

Calendar No. 53108TH CONGRESS
1ST SESSION**S. 15**

To amend the Public Health Service Act to provide for the payment of compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures, to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States, and to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program.

IN THE SENATE OF THE UNITED STATES

MARCH 11, 2003

Mr. GREGG (for himself, Mr. FRIST, Mr. ALEXANDER, Mr. WARNER, Mr. ENZI, Mr. SESSIONS, Mr. ROBERTS, Mr. GRAHAM of South Carolina, Mr. BOND, Mr. INHOFE, and Mr. STEVENS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

MARCH 25, 2003

Reported by Mr. GREGG, with an amendment

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

A BILL

To amend the Public Health Service Act to provide for the payment of compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures, to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against

★(Star Print)

the United States, and to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
 5 “Biodefense Improvement and Treatment for America
 6 Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—PROTECTION FOR SMALLPOX EMERGENCY PERSONNEL

Sec. 101. Short title.

Sec. 102. Amendment to the Public Health Service Act.

TITLE II—PROJECT BIOSHIELD

Sec. 201. Short title.

Sec. 202. Biomedical countermeasure research and development authorities.

Sec. 203. Biomedical countermeasures procurement.

Sec. 204. Authorization for medical products for use in emergencies.

Sec. 205. Developing new countermeasures and protecting existing countermeasures against bioterrorism.

TITLE III—IMPROVED VACCINE AFFORDABILITY AND AVAILABILITY

Sec. 301. Short title.

Subtitle A—State Vaccine Grants

Sec. 311. Availability of influenza vaccine.

Sec. 312. Program for increasing immunization rates for adults and adolescents; collection of additional immunization data.

Sec. 313. Immunization awareness.

Sec. 314. Supply of vaccines.

Sec. 315. Communication.

Sec. 316. Fast track.

Sec. 317. Study.

Subtitle B—Vaccine Injury Compensation Program

- Sec. 321. Administrative revision of vaccine injury table.
- Sec. 322. Equitable relief.
- Sec. 323. Derivative petitions for compensation.
- Sec. 324. Jurisdiction to dismiss actions improperly brought.
- Sec. 325. Clarification of when injury is caused by factor unrelated to administration of vaccine.
- Sec. 326. Increase in award in the case of a vaccine-related death and for pain and suffering.
- Sec. 327. Basis for calculating projected lost earnings.
- Sec. 328. Allowing compensation for family counseling expenses and expenses of establishing and maintaining guardianship.
- Sec. 329. Allowing payment of interim costs.
- Sec. 330. Procedure for paying attorneys' fees.
- Sec. 331. Extension of statute of limitations.
- Sec. 332. Advisory Commission on Childhood Vaccines.
- Sec. 333. Clarification of standards of responsibility.
- Sec. 334. Clarification of definition of manufacturer.
- Sec. 335. Clarification of definition of vaccine-related injury or death.
- Sec. 336. Clarification of definition of vaccine and definition of physical injury.
- Sec. 337. Amendments to Vaccine Injury Compensation Trust Fund.
- Sec. 338. Ongoing review of childhood vaccine data.
- Sec. 339. Pending actions.
- Sec. 340. Report.

1 **TITLE I—PROTECTION FOR**
 2 **SMALLPOX EMERGENCY PER-**
 3 **SONNEL**

4 **SEC. 101. SHORT TITLE.**

5 This title may be cited as the “Smallpox Emergency
 6 Personnel Protection Act of 2003”.

7 **SEC. 102. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
 8 **ACT.**

9 Part A of title II of the Public Health Service Act
 10 (42 U.S.C. 202 et seq.) is amended by inserting after sec-
 11 tion 224 the following:

12 **“SEC. 224A. PROTECTION FOR SMALLPOX EMERGENCY**
 13 **PERSONNEL.**

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

1 “(1) COVERED COUNTERMEASURE.—The term
2 ‘covered countermeasure’ means a covered counter-
3 measure as specified in article III of the Declara-
4 tion.

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

7 “(A) who is—

8 “(i) a health care worker, a law en-
9 forcement officer, a firefighter, a security-
10 related worker, an emergency medical
11 worker, or a public safety worker who is
12 identified in a State, local, or Department
13 of Health and Human Services plan that is
14 approved by the Secretary; or

15 “(ii) an individual with respect to
16 whom the Secretary determines and de-
17 clares that it is advisable to administer the
18 vaccine (not including any individual to
19 whom the Secretary determines only that
20 such vaccine should be made available);
21 and

22 “(B) to whom a vaccine is administered
23 during the period in which the Declaration is
24 effective (including the portion of such period

1 before the date of enactment of this section)
2 and ending on the later of—

3 “(i) the expiration of the 120-day pe-
4 riod that begins on the effective date of the
5 initial interim final regulations to imple-
6 ment this section;

7 “(ii) the expiration of the 120-day pe-
8 riod that begins on the date on which an
9 individual becomes an individual within a
10 category specified in subparagraph (A); or

11 “(iii) the date on which the Secretary
12 publicly announces that an active case of
13 smallpox has been identified either within
14 or outside the United States.

15 “(3) COVERED INJURY.—The term ‘covered in-
16 jury’ includes—

17 “(A) an injury, disability, illness, condition,
18 or death determined, pursuant to the proce-
19 dures established under subsection (b), to have
20 been sustained as the direct result of adminis-
21 tration to an individual of a covered counter-
22 measure during the effective period of the Dec-
23 laration (other than a minor injury such as
24 minor scarring or minor local reaction); and

1 “(B) an injury, disability, illness, condi-
2 tion, or death determined, pursuant to the pro-
3 cedures established under subsection (b), to
4 have been sustained as the direct result of acci-
5 dental vaccinia inoculation through contact with
6 an individual who is (or who was accidentally
7 inoculated by) an individual in a category speci-
8 fied in Article IV of the Declaration to whom
9 vaccinia vaccine has been administered during
10 the effective period of the Declaration.

