research traineeships and
15 fellowships in technology transfer and
16 healthcare commercialization.

17 “(2) STIPENDS AND ALLOWANCES.—The Sec-
18 retary may provide individuals receiving instruction,
19 a traineeship, or fellowship under paragraph (1)
20 with such stipends and allowances, including
21 amounts for travel, subsistence, and dependents, as
22 the Secretary determines necessary.

23 “(3) EMPLOYEE DETAIL.—The Secretary shall
24 establish guidelines for the temporary leave, for a
25 period of not to exceed 3 years, of not more than

1 220 employees of the National Institutes of Health,
2 to appropriate for-profit organizations that are in
3 the business of developing human therapeutics, vac-
4 cines, devices, or diagnostics and research tools.

5 “(i) GRANTS.—

6 “(1) IN GENERAL.—The Secretary, acting
7 through the Center Director, shall award grants to
8 eligible nonprofit institutions to provide training, in-
9 struction, traineeships, and fellowships under sub-
10 section (h).

11 “(2) USE OF FUNDS.—A nonprofit institution
12 that receives funds under this subsection shall use
13 the amounts provided through the grant to provide
14 training, instruction, traineeships, and fellowships to
15 individuals under subsection (h) with regard to tech-
16 nology transfer and healthcare development.

17 “(3) ELIGIBILITY.—To be eligible for a grant
18 under this subsection, a nonprofit institution shall
19 submit an application to the Secretary in such form,
20 in such manner, and containing such information as
21 the Secretary may require.

22 “(j) AUTHORIZATION OF APPROPRIATIONS.—There
23 is authorized to be appropriated an amount equal to 0.3
24 percent of the amount obligated by the National Institutes

1 of Health in fiscal year 2004 for each fiscal year to carry
2 out this section.”.

3 (b) GOVERNMENT DISCOUNT.—The Secretary of
4 Health and Human Services and the Secretary of Vet-
5 erans Affairs shall ensure that the price that the Federal
6 Government pays for a drug, biological product, human
7 therapeutic, vaccine, or diagnostic developed using tech-
8 nology licensed by the National Institutes of Health does
9 not include reimbursement for any royalty rate previously
10 paid by the technology partner or its assign.

11 **SEC. 1603. TECHNOLOGY DEVELOPMENT OPPORTUNITIES**

12 **ASSESSMENTS.**

13 Section 492A(a) of the Public Health Service Act (42
14 U.S.C. 289a–1(a)) is amended by adding at the end the
15 following:

16 “(3) TECHNOLOGY DEVELOPMENT OPPORTUNI-
17 TIES ASSESSMENT.—Each proposal submitted to the
18 National Institutes of Health shall include an assess-
19 ment, prepared in compliance with the guidelines de-
20 veloped by the National Center for Healthcare Tech-
21 nology Development, of technology development op-
22 portunities, including opportunities that may exist
23 for the proposed research to—

24 “(A) maximize the technology development
25 opportunities and the return on the investment

1 of the Federal Government in research related
2 to the development of human diagnostics, thera-
3 peutics, vaccines, and research tools so that this
4 investment provides clinical benefits to individ-
5 uals;

6 “(B) ensure that research supported by the
7 Federal Government is complimentary to, and
8 not duplicative of or competitive with, private
9 sector research;

10 “(C) speed the development of biomedical
11 research into human diagnostics, therapeutics,
12 vaccines, and research tools; and

13 “(D) reduce the cost and time necessary
14 for the development of human diagnostics,
15 therapeutics, vaccines, and research tools.”.

16 **SEC. 1604. RESOURCES FOR THE NATIONAL CENTER FOR**
17 **HEALTHCARE TECHNOLOGY DEVELOPMENT.**

18 Section 402(b) of the Public Health Service Act (42
19 U.S.C. 282(b)) is amended—

20 (1) in paragraph (13)(B), by striking “and”;

21 (2) in paragraph (14), by striking “title 38,
22 United States Code.” and inserting “title 38, United
23 States Code; and”; and

24 (3) inserting after paragraph (14) the following:

1 “(15) after consultation with the Director of
2 the National Center for Healthcare Technology De-
3 velopment, shall develop programs designed to—

4 “(A) maximize the technology development
5 opportunities and the return on the investment
6 of the Federal Government in research related
7 to the development of human diagnostics, thera-
8 peutics, vaccines, and research tools so that this
9 investment provides clinical benefits to individ-
10 uals;

11 “(B) ensure that research supported by the
12 Federal Government is complimentary to, and
13 not duplicative of or competitive with, private
14 sector research;

15 “(C) speed the development of biomedical
16 research into human diagnostics, therapeutics,
17 vaccines, and research tools; and

18 “(D) reduce the time and cost necessary
19 for the development of human diagnostics,
20 therapeutics, vaccines, and research tools.”.

21 **SEC. 1605. BIENNIAL REPORT OF THE DIRECTOR OF THE**
22 **NATIONAL INSTITUTES OF HEALTH TO THE**
23 **PRESIDENT AND CONGRESS.**

24 Section 403 of the Public Health Service Act (42
25 U.S.C. 283) is amended—

1 (1) in paragraph (4), by striking “area; and”
2 and inserting “area;”;

3 (2) in paragraph (5), by striking “Nursing Re-
4 search.” and inserting “Nursing Research; and”;
5 and

6 (3) by inserting after (5) the following:

7 “(6) a description of the healthcare technology
8 that has been developed for the clinical benefit of in-
9 dividuals with support by the National Institutes of
10 Health in the preceding 2-year period and the spe-
11 cific contribution of research supported by the Na-
12 tional Institutes of Health to this technology.”.

13 **SEC. 1606. AUTHORITY OF THE DIRECTORS OF THE NA-**
14 **TIONAL RESEARCH INSTITUTES; BIENNIAL**
15 **REPORT.**

16 (a) AUTHORITY OF THE DIRECTORS OF THE NA-
17 TIONAL RESEARCH INSTITUTES.—Section 405(b)(1)(A)
18 of the Public Health Service Act (42 U.S.C. 284(b)(1)(A))
19 is amended—

20 (1) in clause (iii), by striking “disabilities, and”
21 and inserting “disabilities;”;

22 (2) in clause (iv), by striking “the environ-
23 ment;” and inserting “the environment, and”; and

24 (3) by inserting after clause (iv) the following:

1 “(v) the expansion of knowledge of the cre-
2 ation, manufacture, or administration of treat-
3 ments of patients suffering from diseases, dis-
4 orders, or disabilities; and”.

5 (b) BIENNIAL REPORT.—Section 407 of the Public
6 Health Service Act (42 U.S.C. 284b) is amended to read
7 as follows:

8 **“SEC. 407. INSTITUTE BIENNIAL REPORT.**

9 “(a) IN GENERAL.—The Director of each national re-
10 search institute, after consultation with the advisory coun-
11 cil for the institute, shall include in the biennial report
12 made under section 403—

13 “(1) a description of the research areas identi-
14 fied as most relevant to the development of tech-
15 nology by the National Center for Healthcare Tech-
16 nology Development Advisory Council;

17 “(2) a description of the activities of the insti-
18 tute;

19 “(3) a description of technology that has been
20 developed and licensed for the clinical benefit of in-
21 dividuals from all research supported by the insti-
22 tute; and

23 “(4) a description of program policies of the Di-
24 rector of the institute.

1 “(b) ADDITIONAL REPORTS.—The Director of each
2 national research institute may prepare such additional re-
3 ports as the Director determines appropriate.

4 “(c) OPPORTUNITY FOR WRITTEN COMMENTS.—The
5 Director of each national research institute shall provide
6 the advisory council for the institute an opportunity for
7 the submission of the written comments described under
8 section 406(g).”.

9 **SEC. 1607. COMMERCIAL RESEARCH AND INVESTIGATIONS.**

10 Section 301(a) of the Public Health Service Act (42
11 U.S.C. 241(a)) is amended in the matter following para-
12 graph (8) by striking “for biomedical and behavioral re-
13 search, substances and living organisms” and inserting
14 “for commercial, biomedical, and behavioral research, sub-
15 stances, resources, rights to intellectual property, and liv-
16 ing organisms”.

17 **SEC. 1608. SBIR/STTR PROGRAM CONSULTATION WITH THE**
18 **DIRECTOR OF THE CENTER OF HEALTHCARE**
19 **TECHNOLOGY DEVELOPMENT.**

20 Section 9 of the Small Business Act (15 U.S.C. 638)
21 is amended—

22 (1) in subsection (g)(3)—

23 (A) in subparagraph (A), by striking “;
24 or” and inserting a semicolon;

1 (B) in subparagraph (B), by inserting “or”
2 after the semicolon; and

3 (C) by adding after subparagraph (B) the
4 following:

5 “(C) the Director of the National Center
6 for Healthcare Technology Development under
7 section 485K of the Public Health Service
8 Act;”; and

9 (2) in subsection (o)(3)—

10 (A) in subparagraph (A), by striking “;
11 or” and inserting a semicolon;

12 (B) in subparagraph (B), by inserting “or”
13 after the semicolon; and

14 (C) by inserting after subparagraph (B)
15 the following:

16 “(C) by the Director of the National Cen-
17 ter for Healthcare Technology Development
18 under section 485K of the Public Health Serv-
19 ice Act;”.

20 **SEC. 1609. PURPOSE OF THE NATIONAL RESEARCH INSTI-
21 TUTES.**

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

24 (1) in section 410 (42 U.S.C. 285), by inserting
25 before the period the following: “, and the conduct

1 and support of the development of healthcare tech-
2 nologies”;

3 (2) in section 418 (42 U.S.C. 285b), by insert-
4 ing before the period the following: “, and the con-
5 duct and support of the development of healthcare
6 technologies”;

7 (3) in section 426 (42 U.S.C. 285c), by insert-
8 ing before the period the following: “, and the con-
9 duct and support of the development of healthcare
10 technologies”;

11 (4) in section 435 (42 U.S.C. 285d), by insert-
12 ing before the period the following: “, and the con-
13 duct and support of the development of healthcare
14 technologies”;

15 (5) in section 443 (42 U.S.C. 285e), by insert-
16 ing before the period the following: “, and the con-
17 duct and support of the development of healthcare
18 technologies”;

19 (6) in section 446 (42 U.S.C. 285f), by insert-
20 ing before the period the following: “, and the con-
21 duct and support of the development of healthcare
22 technologies”;

23 (7) in section 448 (42 U.S.C. 285g), by insert-
24 ing before the period the following: “, and the con-

1 duct and support of the development of healthcare
2 technologies”;

3 (8) in section 453 (42 U.S.C. 285h), by insert-
4 ing before the period the following: “, and the con-
5 duct and support of the development of healthcare
6 technologies”;

7 (9) in section 455 (42 U.S.C. 285i), by insert-
8 ing before the period the following: “, and the con-
9 duct and support of the development of healthcare
10 technologies”;

11 (10) in section 457 (42 U.S.C. 285j), by insert-
12 ing before the period the following: “, and the con-
13 duct and support of the development of healthcare
14 technologies”;

15 (11) in section 461 (42 U.S.C. 285k), by insert-
16 ing before the period the following: “, and the con-
17 duct and support of the development of healthcare
18 technologies”;

19 (12) in section 463 (42 U.S.C. 285l), by insert-
20 ing before the period the following: “, and the con-
21 duct and support of the development of healthcare
22 technologies”;

23 (13) in section 464 (42 U.S.C. 285m), by in-
24 serting before the period the following: “, and the

1 conduct and support of the development of
2 healthcare technologies”;

3 (14) in section 464H (42 U.S.C. 284n), by in-
4 serting before the period the following: “, and the
5 conduct and support of the development of
6 healthcare technologies”;

7 (15) in section 464L (42 U.S.C. 285o), by in-
8 serting before the period the following: “, and the
9 conduct and support of the development of
10 healthcare technologies”;

11 (16) in section 464R (42 U.S.C. 285p), by in-
12 serting before the period the following: “, and the
13 conduct and support of the development of
14 healthcare technologies”;

15 (17) in section 464V (42 U.S.C. 285q), by in-
16 serting before the period the following: “, and the
17 conduct and support of the development of
18 healthcare technologies”; and

19 (18) in section 464Z (42 U.S.C. 285r), by in-
20 serting before the period the following: “, and the
21 conduct and support of the development of
22 healthcare technologies”.

1 **SEC. 1610. CONFORMING AMENDMENT.**

2 Section 401(b)(1) of the Public Health Service Act
3 (42 U.S.C. 281(b)(1)) is amended by adding at the end
4 the following:

5 “(S) The National Center for Healthcare Tech-
6 nology Development.”.

7 **SEC. 1611. EFFECTIVE DATE.**

8 This title shall take effect on October 1, 2005, or
9 upon the date of enactment of this title, whichever occurs
10 later.

11 **Subtitle B—Protecting Government**
12 **Investment in Basic Biomedical**
13 **Research**

14 **SEC. 1621. FINDINGS.**

15 Congress finds that—

16 (1) the rate of return on the Federal Govern-
17 ment’s investment in basic biomedical research is
18 maximized when the intellectual property for that re-
19 search is effectively transferred to commercial enti-
20 ties for development into healthcare products for the
21 benefit of patients;

22 (2) intellectual property for research supported
23 by the National Institutes of Health is often not
24 competitive with intellectual property for research
25 supported by private investors due to inefficiencies
26 of the technology transfer process and the con-

1 sequent erosion of the term of the patents for the
2 technology; and

3 (3) to protect the Federal Government's invest-
4 ment in basic biomedical research and to maximize
5 the likelihood that technology will be developed into
6 healthcare products, a patent that is not affected by
7 the inefficiencies in the technology transfer process
8 should be granted.

9 **SEC. 1622. UTILIZATION AND AVAILABILITY.**

10 (a) IN GENERAL.—An entity with respect to which
11 an affirmative determination is made under section
12 301(b)(4) shall maximize the utilization of a research tool
13 involved for the development of countermeasures, includ-
14 ing making the research tool available on commercially
15 reasonable terms to other entities certified under section
16 301(b)(4) to develop countermeasures.

17 (b) RULE OF CONSTRUCTION.—Nothing in this title
18 or chapter 18 of title 35, United States Code, shall be
19 construed to restrict the right of an entity described in
20 subsection (a) to—

21 (1) secure and enforce a patent regarding a re-
22 search tool;

23 (2) enter into exclusive, revocable, and non-
24 transferable licenses of a research tool; or

1 (3) impose limits on royalty- or product- reach-
 2 through or downstream rights or agreements on fu-
 3 ture countermeasures, or option rights with respect
 4 to a research tool.

5 **SEC. 1623. RESTORATION OF TERM OF UNEXPLOITED PAT-**
 6 **ENTS ON GOVERNMENT SPONSORED INVEN-**
 7 **TIONS RELATING TO COUNTERMEASURES.**

8 (a) IN GENERAL.—Chapter 14 of title 35, United
 9 States Code, is amended by adding at the end the fol-
 10 lowing:

11 **“§ 159. Patent term restoration for unexploited pat-**
 12 **ents on Government sponsored inven-**
 13 **tions**

14 “(a) DEFINITIONS.—In this section:

15 “(1) ELIGIBLE GOVERNMENT-SPONSORED IN-
 16 VENTION.—The term ‘eligible Government-supported
 17 invention’ means an invention supported in part by
 18 funds appropriated to the National Institutes of
 19 Health that may be used to produce a counter-
 20 measure to a terror agent, infectious disease or
 21 other disease or condition or is subject to the provi-
 22 sions of chapter 18 of title 35, United States Code.

23 “(2) ELIGIBLE GOVERNMENT PATENT.—The
 24 term ‘eligible Government patent’ means a patent
 25 that—

1 “(A) claims an eligible Government-sup-
2 ported invention;

3 “(B) has not been extended or restored
4 under section 156, 156a, or 158; and

5 “(C) has not been licensed prior to a date
6 that is 2 years before the date the patent will
7 expire.

8 “(3) EFFECTIVE EXPLOITATION OF DATE OF
9 THE PATENT.—The term ‘effective exploitation date
10 of the patent’ means the date that is the later of—

11 “(A) the date that the patent is licensed to
12 an entity that is not a Federal agency, as that
13 term is defined in section 201(a), for purposes
14 of development or commercialization of the pat-
15 ented invention; or

16 “(B) if the patent claims a product, a
17 method of using a product or a method of using
18 a product as defined in section 156(a), the date
19 that such product is approved under section
20 505(b)(1) of the Federal Food Drug and Cos-
21 metic Act (21 U.S.C. 355(b)(1)) or under sec-
22 tion 351 of the Public Health Service Act (42
23 U.S.C. 262).

24 “(b) PATENT TERM RESTORATION FOR ELIGIBLE
25 GOVERNMENT PATENTS.—

1 “(1) IN GENERAL.—Notwithstanding the provi-
2 sions of section 154, the term of an eligible Govern-
3 ment patent shall be restored by a period equal to
4 the number of days starting on the date that the
5 patent is issued and ending on the date of effective
6 exploitation date of the patent.

7 “(2) LIMITATION.—No eligible Government pat-
8 ent shall be restored under this section unless—

9 “(A) the Director of the National Insti-
10 tutes of Health (referred to in this section as
11 the ‘Director of NIH’) determines that the li-
12 censing of such patent will assist in the develop-
13 ment of countermeasures, medicines, vaccines,
14 and other technology potentially beneficial to
15 patients; and

16 “(B) prior to the expiration of the patent,
17 the Director of NIH submits an application to
18 the Director to restore the term of the patent
19 under subsection (c).

20 “(c) PROCEDURE FOR RESTORING TERM OF ELIGI-
21 BLE GOVERNMENT PATENT.—

22 “(1) IN GENERAL.—The Director of NIH shall
23 request restoration of an eligible Government patent
24 by submitting a written application to the Director.

1 “(2) CONTENTS OF APPLICATION.—An applica-
2 tion under this section shall—

3 “(A) be sent to the Director prior to the
4 date that is 45 days before the patent expires;

5 “(B) set forth the period of the restoration
6 requested; and

7 “(C) provide an explanation of the basis of
8 the conclusion of the Director of NIH that the
9 requirements of subparagraph (A) are met with
10 respect to the patent being restored.

11 “(3) EFFECT OF SECTION.—The Director of
12 NIH shall promulgate regulations to give effect to
13 this section, including procedures that permit the
14 restoration of patents in respect of which title has
15 been transferred under section 202.