11 “(4) DECLARATION.—The term ‘Declaration’
12 means the Declaration Regarding Administration of
13 Smallpox Countermeasures issued by the Secretary
14 of Health and Human Services on January 24,
15 2003, and published in the Federal Register on Jan-
16 uary 28, 2003, including any subsequent amend-
17 ment.

18 “(5) ELIGIBLE INDIVIDUAL.—The term ‘eligible
19 individual’ means an individual who is (as deter-
20 mined in accordance with section 3)—

21 “(A) a covered individual who sustains a
22 covered injury as the direct result of adminis-
23 tration of a covered countermeasure; or

1 “(B) any individual who contracts vaccinia
2 during the effective period of the Declaration or
3 within 30 days after the end of such period—

4 “(i) to whom vaccinia vaccine was not
5 administered;

6 “(ii) who has resided with, or has
7 been in close contact with, a covered indi-
8 vidual; and

9 “(iii) who sustains a covered injury as
10 the direct result of contracting vaccinia.

11 “(6) SECRETARY.—Except as provided other-
12 wise, the term ‘Secretary’ means the Secretary of
13 Health and Human Services.

14 “(b) DETERMINATION OF ELIGIBILITY.—

15 “(1) IN GENERAL.—The Secretary, in consulta-
16 tion with the Attorney General and the Secretary of
17 Labor, shall establish administrative procedures for
18 determining, as applicable with respect to an indi-
19 vidual—

20 “(A) whether the individual is an eligible
21 individual;

22 “(B) whether the individual has sustained
23 a covered injury or injuries for which medical
24 benefits and employment income-loss compensa-
25 tion may be available under subsections (d) and

1 (e), and the amount of such benefits or com-
2 pensation; and

3 “(C) whether the covered injury or injuries
4 of the individual constitute a compensable dis-
5 ability, or caused the individual’s death, for
6 purposes of benefits under subsection (f).

7 “(2) COVERED INDIVIDUALS.—The Secretary
8 may accept a certification, by a Federal, State, or
9 local government entity or private health care entity
10 participating in the administration of covered coun-
11 termeasures under the Declaration, that an indi-
12 vidual is an individual in a category specified in arti-
13 cle IV of the Declaration to whom such a counter-
14 measure has been administered by the applicable
15 deadline specified in subsection (a)(2)(B), as estab-
16 lishing that the individual is a covered individual.

17 “(3) DETERMINATION OF CAUSATION.—

18 “(A) INJURIES SPECIFIED IN INJURY
19 TABLE.—In any case where an injury or other
20 adverse effect specified in the injury table es-
21 tablished under subsection (c) as a known effect
22 of a covered countermeasure manifests in an in-
23 dividual within the time period specified in such
24 table, such injury or other effect shall be

1 rebuttably presumed to have resulted from ad-
2 ministration of such covered countermeasure.

3 “(B) OTHER DETERMINATIONS.—In mak-
4 ing determinations other than those described
5 in subparagraph (A) as to the causation or se-
6 verity of an injury, the Secretary shall take into
7 consideration all relevant medical and scientific
8 evidence presented for consideration, and may
9 obtain and consider the views of qualified med-
10 ical experts.

11 “(4) DEADLINE FOR FILING CLAIM.—The Sec-
12 retary shall not consider any claim for a benefit
13 under this subsection with respect to an individual
14 that is filed later than 1 year after—

15 “(A) the date a covered countermeasure
16 was administered to the individual; or

17 “(B) in the case of a claim based on con-
18 tact vaccination (as described in subsection
19 (a)(5)(B)), the date of the first symptom or
20 manifestation of onset of an adverse effect of
21 such vaccination.

22 “(5) REVIEW OF DETERMINATION.—

23 “(A) SECRETARY’S REVIEW AUTHORITY.—
24 The Secretary may review a determination
25 under this subsection at any time on the Sec-

1 retary’s own motion or on application, and may
2 affirm, vacate, or modify such determination.

3 “(B) SECRETARY’S ACTION NOT JUDI-
4 CIALLY REVIEWABLE.—The determinations of
5 the Secretary under this subsection shall not be
6 subject to review by another official of the
7 United States or by a court by mandamus or
8 otherwise.

9 “(c) COUNTERMEASURE INJURY TABLE.—

10 “(1) SMALLPOX COUNTERMEASURE INJURY
11 TABLE.—The Secretary shall establish by interim
12 final regulation a table identifying—

13 “(A) adverse effects (including injuries,
14 disabilities, illnesses, conditions, and deaths)
15 that shall be presumed to result from the ad-
16 ministration of (or exposure to) a covered coun-
17 termeasure; and

18 “(B) the time periods in which the first
19 symptom, or manifestation of onset of each
20 such adverse effect, must manifest in order for
21 such presumption to apply.

22 “(2) AMENDMENTS.—The Secretary may
23 amend by regulation the table established under
24 paragraph (1). Such amendments shall apply retro-
25 actively to claims filed or pending at the time of the

1 promulgation of final amending regulations and to
2 claims filed after such promulgation.

3 “(d) ~~MEDICAL BENEFITS.~~—

4 “(1) ~~IN GENERAL.~~—Subject to paragraph (2),
5 an eligible individual shall be entitled to payment by
6 the Secretary for medical items and services as rea-
7 sonable and necessary to treat a covered injury. The
8 Secretary may consider the provisions of chapter 81
9 of title 5, United States Code, (and the imple-
10 menting regulations with respect to such chapter) in
11 determining the amount of such payment and the
12 circumstances under which such payments are rea-
13 sonable and necessary.