16 “(d) DEFERRAL OF PAYMENT OF PATENT ISSUE
17 FEES FOR ELIGIBLE GOVERNMENT PATENTS.—The Fed-
18 eral agency that has rights in an invention subject to a
19 patent application under chapter 18 may defer the pay-
20 ment of fees under section 41 due for issuance of an eligi-
21 ble Government patent until the date that is 90 days after
22 the date that the patent been licensed to an entity that
23 is not a Federal agency as that term is defined in section
24 201(a). Not later than 30 days after the date a notice
25 of allowance of the patent application is mailed by the Di-

1 rector, the applicant shall inform the Director that it is
2 invoking this section with respect to the application. The
3 Director shall issue the patent for the National Institutes
4 of Health-supported technology notwithstanding the non-
5 payment of the issue fee, subject to the provisions of this
6 section.

7 “(e) PROCEDURES APPLICABLE TO PATENT TERM
8 RESTORATION APPLICATIONS.—The Director has the au-
9 thority to accept an application submitted under this sec-
10 tion and sections 156, 156a, and 158 after the date speci-
11 fied in such sections in exceptional circumstances or where
12 good cause is shown for the delay in submitting the appli-
13 cation, except no application may be accepted under any
14 of these sections more than 30 days after the date speci-
15 fied in such section.

16 “(f) RULES OF CONSTRUCTION REGARDING RE-
17 SEARCH TOOLS.—Nothing in this section or chapter 18
18 of title 35, United States Code, shall be construed to re-
19 strict the right of an entity to—

20 “(i) secure and enforce patents with
21 regard to research tools;

22 “(ii) enter into exclusive, revocable,
23 and nontransferable licenses of such re-
24 search tools; or

1 “(iii) impose limits on royalty- or
2 product-reach-through or downstream
3 rights or agreements on future counter-
4 measures or products, or option rights with
5 respect to a research tool.”.

6 (d) DISCRETIONARY WAIVER OF MARCH-IN RIGHTS
7 AND EXCLUSIVE LICENSING.—

8 (1) IN GENERAL.—The owner of a patent over
9 which the Government has rights under chapter 18
10 of title 35, United States Code, may request that a
11 Federal agency under whose funding a subject in-
12 vention was made may waive rights the Government
13 has under sections 200, 203, and 209 of title 35,
14 United States Code.

15 (2) REQUESTS.—If a request under paragraph
16 (1) is made within 90 days after the date that the
17 entity obtained title to the patent, the Federal agen-
18 cy shall grant the request.

19 (c) FEDERALLY OWNED INVENTIONS.—Section
20 209 of title 35, United States Code, (as amended by
21 section 301) is amended—

22 (A) by redesignating subsections (f) and
23 (g) as subsections (g) and (h), respectively; and

24 (B) by inserting after subsection (e) the
25 following:

1 “(f) TERMS AND CONDITIONS OF EXCLUSIVE LI-
 2 CENSE.—Each exclusive license granted shall include a
 3 provision that, at the discretion of the licensee, the li-
 4 censee may act as the agent for the licensor with respect
 5 to any patent for the licensed invention for purposes of
 6 extending a patent under section 156a or 158.”.

7 (d) TECHNICAL AND CONFORMING AMENDMENT.—
 8 The table of sections for chapter 14 of title 35, United
 9 States Code, is amended by adding after the item relating
 10 to section 158 the following:

“159. Patent term restoration for unexploited patents on Government
 sponsored inventions.”.

11 **SEC. 1624. ENCOURAGING THE PATENTING OF RESEARCH**
 12 **TOOLS.**

13 Section 200 of title 35, United States Code, is
 14 amended by striking “enterprise without unduly encum-
 15 bering future research and discovery” and inserting “en-
 16 terprise”.

17 **SEC. 1625. EFFECTIVE DATE.**

18 This title takes effect on October 1, 2005, or upon
 19 the date of enactment of this title, whichever occurs later.

20 **Subtitle C—Partnership Challenge**
 21 **Grants**

22 **SEC. 1631. PARTNERSHIP CHALLENGE GRANTS.**

23 Part B of title III of the Public Health Service Act
 24 (42 U.S.C. 243 et seq.) (as amended by sections 202,

1 1901, 2101, 2102, and 1401) is amended by inserting
2 after section 319F–7 (as added by section 1401) the fol-
3 lowing:

4 **“SEC. 319F–8. NATIONAL INSTITUTES OF HEALTH COUN-**
5 **TERMEASURES PARTNERSHIP CHALLENGE**
6 **GRANTS.**

7 “(a) GRANTS AUTHORIZED.—The Director of the
8 National Institutes of Health (in this section referred to
9 as the ‘Director’), in consultation with the Director of the
10 Centers for Disease Control and Prevention, is authorized
11 to award, in consultation with the Foundation for the Na-
12 tional Institutes of Health, partnership challenge grants
13 to promote joint ventures between the National Institutes
14 of Health, the Foundation for the National Institutes of
15 Health, its grantees, qualified clinical countermeasures de-
16 livery centers, and for-profit biotechnology, pharma-
17 ceutical, and medical device industries for the development
18 of countermeasures and research tools.

19 “(b) REGULATIONS.—The Director shall issue regu-
20 lations within 90 days of the date of enactment of this
21 section to implement the awarding of grants under sub-
22 section (a).

23 “(c) RULE OF CONSTRUCTION.—Nothing in this sec-
24 tion shall be construed to preclude an entity that receives
25 a partnership challenge grant under this section from also

1 being certified as being eligible for the tax, procurement,
 2 intellectual property, and liability incentives provided for
 3 under the amendments made by subtitle A of title III of
 4 the Project BioShield II Act of 2005.

5 “(d) SAFETY TRAINING PROGRAM.—The Director of
 6 NIH, in consultation with the Director of the Centers for
 7 Disease Control and Prevention, shall establish a safety
 8 training program for researchers working in biosafety level
 9 3 or 4 facilities.

10 “(e) TRANSFER OF FUNDS.—The Director is author-
 11 ized to transfer funds to the Foundation for the National
 12 Institutes of Health to be used for partnership grants and
 13 other costs associated with administering this section.

14 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
 15 are authorized to be appropriated such sums as may be
 16 necessary for each of fiscal years 2004, 2005, 2006, 2007,
 17 and 2008 for the purpose of carrying out this section.”

18 **TITLE XVII—DEVELOPMENT OF**
 19 **COUNTERMEASURE RE-**
 20 **SEARCH AT THE DEPART-**
 21 **MENT OF DEFENSE**

22 **SEC. 1701. DEVELOPMENT OF COUNTERMEASURE RE-**
 23 **SEARCH AT THE DEPARTMENT OF DEFENSE.**

24 There are authorized to be appropriated to the De-
 25 partment of Health and Human Services, including funds

1 appropriated under the Project BioShield Act of 2004 and
2 this Act, such sums as may be necessary to secure and
3 facilitate the development of countermeasures, as defined
4 in section 319F–3 of the Public Health Service Act (as
5 added by section 202), and infectious disease research at
6 the Department of Defense.

7 **SEC. 1702. REQUEST BY THE DEPARTMENT OF DEFENSE.**

8 (a) **IN GENERAL.**—Upon request by the Secretary of
9 Defense, the Secretary of Health and Human Services
10 may establish interagency agreements, under terms ac-
11 ceptable to the Secretary of Health and Human Services,
12 in which the Department of Defense may order counter-
13 measures under procurement contracts or procurement
14 pools established by the Secretary of Health and Human
15 Services.

16 (b) **PROCESSING OF ORDERS.**—The ordering of a
17 countermeasure under an agreement under subsection (a)
18 (including transfers of appropriated funds between the
19 Department of Defense and the Department of Health
20 and Human Services to pay for such orders) may be con-
21 ducted pursuant to section 1535 of title 31, United States
22 Code, if such order is processed under the terms estab-
23 lished—

1 (1) by the Secretary in the interagency agree-
2 ment described under subsection (a) for all other or-
3 ders; and

4 (2) in the Project BioShield Act of 2004 and
5 the Project BioShield II Act of 2005 (and the
6 amendments made by such Acts) with respect to the
7 procurement of countermeasures under section
8 319F–2 and section 319F–1 of the Public Health
9 Service Act.

10 **SEC. 1703. EXPANDED PUBLIC-PRIVATE PARTNERSHIP**
11 **AGREEMENTS FOR RESEARCH AND DEVELOP-**
12 **MENT.**

13 (a) COOPERATIVE RESEARCH AND DEVELOPMENT
14 AGREEMENTS.—

15 (1) AUTHORITY.—In order to develop counter-
16 measures and research tools, the Secretary of De-
17 fense may—

18 (A) authorize the directors or commanders
19 of laboratories and technical activities to enter
20 into agreements under section 3710a of title 15,
21 United States Code; and

22 (B) subject to requirements analogous to
23 those governing the licensing of federally owned
24 inventions under section 209 of title 35, United
25 States Code, grant nonexclusive, exclusive, or

1 partially exclusive licenses, royalty-free or for
2 royalties or other consideration, for computer
3 software developed at a laboratory or technical
4 activity that would, if the information involved
5 were obtained from a non-Federal source, con-
6 stitute a trade secret or commercial or financial
7 information that is privileged or confidential
8 under the meaning of section 552(b)(4) of title
9 5, United States Code.

10 (2) PROTECTION OF SOFTWARE.—The Sec-
11 retary of Defense shall provide appropriate pre-
12 cautions against the unlicensed dissemination of any
13 software licensed under paragraph (1)(B), including
14 exemption from subchapter II of chapter 5 of title
15 5, United States Code (commonly known as the Ad-
16 ministrative Procedure Act), for a period of up to 5
17 years after the development of the software by the
18 laboratory or technical activity.

19 (b) ROYALTIES.—

20 (1) IN GENERAL.—Except as provided in para-
21 graph (2), any royalties or other payments received
22 by the Department of Defense from licensing com-
23 puter software under subsection (a)(1)(B) shall be
24 disposed of as follows:

1 (A) The Department may provide appro-
2 priate incentives, from royalties or other pay-
3 ments, to laboratory and technical activity em-
4 ployees who are not developers of such com-
5 puter software but who substantially increased
6 the technical value of the software.

7 (B) The Department shall retain the royal-
8 ties and other payments received until the De-
9 partment or the laboratory or technical activity
10 involved makes payments to employees of a lab-
11 oratory or technical activity under subpara-
12 graph (A).

13 (C) The balance of the royalties or other
14 payments shall be transferred by the Depart-
15 ment of Defense to the accounts of any of its
16 laboratories and technical activities, with the
17 majority share of the royalties or other pay-
18 ments from any invention going to the account
19 of the laboratory or technical activity respon-
20 sible for the invention. The royalties or other
21 payments so transferred may be used or obli-
22 gated by a laboratory or technical activity dur-
23 ing the fiscal year in which they are received or
24 during the 2 succeeding fiscal years—

1 (i) to reward scientific, engineering,
2 and technical employees of the laboratory
3 or technical activity, including developers
4 of sensitive or classified technology, re-
5 gardless of whether the technology has
6 commercial applications;

7 (ii) to further scientific exchange
8 among the laboratories and technical ac-
9 tivities of the Department;

10 (iii) for education and training of em-
11 ployees consistent with the research and
12 development missions and objectives of the
13 Department or the laboratory or technical
14 activity, and for other activities that in-
15 crease the potential for transfer of the
16 technology of the laboratories and technical
17 activities;

18 (iv) for payment of expenses inci-
19 dental to the administration and licensing
20 of computer software or other intellectual
21 property made at that laboratory or tech-
22 nical activity, including the fees or other
23 costs for the services of other agencies,
24 persons, or organizations for intellectual

1 property management and licensing serv-
2 ices; or

3 (v) for scientific research and develop-
4 ment consistent with the research and de-
5 velopment missions and objectives of the
6 laboratory or technical activity.

7 (D) All royalties or other payments re-
8 tained by the Department or laboratory or tech-
9 nical activity after payments have been made
10 pursuant to subparagraphs (A), (B), and (C)
11 that are unobligated and unexpended at the end
12 of the second fiscal year succeeding the fiscal
13 year in which the royalties and other payments
14 were received shall be paid into the Treasury of
15 the United States.

16 (2) EXCESS PAYMENTS.—If, after payments to
17 employee-developers under paragraph (1), the royal-
18 ties or other payments received by the Department
19 of Defense in any fiscal year exceed 5 percent of the
20 budget of the Department for that year, 75 percent
21 of such excess shall be paid to the Treasury of the
22 United States and the remaining 25 percent may be
23 used or obligated as described in paragraph (1)(C).
24 Any funds not so used or obligated shall be paid into
25 the Treasury of the United States.

1 (3) TREATMENT OF PAYMENTS.—Any payment
2 made to an employee under this subsection shall be
3 in addition to the regular pay of the employee and
4 to any other awards made to the employee, and shall
5 not affect the entitlement of the employee to any
6 regular pay, annuity, or award to which such em-
7 ployee is otherwise entitled or for which such em-
8 ployee is otherwise eligible or limit the amount
9 thereof. Any such payment made to an employee-de-
10 veloper shall continue after the developer leaves the
11 laboratory or technical activity or the Department.
12 Payments made under this section shall not exceed
13 \$150,000 per year to any one person, unless the
14 President approves a larger award (with the amount
15 in excess of \$150,000 being treated as a Presidential
16 award under section 4504 of title 5, United States
17 Code).

18 (c) REGULATIONS.—The Secretary of Defense shall
19 promulgate regulations implementing this section.

20 (d) INFORMATION IN REPORT.—The report required
21 under section 2515(d) of title 10, United States Code,
22 shall include information regarding the implementation
23 and effectiveness of this section.

24 (e) LABORATORY AND TECHNICAL ACTIVITY DE-
25 FINED.—As used in this section, the terms “laboratory”

1 and “technical activity” mean any facility or group of fa-
2 cilities that is owned, leased, operated, or otherwise used
3 by the Department of Defense to perform research, devel-
4 opment, engineering, testing, or evaluation. The term in-
5 cludes Department of Defense universities, depots, logis-
6 tics centers, test centers, shipyards, arsenals, or similar
7 organizations that perform these activities in any capacity
8 consistent with their missions, regardless of whether such
9 activities are a primary or substantial element of such mis-
10 sions. This definition also shall be used by Department
11 of Defense entities when entering into cooperative re-
12 search and development agreements under section 3710a
13 of title 15, United States Code.

14 (f) EFFECTIVE DATE AND EXPIRATION.—The au-
15 thority provided for in this section is for a pilot program
16 to test the effectiveness of this authority and shall expire
17 on December 31, 2009.

18 **TITLE XVIII—MILLENNIUM**
19 **MEDICINE DISCOVERY AWARD**

20 **SEC. 1801. MILLENNIUM MEDICINE DISCOVERY AWARD.**

21 Part P of title III of the Public Health Service Act
22 (42 U.S.C. 280 et seq.) is amended by adding at the end
23 the following:

1 **“SEC. 3990. MILLENNIUM MEDICINE DISCOVERY AWARD.**

2 “(a) ESTABLISHMENT OF AWARD.—There is estab-
3 lished an award to be known as the Millennium Medicine
4 Discovery Award (referred to in the section as the
5 ‘Award’).

6 “(b) PURPOSE OF AWARD.—The Secretary shall
7 present the Award to an individual, institution of higher
8 learning (as defined in section 101(a) of the Higher Edu-
9 cation Act of 1965 (20 U.S.C. 1001(a)), or commercial
10 entity that—

11 “(1) discovers a vaccine or therapeutic that
12 cures or prevents AIDS;

13 “(2) discovers a vaccine or therapeutics that
14 prevents infection from malaria;

15 “(3) discovers a new class of anti-microbials; or

16 “(4) attains another achievement in infectious
17 disease research as determined by the Secretary.

18 “(c) REGULATIONS.—

19 “(1) IN GENERAL.—The Secretary shall by reg-
20 ulation establish the medical discoveries for which
21 the Award may be conferred, the amount of the
22 award, and the application process for the Award.

23 “(2) LIMITATION.—The amount of an Award
24 under this section, which shall be in the form of
25 cash, shall not exceed \$100,000,000 per discovery.

1 “(d) EXAMPLES OF DISCOVERIES.—Discoveries that
2 may qualify for an Award under this section may include
3 1 of the following:

4 “(1) An oral vaccine delivery system, or needle-
5 free system, that provides primary immunization
6 against bioterrorism agents, infectious disease, or
7 significant diseases of the developing world.

8 “(2) A new adjuvant for vectored or recom-
9 binant DNA vaccines that induce and sustain both
10 cellular and humeral responses in humans that is di-
11 rected at bioterrorism agents, infectious diseases, or
12 significant diseases of the developing world.

13 “(3) A vaccine that provides lifelong protection
14 against HIV–1 infection, or a vaccine that lessens
15 the viral load in those immunized people who become
16 infected or that delays the clinical progression of dis-
17 ease and decreases transmission of the virus through
18 the immunized population.

19 “(4) A microbicide that prevents or significantly
20 reduces HIV transmission and other infections. In
21 this paragraph, the term ‘microbicide’ means a
22 range of products, including those products in gel,
23 cream, film, ring, or suppository form that, when ap-
24 plied topically, prevent HIV transmission and other
25 sexually transmitted diseases.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
 2 are authorized to be appropriated such sums as may be
 3 necessary to carry out this section. The Secretary shall
 4 secure ½ of the funding for the Awards under this section
 5 from other entities, including nonprofit institutions.”.

6 **TITLE XIX—FOOD AND DRUG**
 7 **ADMINISTRATION**

8 **SEC. 1901. OTHER INCENTIVES.**

9 Part B of title III of the Public Health Service Act
 10 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
 11 tion 319F-3 (as added by section 202) the following:

12 **“SEC. 319F-4. ACCELERATED APPROVAL OF COUNTER-**
 13 **MEASURES.**

14 “(a) IN GENERAL.—The Secretary may designate a
 15 countermeasure as a fast-track product pursuant to sec-
 16 tion 506 of the Federal Food, Drug, and Cosmetic Act
 17 (21 U.S.C. 356) or as a device granted priority review pur-
 18 suant to section 515(d)(5) of such Act (21 U.S.C.
 19 366e(d)(5)). Such a designation may be made prior to the
 20 submission of—

21 “(1) a request for designation by the sponsor or
 22 applicant; or

23 “(2) an application for the investigation of the
 24 drug under section 505(i) (21 U.S.C. 355(i)) of such
 25 Act or section 351(a)(3).

1 Nothing in this subsection shall be construed to pro-
2 hibit a sponsor or applicant from declining such a designa-
3 tion.

4 “(b) USE OF ANIMAL TRIALS.—A drug for which ap-
5 proval is sought under section 505(d) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355(d)) or section 351
7 on the basis of evidence of effectiveness that is derived
8 from animal studies may be designated as a fast-track
9 product for purposes of this section.

10 “(c) PRIORITY REVIEW.—

11 “(1) IN GENERAL.—A countermeasure that is a
12 drug or biological product shall be subject to the
13 performance goals established by the Commissioner
14 of Food and Drugs for priority drugs or biological
15 products.

16 “(2) DEFINITION.—In this subsection, the term
17 ‘priority drugs or biological products’ means a drug
18 or biological product that is the subject of a drug
19 application referred to in section 101(4) of the Food
20 and Drug Administration Modernization Act of
21 1997.”.

22 **SEC. 1902. SYSTEMS BIOLOGY.**

23 (a) FINDINGS.—Congress makes the following find-
24 ings:

1 (1) Systems biology, the application of com-
2 putational tools to understand the dynamic behavior
3 of biological networks as integrated systems rather
4 than isolated parts, is an emerging field of research.

5 (2) Open-source systems biology can play a role
6 in accelerating understanding of complex biological
7 systems, increasing confidence in the analysis and
8 prioritization of drug targets, enabling predictive
9 toxicology, and other emerging capabilities.

10 (3) Such capabilities can lead to shorter drug
11 development times, speeding the delivery of needed
12 medication to address public health concerns, and
13 may help decrease or manage the high risks associ-
14 ated with the entire drug development system, re-
15 sulting in a reduction of the mounting costs of drug
16 development and an increase in the number of new
17 entities brought to market to improve public health.

18 (b) IMPLEMENTATION OF BIOLOGY RESEARCH PRO-
19 GRAMS.—The Secretary of Health and Human Services
20 shall promulgate regulations implementing—

21 (1) systems biology research programs, includ-
22 ing systems biology tool development, model develop-
23 ment, and integration of such research into experi-
24 mental frameworks validating and exploiting re-
25 search results;

1 (2) research efforts, including systems biology
2 approaches, directed to address the detection of bio-
3 threat agents through blood samples; and

4 (3) such programs described in the Food and
5 Drug Report of March 2004 entitled “Critical Path
6 Initiative” that enable the development of tools and
7 methods for the rapid approval of safe medications
8 for the treatment of anticipated biohazards.

9 **SEC. 1903. BIOTERROR AND INFECTIOUS DISEASE PROVI-**
10 **SIONS.**

11 (a) BIOTERROR AND INFECTIOUS DISEASE PROVI-
12 SIONS.—Chapter V of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 351 et seq.) is amended by adding
14 at the end the following:

15 **“Subchapter F—Bioterror and Infectious**
16 **Disease Products**

17 **“SEC. 571. DEFINITIONS.**

18 “In this subchapter:

19 “(1) BIOLOGICAL AGENT.—The term ‘biological
20 agent’, ‘biological toxin’, or any variation of any
21 such term, means any microorganism, virus, infec-
22 tious substance, or biological product, that may be
23 used in a manner that is intended to cause wide-
24 spread death or serious bodily injury, including bio-
25 logical agents and toxins described in paragraphs (1)

1 and (2) of section 178 of title 18, United States
2 Code.

3 “(2) BIOTERROR OR INFECTIOUS DISEASE
4 PRODUCT.—The term ‘bioterror or infectious disease
5 product’ means a countermeasure against a biological
6 agent.

7 “(3) COUNTERMEASURE.—The term ‘counter-
8 measure’ means—

9 “(A) a vaccine and related delivery system,
10 anti-infective, microbicide, diagnostic tech-
11 nology, drug, biological product, or other tech-
12 nology that can be used to diagnose, treat, or
13 prevent infection with or bodily harm from, or
14 the spread of, a biological or chemical agent or
15 toxin on the list described in section 319F-3(f)
16 of the Public Health Service Act, and that is
17 subject to applicable provisions of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 301
19 et seq.), the Public Health Service Act (42
20 U.S.C. 201 et seq.), or the Virus-Serum-Toxin
21 Act (21 U.S.C. 151 et seq.);

22 “(B) a therapy, diagnostic, or piece of
23 equipment that may be used to detect, treat, or
24 prevent bodily harm that may be caused by the

1 use of nuclear or radiological material as a ter-
2 ror weapon;

3 “(C) a qualified countermeasure, as de-
4 fined in section 319F-1 of the Public Health
5 Service Act (42 U.S.C. 247d-6a); and

6 “(D) a security countermeasure, as defined
7 in section 319F-2 (42 U.S.C. 246d-6b).

8 “(4) INFECTIOUS DISEASE.—

9 “(A) IN GENERAL.—The term ‘infectious
10 disease’ means a disease in humans caused
11 by—

12 “(i) a microbe (including a bacteria,
13 virus, fungus, or parasite) that is acquired
14 by a person that reproduces in that person;

15 “(ii) microbial products (such as botu-
16 linum toxin); or

17 “(iii) a prion.

18 “(B) INCLUSION.—

19 “(i) a disease in humans caused by a
20 microorganism, whether or not—

21 “(I) such microorganism is ac-
22 quired by an individual through
23 human-to-human contact; or

24 “(II) if the individual is initially
25 symptomatic of the disease; and

1 “(ii) zoonotic diseases that may find
2 hosts in animal and human populations.

3 **“SEC. 572. DEPUTY COMMISSIONER FOR BIOLOGICAL,**
4 **CHEMICAL, NUCLEAR, RADIOLOGICAL, AND**
5 **INFECTIOUS DISEASE PRODUCTS.**

6 “(a) ESTABLISHMENT OF OFFICE.—There is estab-
7 lished within the Office of Counterterrorism of the Office
8 of the Commissioner of the Food and Drug Administra-
9 tion an Office of the Deputy Commissioner for Biological,
10 Chemical, Nuclear, Radiological, and Infectious Disease
11 Products (referred to in this section as the ‘Deputy Com-
12 missioner’).

13 “(b) DUTIES.—The Deputy Commissioner shall—

14 “(1) oversee, plan, and direct resources and
15 personnel of the Center for Biologies Evaluation and
16 Research, the Center for Drug Evaluation and Re-
17 search, and other relevant offices within the Food
18 and Drug Administration, toward the evaluation of
19 products for the prevention, surveillance, diagnosis,
20 and treatment of biological, chemical, nuclear, radio-
21 logical, and emerging infectious disease threats;

22 “(2) review not less than annually, the progress
23 of such offices with respect to the functions de-
24 scribed under paragraph (1); and

1 “(3) consult with the Commissioner of Food
2 and Drugs with respect to carrying out the duties
3 described under paragraph (1).

4 “(e) AUTHORITY.—The Deputy Commissioner
5 shall have the authority to address staffing needs
6 and compensation for shortfalls resulting from any
7 waiver of user fees under section 574.

8 **“SEC. 573. ACCELERATED APPROVAL FOR CERTAIN PROD-**
9 **UCTS.**

10 “The Secretary shall, at the request of the sponsor
11 of a new bioterror or infectious disease product, deem such
12 countermeasure a fast track product under section 506
13 if—

14 “(1) there is no other countermeasure product
15 approved by the Food and Drug Administration suf-
16 ficient to respond to the bioterror or pathogen threat
17 addressed by such new product; and

18 “(2) the bioterror or pathogen threat addressed
19 by such new product is eminent, as determined by
20 the Secretary, in consultation with the Secretary of
21 Homeland Security and the Director of the Centers
22 for Disease Control and Prevention.

23 **“SEC. 574. WAIVER OF USER FEES.**

24 “(a) IN GENERAL.—The Secretary shall waive the as-
25 sessment of a user fee under chapter VII to the application

1 and approval of a bioterror or infectious disease product.
2 Such waivers shall not result in a reduction of funds avail-
3 able to the Secretary for conducting review of such appli-
4 cations and approvals.

5 “(b) LIMITATION.—The Secretary shall not waive an
6 assessment of a user fee under subsection (a) for an appli-
7 cant more than once.”.

8 **SEC. 1904. APPROVALS OF CERTAIN DRUGS BASED ON ANI-**
9 **MAL TRIALS.**

10 (a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
11 Section 505(d) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 355(d)) is amended by adding at the end
13 the following: “In the case of drugs and diagnostic devices
14 for use against infectious disease or lethal or permanently
15 disabling toxic biological, chemical, radiological, nuclear,
16 or other substances, when adequate and well-controlled
17 studies of effectiveness in humans cannot ethically be con-
18 ducted because the studies would involve administering a
19 potentially lethal or permanently disabling toxic substance
20 or organism to healthy human volunteers, and when ade-
21 quate field trials assessing use of the drug or diagnostic
22 device (in situations such as after accidental or hostile ex-
23 posure to the substance) have not been feasible or where
24 adequate volumes of human samples for diagnosis from
25 previous exposures is not available, the Secretary may

1 grant approval based on evidence of effectiveness derived
2 from appropriate studies in animals. The Secretary may
3 promulgate regulations establishing standards, criteria,
4 and procedures for use of the authority contained in the
5 preceding sentence.”.

6 (b) PUBLIC HEALTH SERVICE ACT.—Section 351 of
7 the Public Health Service Act (42 U.S.C. 262) is amended
8 by adding at the end the following:

9 “(k) APPROVAL OF CERTAIN PRODUCTS AND DIAG-
10 NOSTIC DEVICES BASED ON ANIMAL TRIALS.—In the
11 case of biological products and diagnostic devices for use
12 against infectious disease, or lethal or permanently dis-
13 abling toxic biological, chemical, radiological, nuclear, or
14 other substances, when definitive human effectiveness
15 studies in humans cannot ethically be conducted because
16 the studies would involve administering a potentially lethal
17 or permanently disabling toxic substance or organism to
18 healthy human volunteers, and when adequate field trials
19 assessing use of the drug (in situations such as after acci-
20 dental or hostile exposure to the substance) have not been
21 feasible, the Secretary may grant approval based on evi-
22 dence of effectiveness derived from appropriate studies in
23 animals. The Secretary may promulgate regulations estab-
24 lishing standards, criteria, and procedures for use of the
25 authority provided under this subsection.”.

1 (c) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated such sums as may be
3 necessary to carry out this section (and the amendments
4 made by this section).

5 **SEC. 1905. CLINICAL TRIAL GUIDELINES FOR ANTI-**
6 **INFECTIVES.**

7 Chapter V of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 351 et seq.) is amended by inserting after
9 section 510 the following:

10 **“SEC. 511. CLINICAL TRIAL GUIDELINES FOR ANTI-**
11 **INFECTIVES.**

12 “(a) IN GENERAL.—Not later than 1 year after the
13 date of enactment of the Project BioShield II Act of 2005,
14 the Secretary, acting through the Commissioner of Food
15 and Drugs, shall issue guidelines for the conduct of clin-
16 ical trials with respect to anti-microbials, including anti-
17 microbials to treat resistant pathogens, bacterial menin-
18 gitis, acute bacterial sinusitis, acute bacterial otitis media,
19 and acute exacerbation of chronic bronchitis. Such guide-
20 lines shall indicate the appropriate animal models of infec-
21 tion, in vitro techniques, and valid microbiologic surrogate
22 markers.

23 “(b) REVIEW.—Not later than 5 years after the date
24 of enactment of the Project BioShield II Act of 2005, the
25 Secretary, acting through the Commissioner of Food and

1 Drugs, shall review and update the guidelines described
2 under subsection (a) to reflect developments in scientific
3 and medical information and technology.”.

4 **SEC. 1906. AUTHORIZATION OF APPROPRIATIONS FOR FDA**
5 **PURCHASE OF MICROBIOLOGICAL DATA.**

6 (a) IN GENERAL.—There are authorized to be appro-
7 priated \$3,000,000 for fiscal year 2007 for the purpose
8 of strengthening the ability of the Food and Drug Admin-
9 istration to evaluate antibiotics for the treatment of tar-
10 geted pathogens.

11 (b) SOLE PURPOSE.—Such funds shall be used solely
12 for the purpose of contracting with entities that the Sec-
13 retary of Health and Human Services determines capable
14 of providing national, real-time microbiological data rel-
15 evant to antibiotic sensitivity of all clinically relevant
16 strains of bacterial pathogens.

17 **SEC. 1907. AUTHORIZATION OF APPROPRIATIONS TO IM-**
18 **PLEMENT PUBLIC HEALTH SERVICE ACTION**
19 **PLAN TO COMBAT ANTIMICROBIAL RESIST-**
20 **ANCE.**

21 To implement the Public Health Service action plan
22 to combat antimicrobial resistance (Public Health Action
23 Plan to Combat Antimicrobial Resistance, Part 1: Domes-
24 tic Issues (January 18, 2001)) as developed by the Inter-
25 agency Antimicrobial Resistance Task Force authorized

1 under section 319E of the Public Health Service Act (42
2 U.S.C. 247d–5), there are authorized to be appropriated
3 \$25,000,000 for fiscal year 2007.

4 **TITLE XX—ANIMAL MODELS**

5 **SEC. 2001. ANIMAL MODELS FOR CERTAIN DISEASES.**

6 (a) FINDING.—Congress finds that the development
7 of well-characterized animal models for identified threat
8 agents is crucial for testing the efficacy of medical coun-
9 termeasures, and that data is crucial for licensure of prod-
10 ucts to protect the Nation, particularly those animals ge-
11 netically designed and bred to mimic the disease or toxic
12 response of humans to a particular biological insult.

13 (b) ESTABLISHMENT OF WORKING GROUP; GRANTS
14 TO STUDY ANIMAL RESPONSES.—Subpart 6 of part C of
15 title IV of the Public Health Service Act (42 U.S.C. 285f
16 et seq.) is amended by adding at the end the following:
17 **“SEC. 447C. ESTABLISHMENT OF WORKING GROUP.**

18 “(a) IN GENERAL.—The Director of the Institute, in
19 consultation with the Assistant Secretary for Medical
20 Readiness and Response of the Department of Homeland
21 Security and the Director of the Centers for Disease Con-
22 trol and Prevention, shall establish a working group to
23 carry out the duties described in subsection (b) (referred
24 to in this section as the ‘Working Group’).

1 “(b) DUTIES.—The Working Group shall determine
2 the most pressing scientific gaps in understanding that
3 must be addressed to create accurate animal models used
4 to determine disease processes for agents that threaten
5 humans.

6 “(c) MEMBERSHIP.—The Working Group shall in-
7 clude not less than one Director of a center in the National
8 Private Research Program.

9 **“SEC. 447D. GRANTS TO STUDY ANIMAL RESPONSES.**

10 “(a) IN GENERAL.—The Secretary, in consultation
11 with the Commissioner of Food and Drugs and the Sec-
12 retary of Homeland Security, shall—

13 “(1) establish and award grants under this sec-
14 tion to eligible entities to study the physiological re-
15 sponses of certain animal species to bioterrorism
16 agents and other infectious agents; and

17 “(2) coordinate efforts to identify and develop
18 well-characterized animal models, including cor-
19 relates of protection, when feasible, for categories of
20 infectious diseases, and classes of toxins considered
21 the most likely threats to human populations, as
22 identified as bioterror agents by the Office of Emer-
23 gency Preparedness and Response of the Centers for
24 Disease Control and Prevention.

1 “(b) ELIGIBILITY; APPLICATION.—To be eligible to
2 receive a grant under this section, an entity shall—

3 “(1) provide assurances to the Secretary that
4 the entity has a biosafety level 3 or 4 facility that
5 is approved by the Centers for Disease Control and
6 Prevention or has a contractual relationship with
7 such a facility; and

8 “(2) with respect to an animal biosafety lab,
9 provide assurances that such lab is in compliance
10 with the Guide for the Care and Use of Laboratory
11 Animals and the Animal Welfare Act (7 U.S.C. 2131
12 note); and

13 “(3) submit to the Secretary an application at
14 such time, in such manner, and containing such in-
15 formation as the Secretary may require.

16 “(c) BENEFITS UNDER PROJECT BIOSHIELD.—

17 “(1) IN GENERAL.—If the Secretary determines
18 that an entity receiving a grant under this section
19 has successfully and thoroughly created an animal
20 model for the purpose of testing and regulating
21 novel countermeasures, such animal model shall be
22 considered a research tool for purposes of receiving
23 the benefits under the amendments made by the
24 Project BioShield II Act of 2005.

1 “(2) CLARIFICATION.—An animal model may
2 be developed, and subsequently recommended by the
3 Food and Drug Administration, separately from a
4 countermeasure application so that such animal
5 model is regarded as a research tool for the counter-
6 measure and such Administration may require such
7 recommended animal model in clinical trials to fulfill
8 regulatory requirements.

9 “(d) DEFINITIONS.—

10 “(1) BIOSAFETY LEVEL 3 FACILITY.—The term
11 ‘biosafety level 3 facility’ means a facility described
12 in section 627.15 of title 32, Code of Federal Regu-
13 lations (or any successor regulation).

14 “(2) BIOSAFETY LEVEL 4 FACILITY.—The term
15 ‘biosafety level 4 facility’ means a facility described
16 in section 627.16 of title 32, Code of Federal Regu-
17 lations (or any successor regulation).

18 “(3) RESEARCH TOOL.—The term ‘research
19 tool’ includes the full range of tools that scientists
20 may use in the laboratory, including animal disease
21 models, cell lines, cell line cultures for the produc-
22 tion of biologics, monoclonal and polyclonal anti-
23 bodies, reagents, drug delivery technologies, vaccine
24 adjuvants, laboratory animals, large animals includ-
25 ing nonhuman primates and large animals used for

1 drug production, growth factors, combinatorial
2 chemistry and DNA libraries, antigen libraries,
3 clones and cloning tools (such as PCR or Real Time
4 PCR), methods, laboratory equipment and machines,
5 databases, and other technologies that enable the
6 rapid and effective development of countermeasures,
7 including diagnostics, vaccines, and drugs.

8 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
9 are authorized to be appropriated such sums as may be
10 necessary for the development of animals models described
11 under subsection (a)(2).”.

12 **SEC. 2002. ANIMAL MODELS FIVE-YEAR INITIATIVE.**

13 (a) FINDINGS.—Congress finds the following:

14 (1) The United States Government has made
15 an unprecedented commitment to expanding and ad-
16 vancing the biomedical research program at the Na-
17 tional Institutes of Health, and the success of the
18 Government’s efforts is contingent upon the avail-
19 ability of quality resources that will enable and en-
20 hance all research endeavors ranging from the most
21 basic and fundamental to the most highly innovative.