14 “(2) ~~LIMITATIONS.~~—

15 “(A) ~~BENEFITS SECONDARY TO OTHER~~
16 ~~COVERAGE.~~—The obligation of the Secretary to
17 pay for any services or benefits under para-
18 graph (1) shall be secondary to the obligation
19 of the United States or any third party (includ-
20 ing any State or local governmental entity, pri-
21 vate insurance carrier, or employer) under any
22 other provision of law or contractual agreement,
23 to pay for or provide such services or benefits.

24 “(B) ~~NO BENEFITS FOR MEDICARE-ELIGI-~~
25 ~~BLE INDIVIDUAL.~~—No benefits shall be avail-

1 able to an individual under this subsection with
2 respect to any period in which the individual is
3 eligible for benefits under title XVIII of the So-
4 cial Security section (42 U.S.C. 1395 et seq.).

5 “(e) COMPENSATION FOR LOST EMPLOYMENT IN-
6 COME.—

7 “(1) IN GENERAL.—Subject to paragraphs (2)
8 and (3), an eligible individual shall be entitled to
9 payment of compensation by the Secretary for loss
10 of employment income incurred as a result of a cov-
11 ered injury, at the rate specified in paragraph (2).

12 “(2) AMOUNT OF COMPENSATION.—

13 “(A) IN GENERAL.—Compensation under
14 this subsection shall be at the rate of $66\frac{2}{3}$ per-
15 cent of monthly pay. The Secretary may con-
16 sider the provisions of sections 8114 and 8115
17 of title 5, United States Code (and any imple-
18 menting regulations) in determining the amount
19 of such payment and the circumstances under
20 which such payments are reasonable and nec-
21 essary.

22 “(B) TREATMENT OF SELF-EMPLOYMENT
23 INCOME.—For purposes of this subsection—

24 “(i) the term ‘employment income’ in-
25 cludes income from self-employment; and

1 “(ii) for purposes of computation of
2 pay and determination of wage-earning ca-
3 pacity under subparagraph (A), self-em-
4 ployment income shall be treated as wages.

5 ~~“(3) LIMITATIONS.—~~

6 ~~“(A) BENEFITS SECONDARY TO OTHER~~
7 ~~COVERAGE.—The obligation of the Secretary to~~
8 ~~pay compensation under paragraph (1) shall be~~
9 ~~secondary to the obligation of the United States~~
10 ~~or any third party (including any State or local~~
11 ~~governmental entity, private insurance carrier,~~
12 ~~or employer), under any other law or contrac-~~
13 ~~tual agreement, to pay compensation for loss of~~
14 ~~employment income.~~

15 ~~“(B) NO BENEFITS FOR DEATH OR PER-~~
16 ~~MANENT AND TOTAL DISABILITY.—No payment~~
17 ~~shall be made under this subsection in com-~~
18 ~~ensation for loss of employment income due to~~
19 ~~the death or permanent and total disability of~~
20 ~~an eligible individual.~~

21 ~~“(C) LIMIT ON TOTAL BENEFITS.—Total~~
22 ~~benefits paid to an individual under this sub-~~
23 ~~section shall not exceed \$50,000.~~

24 ~~“(D) WAITING PERIOD.—An eligible indi-~~
25 ~~vidual is not entitled to compensation under~~

1 this subsection for the first 5 work days of dis-
2 ability.

3 ~~“(f) PAYMENT FOR DEATH AND PERMANENT, TOTAL~~
4 ~~DISABILITY.—~~

5 ~~“(1) BENEFIT FOR PERMANENT AND TOTAL~~
6 ~~DISABILITY.—Subject to the succeeding provisions of~~
7 ~~this subsection, an eligible individual who is deter-~~
8 ~~mined, in accordance with the procedures established~~
9 ~~under subsection (b), to have a covered injury or in-~~
10 ~~juries meeting the definition of disability in section~~
11 ~~216(i) of the Social Security Act (42 U.S.C. 416(i))~~
12 ~~shall be entitled to have payment made by the Sec-~~
13 ~~retary of an amount determined under paragraph~~
14 ~~(3), in the same manner as disability benefits are~~
15 ~~paid pursuant to the Public Safety Officers’ Benefits~~
16 ~~Program under subpart 1 of part L of title I of the~~
17 ~~Omnibus Crime Control and Safe Streets Act of~~
18 ~~1968 (42 U.S.C. 3796 et seq.) with respect to an eli-~~
19 ~~gible public safety officer.~~

20 ~~“(2) DEATH BENEFIT.—Subject to the sue-~~
21 ~~ceeding provisions of this subsection, in the case of~~
22 ~~an eligible individual whose death is determined, in~~
23 ~~accordance with the procedures established under~~
24 ~~subsection (b), to have directly resulted from a cov-~~
25 ~~ered injury or injuries a death benefit in the amount~~

1 determined under paragraph (3) shall be payable by
2 the Secretary to the survivor or survivors in the
3 same manner as death benefits are paid pursuant to
4 the Public Safety Officers' Benefits Program under
5 subpart 1 of part L of title I of the Omnibus Crime
6 Control and Safe Streets Act of 1968 (42 U.S.C.
7 3796 et seq.) with respect to an eligible deceased
8 public safety officer.

9 “(3) BENEFIT AMOUNT.—The amount of the
10 disability or death benefit under paragraph (1) or
11 (2) in a fiscal year shall, subject to paragraph
12 (5)(B), equal the amount of the comparable benefit
13 calculated under the Public Safety Officers' Benefits
14 Program under subpart 1 of part L of title I of the
15 Omnibus Crime Control and Safe Streets Act of
16 1968 (42 U.S.C. 3796 et seq.) in such fiscal year,
17 without regard to any reduction attributable to a
18 limitation on appropriations.