22 (2) Biomedical research has relied on such
23 quality resource, the National Primate Research
24 Centers Program, for more than 40 years, for re-

1 search models and expertise with non-human pri-
2 mates.

3 (3) The National Primate Research Centers
4 Program is comprised of a network of 8 National
5 Primate Research Centers (referred to in this sec-
6 tion “NPRCs”) that provide centralized housing and
7 care for non-human primates, as well as the facilities
8 and support necessary for research conducted with
9 such primates. Scientists from almost every State
10 use the resources of the NPRCs for a vast array of
11 studies.

12 (4) As a result of expanded investment in bio-
13 medical research from 2000 to 2005, the demand for
14 the resources of the NPRCs has increased signifi-
15 cantly, but several important impediments have be-
16 come barriers to successful non-human primate re-
17 search, including the limited number of such pri-
18 mates available, the lack of infrastructure to breed
19 and house animals for research, and the need for
20 trained staff for handling and sophisticated care.

21 (5) In order to remedy such problems, the Na-
22 tional Institutes of Health needs to support a Fed-
23 eral advancement initiative for the NPRCs that ad-
24 dresses the necessary upgrades and program capac-
25 ity expansions.

1 (b) FIVE-YEAR INITIATIVE FOR PRIMATE CEN-
2 TERS.—

3 Subpart 1 of Part E of title IV of the Public Health
4 Service Act (42 U.S.C. 287 et seq.) is amended by—

5 (1) redesignating the section 481C as added by
6 Public Law 106-505 as section 481D; and

7 (2) by adding at the end the following:

8 **“SEC. 481E. FIVE-YEAR INITIATIVE FOR PRIMATE CENTERS.**

9 “(a) IN GENERAL.—The Secretary shall provide ad-
10 ditional sums to the base grants provided to the National
11 Primate Research Centers by the National Center for Re-
12 search Resources in order to—

13 “(1) increase domestic breeding capabilities;

14 “(2) develop bridging programs to effectively
15 utilize additional primate species;

16 “(3) increase the quality and capacity of pri-
17 mate housing and breeding facilities and the avail-
18 ability of related state-of-the-art diagnostic and clin-
19 ical support equipment for primates; and

20 “(4) increase the number of personnel trained
21 in primate care and management at the National
22 Primate Research Centers.

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

1 **TITLE XXI—STRENGTHENING OF**
2 **THE VACCINE INDUSTRY**
3 **Subtitle A—Biologics, Adjuvants,**
4 **and Cell Culture Development**

5 **SEC. 2101. BIOLOGICS MANUFACTURING CAPACITY INCEN-**
6 **TIVES.**

7 Part B of title III of the Public Health Service Act
8 (42 U.S.C. 243 et seq.) (as amended by sections 202 and
9 1901) is amended by inserting after section 319F–4 (as
10 added by section 1901) the following:

11 **“SEC. 319F–5. BIOLOGICS MANUFACTURING CAPACITY IN-**
12 **CENTIVES.**

13 “(a) SURVEY AND PLAN.—Not later than 90 days
14 after the date of enactment of the Project BioShield II
15 Act of 2005, the Secretary shall—

16 “(1) conduct a survey of the biologics manufac-
17 turing and filling facilities, including those for the
18 production of antibiotics, vaccines, monoclonal and
19 polyclonal antibodies, recombinant proteins, and
20 plant compounds using cell culture methods, recom-
21 binant technology or other techniques, as well as
22 those for the production of antibodies and other
23 blood products from human and animal blood, oper-
24 ating in the United States and determine whether
25 additional manufacturing facilities that will be need-

1 ed (and if so the number of such facilities) to manu-
2 facture and stockpile biologically active materials for
3 bioterrorist attacks or infectious disease outbreaks;
4 and

5 “(2) develop a plan to ensure that sufficient
6 biologics manufacturing and filling facilities are
7 available in the United States, Canada, Mexico, Eu-
8 rope, and Japan, when they are needed, including an
9 analysis of the feasibility of the Federal Government
10 contracting for the construction and maintenance of
11 such facilities or of providing tax and other incen-
12 tives for the construction and maintenance of such
13 facilities by private sector entities.

14 “(b) SUBMISSION TO CONGRESS.—The Secretary
15 shall submit the plan developed under subsection (a)(2)
16 to Congress together with recommendations concerning
17 the manner in which to ensure that the needed biologics
18 manufacturing facilities available for the production of
19 countermeasures under this title are constructed and
20 available, including the siting, design and certification
21 costs, costs of training and recruitment of expert staff,
22 and other costs associated with such facilities.

23 “(c) INCENTIVES FOR THE CONSTRUCTION OF BIO-
24 LOGICS MANUFACTURING FACILITIES AVAILABLE FOR
25 THE PRODUCTION OF COUNTERMEASURES.—The Sec-

1 retary shall issue regulations regarding the selection of an
2 entity that agrees to operate as a biologics manufacturing
3 facility available for the production of countermeasures
4 under this title in accordance with the plan developed
5 under subsection (a)(2) for the investment tax credit pro-
6 vided under the amendments made by title III of the
7 Project BioShield II Act of 2005. Such regulations shall
8 state when such an entity shall be available and the terms
9 for the use for the production of such countermeasures.
10 If an entity is constructed to produce such counter-
11 measures, such entity shall provide notice that such entity
12 is available to produce such countermeasures.”.

13 **SEC. 2102. BIOLOGICS MANUFACTURING EFFICIENCY IN-**
14 **CENTIVES.**

15 Part B of title III of the Public Health Service Act
16 (42 U.S.C. 243 et seq.) (as amended by sections 202,
17 1901, and 2101) is amended by inserting after section
18 319F-5 (as added by section 2101) the following:

19 **“SEC. 319F-6. BIOLOGICS MANUFACTURING EFFICIENCY IN-**
20 **CENTIVES.**

21 “(a) FINDINGS.—Congress finds that—

22 “(1) the manufacturing of biologics, which are
23 derived from living organisms, is an art as well as
24 a science;

1 “(2) the efficiency of the biologics manufac-
2 turing process determines the output capacity, pu-
3 rity, and manufacturing cost of antibiotics, vaccines,
4 recombinant proteins, plant compounds, antibodies,
5 and blood products;

6 “(3) technical advances in manufacturing
7 sciences for biologics can increase the capacity of the
8 Federal Government to ensure that antibiotics, vac-
9 cines, recombinant proteins, plant compounds, anti-
10 bodies, and blood products are available as part of
11 a bioterror or infectious disease plan and to reduce
12 the cost of manufacturing and stockpiling these vac-
13 cines, recombinant proteins, plant compounds, anti-
14 bodies, and blood products; and

15 “(4) the subjects of research relating to the
16 manufacturing of biologics may include the develop-
17 ment of—

18 “(A) additional well-characterized cell lines
19 or host strains for antibiotics, vaccines, recom-
20 binant proteins, plant compounds, and
21 monoclonal and polyclonal antibody production;

22 “(B) new biologic and chemical standards
23 for use in product testing, including testing of
24 potency and purity;

1 “(C) improved preservatives for vaccines or
2 other biologics to prolong shelf-life;

3 “(D) adjuvants that enhance the immune
4 response;

5 “(E) tests to determine contamination with
6 human or animal viruses or prions;

7 “(F) improved tests of potency and purity
8 during the manufacturing process, not just for
9 the final product;

10 “(G) improved characterization of biologics
11 at the macro-molecular level;

12 “(H) processes that enhance the yield and
13 quality of biologics;

14 “(I) improved methods that enhance dis-
15 infection and sterilization of material and facili-
16 ties;

17 “(J) new methods to improve output, man-
18 ufacturing costs, and product quality with a
19 particular emphasis on downstream processing
20 (separation and purification) where particular
21 bottlenecks occur with much lost product, com-
22 plexity, and very high costs; and

23 “(K) improved methods for decontamina-
24 tion of production facilities to enable switching
25 from one product to another.

1 “(b) SURVEY AND PLAN.—Not later than 180 days
2 after the date of enactment of the Project BioShield II
3 Act of 2005, the Secretary shall—

4 “(1) conduct a survey of existing biologics man-
5 ufacturing sciences and determine whether technical
6 advances in such sciences might increase the bio-
7 logics output capacity and purity, and lower the
8 manufacturing cost of antibiotics, vaccines, recom-
9 binant proteins, plant compounds, antibodies, and
10 blood products; and

11 “(2) develop a plan to provide incentives to en-
12 hance scientific research to develop new technologies
13 identified under the survey conducted under para-
14 graph (1), including a list of the possible tech-
15 nologies that may be developed and the possible in-
16 centives that may lead to their development.

17 “(c) SUBMISSION TO CONGRESS.—The Secretary
18 shall submit the plan developed under subsection (b)(2)
19 to Congress together with recommendations concerning
20 the provision of funding or incentives for the conduct of
21 scientific research to develop new technologies relating to
22 biologics manufacturing sciences.

23 “(d) INCENTIVES.—The Secretary shall establish a
24 program under which entities that agree to develop new
25 technologies, or improve existing technologies, in accord-

1 ance with the plan developed under subsection (b)(2) are
2 eligible for the tax incentives provided for under the
3 amendments made by section 312 of the Project BioShield
4 II Act of 2005.”.

5 **SEC. 2103. DEVELOPMENT OF VACCINE ADJUVANTS.**

6 (a) FINDINGS.—Congress finds the following:

7 (1) New vaccines are under development and
8 testing for the control of infectious diseases includ-
9 ing human immunodeficiency virus infection, an-
10 thrax, avian flu, and many others, and additional in-
11 fectious diseases can be anticipated with advanced
12 rapid, along with advanced rapid production of vac-
13 cine technologies.

14 (2) Most new vaccines are composed of syn-
15 thetic, recombinant, or highly purified subunit anti-
16 gens that are safer than those in use as of the date
17 of enactment of this Act, but their purity can result
18 in a weaker protective response from the vaccine re-
19 cipient.

20 (3) Vaccines are administered to protect a
21 healthy population, and any complications with vac-
22 cines result in swift and severe public and legal re-
23 sponses.

24 (4) Adjuvants are chemicals that enhance the
25 specific protective immune response of vaccines.

1 (5) As of 2005, there is one aluminum salt-
2 based adjuvant used in vaccines licensed in the
3 United States.

4 (6) Standardized methods to evaluate new vac-
5 cine adjuvant safety must be implemented for
6 human vaccines that are to be formulated with novel
7 adjuvants.

8 (7) Vaccine adjuvants should receive highest
9 priority by the Food and Drug Administration and
10 the National Institute of Allergy and Infectious Dis-
11 eases, as the failure to develop and approve them
12 will result in the inability to deploy effective counter-
13 measures against bioterrorism or naturally occurring
14 infectious diseases, even when vaccine development
15 is achieved.

16 (b) VACCINE ADJUVANT PRIORITY.—The Secretary
17 of Health and Human Services shall promulgate regula-
18 tions that establish—

19 (1) priority handling procedures, which may in-
20 cluded expedited review and fee waivers, at the Food
21 and Drug Administration with respect to vaccine ad-
22 juvants; and

23 (2) methods for evaluating the safety of—

1 (A) adjuvants, separate from the methods
2 used to evaluate the safety and effectiveness of
3 adjuvants with vaccine agents; and

4 (B) adjuvants used in conjunction with one
5 or more vaccine agent.

6 (c) INCENTIVES FOR VACCINE ADJUVANT PRO-
7 DUCERS.—

8 (1) IN GENERAL.—Persons that produce adju-
9 vants shall be entitled to receive the incentives under
10 title III (and the amendments made by that title).

11 (2) DEFENSE OF CERTAIN MALPRACTICE AND
12 NEGLIGENCE SUITS.—Section 224 of the Public
13 Health Service Act (42 U.S.C. 233) (as amended by
14 title III of this Act) shall apply to vaccine adjuvants
15 developed for use in bioterrorism countermeasures or
16 to treat or prevent infectious disease in the same
17 manner as such section applies to covered counter-
18 measures (as defined by such section).

19 (d) REQUESTS FOR PROPOSALS.—The Secretary of
20 Health and Human Services shall develop and publish in
21 the Federal Register a request for proposals with respect
22 to adjuvant development and production.

23 (e) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated such sums as may be
25 necessary carry out this section.

1 **SEC. 2104. CELL CULTURE OR RECOMBINANT VACCINES.**

2 (a) GRANTS.—The Director of the National Insti-
3 tutes of Health, in consultation with the Commissioner of
4 Food and Drugs and the Director of the Centers of Dis-
5 ease Control and Prevention, may award grants to eligible
6 entities for the development of cell-culture and other vac-
7 cine production technologies.

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

10 (1) be a public or private entity determined ap-
11 propriate by the Director of the National Institutes
12 of Health; and

13 (2) prepare and submit to the Director an ap-
14 plication at such time, in such manner, and con-
15 taining such information as the Director may re-
16 quire.

17 (c) USE OF FUNDS.—An entity shall use amounts re-
18 ceived under a grant under this section to carry out activi-
19 ties leading to the development of cell-culture and other
20 vaccine production technology, including the retooling of
21 outdated plants and the construction of new manufac-
22 turing plants.

23 (d) ACTIVITIES OF THE FOOD AND DRUG ADMINIS-
24 TRATION.—To further the goal of increasing the produc-
25 tion of cell culture and other vaccines, the Food and Drug
26 Administration shall—

1 (1) develop updated regulations relating to the
2 approval of cell culture and other vaccines; and

3 (2) as part of such regulations, provide for pri-
4 ority to be given to the inspection and evaluation of
5 cell culture and other vaccine manufacturing plants.

6 (e) ACTIVITIES OF THE SECRETARY.—To further the
7 goal of increasing the production of cell culture and other
8 vaccines, the Secretary of Health and Human Services
9 shall—

10 (1) develop a strategic plan for the distribution
11 of biologicals developed at facilities constructed
12 under a grant under this section in the case of an
13 infectious disease outbreak; and

14 (2) not later than 6 months after the date of
15 enactment of this Act, submit to the appropriate
16 committees of Congress a report on the strategy de-
17 veloped under paragraph (1) and on the status and
18 use of previous vaccine development grants.

19 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
20 authorized to be appropriated such sums as may be nec-
21 essary to carry out this section.

1 Subtitle B—Influenza Vaccine

2 **CHAPTER 1—INFLUENZA VACCINE**

3 **AWARENESS CAMPAIGN**

4 **SEC. 2111. AWARENESS CAMPAIGN AND EDUCATION AND**
5 **OUTREACH EFFORTS.**

6 Part P of title III of the Public Health Service Act
7 (42 U.S.C. 280g et seq.) is amended by adding at the end
8 the following:

9 **“SEC. 3990. AWARENESS CAMPAIGN AND EDUCATION AND**
10 **OUTREACH EFFORTS.**

11 “(a) CAMPAIGN.—The Secretary, acting through the
12 Director of the Centers for Disease Control and Preven-
13 tion (in this section referred to as the ‘Director’), shall
14 conduct a public awareness campaign and education and
15 outreach efforts each year during the time period pre-
16 ceding the influenza season on each of the following:

17 “(1) The importance of receiving the influenza
18 vaccine.

19 “(2) Which populations the Director rec-
20 ommends to receive the influenza vaccine to prevent
21 health complications associated with influenza, in-
22 cluding health care workers and household contacts.

23 “(3) Professional medical education of physi-
24 cians, nurses, pharmacists, and other health care

1 providers and such providers' associated organiza-
2 tions.

3 “(4) Information that emphasizes the safety
4 and benefit of recommended vaccines for the public
5 good.

6 “(b) OUTREACH TO MEDICARE RECIPIENTS.—

7 “(1) IN GENERAL.—The Administrator of the
8 Centers for Medicare & Medicaid Services shall, at
9 the earliest possible time in the influenza vaccine
10 planning and production process, reach out to pro-
11 viders of medicare services, including managed care
12 providers, nursing homes, hospitals, and physician
13 offices to urge early and full preordering of the in-
14 fluenza vaccine so that production levels can accom-
15 modate the needs for the influenza vaccine.

16 “(2) RATES OF IMMUNIZATION AMONG MEDI-
17 CARE RECIPIENTS.—The Director shall work with
18 the Administrator of the Centers for Medicare &
19 Medicaid Services to publish the rates of influenza
20 immunization among individuals receiving assistance
21 under the medicare program under title XVIII of the
22 Social Security Act (42 U.S.C. 1395 et seq.).

23 “(c) STATE AND PUBLIC HEALTH ADULT IMMUNIZA-
24 TION ACTIVITIES.—The Director shall support the devel-
25 opment of State adult immunization programs that place

1 emphasis on improving influenza vaccine delivery to high-
 2 risk populations and the general population, including the
 3 exploration of improving access to the influenza vaccine.

4 “(d) EFFICACY OF VACCINE.—The Director shall
 5 work with appropriate agencies in conducting a study to
 6 assess the efficacy of the influenza vaccine.

7 “(e) EXISTING MODES OF COMMUNICATION.—In car-
 8 rying out the public awareness campaign and education
 9 and outreach efforts under subsections (a) and (b), the
 10 Director may use existing websites or structures for com-
 11 munication.

12 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
 13 are authorized to be appropriated to carry out this section
 14 \$10,000,000 for each of fiscal years 2005 through 2009.”.

15 **CHAPTER 2—ENCOURAGING VACCINE**

16 **PRODUCTION CAPACITY**

17 **SEC. 2121. INCENTIVES FOR THE CONSTRUCTION OF VAC-** 18 **CINE MANUFACTURING FACILITIES.**

19 (a) VACCINE MANUFACTURING FACILITIES INVEST-
 20 MENT TAX CREDIT.—

21 (1) ALLOWANCE OF CREDIT.—Section 46 of the
 22 Internal Revenue Code of 1986 (relating to amount
 23 of investment credit) is amended by striking “and”
 24 at the end of paragraph (1), by striking the period
 25 at the end of paragraph (2) and inserting “, and”,

1 and by adding at the end the following new para-
2 graph:

3 “(3) the vaccine manufacturing facilities invest-
4 ment credit.”.

5 (2) AMOUNT OF CREDIT.—Subpart E of part
6 IV of subchapter A of chapter 1 of such Code (relat-
7 ing to rules for computing investment credit) is
8 amended by inserting after section 48 the following
9 new section:

10 **“SEC. 48A. VACCINE MANUFACTURING FACILITIES CREDIT.**

11 “(a) IN GENERAL.—For purposes of section 46, the
12 influenza vaccine manufacturing facilities investment cred-
13 it for any taxable year is an amount equal to 20 percent
14 of the qualified investment for such taxable year.