19 “(4) BENEFIT IN ADDITION TO MEDICAL BENE-
20 FITS.—A benefit under this subsection shall be in
21 addition to any amounts to which an eligible indi-
22 vidual may be entitled as medical benefits under
23 subsection (d).

24 “(5) LIMITATIONS.—

1 “(A) **DISABILITY BENEFITS.**—No benefit
2 is payable under paragraph (1) with respect to
3 the disability of an eligible individual if—

4 “(i) a disability benefit is paid or pay-
5 able with respect to such individual under
6 Public Safety Officers’ Benefits Program
7 under subpart 1 of part L of title I of the
8 Omnibus Crime Control and Safe Streets
9 Act of 1968 (42 U.S.C. 3796 et seq.); or

10 “(ii) a death benefit is paid or payable
11 with respect to such individual under para-
12 graph (2) or the Public Safety Officers’
13 Benefits Program under subpart 1 of part
14 L of title I of the Omnibus Crime Control
15 and Safe Streets Act of 1968 (42 U.S.C.
16 3796 et seq.).

17 “(B) **DEATH BENEFITS.**—No benefit is
18 payable under paragraph (2) with respect to the
19 death of an eligible individual if—

20 “(i) a disability benefit is paid with
21 respect to such individual under paragraph
22 (1) or the Public Safety Officers’ Benefits
23 Program under subpart 1 of part L of title
24 I of the Omnibus Crime Control and Safe

1 Streets Act of 1968 (42 U.S.C. 3796 et
2 seq.); or

3 “(ii) a death benefit is paid or payable
4 with respect to such individual under the
5 Public Safety Officers’ Benefits Program
6 under subpart 1 of part L of title I of the
7 Omnibus Crime Control and Safe Streets
8 Act of 1968 (42 U.S.C. 3796 et seq.).

9 “(g) ADMINISTRATION.—

10 “(1) ADMINISTRATION BY AGREEMENT WITH
11 OTHER AGENCY OR AGENCIES.—The Secretary may
12 administer any or all of the provisions of this section
13 through Memorandum of Agreement with the Attor-
14 ney General or the Secretary of Labor.

15 “(2) REGULATIONS.—The head of the agency
16 administering this section or any provisions thereof
17 (including any agency head administering such sec-
18 tion or provisions through a Memorandum of Agree-
19 ment under paragraph (1)) may promulgate such
20 implementing regulations as may be determined nec-
21 essary and appropriate. Initial implementing regula-
22 tions may be interim final regulations.

23 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated such sums as may be
25 necessary for fiscal year 2003 and each succeeding fiscal

1 year to carry out this section, to remain available until
 2 expended, including administrative costs and costs of pro-
 3 vision and payment of benefits.

4 “(i) RELATIONSHIP TO OTHER LAWS.—

5 “(1) NO PREEMPTION OF INDIVIDUAL
 6 RIGHTS.—Except as otherwise provided in this sec-
 7 tion, nothing in this section shall be construed to
 8 override or limit any rights an individual may have
 9 to seek compensation, benefits, or redress under any
 10 other provision of Federal or State law.

11 “(2) RELATIONSHIP TO THE FEDERAL TORT
 12 CLAIMS ACT.—

13 “(A) EXHAUSTION REQUIREMENT.—An in-
 14 dividual may not seek any remedy that may be
 15 available under section 224(p) (providing a
 16 cause of action under the Federal Tort Claims
 17 Act for injuries resulting from administration of
 18 smallpox countermeasures under such section
 19 224(p)) unless such individual has first filed a
 20 claim for payment or compensation under this
 21 section and has received a final determination
 22 with respect to such claim.

23 “(B) OFFSET OF COMPENSATION AGAINST
 24 FEDERAL TORT CLAIMS ACT RECOVERY.—The
 25 value of any compensation or benefits paid to

1 an individual, or the survivor or survivors of
 2 such an individual, or the estate of the indi-
 3 vidual pursuant to a claim under this section
 4 shall be offset against any amount to which
 5 such individual or the individual's survivor, sur-
 6 vivors, or estate are entitled under section
 7 224(p).

8 “(3) PREEMPTION OF STATE LAWS PROVIDING
 9 EXCLUSIVE REMEDY FOR WORK-RELATED INJU-
 10 RIES.—No provision of a State workers' compensa-
 11 tion law or other State law shall be construed to bar
 12 claims or benefits under this section, to the extent
 13 that it purports to make such State law the exclu-
 14 sive remedy for a work-related injury or otherwise to
 15 make benefits under this section unavailable to an
 16 otherwise eligible individual.”.

17 **TITLE II—PROJECT BIOSHIELD**

18 **SEC. 201. SHORT TITLE.**

19 This title may be cited as the “Project BioShield Act
 20 of 2003”.

21 **SEC. 202. BIOMEDICAL COUNTERMEASURE RESEARCH AND** 22 **DEVELOPMENT AUTHORITIES.**

23 Part B of title IV of the Public Health Service Act
 24 (42 U.S.C. 284 et seq.) is amended by adding at the end
 25 the following:

1 **“SEC. 409I. BIOMEDICAL COUNTERMEASURE RESEARCH**
2 **AND DEVELOPMENT.**

3 **“(a) IN GENERAL.—**

4 **“(1) AUTHORITY.—**In carrying out research re-
5 sponsibilities under this Act, the Secretary may con-
6 duct and support research and development with re-
7 spect to biomedical countermeasures.