15 “(b) QUALIFIED INVESTMENT.—

16 “(1) IN GENERAL.—For purposes of subsection
17 (a), the qualified investment for any taxable year is
18 the basis of each influenza vaccine manufacturing
19 facilities property placed in service by the taxpayer
20 during such taxable year.

21 “(2) VACCINE MANUFACTURING FACILITIES
22 PROPERTY.—For purposes of this section, the term
23 ‘influenza vaccine manufacturing facilities property’
24 means real and tangible personal property—

1 “(A)(i) the original use of which com-
2 mences with the taxpayer, or

3 “(ii) which is acquired through purchase
4 (as defined by section 179(d)(2)),

5 “(B) which is depreciable under section
6 167,

7 “(C) which is used for the manufacture,
8 distribution, or research and development of
9 vaccines, and

10 “(D) which is in compliance with any
11 standards and regulations which are promul-
12 gated by the Food and Drug Administration,
13 the Occupational Safety and Health Adminis-
14 tration, or the Environmental Protection Agen-
15 cy and which are applicable to such property.

16 “(c) CERTAIN PROGRESS EXPENDITURE RULES
17 MADE APPLICABLE.—Rules similar to rules of subsections
18 (c)(4) and (d) of section 46 (as in effect on the day before
19 the date of the enactment of the Revenue Reconciliation
20 Act of 1990) shall apply for purposes of this subsection.

21 “(d) TERMINATION.—This subsection shall not apply
22 to any property placed in service after December 31,
23 2009.”.

24 (b) TECHNICAL AMENDMENTS.—

1 (1) Clause (iii) of section 49(a)(1)(C) of such
2 Code is amended to read as follows:

3 “(iii) the basis of any vaccine manu-
4 facturing facilities property.”.

5 (2) Subparagraph (E) of section 50(a)(2) of
6 such Code is amended by inserting “or 48A(c)” be-
7 fore the period.

8 (3) The table of sections for subpart E of part
9 IV of subchapter A of chapter 1 of such Code is
10 amended by inserting after the item relating to sec-
11 tion 48 the following:

“Sec. 48A. Vaccine manufacturing facilities credit.”.

12 (c) EFFECTIVE DATE.—The amendments made by
13 this section shall apply to property placed in service after
14 December 31, 2004, under rules similar to the rules of
15 section 48(m) of the Internal Revenue Code of 1986 (as
16 in effect on the day before the date of enactment of the
17 Revenue Reconciliation Act of 1990).

18 **CHAPTER 3—ENSURING SUFFICIENT FLU**
19 **VACCINE SUPPLY**

20 **SEC. 2131. VACCINE SUPPLY.**

21 Title XXI of the Public Health Service Act (42
22 U.S.C. 300aa–1 et seq.) is amended by adding at the end
23 the following:

1 “Subtitle 3—Influenza Vaccine

2 “VACCINE SUPPLY

3 “SEC. 2141. (a) REQUESTS FOR MORE DOSES.—

4 “(1) IN GENERAL.—Not later than March 15 of
5 each year, the Secretary shall enter into contracts
6 with manufacturers to produce such additional doses
7 of the influenza vaccine as determined necessary by
8 the Secretary.

9 “(2) CONTENT OF CONTRACT.—A contract for
10 additional doses shall provide that the manufacturer
11 will be compensated by the Secretary at an equitable
12 rate negotiated by the Secretary and the manufac-
13 turer for any doses that—

14 “(A) were not sold by the manufacturer
15 through routine market mechanisms at the end
16 of the influenza season for that year; and

17 “(B) were requested by the Secretary to be
18 produced by such manufacturer.

19 “(3) WHEN SUCH VACCINE PURCHASES
20 SHOULD TAKE PLACE.—The Secretary may purchase
21 from the manufacturer the doses for which it has
22 contracted at any time after which it is determined
23 by the Secretary, in consultation with the manufac-
24 turer, that the doses will likely not be absorbed by
25 the private market.

1 “(b) CONTINGENCY PLAN.—The Secretary shall en-
 2 courage States to develop a contingency plan, in coordina-
 3 tion with the Department of Health and Human Services,
 4 for maximizing influenza immunization for high-risk popu-
 5 lations in the event of a delay or shortage of the influenza
 6 vaccine.

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

10 **CHAPTER 4—PREPARING FOR A**
 11 **PANDEMIC OR EPIDEMIC**

12 **SEC. 2141. PREPARATION FOR INFLUENZA PANDEMIC OR**
 13 **EPIDEMIC; ANTI-VIRALS SUPPLY.**

14 Subtitle 3 of title XXI of the Public Health Service
 15 Act, as added by section 2131, is amended by adding at
 16 the end the following:

17 “PREPARATION FOR INFLUENZA PANDEMIC OR EPIDEMIC

18 “SEC. 2142. (a) ESTABLISHMENT OF A PROTOCOL.—
 19 The Secretary, acting through the Director of the Na-
 20 tional Vaccine Program (referred to in this section as the
 21 ‘Director of the Program’), shall continue progress on the
 22 pandemic preparedness plan and, in consultation with the
 23 Director of the Centers for Disease Control and Preven-
 24 tion, establish a protocol to attempt to prevent, prepare
 25 for, and respond to an influenza pandemic or epidemic.

1 Such protocol shall be updated as determined appropriate
2 by the Director of the Program.

3 “(b) CONTENTS OF PROTOCOL.—The protocol estab-
4 lished under subsection (a) shall—

5 “(1) improve upon the current influenza vac-
6 cines and production and dissemination methods;
7 and

8 “(2) address—

9 “(A) methods to coordinate dissemination
10 of the influenza vaccine to key populations in
11 the event of an influenza pandemic or epidemic;

12 “(B) expansion of influenza vaccine manu-
13 facturing capacity (including making advance
14 arrangements for ensuring the availability of
15 raw materials) to respond to the needs of the
16 United States during an influenza pandemic or
17 epidemic;

18 “(C) alternative ways to manufacture or
19 produce the influenza vaccine;

20 “(D) alternative methods to prevent the
21 spread of, and complications associated with,
22 influenza, including anti-viral medications;

23 “(E) vaccine manufacturing capacity, pro-
24 duction, and dissemination to improve pre-

1 paredness for immediate pandemic threats,
2 which may include avian influenza;

3 “(F) a tracking method for publicly and
4 privately sold doses of the influenza vaccine to
5 enable the Director of the Program to deter-
6 mine, after consultation with manufacturers of
7 the influenza vaccine, how much supply is in
8 circulation in the case of an influenza pandemic
9 or epidemic; and

10 “(G) other issues determined by the Direc-
11 tor of the Program to be appropriate.

12 “(c) COORDINATION; PREPARATION; PREVENTION.—
13 In establishing the protocol under subsection (a), the Di-
14 rector of the Program shall—

15 “(1) coordinate with health care providers,
16 manufacturers, research institutions, health care or-
17 ganizations, and other expert stakeholders;

18 “(2) continue building international and na-
19 tional surveillance capacity;

20 “(3) continue to engage in epidemiological stud-
21 ies and research on novel influenza viruses; and

22 “(4) assist States with preparedness activities
23 for a rapid State and local response to an influenza
24 pandemic, including exploring methods of making

1 the influenza vaccine more accessible to the general
2 population.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to carry out this section
5 \$150,000,000 for each of fiscal years 2005 through 2009.

6 **“SEC. 2143. INFLUENZA ANTI-VIRALS SUPPLY.**

7 “(a) IN GENERAL.—The Secretary shall establish a
8 stockpile of anti-virals to use for rapid response to an in-
9 fluenza outbreak.

10 “(b) AMOUNT.—The stockpile established under sub-
11 section (a) shall be of sufficient quantity to treat not less
12 than 2 percent of the population of the United States.”.

13 **CHAPTER 5—REPORT AND**

14 **ADMINISTRATION**

15 **SEC. 2151. REPORT TO CONGRESS.**

16 Not later than 180 days after the date of enactment
17 of this Act, the Director of the Centers for Disease Control
18 and Prevention, in consultation with the Assistant Sec-
19 retary for Medical Readiness and Response of the Depart-
20 ment of Homeland Security and the Director of the Na-
21 tional Institute for Allergy and Infectious Disease of the
22 National Institutes of Health, shall submit a report to
23 Congress that describes alternatives to traditional vaccines
24 and anti-viral therapeutics for viral diseases, including
25 negative immunomodulation compounds that partially

1 suppress a macrophage-dependent innate immune re-
2 sponse of an individual to viral pathogens, in order to de-
3 crease morbidity and mortality from an excessive immune
4 response.

5 **SEC. 2152. SIMPLIFIED ADMINISTRATION OF VACCINE SUP-**
6 **PLY.**

7 Section 1928(d)(6) of the Social Security Act (42
8 U.S.C. 1396s(d)(6)) is amended by inserting before the
9 last sentence the following: “The Secretary may sell such
10 quantities of vaccines from such supply as the Secretary
11 determines appropriate. Proceeds received from such sales
12 shall be available to the Secretary solely for the purposes
13 of this section and shall remain available until expended.

14 **SEC. 2153. MEDICARE COVERAGE OF VACCINES AND PRO-**
15 **PHYLAXIS AS COUNTERMEASURES.**

16 (a) FINDINGS.—Congress finds the following:

17 (1) In the event of a bioterrorism attack or in-
18 fectionous disease outbreak, it is in the public interest
19 to ensure appropriate and timely voluntary utiliza-
20 tion of critical vaccines and other prophylaxis
21 against these pathogens.

22 (2) Such voluntary utilization in such emer-
23 gency will be increased if the vaccines and other pro-
24 phylaxis are covered under Medicare Part B.

1 (3) Such voluntary utilization reduces adverse
2 impacts on the public health infrastructure and as-
3 sists in containing the pathogen without the need to
4 impose quarantines.

5 (4) Coverage and reimbursement for most vac-
6 cines and other prophylaxis currently is not available
7 under Medicare Part B.

8 (5) Medicare Part B does cover diagnostic serv-
9 ices as well as drugs and biological products that are
10 administered incident to a physician's services that
11 are not usually self-administered by the patient as
12 long as they are "reasonable and necessary for the
13 diagnosis or treatment of illness or injury or to im-
14 prove the function of a malformed body member".

15 (6) The public interest would be served best by
16 extending Medicare Part B coverage and reimburse-
17 ment to vaccines and prophylaxis that would combat
18 a wide variety of chemical and biological agents, tox-
19 ins, nuclear and radiological materials, and emerging
20 infectious diseases.

21 (b) AMENDMENT TO THE SOCIAL SECURITY ACT TO
22 EXTEND COVERAGE.—Section 1861(s)(10)(A) of the So-
23 cial Security Act (42 U.S.C. 1396x(s)(10)(A)) is amended
24 by inserting “, a vaccine or prophylaxis against any of the
25 agents, toxins, or materials on the list developed by the

1 Secretary under section 319F–3(f) of the Public Health
2 Service Act and its administration” after “pneumococcal
3 vaccine and its administration”.

4 (c) EFFECTIVE DATE.—The amendment made by
5 subsection (b) shall apply to items furnished on or after
6 the date of enactment of this Act.

7 **TITLE XXII—GAAP ACCOUNTING**
8 **FOR VACCINE REVENUE REC-**
9 **OGNITION**

10 **SEC. 2201. GAAP ACCOUNTING FOR VACCINE PROCURE-**
11 **MENT.**

12 Not later than 180 days after the date of enactment
13 of this Act, the Secretary of Health and Human Services
14 and the Secretary of Homeland Security, in consultation
15 with appropriate representatives from the Securities and
16 Exchange Commission (as determined by such Secre-
17 taries) shall meet to determine—

18 (1) how contracts entered into under the
19 Project BioShield Act of 2004 and the Project Bio-
20 Shield II Act of 2005 (and the amendments made
21 by such Acts) may be structured so that a person
22 that enters such a contract can recognized revenue
23 under General Acceptable Accounting Principles ac-
24 counting rules; or

1 (2) how the Securities and Exchange Commis-
2 sion may interpret its Staff Accounting Bulletin
3 Number 104 of December 17, 2003, to achieve the
4 result described under paragraph (1).

5 **TITLE XXIII—HUMAN CLINICAL**
6 **TRIALS AND DRUGS FOR**
7 **RARE DISEASES AND CONDI-**
8 **TIONS**

9 **SEC. 2301. EXPANDED HUMAN CLINICAL TRIALS QUALI-**
10 **FYING FOR ORPHAN DRUG CREDIT.**

11 (a) EXPANDED HUMAN CLINICAL TRIALS QUALI-
12 FYING FOR ORPHAN DRUG CREDIT.—

13 (1) IN GENERAL.—Subclause (I) of section
14 45C(b)(2)(A)(ii) of the Internal Revenue Code of
15 1986 is amended to read as follows:

16 “(I) after the date that the appli-
17 cation is filed for designation under
18 such section 526, and”.

19 (2) CONFORMING AMENDMENTS.—Clause (i) of
20 section 45C(b)(2)(A) of the Internal Revenue Code
21 of 1986 is amended by inserting “which is” before
22 “being” and by inserting before the comma at the
23 end “and which is designated under section 526 of
24 such Act”.

1 (3) EFFECTIVE DATE.—The amendments made
2 by this subsection shall apply to amounts paid or in-
3 curred after December 31, 2003.

4 (b) PUBLICATION OF FILING AND APPROVAL OF RE-
5 QUESTS FOR DESIGNATION OF DRUGS FOR RARE DIS-
6 EASES OR CONDITIONS.—Subsection (c) of section 526 of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 360bb) is amended to read as follows:

9 “(c) Not less than monthly, the Secretary shall pub-
10 lish in the Federal Register, and otherwise make available
11 to the public, notice of requests for designation of a drug
12 under subsection (a) and approvals of such requests. Such
13 notice shall include—

14 “(1) the name and address of the manufacturer
15 and the sponsor;

16 “(2) the date of the request for designation or
17 of the approval of such request;

18 “(3) the nonproprietary name of the drug and
19 the name of the drug under which an application is
20 filed under section 505(b) of this Act or section 351
21 of the Public Health Service Act;

22 “(4) the rare disease or condition for which the
23 designation is requested or approved; and

24 “(5) the proposed indication for use of the
25 product.”.

1 **TITLE XXIV—HEALTHCARE SYS-**
2 **TEM COLLECTION OF CLIN-**
3 **ICAL DATA REGARDING SAFE-**
4 **TY AND EFFECTIVENESS OF**
5 **COUNTERMEASURES**

6 **SEC. 2401. FINDINGS; DEFINITIONS.**

7 (a) PURPOSE.—The purpose of this title is to provide
8 necessary protocols and funding to ensure that real time
9 clinical data about a countermeasure, as it is utilized, may
10 be extracted in order to assess the appropriate role of such
11 countermeasure in responding to a terror attack or out-
12 break of infectious disease.

13 (b) DEFINITIONS.—In this title:

14 (1) CLINICAL COUNTERMEASURES DELIVERY.—
15 The term “clinical countermeasures delivery” refers
16 to the coordinated development, implementation, and
17 evaluation of consistent clinical countermeasures
18 policies, diagnostic procedures and protocols, edu-
19 cation and training, and necessary medical capacities
20 (such as administrative support, infrastructure in-
21 cluding healthcare epidemiology, laboratories, infor-
22 mation systems, leadership and expert personnel, re-
23 search capability, equipment and supplies) for the
24 healthcare delivery and response community within a
25 defined geographic area that takes into account pop-

1 ulations at risk and vulnerabilities to pathogens and
2 agents.

3 (2) CLINICAL COUNTERMEASURES DELIVERY
4 CENTER.—The term “clinical countermeasures deliv-
5 ery center” means a nonprofit health or public
6 health, medical center, or public hospital, including
7 an academic health center or other similar organiza-
8 tion, that dedicates a significant percentage of its re-
9 sources for the coordination of healthcare delivery,
10 research, education, and integrated community serv-
11 ices, as determined by the Assistant Secretary for
12 Medical Readiness and Response of the Department
13 of Homeland Security.

14 (3) EMERGENCY SITUATION.—The term “emer-
15 gency situation” means a natural or man-made
16 event that requires an emergency response and is
17 designated as an emergency by the President, a Gov-
18 ernor through an appropriate State emergency man-
19 agement coordinator, local government executive, or
20 a county emergency manager (only with respect to
21 a condition for a period not to exceed 24 hours
22 pending review and approval by a Governor) in
23 which clinical countermeasures may or will be uti-
24 lized.

1 (4) HEALTHCARE DELIVERY AND RESPONSE
2 COMMUNITY.—The term “healthcare delivery and re-
3 sponse community” means individuals, entities, and
4 institutions that provide—

5 (A) direct patient healthcare, public health,
6 or community health; or

7 (B) emergency medical care, such as emer-
8 gency medical, fire, and police services.

9 (5) QUALIFIED CLINICAL COUNTERMEASURES
10 DELIVERY CENTER.—The term “qualified clinical
11 countermeasures delivery center” means a clinical
12 countermeasures delivery center that has been cer-
13 tified under section 2402 as in compliance with the
14 requirements of section 2403.

15 (6) ASSISTANT SECRETARY.—The term “Assist-
16 ant Secretary” means the Assistant Secretary for
17 Medical Readiness and Response of the Department
18 of Homeland Security.

19 **SEC. 2402. CERTIFICATION OF CLINICAL COUNTER-**
20 **MEASURES DELIVERY CENTERS.**

21 (a) ESTABLISHMENT OF PROGRAM.—The Assistant
22 Secretary shall establish and administer a program to cer-
23 tify clinical countermeasures delivery centers as qualified
24 clinical countermeasures delivery centers for purposes of
25 ensuring that—

1 (1) the coordinated development, implementa-
2 tion, and evaluation of clinical countermeasures will
3 precede and follow the utilization of the clinical
4 countermeasures developed under this Act (or the
5 amendments made by this Act) or otherwise avail-
6 able to respond to a biological, chemical, nuclear, ra-
7 diological, or explosive event or other emergency sit-
8 uation; and

9 (2) such countermeasures are delivered to af-
10 fected and at-risk populations within a therapeuti-
11 cally effective time period.

12 (b) APPLICATION.—

13 (1) IN GENERAL.—To be certified as a qualified
14 clinical countermeasures delivery center, a clinical
15 countermeasures delivery center shall submit to the
16 Assistant Secretary an application at such time, in
17 such manner, and containing such information as
18 the Assistant Secretary shall require.