8 **“(2) IMPLEMENTATION.—**

9 **“(A) IN GENERAL.—**Except as provided in
10 subparagraph (C), authorities assigned by this
11 section to the Secretary shall be carried out
12 through the Director of NIH and the Director
13 of the National Institute of Allergy and Infee-
14 tious Diseases.

15 **“(B) LEAD INSTITUTE.—**The National In-
16 stitute of Allergy and Infectious Diseases shall
17 be the lead institute for biomedical counter-
18 measure research and development under this
19 section.

20 **“(C) CHEMICAL, RADIOLOGICAL, AND NU-**
21 **CLEAR AGENTS.—**To the extent that an author-
22 ity described in subparagraph (A) is exercised
23 with respect to a chemical, radiological, or nu-
24 clear agent, the Secretary may authorize the
25 Director of NIH to carry out the authority
26 through any national research institute.

1 ~~“(3) INTERAGENCY COOPERATION.—~~

2 ~~“(A) IN GENERAL.—In carrying out activi-~~
3 ~~ties under this section, the Secretary is author-~~
4 ~~ized, subject to subparagraph (B), to enter into~~
5 ~~interagency agreements and other collaborative~~
6 ~~undertakings with other agencies of the Federal~~
7 ~~Government and to use other agencies of the~~
8 ~~Department of Health and Human Services.~~

9 ~~“(B) LIMITATION.—An agreement or un-~~
10 ~~dertaking under this paragraph may not au-~~
11 ~~thorize another agency to exercise the authori-~~
12 ~~ties provided to the Secretary by this section.~~

13 ~~“(b) EXPEDITED PROCUREMENT AUTHORITY.—~~

14 ~~“(1) INCREASED SIMPLIFIED ACQUISITION~~
15 ~~THRESHOLD FOR BIOMEDICAL COUNTERMEASURE~~
16 ~~PROCUREMENTS.—~~

17 ~~“(A) IN GENERAL.—For any procurement~~
18 ~~by the Secretary, of property or services for use~~
19 ~~(as determined by the Secretary) in performing,~~
20 ~~administering, or supporting biomedical coun-~~
21 ~~termeasure research or development, the~~
22 ~~amount specified in section 4(11) of the Office~~
23 ~~of Federal Procurement Policy Act (41 U.S.C.~~
24 ~~403(11)), as applicable pursuant to section~~
25 ~~302A(a) of the Federal Property and Adminis-~~

1 trative Services Act of 1949 (41 U.S.C.
2 252a(a)), shall be deemed to be \$25,000,000 in
3 the administration, with respect to such pro-
4 curement, of—

5 “(i) section 303(g)(1)(A) of the Fed-
6 eral Property and Administrative Services
7 Act of 1949 (41 U.S.C. 253(g)(1)(A)) and
8 its implementing regulations; and

9 “(ii) section 302A(b) of such Act (41
10 U.S.C. 252a(b)) and its implementing reg-
11 ulations.

12 “(B) INTERNAL CONTROLS TO BE INSTI-
13 TUTED.—The Secretary shall institute appro-
14 priate internal controls for procurements made
15 under this paragraph, including requirements
16 with respect to documenting the justification
17 for use of the authority provided in this para-
18 graph.

19 “(2) USE OF NONCOMPETITIVE PROCEDURES.—
20 In addition to any other authority to use procedures
21 other than competitive procedures for procurements,
22 the Secretary may use such other noncompetitive
23 procedures when—

24 “(A) the procurement is as described by
25 paragraph (1)(A); and

1 “(B) the property or services needed by
2 the Secretary are available from only one re-
3 sponsible source or only from a limited number
4 of responsible sources, and no other type of
5 property or services will meet the needs of the
6 Secretary.

7 ~~“(3) INCREASED MICROPURCHASE THRESH-~~
8 ~~OLD.—~~

9 “(A) IN GENERAL.—For a procurement
10 described by paragraph (1)(A), the amount
11 specified in subsections (e), (d), and (f) of sec-
12 tion 32 of the Office of Federal Procurement
13 Policy Act (41 U.S.C. 428) shall be deemed to
14 be \$15,000 in the administration of that section
15 with respect to such procurement.

16 “(B) INTERNAL CONTROLS TO BE INSTI-
17 TUTED.—The Secretary shall institute appro-
18 priate internal controls for procurements that
19 are made under this paragraph and that are
20 greater than \$2,500.

21 “(C) EXCEPTION TO PREFERENCE FOR
22 PURCHASE CARD MECHANISM.—No provision of
23 law establishing a preference for using a Fed-
24 eral Government purchase card method for pur-
25 chases shall apply to procurements made under

1 this paragraph and that are greater than
2 \$2,500.

3 “(e) ~~AUTHORITY TO EXPEDITE PEER REVIEW.~~—The
4 Secretary may, as the Secretary determines necessary to
5 respond to pressing research and development needs under
6 this section, employ such expedited peer review procedures
7 (including consultation with appropriate scientific experts)
8 as the Secretary, in consultation with the Director of NIH,
9 determines to be appropriate to obtain an assessment of
10 scientific and technical merit and likely contribution to the
11 field of biomedical countermeasure research, in place of
12 the peer review and advisory council review procedures
13 that would otherwise be required under sections 301(a)(3),
14 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as
15 applicable to a grant, contract, or cooperative agree-
16 ment—

17 “(1) that is for performing, administering, or
18 supporting biomedical countermeasure research and
19 development; and

20 “(2) the amount of which is not greater than
21 \$1,500,000.

22 “(d) ~~FACILITIES AUTHORITY.~~—

23 “(1) ~~AGENCY FACILITIES.~~—In addition to any
24 similar authority provided under any other provision

1 of law, in carrying out this section, the Secretary
2 may—

3 “(A) acquire, lease, construct, improve,
4 renovate, remodel, repair, operate, and maintain
5 laboratories, other research facilities and equip-
6 ment, and other real or personal property as
7 the Secretary determines necessary for the pur-
8 pose of performing, administering, and sup-
9 porting biomedical countermeasure research
10 and development; and

11 “(B) acquire, without regard to section
12 8141 of title 40, United States Code, by lease
13 or otherwise, through the Administrator of Gen-
14 eral Services, buildings or parts of buildings in
15 the District of Columbia.

16 “(2) FACILITIES OF GRANTEE OR COOPERATIVE
17 AGREEMENT PARTNER.—

18 “(A) IN GENERAL.—The Secretary may
19 exercise the authorities described in section
20 481A with respect to biocontainment labora-
21 tories and other related or ancillary specialized
22 research facilities as the Secretary determines
23 necessary for the purpose of performing, admin-
24 istering, and supporting biomedical counter-
25 measure research and development.

1 “(B) AVAILABILITY OF FACILITY TO SEC-
2 RETARY.—A grant or cooperative agreement
3 under subparagraph (A) may provide that the
4 facility that is the object of such grant or coop-
5 erative agreement shall be available as needed
6 to the Secretary to respond to public health
7 emergencies affecting national security.

8 “(C) TWENTY YEAR USE REQUIREMENT.—
9 A grant or cooperative agreement under this
10 paragraph shall include an agreement by the
11 grantee or cooperative agreement partner that,
12 for not less than 20 years after the completion
13 of the acquisition, construction, or other work
14 described in subparagraph (A), the facility will
15 be used for the purposes of the research and
16 development for which it is to be acquired, con-
17 structed, or otherwise improved.

18 “(D) AMOUNT OF GRANT; COST-SHARING;
19 PAYMENTS.—The provisions of section 481A(e)
20 shall apply to a grant or cooperative agreement
21 under this paragraph, except that—

22 “(i) authorities exercised under that
23 section by the Director of the National
24 Center for Research Resources shall, for

1 purposes of this paragraph, be exercised by
2 the Secretary; and

3 “(ii) for purposes of this paragraph,
4 each of the percentages in subparagraphs
5 (A) and (B) of section 481A(e)(1) shall be
6 deemed to be 75 percent.

7 “(E) RECAPTURE OF PAYMENTS.—If, not
8 later than 20 years after the completion of con-
9 struction for which a grant or cooperative
10 agreement has been awarded under this para-
11 graph, the facility shall cease to be used for the
12 research and development purposes for which it
13 was constructed (unless the Secretary deter-
14 mines, in accordance with regulations, that
15 there is good cause for releasing the applicant
16 or other owner from obligation to do so); the
17 United States shall be entitled to recover from
18 the applicant or other owner of the facility the
19 amount bearing the same ratio to the current
20 value (as determined by an agreement between
21 the parties or by action brought in the United
22 States District Court for the district in which
23 such facility is situated) of the facility as the
24 amount of the Federal participation bore to the

1 cost of the construction, acquisition, or other
2 improvement of such facility.

3 “(e) AUTHORITY FOR PERSONAL SERVICES CON-
4 TRACTS.—

5 “(1) IN GENERAL.—For the purpose of per-
6 forming, administering, and supporting biomedical
7 countermeasure research and development, the Sec-
8 retary may, as the Secretary determines necessary to
9 respond to pressing research and development needs
10 under this section, obtain by contract (in accordance
11 with section 3109 of title 5, United States Code, but
12 without regard to the limitations in such section on
13 the period of service and on pay) the personal serv-
14 ices of experts or consultants who have scientific or
15 other professional qualifications.

16 “(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

17 “(A) IN GENERAL.—A person carrying out
18 a contract under paragraph (1), and an officer,
19 employee, or governing board member of such
20 person, shall be deemed to be an employee of
21 the Department of Health and Human Services
22 for purposes of claims under sections 1346(b)
23 and 2672 of title 28, United States Code, for
24 money damages for personal injury, including

1 death, resulting from performance of functions
2 under such contract.

3 “(B) EXCLUSIVITY OF REMEDY.—The
4 remedy provided by subparagraph (A) shall be
5 exclusive of any other civil action or proceeding
6 by reason of the same subject matter against
7 the person, officer, employee, or governing
8 board member.

9 “(3) INTERNAL CONTROLS TO BE INSTI-
10 TUTED.—

11 “(A) IN GENERAL.—The Secretary shall
12 institute appropriate internal controls for con-
13 tracts under this subsection, including proce-
14 dures for the Secretary to make a determina-
15 tion of whether a person, or an officer, em-
16 ployee, or governing board member of a person,
17 is deemed to be an employee of the Department
18 of Health and Human Services pursuant to
19 paragraph (2).

20 “(B) DETERMINATION OF EMPLOYEE STA-
21 TUS TO BE FINAL.—A determination by the
22 Secretary under subparagraph (A) that a per-
23 son, or an officer, employee, or governing board
24 member of a person, is or is not deemed to be
25 an employee of the Department of Health and

1 Human Services shall be final and binding on
2 the Secretary and the Attorney General and
3 other parties to any civil action or proceeding.