19 (2) APPROVAL.—In determining whether to ap-
20 prove an application under paragraph (1), the As-
21 sistant Secretary shall ensure that the clinical coun-
22 termeasures delivery center is in compliance with the
23 criteria developed pursuant to section 2403.

24 (c) REQUIREMENTS.—Upon approval of an applica-
25 tion under subsection (b), a qualified clinical counter-

1 measures delivery center within a specified geographic
2 area and representing an affected or at risk population,
3 shall—

4 (1) during the pre-event phase, develop, test
5 (through exercises), and have in place plans for clin-
6 ical countermeasures delivery, in accordance with
7 section 2404;

8 (2) during the pre-event phase, prepare, test,
9 and have in place plans to develop new, and to main-
10 tain existing, collaborations with members of the
11 healthcare delivery and response community;

12 (3) during the event phase, deliver clinical
13 countermeasures to affected and at-risk populations
14 in a therapeutically effective time period and provide
15 medical management and treatment of adverse
16 events arising from utilization of clinical counter-
17 measures developed in response to an emergency sit-
18 uation;

19 (4) during the event phase, communicate pre-
20 liminary findings regarding the delivery and efficacy
21 of clinical countermeasures to appropriate Federal,
22 State, and local public health authorities;

23 (5) during the post event phase, have in place
24 a validated process of metrics and measures for eval-
25 uating the effectiveness of clinical countermeasures

1 through clinical research, including external evalua-
2 tion, quality assurance and mitigation, and an eval-
3 uation of the clinical countermeasures delivery cen-
4 ter's capability to respond to the needs of popu-
5 lations at risk and address potential hazard
6 vulnerabilities; and

7 (6) during the post-event phase, share informa-
8 tion about the effectiveness of countermeasures and
9 the capability of the countermeasure delivery centers
10 to respond to the event to appropriate Federal,
11 State, and local public health authorities.

12 (d) STANDARDS.—The Assistant Secretary shall set
13 standards to ensure that qualified clinical counter-
14 measures delivery centers remain prepared to fulfill the
15 functions described under this section in the event of an
16 emergency situation.

17 **SEC. 2403. ELIGIBILITY CRITERIA.**

18 (a) IN GENERAL.—The Assistant Secretary shall es-
19 tablish by regulation criteria for the certification of clinical
20 countermeasures delivery centers as qualified clinical
21 countermeasures delivery centers for purposes of this title.

22 (b) MINIMUM QUALIFICATIONS.—The criteria devel-
23 oped under subsection (a) shall require that a qualified
24 clinical countermeasures delivery center—

1 (1) be a nonprofit healthcare provider that is
2 directly affiliated with an accredited medical teach-
3 ing institution, accredited school of public health, or
4 an institution of higher education (as defined by sec-
5 tion 101(a) of the Higher Education Act of 1965
6 (20 U.S.C. 1001(a))); and

7 (2) have in place—

8 (A) plans for clinical countermeasures de-
9 livery in accordance with section 2404;

10 (B) collaborating agreements with mem-
11 bers of its healthcare delivery and response
12 community;

13 (C) plans to participate annually in at
14 least 1 major exercise of plans and systems
15 demonstrating coordination among representa-
16 tives of its healthcare delivery and response
17 community, as evaluated by the Secretary;

18 (D) operating and managing clinical plans
19 to deliver healthcare to affected and at risk
20 populations in response to an emergency situa-
21 tion; and

22 (E) a validated process—

23 (i) of metrics and measures for evalu-
24 ating the effectiveness of the delivery cen-
25 ter’s capability to meet the needs of af-

1 fected and at risk populations and address
2 potential vulnerabilities to hazards; and
3 (ii) for sharing the results and data
4 from the plans and activities required
5 under this subsection.

6 **SEC. 2404. POLICIES, PROCEDURES, AND PROTOCOLS FOR**
7 **THE DELIVERY OF CLINICAL COUNTER-**
8 **MEASURES.**

9 (a) IN GENERAL.—The Assistant Secretary, in con-
10 sultation with the Commissioner of the Food and Drug
11 Administration, the Director of the Centers for Disease
12 Control and Prevention, the Health Resources Services
13 Administration, the Commissioner of Medicare and Med-
14 icaid, and other regulatory and accreditation agencies, as
15 appropriate, shall establish policies, procedures, and proto-
16 cols to ensure the coordinated delivery of clinical counter-
17 measures as described in section 2402(c).

18 (b) DESCRIPTION.—The policies, procedures, and
19 protocols established under subsection (a) shall be de-
20 signed to—

- 21 (1) foster cooperation and coordination among
22 qualified clinical countermeasures delivery centers;
- 23 (2) ensure the implementation, delivery and
24 evaluation of clinical countermeasures among the
25 healthcare delivery and response community; and

1 (3) identify and address the clinical, oper-
2 ational, ethical, and legal issues that may arise dur-
3 ing an emergency situation.

4 (c) DUTIES OF CENTERS.—The qualified clinical
5 countermeasures delivery centers shall—

6 (1) meet the requirements described in subpara-
7 graphs (A) and (B) of section 2403(b)(2);

8 (2) participate annually in at least 1 major ex-
9 ercise of plans and systems demonstrating the co-
10 ordination of clinical countermeasures among rep-
11 resentatives of its healthcare delivery and response
12 community;

13 (3) have in place operating and clinical plans—

14 (A) to deliver clinical countermeasures
15 within a therapeutically effective time period to
16 affected and at risk populations in response to
17 an emergency situation; and

18 (B) for the medical management and treat-
19 ment of adverse events arising from utilization
20 of clinical countermeasures developed in re-
21 sponse to an emergency situation; and

22 (4) have in place a validated process—

23 (A) of metrics and measures for—

24 (i) evaluating the effectiveness of clin-
25 ical countermeasures, including external

1 evaluation, quality assurance, and mitiga-
2 tion; and

3 (ii) evaluating the clinical counter-
4 measures delivery center's capability to
5 meet the needs of affected and at risk pop-
6 ulations and address potential
7 vulnerabilities to hazards; and

8 (B) for sharing the results and data from
9 the plans and activities required under this sub-
10 section.

11 **SEC. 2405. INCENTIVES FOR QUALIFIED CLINICAL COUN-**
12 **TERMEASURES DELIVERY CENTERS.**

13 A clinical countermeasures delivery center that is cer-
14 tified by the Assistant Secretary as a qualified clinical
15 countermeasures delivery center—

16 (1) shall be entitled to reimbursement—

17 (A) for the costs associated with prepared-
18 ness for clinical countermeasures delivery and
19 maintaining readiness for a healthcare emer-
20 gency requiring the use of clinical counter-
21 measures, including training exercises and edu-
22 cational programs;

23 (B) for costs associated with the imple-
24 mentation, delivery, and evaluation of clinical
25 countermeasures in the event of a healthcare

1 emergency in which clinical countermeasures,
2 including those developed under this Act (or the
3 amendments made by this Act), are utilized;
4 and

5 (C) for costs associated with the post-event
6 initiatives involved with the delivery of clinical
7 countermeasures in the event of a healthcare
8 emergency in which clinical countermeasures,
9 including those developed under this Act (or the
10 amendments made by this Act), are utilized;
11 and

12 (2) at the discretion of the Assistant Secretary,
13 may receive 1 or more of the following:

14 (A) Bonus payment under the Medicare
15 program under title XVIII of the Social Secu-
16 rity Act (42 U.S.C. 1395 et seq.) for the reim-
17 bursement of expenditures incurred in connec-
18 tion with the implementation of activities under
19 this title.

20 (B) Increased graduate medical education
21 reimbursement for expenditures incurred in
22 connection with the implementation of activities
23 under this title.

24 (C) The application and receipt of sur-
25 charges with respect to reimbursements under

1 the Medicare or Medicaid programs under title
2 XVIII or XIX of the Social Security Act (42
3 U.S.C. 1395 or 1396 et seq.) paid to the quali-
4 fied clinical countermeasures delivery centers.

5 (D) Participation in a program to receive
6 temporary personnel replacements, salary reim-
7 bursements, and training cost reimbursement,
8 to be applied to the personnel of qualified clin-
9 ical countermeasures delivery centers that
10 choose to obtain specialized training in emer-
11 gency preparedness or that want to obtain spe-
12 cial certifications.

13 (E) Malpractice and tort liability indem-
14 nification for the qualified clinical counter-
15 measures delivery centers and the personnel
16 supporting such centers for legal fees and judg-
17 ments incurred in connection with the imple-
18 mentation of activities under this title.

19 (F) Worker's compensation indemnification
20 with respect to qualified clinical counter-
21 measures delivery centers' personnel in connec-
22 tion with the implementation of programs under
23 this title during periods of training and emer-
24 gency situations.

1 (G) Notwithstanding the requirements of
2 section 1867 of the Social Security Act (42
3 U.S.C. 1395dd), commonly known as the Emer-
4 gency Medical Treatment and Active Labor Act,
5 the ability of qualified clinical countermeasures
6 delivery centers to pre-triage patients during an
7 emergency situation, including triaging based
8 on nonemergent conditions to other hospitals,
9 ambulatory facilities, or other appropriate
10 healthcare entities.

11 (H) Indemnification by the Federal Gov-
12 ernment for legal fees incurred by the qualified
13 clinical countermeasures delivery centers during
14 an emergency situations, as well as worker's
15 compensation and overall liability coverage dur-
16 ing such a situation and during periods of
17 training.

18 (I) The assistance of Federal personnel or
19 armed forces personnel for the planning and
20 support of training and training exercises for
21 the personnel of the qualified clinical counter-
22 measures delivery centers.

23 (J) The provision of family support serv-
24 ices for workers, including emergency manage-
25 ment and public health agencies personnel, sup-

1 porting the center during an emergency situa-
2 tion to allow for communication access to such
3 workers during such situation, priority standing
4 for access to vaccines and other recommended
5 interventions, and other services to help work-
6 ers function effectively in such a situation.

7 **SEC. 2406. AUTHORIZATION OF APPROPRIATIONS.**

8 There are authorized to be appropriated such sums
9 as may be necessary to carry out this title.

10 **TITLE XXV—CENTERS FOR DIS-**
11 **EASE CONTROL AND PREVEN-**
12 **TION**

13 **SEC. 2501. GLOBAL DISEASE DETECTION TRUST FUND.**

14 (a) IN GENERAL.—

15 (1) ESTABLISHMENT OF FUND.—There is es-
16 tablished within the Centers for Disease Control and
17 Prevention a Global Disease Detection Trust Fund
18 (referred to in this title as the “Detection Trust
19 Fund”).

20 (2) ADMINISTRATION.—The Detection Trust
21 Fund shall be administered by the Director of the
22 Centers for Disease Control and Prevention.

23 (3) PURPOSES.—The purposes of the Detection
24 Trust Fund are to—

1 (A) detect, verify, and respond to infec-
2 tious disease outbreaks around the world more
3 quickly, including threats such as avian influ-
4 enza and the development of antimicrobial re-
5 sistance that emerge outside the United States;

6 (B) control intentional or naturally occur-
7 ring health threats at their origin and prevent
8 international spread;

9 (C) protect the health and safety of United
10 States citizens and officials traveling or living
11 abroad; and

12 (D) protect the economic interests of the
13 United States and its partners from threats to
14 health.

15 (b) USE OF FUND.—

16 (1) IN GENERAL.—The Director of the Centers
17 for Disease Control and Prevention may expend not
18 more than \$250,000,000 in each fiscal year from the
19 Detection Trust Fund on global disease detection ac-
20 tivities, which may include—

21 (A) conducting—

22 (i) disease surveillance activities;

23 (ii) field investigations;

24 (iii) training and development activi-
25 ties; and

- 1 (iv) research on methods and ap-
2 proaches for detection and control of
3 threats to health described in subsection
4 (a)(3);
- 5 (B) developing information and commu-
6 nications technology;
- 7 (C) improving infectious disease epidemi-
8 ology;
- 9 (D) providing technical assistance for dis-
10 ease prevention and control programs;
- 11 (E) ensuring the capacity to prepare for
12 and respond to emerging and unknown public
13 health threats and emergencies; and
- 14 (F) developing and maintaining of labora-
15 tory capacity.

16 (2) LIMITATION.—Amounts expended from the
17 Detection Trust Fund shall not be funded through
18 reductions in the annual appropriations for related
19 activities of the Centers for Disease Control and
20 Prevention.

21 (c) AUTHORIZATION OF APPROPRIATIONS.—There
22 are authorized to be appropriated \$1,250,000,000 to the
23 Detection Trust Fund to carry out this section.

1 **SEC. 2502. ENVIRONMENTAL MICROBIOLOGY FACILITY**
2 **STUDY AND REPORT.**

3 Not later than 6 months after the date of enactment
4 of this Act, the Director of the Centers for Disease Control
5 and Prevention shall—

6 (1) conduct a study on the feasibility of devel-
7 oping an environmental microbiology facility as part
8 of the National Interagency Biodefense Campus at
9 Fort Detrick, Maryland; and

10 (2) submit to Congress a report that describes
11 the findings of the study under paragraph (1), in-
12 cluding—

13 (A) the need for such a facility and the po-
14 tential benefits of developing such a facility as
15 part of the Interagency campus;

16 (B) the feasibility of constructing such a
17 facility, and

18 (C) the projected cost and timetable for
19 the construction of such a facility.

20 **SEC. 2503. ENFORCEMENT OF QUARANTINES.**

21 (a) PENALTIES.—Section 368 (42 U.S.C. 271) is
22 amended—

23 (1) in subsection (a), by striking “\$1,000 or by
24 imprisonment for not more than one year” and in-
25 serting “\$250,000 or by imprisonment for not more
26 than 10 years”; and

1 (2) in subsection (b), by striking “\$5,000” and
2 inserting “\$1,000,000”.

3 (b) PANEL PHYSICIAN QUALITY CONTROL.—Section
4 361 of the Public Health Service Act (42 U.S.C. 264) is
5 amended by adding at the end the following:

6 “(f) Where the United States enters into agreements,
7 contracts, or other arrangements with physicians or other
8 healthcare providers and laboratories in foreign countries
9 for the purpose of conducting health screening on aliens
10 seeking temporary or permanent residence in the United
11 States, the Secretary shall evaluate each such physician
12 or provider on an annual basis to certify that the physician
13 or provider adequately complies with applicable regula-
14 tions governing the medical screening of applicants for
15 entry into the United States. The Secretary may assess
16 certification or user fees to support the annual evaluation,
17 quality control, and certification of panel physicians per-
18 forming such foreign medical screenings.”.

19 **SEC. 2504. EDUCATIONAL CAMPAIGN AT THE CENTERS FOR**
20 **DISEASE CONTROL AND PREVENTION.**

21 (a) IN GENERAL.—The Director of the Centers for
22 Disease Control and Prevention shall, in consultation with
23 relevant stakeholders, carry out a 2-phase, national edu-
24 cational campaign to make available information about the
25 possible public health measures that might be imple-

1 mented in the event of a pandemic outbreak or a bioterror
2 attack involving an infectious disease.

3 (b) CAMPAIGN CONTENT.—

4 (1) IN GENERAL.—The campaign established
5 under subsection (a) may include information re-
6 garding—

7 (A) the circumstances under which a range
8 of public health measures might be imple-
9 mented;

10 (B) the concepts of person-to-person
11 spread, quarantine, isolation, and movement re-
12 striction;

13 (C) mass pre- and post-exposure prophylaxis,
14 the use of off-label drugs, and other ex-
15 traordinary measures to protect the public
16 health;

17 (D) the rationale and benefits to the public
18 of implementing such public health measures;
19 and

20 (E) the legal rights of citizens in the event
21 such public health measures are implemented.

22 (2) CAMPAIGN PHASE 1.—

23 (A) IN GENERAL.—In Phase 1 of the cam-
24 paign established under subsection (a), the Di-
25 rector of the Centers for Disease Control and

1 Prevention shall consult with a diverse advisory
2 panel in the preparation of nationally standard-
3 ized messages and guidance about the range of
4 medical and nonmedical interventions to inter-
5 rupt disease transmission.

6 (B) COMPOSITION OF ADVISORY PANEL.—

7 The advisory panel consulted under subpara-
8 graph (A) shall include—

9 (i) representatives of State and local
10 governments and nongovernmental public
11 health agencies;

12 (ii) public health experts and medical
13 practitioners who have real-world experi-
14 ence in crisis management and risk com-
15 munication;

16 (iii) business leaders;

17 (iv) members of the lay public; and

18 (v) subject matter experts in bioethics,
19 risk communication, health education, com-
20 munity organization, advertising, and pub-
21 lic relations.

22 (C) COLLECTION OF INFORMATION.—To
23 direct the deliberations of the advisory panel,
24 the Director of the Centers for Disease Control
25 and Prevention shall collect and synthesize ex-

1 tant information regarding community-level dis-
2 ease containment measures, including assess-
3 ment of interventions during the SARS out-
4 break.

5 (3) CAMPAIGN PHASE 2.—

6 (A) PURPOSE.—The purpose of Phase 2 of
7 the campaign established under subsection (a)
8 shall be to augment at the State and local level
9 nationally standardized messages to address
10 specific community needs and concerns.

11 (B) ESTABLISHMENT OF GRANT.—

12 (i) IN GENERAL.—The Director of the
13 Centers for Disease Control and Preven-
14 tion shall award grants to 5 local health
15 departments (that are regionally and de-
16 mographically diverse) to design and de-
17 liver educational campaigns targeted for
18 their community with respect to the plans
19 of the health departments for imple-
20 menting a range of public health interven-
21 tions in the context of a pandemic out-
22 break or biological attack.

23 (ii) APPLICATION.—Local public
24 health departments shall submit to the
25 Secretary an application to receive a grant

1 under clause (i) at such time, in such man-
2 ner, and containing such information as
3 the Secretary may require.

4 (c) AUTHORIZATION OF APPROPRIATIONS.—There
5 are authorized to be appropriated \$20,000,000 for each
6 of fiscal years 2006 through 2010 to carry out this sec-
7 tion.

8 **TITLE XXVI—ZOO NOTIC DISEASE**
9 **SURVEILLANCE**

10 **SEC. 2601. ZOO NOTIC DISEASE SURVEILLANCE.**

11 (a) FINDINGS.—Congress makes the following find-
12 ings:

13 (1) Seventy percent of the known bioterrorist
14 agents are zoonotic.

15 (2) Emerging infectious diseases such as SARS,
16 monkeypox, and West Nile virus have emerged from
17 animal origins.

18 (2) Early warning of impending zoonotic dis-
19 ease outbreaks has failed in sentinel animal popu-
20 lations during zoonotic outbreaks such as SARS,
21 monkeypox, and West Nile virus.

22 (3) There is no way to predict what species
23 might serve as sentinels in emerging infectious dis-
24 eases or bioterrorist events.

1 (4) Many animals, such as dogs, cats, and ex-
2 otic pets, do not fall under the jurisdiction of any
3 Federal agency.

4 (5) There is a lack of focus on the detection of
5 zoonotic threats in sentinel or reservoir animal popu-
6 lations prior to human involvement.

7 (6) There is a continued inability to share real-
8 time data across the human and veterinary agencies
9 on zoonotic threats.

10 (b) ESTABLISHMENT OF WORKING GROUP.—The
11 Secretary of Homeland Security, in consultation with the
12 Secretary of Health and Human Services, the Secretary
13 of Agriculture, the Secretary of the Interior, and the Sec-
14 retary of Defense shall establish a Zoonotic Disease Work-
15 ing Group within the Department of Homeland Security
16 (referred to in this section as the “Working Group”).

17 (c) DUTIES OF WORKING GROUP.—

18 (1) IN GENERAL.—The Working Group shall
19 conduct a study of all matters relating to the cre-
20 ation of an integrated (human and animal) real-time
21 zoonotic disease surveillance network and make rec-
22 ommendations that address gaps in surveillance ac-
23 tivities.

24 (2) MATTERS STUDIED.—The Working Group
25 shall—

1 (A) evaluate the status of zoonotic disease
2 surveillance by Federal agencies and the private
3 sector as of the date of enactment of this Act;

4 (B) identify—

5 (i) existing bioterrorism funds in Fed-
6 eral and State agencies;

7 (ii) budgets that could be redirected
8 toward improving the ability to detect and
9 report zoonotic threats across species han-
10 dled by veterinary and wildlife institutions;

11 and

12 (iii) existing laboratory facilities for
13 zoo animals, pets, and exotic collections
14 that could be networked, equipped, and
15 funded for such purpose; and

16 (C) consult private sector representatives,
17 including those with expertise on non-agricul-
18 tural species, exotic pets, and zoo animals, rep-
19 resentatives of State and local public health
20 agencies, and representatives from veterinarians
21 and laboratories.

22 (3) SUBMISSION OF REPORT.—Not later than 8
23 months after the date of enactment of this Act, the
24 Working Group shall submit a report to the Sec-

1 (C) the hesitancy of producers to report
2 disease outbreaks for fear of uncompensated
3 culling or quarantine;

4 (D) the declining pool of veterinarians and
5 diagnosticians trained to recognize foreign ani-
6 mal diseases;

7 (E) larger breeding herds, which reduce in-
8 dividual animal health observations and may
9 cause illnesses to remain undetected; and

10 (F) inadequate laboratory diagnostic capa-
11 bility at the national and local levels;

12 (5)(A) countermeasures should be developed to
13 both prevent and control agroterrorism;

14 (B) incentives under title III (and amendments
15 made by that title) should be made available to per-
16 sons who develop and manufacture those counter-
17 measures;

18 (C) threats to biosecurity should be identified
19 through cooperative decisions made by the Secretary
20 and the Secretary of Homeland Security;

21 (D) the Secretary regulates and approves bio-
22 logical and chemical agents and toxins under the
23 Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.); and

24 (E) the Secretary of Health and Human Serv-
25 ices, acting through the Center for Veterinary Medi-

1 cine of the Food and Drug Administration, regulates
2 and approves new animal drugs under section 512 of
3 the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 360b);

5 (6) preventative countermeasures (including all
6 equipment, materials, drugs, personnel, and training
7 necessary to interdict the spread of animal and plant
8 diseases efficiently and effectively) should include—

9 (A) increased funding for the Animal and
10 Plant Health Inspection Service to increase
11 training and better protect the borders of the
12 United States;

13 (B) increased funding for exotic animal
14 and plant disease research conducted in coun-
15 tries in which exotic diseases are endemic;

16 (C) improved use, by persons under con-
17 tract with the Federal Government to develop
18 countermeasures, of appropriate containment
19 facilities controlled by the Federal Government
20 (such as the National Veterinary Disease Lab-
21 oratory in Ames, Iowa or Plum Island, New
22 York); and

23 (D) increased funding for vaccine and anti-
24 biotic research;

25 (7) control countermeasures should include—

1 (A) recruiting, training, and equipping
2 field personnel;

3 (B) developing rapid and specific diag-
4 nostic tests;

5 (C) developing a stockpile of counter-
6 measures to biological and chemical agents and
7 toxins of consequence to the agricultural com-
8 munity, as determined by the Secretary, with
9 adequate funding for the development of the
10 stockpile;

11 (D) researching and stockpiling of
12 antiviral, antifungal, antibacterial, and vector
13 control agents; and

14 (E) a national system of livestock identi-
15 fication and movement surveillance; and

16 (8) an effective system of countermeasures
17 against agroterrorism will require initial centraliza-
18 tion followed by dissemination of policies and prac-
19 tices to a local level.

20 **SEC. 2702. DEFINITIONS.**

21 In this Act:

22 (1) **AGRICULTURAL DISEASE.**—The term “agri-
23 cultural disease” means an outbreak of a plant or
24 animal disease, or a pest infestation, that requires
25 prompt action in order to prevent injury or damage

1 to people, plants, livestock, property, the economy,
2 or the environment.

3 (2) AGRICULTURAL DISEASE EMERGENCY.—

4 The term “agricultural disease emergency” means
5 an agricultural disease that the Secretary determines
6 to be an emergency under—

7 (A) section 415 of the Plant Protection
8 Act (7 U.S.C. 7715); or

9 (B) section 10407(b) of the Animal Health
10 Protection Act (7 U.S.C. 8306(b)).

11 (3) AGRICULTURE.—The term “agriculture” in-
12 cludes—

13 (A) the science and practice of activities
14 relating to food, feed, and fiber production,
15 processing, marketing, distribution, use, and
16 trade;

17 (B) family and consumer science, nutri-
18 tion, food science and engineering, agricultural
19 economics, and other social sciences; and

20 (C) forestry, wildlife science, fishery
21 science, aquaculture, floraculture, veterinary
22 medicine, and other environmental and natural
23 resource sciences.

1 (4) AGROTERRORISM.—The term
2 “agroterrorism” means the commission of an
3 agroterrorist act.

4 (5) AGROTERRORIST ACT.—The term
5 “agroterrorist act” means a criminal act consisting
6 of causing or attempting to cause damage or harm
7 to, or destruction or contamination of, a crop, live-
8 stock, farm or ranch equipment, material or prop-
9 erty associated with agriculture, or a person engaged
10 in agricultural activity, that is committed with the
11 intent—

12 (A) to intimidate or coerce a civilian popu-
13 lation; or

14 (B) to influence the policy of a government
15 by intimidation or coercion.

16 (6) BIOSECURITY.—

17 (A) IN GENERAL.—The term “biosecurity”
18 means protection from the risks posed by bio-
19 logical, chemical, or radiological agents to—

20 (i) plant or animal health;

21 (ii) the agricultural economy;

22 (iii) the environment; or

23 (iv) human health.

24 (B) INCLUSIONS.—The term “biosecurity”
25 includes the exclusion, eradication, and control

1 of biological agents that cause plant or animal
2 diseases.

3 (7) COUNTERMEASURE.—The term “counter-
4 measure” has the meaning given that term in sec-
5 tion 319F–3 of the Public Health Service Act (as
6 added by section 202).

7 (8) INDIAN TRIBE.—The term “Indian tribe”
8 has the meaning given the term in section 4 of the
9 Indian Self-Determination and Education Assistance
10 Act (25 U.S.C. 450b).

11 (9) SECRETARY.—The term “Secretary” means
12 the Secretary of Agriculture.

13 (10) TRIBAL GOVERNMENT.—The term “tribal
14 government” means the governing body of an Indian
15 tribe.

16 **SEC. 2703. ESTABLISHMENT OF WORKING GROUP.**

17 The Secretary, in consultation with the Secretary of
18 Health and Human Services and the Secretary of Home-
19 land Security, shall establish a working group (referred
20 to in this title as the “Working Group”) that shall include
21 representatives of—

22 (1) appropriate agencies of the Department of
23 Agriculture, appointed by the Secretary;

1 (2) the Centers for Disease Control and Preven-
2 tion, appointed by the Secretary of Health and
3 Human Services;

4 (3) the Center for Veterinary Medicine of the
5 Food and Drug Administration, appointed by the
6 Secretary of Health and Human Services, in con-
7 sultation with the Secretary of Defense and the Sec-
8 retary of Homeland Security;

9 (4) the Department of Homeland Security, ap-
10 pointed by the Secretary of Homeland Security; and

11 (5) the Animal Health Institute.

12 **SEC. 2704. DUTIES.**

13 (a) STUDY.—

14 (1) IN GENERAL.—The Working Group shall
15 conduct a study of all matters relating to developing
16 countermeasures against agroterrorism in the
17 United States.

18 (2) MATTERS TO BE STUDIED.—The matters to
19 be studied by the Working Group shall include—

20 (A) the nature of United States prepared-
21 ness for agroterrorism threats to crops and live-
22 stock in the United States, including an evalua-
23 tion of the progress of ongoing research, stud-
24 ies, and programs;

1 (B) the availability of countermeasures
2 against agroterrorism threats;

3 (C) the strategy used to develop such
4 qualified countermeasures to both prevent and
5 control an agroterrorism threat;

6 (D) the appropriateness of adapting the in-
7 centives established by the amendments made
8 by the Project BioShield Act of 2004 (118 Stat.
9 835) and by this Act (including amendments
10 made by this Act), to such countermeasures
11 against agroterrorism;

12 (E) whether technological innovation is re-
13 quired to complete the identification, border se-
14 curity, and transit surveillance of livestock;

15 (F) the appropriateness of entering into bi-
16 lateral agreements with countries in which ex-
17 otic animal disease vaccines that are approved
18 by the Department of Agriculture are produced
19 in order to provide for the use of the vaccines
20 by the United States in the case of an emer-
21 gency;

22 (G) the feasibility of producing certain vac-
23 cines, especially vaccines for foot and mouth
24 disease, in the continental United States;

1 (H) the feasibility of leasing Plum Island,
2 New York, for use as a commercial vaccine pro-
3 duction facility; and

4 (I) the provision of funds for the Agency
5 for International Development to establish an
6 office of animal and plant health, the mission of
7 which is to assist countries in controlling and
8 eradicating diseases that pose a threat to agri-
9 culture in the United States.

10 (b) RECOMMENDATIONS.—The Working Group shall
11 develop recommendations on—

12 (1) specific requirements needed to accelerate
13 the development of countermeasures against
14 agroterrorism, including research tools, biologics,
15 and therapeutics; and

16 (2) if the Working Group determines that the
17 commercial agricultural industry is incapable or has
18 inadequate resources to fulfill the biosecurity needs
19 of the United States, adapting the incentives de-
20 scribed in subparagraph (D) of subsection (a)(2).

21 (c) REPORT.—Not later than 1 year after the date
22 of enactment of this Act, the Working Group shall submit
23 to the appropriate committees of Congress a report that
24 contains—

1 (1) a detailed statement of the findings and
2 conclusions of the Working Group; and

3 (2) the recommendations of the Working Group
4 for such legislation and administrative actions as the
5 Working Group considers appropriate.

6 **SEC. 2705. STATE AND LOCAL ASSISTANCE.**

7 (a) STUDY.—

8 (1) IN GENERAL.—In consultation with the
9 steering committee of the National Animal Health
10 Emergency Management System and other stake-
11 holders, the Secretary shall conduct a study to—

12 (A) determine the best use of epidemiolo-
13 gists, animal and plant pathologists, computer
14 modelers, and statisticians as members of emer-
15 gency response task forces that handle foreign
16 or emerging agricultural disease emergencies;
17 and

18 (B) identify the types of data that are nec-
19 essary for proper modeling and analysis of agri-
20 cultural disease emergencies.

21 (2) REPORT.—Not later than 180 days after
22 the date of enactment of this Act, the Secretary
23 shall submit a report that describes the results of
24 the study under paragraph (1) to—

1 (A) the Secretary of Homeland Security;
2 and

3 (B) the head of any other agency involved
4 in response planning for agricultural disease
5 emergencies.

6 (b) GEOGRAPHIC INFORMATION SYSTEM GRANTS.—

7 (1) IN GENERAL.—The Secretary, in consulta-
8 tion with the Secretary of Homeland Security and
9 the Secretary of the Interior, shall establish a pro-
10 gram under which the Secretary shall provide grants
11 to States and local governments to develop capabili-
12 ties to use a geographic information system or sta-
13 tistical model for an epidemiological assessment in
14 the event of an agricultural disease emergency.

15 (2) AUTHORIZATION OF APPROPRIATIONS.—

16 There are authorized to be appropriated such sums
17 as may be necessary to carry out this subsection.

18 (c) GRANTS TO FACILITATE PARTICIPATION OF
19 STATE AND LOCAL ANIMAL AND PLANT HEALTHCARE
20 OFFICIALS.—

21 (1) IN GENERAL.—The Secretary of Homeland
22 Security, in coordination with the Secretary, shall
23 establish a program under which the Secretary of
24 Homeland Security shall provide grants to commu-
25 nities to facilitate the participation of State and

1 local animal and plant healthcare officials in commu-
2 nity emergency planning efforts.

3 (2) AUTHORIZATION OF APPROPRIATIONS.—

4 There is authorized to be appropriated such sums as
5 may be necessary to carry out this subsection.

6 (d) BIOSECURITY AWARENESS AND PROGRAMS.—

7 (1) IN GENERAL.—The Secretary shall imple-
8 ment a public awareness campaign for farmers,
9 ranchers, and other agricultural producers that em-
10 phasizes—

11 (A) the need for heightened biosecurity on
12 farms; and

13 (B) reporting to the Department of Agri-
14 culture any agricultural disease anomaly.

15 (2) ON-FARM BIOSECURITY.—

16 (A) IN GENERAL.—Not later than 240
17 days after the date of enactment of this Act,
18 the Secretary, in consultation with associations
19 of agricultural producers and taking into con-
20 sideration research conducted under the Na-
21 tional Agricultural Research, Extension, and
22 Teaching Policy Act of 1977 (7 U.S.C. 3101 et
23 seq.), shall—

24 (i) develop guidelines—

1 (I) to improve monitoring of vehi-
2 cles and materials entering or leaving
3 farm or ranch operations; and

4 (II) to control human traffic en-
5 tering or leaving farm or ranch oper-
6 ations; and

7 (ii) distribute the guidelines developed
8 under clause (i) to agricultural producers
9 through agricultural informational semi-
10 nars and biosecurity training sessions.

11 (B) AUTHORIZATION OF APPROPRIA-
12 TIONS.—

13 (i) IN GENERAL.—There are author-
14 ized to be appropriated such sums as may
15 be necessary to carry out this paragraph.

16 (ii) INFORMATION PROGRAM.—Of the
17 amounts made available under clause (i),
18 the Secretary may use such sums as are
19 necessary to establish in each State an in-
20 formation program to distribute the bio-
21 security guidelines developed under sub-
22 paragraph (A)(i).

23 (3) BIOSECURITY GRANT PILOT PROGRAM.—

24 (A) INCENTIVES.—

1 (i) IN GENERAL.—Not later than 240
2 days after the date of enactment of this
3 Act, the Secretary shall develop a pilot
4 program to provide incentives, in the form
5 of grants or low-interest loans, to agricul-
6 tural producers to restructure farm and
7 ranch operations (based on the biosecurity
8 guidelines developed under paragraph
9 (2)(A)(i)) to achieve the goals described in
10 clause (ii).

11 (ii) GOALS.—The goals referred to in
12 clause (i) are—

13 (I) to control access to farms and
14 ranches by persons intending to com-
15 mit agroterrorist acts;

16 (II) to prevent the introduction
17 and spread of agricultural diseases;
18 and

19 (III) to take other measures to
20 ensure biosecurity.

21 (iii) LIMITATION.—The amount of a
22 grant or low-interest loan provided under
23 this paragraph shall not exceed \$10,000.

1 (B) REPORT.—Not later than 3 years after
2 the date of enactment of this Act, the Secretary
3 shall submit to Congress a report that—

4 (i) describes the implementation of
5 the pilot program; and

6 (ii) makes recommendations for ex-
7 panding the pilot program.

8 (C) AUTHORIZATION OF APPROPRIA-
9 TIONS.—There are authorized to be appro-
10 priated such sums as may be necessary to carry
11 out this paragraph.

12 **SEC. 2706. INTERAGENCY COORDINATION.**

13 (a) AGRICULTURAL DISEASE LIAISONS.—

14 (1) AGRICULTURAL DISEASE MANAGEMENT LI-
15 AISON.—The Secretary of Homeland Security shall
16 establish a senior level position within the Federal
17 Emergency Management Agency the primary re-
18 sponsibility of which is to serve as a liaison for agri-
19 cultural disease management between—

20 (A) the Department of Homeland Security;

21 and

22 (B)(i) the Federal Emergency Manage-
23 ment Agency;

24 (ii) the Department of Agriculture;

1 (iii) other Federal agencies responsible for
2 a response to an emergency relating to an agri-
3 culture disease;

4 (iv) the emergency management commu-
5 nity;

6 (v) State emergency and agricultural offi-
7 cials;

8 (vi) tribal governments; and

9 (vii) industries affected by agricultural dis-
10 ease.

11 (2) ANIMAL HEALTH CARE LIAISON.—The Sec-
12 retary of Health and Human Services shall establish
13 within the Department of Health and Human Serv-
14 ices a senior level position the primary responsibility
15 of which is to serve as a liaison between—

16 (A) the Department of Health and Human
17 Services; and

18 (B)(i) the Department of Agriculture;

19 (ii) the animal health community;

20 (iii) the emergency management commu-
21 nity;

22 (iv) tribal governments; and

23 (v) industries affected by agricultural dis-
24 ease.