4 ~~“(4) NUMBER OF PERSONAL SERVICES CON-~~
5 ~~TRACTS LIMITED.—The number of experts and con-~~
6 ~~sultants whose personal services are obtained under~~
7 ~~paragraph (1) shall not exceed 30 at any time.~~

8 ~~“(f) STREAMLINED PERSONNEL AUTHORITY.—~~

9 ~~“(1) IN GENERAL.—In addition to any other~~
10 ~~personnel authorities, the Secretary may, as the Sec-~~
11 ~~retary determines necessary to respond to pressing~~
12 ~~research and development needs under this section,~~
13 ~~without regard to such provisions of title 5, United~~
14 ~~States Code, governing appointments in the competi-~~
15 ~~tive service, and without regard to the provisions of~~
16 ~~chapter 51 and subchapter III of chapter 53 of such~~
17 ~~title relating to classification and General Schedule~~
18 ~~pay rates, appoint professional and technical employ-~~
19 ~~ees, not to exceed 30 such employees at any time,~~
20 ~~to positions in the National Institutes of Health to~~
21 ~~perform, administer, or support biomedical counter-~~
22 ~~measure research and development in carrying out~~
23 ~~this section.~~

24 ~~“(2) INTERNAL CONTROLS TO BE INSTI-~~
25 ~~TUTED.—The Secretary shall institute appropriate~~

1 internal controls for appointments under this sub-
2 section.

3 “(g) DEFINITION.—As used in this section, the term
4 ‘biomedical countermeasure’ means a drug (as that term
5 is defined by section 201(g)(1) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 321(g)(1))), biological prod-
7 uct (as that term is defined by section 351(i) of this Act
8 (42 U.S.C. 262(i))), or device (as that term is defined by
9 section 201(h) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 321(h))) that is used—

11 “(1) to treat, identify, or prevent harm from
12 any biological, chemical, radiological, or nuclear
13 agent that may cause a public health emergency af-
14 fecting national security; or

15 “(2) to treat, identify, or prevent harm from a
16 condition that may result in adverse health con-
17 sequences or death and may be caused by admin-
18 istering a drug, biological product, or device that is
19 used as described in paragraph (1).

20 “(h) ACTIONS COMMITTED TO AGENCY DISCRE-
21 TION.—Actions by the Secretary under the authority of
22 this section are committed to agency discretion.”.

1 **SEC. 203. BIOMEDICAL COUNTERMEASURES PROCURE-**
 2 **MENT.**

3 Section 121 of the Public Health Security and Bioter-
 4 rorism Preparedness and Response Act of 2002 (42
 5 U.S.C. 300hh-12) is amended—

6 (1) by redesignating subsections (e) through (e)
 7 as subsections (d) through (f), respectively; and

8 (2) by inserting after subsection (b) the fol-
 9 lowing:

10 “(e) BIOMEDICAL COUNTERMEASURES PROCURE-
 11 MENT.—

12 “(1) DETERMINATION OF MATERIAL
 13 THREATS.—

14 “(A) RISK OF USE.—The Secretary, in
 15 consultation with the heads of other agencies as
 16 appropriate, shall on an ongoing basis—

17 “(i) assess current and emerging
 18 threats of use of chemical, biological, radi-
 19 ological, and nuclear agents; and

20 “(ii) determine which of such agents
 21 present a material risk of use against the
 22 United States population.

23 “(B) PUBLIC HEALTH IMPACT.—The Sec-
 24 retary of Health and Human Services, in con-
 25 sultation with the Secretary, shall on an ongo-
 26 ing basis—

1 “(i) assess the potential public health
2 consequences of use against the United
3 States population of agents identified
4 under subparagraph (A)(ii); and

5 “(ii) determine, on the basis of such
6 assessment, the agents for which counter-
7 measures are necessary to protect the pub-
8 lic health.

9 “(2) ASSESSMENT OF AVAILABILITY AND AP-
10 PROPRIATENESS OF COUNTERMEASURES.—The Sec-
11 retary of Health and Human Services, in consulta-
12 tion with the Secretary, shall assess on an ongoing
13 basis the availability and appropriateness of specific
14 countermeasures to address specific threats identi-
15 fied under paragraph (1).

16 “(3) SECRETARY’S DETERMINATION OF COUN-
17 TERMEASURES APPROPRIATE FOR PROCUREMENT
18 UNDER THIS SUBSECTION.—

19 “(A) IN GENERAL.—The Secretary of
20 Health and Human Services, in accordance
21 with this paragraph, shall identify specific coun-
22 termeasures to threats identified under para-
23 graph (1) that such Secretary determines, in
24 consultation with the Secretary of Homeland
25 Security, to be appropriate for procurement

1 with appropriations under this subsection for
2 inclusion in the stockpile under subsection (a).

3 “(B) REQUIREMENTS.—In order for the
4 Secretary of Health and Human Services to
5 make the determination under subparagraph
6 (A) with respect to a countermeasure, the fol-
7 lowing requirements must be met:

8 “(i) DETERMINATION OF QUALIFIED
9 COUNTERMEASURE.—Such Secretary must
10 determine that the product is a qualified
11 countermeasure (as defined in paragraph
12 (7)).

13 “(ii) DETERMINATION OF QUANTITIES
14 NEEDED AND FEASIBILITY OF PRODUC-
15 TION AND DISTRIBUTION.—Such Secretary
16 must determine—

17 “(I) the quantities of the product
18 that will be needed to meet the needs
19 of the stockpile; and

20 “(II) that production and deliv-
21 ery within 5 years of sufficient quan-
22 tities of the product, as so deter-
23 mined, is reasonably expected to be
24 feasible.