25 (b) TRANSPORTATION.—

1 (1) IN GENERAL.—The Secretary of Transpor-
2 tation, in consultation with the Secretary and the
3 Secretary of Homeland Security, shall—

4 (A) publish in the Federal Register pro-
5 posed guidelines for restrictions on interstate
6 transportation of an agricultural commodity or
7 product in response to an agricultural disease;

8 (B) provide for a comment period of not
9 less than 90 days for the proposed guidelines;
10 and

11 (C) establish final guidelines, taking into
12 consideration any comment received under sub-
13 paragraph (B); and

14 (2) provide the guidelines described in para-
15 graph (1) to officers and employees of—

16 (A) the Department of Agriculture;

17 (B) the Department of Transportation;

18 and

19 (C) the Department of Homeland Security.

20 **SEC. 2707. REGIONAL, STATE, AND LOCAL PREPAREDNESS.**

21 (a) ENVIRONMENTAL PROTECTION AGENCY.—The
22 Administrator of the Environmental Protection Agency, in
23 consultation with the Secretary, shall cooperate with re-
24 gional, State, and local disaster preparedness officials to
25 include consideration of the potential environmental ef-

1 facts of a response activity in planning a response to an
2 agricultural disease.

3 (b) DEPARTMENT OF AGRICULTURE.—The Sec-
4 retary, in consultation with the Secretary of Homeland Se-
5 curity, shall—

6 (1) develop and implement procedures to pro-
7 vide information to, and share information among,
8 Federal, regional, State, tribal, and local officials re-
9 garding agricultural threats, risks, and
10 vulnerabilities; and

11 (2) cooperate with State agricultural officials,
12 State and local emergency managers, representatives
13 from State land grant colleges and research univer-
14 sities, agricultural producers, and agricultural trade
15 associations to establish local response plans for ag-
16 ricultural diseases.

17 (c) FEDERAL EMERGENCY MANAGEMENT AGEN-
18 CY.—The Director of the Federal Emergency Manage-
19 ment Agency, in consultation with the Secretary, shall—

20 (1) establish a task force consisting of agricul-
21 tural producers and State and local emergency re-
22 sponse officials to identify the best practices for re-
23 gional and State agricultural disease programs;

1 (2) distribute to States, tribal governments, and
2 localities a report that describes the best practices
3 identified under paragraph (1); and

4 (3) design packages containing exercises for
5 training, based on the identified best practices, in
6 the form of printed materials and electronic media,
7 for distribution to State and local emergency man-
8 agers, State agricultural officials, and tribal govern-
9 ment officials.

10 **SEC. 2708. INTERNATIONAL ACTIVITIES.**

11 (a) INTERNATIONAL AGRICULTURAL DISEASE SUR-
12 VEILLANCE.—Not later than 1 year after the date of en-
13 actment of this Act, the Secretary, in consultation with
14 the Secretary of State and the Administrator of the Agen-
15 cy for International Development, shall submit to Con-
16 gress a report that describes measures taken by the Sec-
17 retary to—

18 (1) streamline the process of notification by the
19 Secretary to Federal agencies in the event of an ag-
20 ricultural disease in a foreign country; and

21 (2) cooperate with representatives of foreign
22 countries, international organizations, and industry
23 to develop and implement methods of sharing infor-
24 mation relating to international agricultural diseases
25 and unusual agricultural activities.

1 (b) INSPECTIONS OF IMPORTED AGRICULTURAL
2 PRODUCTS.—The Secretary of Homeland Security shall—

3 (1) cooperate with the Secretary and any appro-
4 priate Federal intelligence official to improve the
5 ability of the Department of Agriculture to identify
6 agricultural commodities and products, livestock,
7 and other goods imported from suspect locations
8 that are recognized by the intelligence community
9 as—

10 (A) having experienced an agricultural ter-
11 rorist activity or an unusual agricultural dis-
12 ease; or

13 (B) harboring or having harbored an
14 agroterrorist; and

15 (2) use the information described in paragraph
16 (1) to establish priorities for inspecting imported ag-
17 ricultural products.

18 (c) BILATERAL MUTUAL ASSISTANCE AGREE-
19 MENTS.—The Secretary of State, in coordination with the
20 Secretary and the Secretary of Homeland Security,
21 shall—

22 (1) enter into mutual assistance agreements
23 with other countries to provide and receive assist-
24 ance in the event of an agricultural disease, includ-
25 ing—

1 (A) training for veterinarians and agri-
2 culture specialists of the United States in the
3 identification, diagnosis, and control of foreign
4 agricultural diseases;

5 (B) providing resources and personnel to a
6 foreign government with limited resources to re-
7 spond to an agricultural disease; and

8 (C) bilateral training programs and exer-
9 cises relating to assistance provided under this
10 paragraph; and

11 (2) provide funding for a program or exercise
12 described in paragraph (1)(C).

13 **SEC. 2709. REVIEW OF LEGAL AUTHORITY.**

14 (a) IN GENERAL.—The Attorney General, in con-
15 sultation with the Secretary, shall conduct a review of
16 State and local laws relating to agroterrorism and biosecu-
17 rity to determine—

18 (1) the extent to which the laws facilitate or im-
19 pede the implementation of a current or proposed re-
20 sponse plan relating to an agricultural disease;

21 (2) whether an injunction issued by a State
22 court could—

23 (A) delay the implementation of a Federal
24 response plan described in paragraph (1); or

1 (B) affect the extent to which an agricul-
2 tural disease spreads; and

3 (3) the types and extent of legal evidence that
4 may be required by a State court before a response
5 plan described in paragraph (1) may be imple-
6 mented.

7 (b) REPORT.—Not later than 180 days after the date
8 of enactment of this Act, the Attorney General shall sub-
9 mit to Congress a report that describes the results of the
10 review under subsection (a) (including any recommenda-
11 tions of the Attorney General).

12 **TITLE XXVIII—GLOBAL DIS-**
13 **TRIBUTION OF MEDICAL**
14 **COUNTERMEASURES**

15 **SEC. 2801. FINDINGS.**

16 Congress finds the following:

17 (1) Experience with infections diseases like HIV
18 and malaria in developing countries illustrate that
19 the United States must work with developing coun-
20 tries to plan for the delivery of products developed
21 under this Act (and the amendments made by this
22 Act).

23 (2) For patients to benefit from these new med-
24 ical interventions, there must be health care pro-

1 viders to prescribe and administer such interventions
2 and assistance to purchase the treatments.

3 (3) The United States Agency for International
4 Development (referred to in this title as “USAID”)
5 should work with its counterparts in other highly in-
6 dustrialized nations to gain assistance in supplying
7 such products. The Department of Health and
8 Human Services and USAID should undertake
9 preapproval planning and multilateral consensus
10 building to assure optimal outcomes for use of such
11 products.

12 **SEC. 2802. REPORT BY USAID.**

13 (a) IN GENERAL.—Not later than 1 year after the
14 date of enactment of this Act, the Administrator of the
15 United States Agency for International Development (re-
16 ferred to in this section as the “Administrator of
17 USAID”), in consultation with the entities described
18 under subsection (b), shall submit to the Committee on
19 Health, Education, Labor, and Pensions of the Senate and
20 the Committee on Energy and Commerce of the House
21 of Representatives the report described under subsection
22 (c).

23 (b) CONSULTING ENTITIES.—In preparing the report
24 under subsection (a), the Administrator of USAID shall
25 consult with the following entities:

- 1 (1) The Secretary of State.
- 2 (2) The United States Global AIDS Coordi-
3 nator and Office of International Health Affairs.
- 4 (3) The Director of the Centers for Disease
5 Control and Prevention.
- 6 (4) The Commissioner of Food and Drugs.
- 7 (5) The Surgeon General.
- 8 (6) The Secretary of Homeland Security.
- 9 (7) The Secretary of Defense.
- 10 (8) The Director of the United States Peace
11 Corps.
- 12 (9) The World Health Organization.
- 13 (10) The United Nations Children’s Fund
14 (UNICEF).
- 15 (11) The United Nations Human Commissioner
16 for Refugees (UNHCR).
- 17 (12) The Global Fund to fight HIV/AIDS, TB
18 and Malaria.
- 19 (13) The Global Alliance for Vaccines and Im-
20 munizations (GAVI).
- 21 (14) The International Committee of the Red
22 Cross, the International Federation of Red Cross
23 and Red Crescent Societies, and the American Red
24 Cross.

1 (15) Other non-profit non-government organiza-
2 tions and foundations with expertise in the distribu-
3 tion of infectious disease countermeasures.

4 (c) REPORT.—

5 (1) IN GENERAL.—The report under subsection
6 (a) shall address—

7 (A) the global distribution of counter-
8 measures procured under the Project BioShield
9 Act of 2004 (Public Law 108–276) and this
10 Act (and the amendments made by such Acts),
11 particularly countermeasures to infectious dis-
12 eases that are not terror weapons and that have
13 a substantial incidence in developing countries;

14 (B) the existing infrastructure with respect
15 to ensuring global distribution of such counter-
16 measures; and

17 (C) plans for strengthening the infrastruc-
18 ture described under subparagraph (B) to en-
19 sure the effective global distribution of such
20 countermeasures.

21 (2) CONTENT OF REPORT.—The report under
22 subsection (a) shall include an analysis with respect
23 to—

24 (A) the procedures by which the appro-
25 priate officials at the Office of Public Health

1 Countermeasure Development of the Depart-
2 ment of Health and Human Services will notify
3 USAID and other agencies of the types, charac-
4 teristics, quantity, and timing of the counter-
5 measures that may become available under the
6 Project BioShield Act of 2004 (Public Law
7 108–276) and this Act (and the amendments
8 made by such Acts);

9 (B) the types and sources of data upon
10 which the Government will rely in determining
11 the numbers and locations of specific popu-
12 lations that might benefit from such counter-
13 measures;

14 (C) the means for ensuring that such
15 countermeasures will be distributed in devel-
16 oping countries that cannot purchase the coun-
17 termeasures;

18 (D) the trade and regulatory barriers to
19 the global distribution of such countermeasures
20 and recommendations for removing such bar-
21 riers;

22 (E) the appropriate—

23 (i) priorities for national and regional
24 distribution of such countermeasures based

1 on public health, medical, and other cri-
2 teria;

3 (ii) terms for the transfer and sale of
4 such countermeasures by the United States
5 and other entities participating in a pro-
6 curement pool established under section
7 319F–3 of the Public Health Service Act
8 (as added by section 202) to other govern-
9 ments or nongovernment organizations and
10 individuals;

11 (iii) labels and information provided
12 to public health officials and individuals re-
13 garding such countermeasures;

14 (iv) protocols for licensing of counter-
15 measures distributed globally, and policies
16 for distribution of unlicensed investiga-
17 tional countermeasures;

18 (v) protocols for assessing the safety
19 and effectiveness of such countermeasures
20 and any contraindications for the utiliza-
21 tion of such countermeasures;

22 (vi) pre- and post-licensing clinical
23 testing of such countermeasures;

1 (vii) strategy for minimizing the devel-
2 opment of natural resistance to such coun-
3 termeasures;

4 (viii) liability and indemnification poli-
5 cies associated with global distribution of
6 countermeasures; and

7 (ix) protections for intellectual prop-
8 erty associated with such countermeasures;
9 and

10 (F) the appropriate protocols for ongoing
11 assessment of the effectiveness of the global dis-
12 tribution strategy, including independent as-
13 sessments.

14 (d) ASSESSMENT BY THE DIRECTOR OF THE CEN-
15 TERS FOR DISEASE CONTROL AND PREVENTION.—The
16 Director of the Centers for Disease Control and Preven-
17 tion shall submit as part of the report under subsection
18 (a), an assessment of—

19 (1) the existing public health infrastructure
20 available to participate in the global distribution of
21 the countermeasures described under subsection
22 (c)(1) and the appropriate strategy for strength-
23 ening the public health infrastructure necessary for
24 the global distribution of such countermeasures;

1 (2) the capacity of international public health
2 agencies to respond to a pandemic or other public
3 health emergency, including distribution of such
4 countermeasures and other medical countermeasures
5 and recommendations for strengthening such capac-
6 ity;

7 (3) the existing information reporting and diag-
8 nostic and detection systems regarding global infec-
9 tious disease and recommendations for strengthening
10 such systems;

11 (4) the capacity of international public health
12 agencies to establish and maintain quarantines or
13 other isolation strategies to contain outbreaks of in-
14 fectious diseases and recommendations for strength-
15 ening such capacity;

16 (5) the long-term impact on health and chronic
17 disease of distributing such countermeasures;

18 (6) the ability of the United States to provide
19 long-term medical and supportive care for victims of
20 an infectious disease, or adverse effects of a counter-
21 measures;

22 (7) the feasibility of creating a Strategic Global
23 Stockpile of countermeasures; and

1 (8) the feasibility of initiating a global pre-
2 paredness fund for a global response to outbreaks of
3 infectious diseases.

4 **TITLE XXIX—ENVIRONMENTAL**
5 **PROTECTION AGENCY; DE-**
6 **CONTAMINATION AND REME-**
7 **DIATION**

8 **SEC. 2901. FINDINGS.**

9 Congress finds the following:

10 (1) Nuclear, biological, and chemical decon-
11 tamination present different challenges for homeland
12 security. Nuclear contamination can be detected eas-
13 ily but can only be remediated by removal of radio-
14 active material.

15 (2) Chemical contamination is relatively easy to
16 detect, dissipates rapidly in warm weather, and inac-
17 tivates under the right circumstances.

18 (3) Biological contamination presents the big-
19 gest challenge, in part, because very large indoor
20 and outdoor areas may become contaminated (hun-
21 dreds of square miles) and, in part, because detec-
22 tion methods and decontamination technologies are
23 not optimally effective.

24 (4) Indoor biological decontamination can be
25 more challenging than outdoor decontamination due

1 to the absence of weathering processes and environ-
2 mental decay.

3 (5) Current indoor biological decontamination
4 methods have emerged from ad hoc emergency re-
5 sponses to the Fall 2001 anthrax letter attacks.

6 (6) Opening one letter containing several grams
7 of *Bacillus anthracis* spores in the Daschle Suite of
8 the Hart Senate Office Building initiated a 3-month
9 remediation and restoration effort that ultimately in-
10 volved 26 Federal buildings at a cost of approxi-
11 mately \$26,000,000.

12 (7) The transit of several other anthrax-laden
13 letters through the Brentwood and Trenton United
14 States Postal Service Processing and Distribution
15 Centers led to an unprecedented 3 and ½ year re-
16 mediation effort involving tens of thousands of envi-
17 ronmental samples and on-site construction of spe-
18 cialized chlorine dioxide decontamination facilities at
19 a total cost of more than \$200,000,000.

20 (8) It is not practical to scale up these oper-
21 ations to handle 1 or more wide-area anthrax re-
22 leases.

23 **SEC. 2902. REPORT ON CAPABILITIES.**

24 (a) IN GENERAL.—Not later than one year after the
25 date of enactment of this Act, the Administrator of the

1 Environmental Protection Agency (referred to in this sec-
2 tion as the “Administrator”), in consultation with the Sec-
3 retary of Defense, the Secretary of Health and Human
4 Services, the Secretary of Homeland Security, and other
5 Federal agencies as determined appropriated by the Ad-
6 ministrator, shall submit to the Committees on Health,
7 Education, Labor, and Pensions, Armed Services, Home-
8 land Security and Governmental Affairs, and Environment
9 and Public Works of the Senate and the Committees on
10 Energy and Commerce, Armed Services, Homeland Secu-
11 rity, and Resources of the House of Representatives, a re-
12 port that—

13 (1) describes—

14 (A) the state of technology for the detec-
15 tion and monitoring of nuclear, biological, and
16 chemical contamination;

17 (B) the technologies and operational con-
18 cepts for indoor and outdoor environmental re-
19 mediation of such contamination;

20 (C) training and doctrine for decontamina-
21 tion;

22 (D) the safety and environmental con-
23 sequences associated with such remediation and
24 decontamination procedures;

1 (E) the financial costs and timelines asso-
2 ciated with such procedures;

3 (F) the number of available decontamina-
4 tion companies and personnel, along with plans
5 for augmenting such workforce in an emer-
6 gency;

7 (G) the health and safety standards used
8 to determine efficacy of clean up procedures,
9 and the state of efforts to define such stand-
10 ards;

11 (H) an assessment of Federal assets to co-
12 ordinate and implement decontamination re-
13 sponses; and

14 (I) the ability of the Environmental Pro-
15 tection Agency and other agencies to train,
16 equip, and field a dedicated homeland defense
17 decontamination capability; and

18 (2) makes recommendations with respect to—

19 (A) defining different contamination events
20 and scenarios;

21 (B) research, technologies, and technology
22 infrastructure, needed to fill technology defi-
23 ciencies;

24 (C) development of doctrine, training, and
25 certification methods for decontamination;

1 (D) methods of enhancing the Federal, as
2 well as industrial, response capability;

3 (E) dual use technologies and programs;

4 (F) methods for coordination among the
5 Department of Defense, the Department of
6 Health and Human Services, the Technology
7 Safety Working Group of the United States
8 Army, the Defense Advanced Research Projects
9 Agency, and the Defense Threat Reduction
10 Agency;

11 (G) development of standards for decon-
12 tamination (both health and environmental);
13 and

14 (H) a joint decontamination research, de-
15 velopment, and operational program.

16 (b) REQUEST BY ADMINISTRATOR.—

17 (1) IN GENERAL.—The Administrator may re-
18 quest that the Secretary of Health and Human
19 Services enter into an interagency agreement, under
20 terms acceptable to the Secretary, in which the En-
21 vironmental Protection Agency may order counter-
22 measures under procurement contracts or procure-
23 ment pools established by the Secretary.

24 (2) PROCESSING OF ORDERS.—The ordering of
25 a countermeasure under an agreement under para-

1 graph (1) (including transfers of appropriated funds
2 between the Environmental Protection Agency and
3 the Department of Health and Human Services to
4 pay for such order) may be conducted pursuant to
5 section 1535 of title 31, United States Code, if such
6 order is processed under the terms established—

7 (A) by the Secretary of Health and
8 Human Services in the interagency agreement
9 described under paragraph (1); and

10 (B) in the Project BioShield Act of 2004
11 and this Act (and the amendments made by
12 such Acts) with respect to the procurement of
13 countermeasures under sections 319F-1 and
14 319F-2 of the Public Health Service Act (42
15 U.S.C. 247d-6a and 247d-6b) (as amended by
16 this Act).

Calendar No. 97

109TH CONGRESS
1ST Session
S. 975

A BILL

To provide incentives to increase research by private sector entities to develop medical countermeasures to prevent, detect, identify, contain, and treat illnesses, including those associated with a biological, chemical, nuclear, or radiological weapons attack or an infectious disease outbreak, and for other purposes.

MAY 9, 2005

Read the second time and placed on the calendar