1 ~~“(iii) DETERMINATION OF NO SIG-~~
2 ~~NIFICANT COMMERCIAL MARKET.—Such~~
3 ~~Secretary shall—~~

4 ~~“(I) determine that, at the time~~
5 ~~of the initial determination under this~~
6 ~~paragraph, there is not a significant~~
7 ~~commercial market for the product~~
8 ~~other than as a homeland security~~
9 ~~threat countermeasure; and~~

10 ~~“(II) annually redetermine and~~
11 ~~report to the President, while a deter-~~
12 ~~mination under subparagraph (A) re-~~
13 ~~mains in effect with respect to the~~
14 ~~product, whether a significant com-~~
15 ~~mercial market exists for the product~~
16 ~~other than as a homeland security~~
17 ~~threat countermeasure.~~

18 ~~“(4) RECOMMENDATION FOR PRESIDENT’S AP-~~
19 ~~PROVAL.—~~

20 ~~“(A) RECOMMENDATION FOR PROCURE-~~
21 ~~MENT.—In the case of a countermeasure that~~
22 ~~the Secretary and the Secretary of Health and~~
23 ~~Human Services have determined is appropriate~~
24 ~~for procurement under this subsection for inclu-~~
25 ~~sion in the stockpile, in accordance with the~~

1 preceding provisions of this subsection, the Sec-
2 retary and the Secretary of Health and Human
3 Services shall jointly submit to the President, in
4 coordination with the Director of the Office of
5 Management and Budget, a recommendation
6 for procurement under this subsection.

7 “(B) PRESIDENTIAL APPROVAL.—A coun-
8 termeasure may be procured under this sub-
9 section only if the President has approved a
10 recommendation under subparagraph (A) with
11 respect to such countermeasure.

12 “(C) NOTICE TO CONGRESS.—The Sec-
13 retary shall notify Congress of each decision of
14 the President to approve a recommendation
15 under subparagraph (A).

16 “(5) PROCUREMENT.—The Secretary of Health
17 and Human Services and the Secretary shall be re-
18 sponsible for the following, for purposes of procure-
19 ment of qualified countermeasures for the stockpile
20 under subsection (a), as approved by the President
21 under paragraph (4):

22 “(A) INTERAGENCY AGREEMENTS.—

23 “(i) FOR PROCUREMENT.—The Sec-
24 retary shall enter into an agreement with
25 the Secretary of Health and Human Serv-

1 ices for the procurement of the counter-
2 measure in accordance with the provisions
3 of this paragraph. Amounts appropriated
4 under paragraph (8) shall be available for
5 the Secretary of Health and Human Serv-
6 ice's costs of such procurement, other than
7 as provided in clause (ii).

8 “(ii) FOR ADMINISTRATIVE COSTS.—

9 The agreement entered into between the
10 Secretary and the Secretary of Health and
11 Human Services for managing the stock-
12 pile under subsection (a) shall provide for
13 reimbursement of the Secretary of Health
14 and Human Service's administrative costs
15 relating to procurements under this sub-
16 section from appropriations to carry out
17 such subsection (a).

18 “(B) PROCUREMENT.—

19 “(i) IN GENERAL.—The Secretary of
20 Health and Human Services shall be re-
21 sponsible for—

22 “(I) arranging for procurement
23 of the countermeasure, including ne-
24 gotiating terms (including quantity,
25 production schedule, and price) of,

1 and entering into, contracts and coop-
2 erative agreements, and for carrying
3 out such other activities as may rea-
4 sonably be required, in accordance
5 with the provisions of this subpara-
6 graph; and

7 “(H) promulgating regulations to
8 implement clauses (v), (vi), and (vii),
9 and any other provisions of this sub-
10 section.

11 “(ii) CONTRACT TERMS.—A contract
12 for procurements under this subsection
13 shall (or, as otherwise specified in this
14 clause, may) include the following terms:

15 “(I) PAYMENT CONDITIONED ON
16 SUBSTANTIAL DELIVERY.—The con-
17 tract shall provide that no payment
18 may be made until delivery has been
19 made of a substantial portion (as de-
20 termined by the Secretary of Health
21 and Human Services) of the total
22 number of units contracted for.

23 “(II) DISCOUNTED PAYMENT
24 FOR UNLICENSED PRODUCT.—The
25 contract may provide for a discounted

1 price per unit of a product that is not
2 licensed or approved as described in
3 paragraph (7)(A) at the time of deliv-
4 ery, and may provide for payment of
5 an additional amount per unit if the
6 product becomes so licensed or ap-
7 proved before the expiration date of
8 the contract (including an additional
9 amount per unit of product delivered
10 before the effective date of such li-
11 censing or approval).

12 “(III) STORAGE BY VENDOR.—

13 The contract may provide that the
14 vendor will provide storage for stocks
15 of a product delivered to the owner-
16 ship of the Government under the
17 contract, for such period and under
18 such terms and conditions as the Sec-
19 retary of Health and Human Services
20 may specify, and in such case
21 amounts appropriated under para-
22 graph (8) shall be available for costs
23 of shipping, handling, storage, and re-
24 lated costs for such product.

1 “(IV) CONTRACT DURATION.—

2 The contract shall be for a period not
3 to exceed 5 years, renewable for addi-
4 tional periods none of which shall ex-
5 ceed 5 years.

6 “(V) TERMINATION FOR NON-

7 DELIVERY.—In addition to any other
8 rights of the Secretary of Health and
9 Human Services to terminate the con-
10 tract, the contract may provide that
11 such Secretary may terminate the
12 contract for failure to deliver a rea-
13 sonable number (as determined by
14 such Secretary) of units of the prod-
15 uct by 3 years after the date the con-
16 tract is entered into; and may further
17 provide that in such case the vendor
18 shall not be entitled to any payment
19 under the contract.

20 “(iii) AVAILABILITY OF SIMPLIFIED

21 ACQUISITION PROCEDURES.—The amount
22 of any procurement under this subsection
23 shall be deemed to be below the threshold
24 amount specified in section 4(11) of the
25 Office of Federal Procurement Policy Act

1 (41 U.S.C. 403(11)), for purposes of appli-
2 cation to such procurement, pursuant to
3 section 302A(a) of the Federal Property
4 and Administrative Services Act of 1949
5 (41 U.S.C. 252a(a)), of—

6 “(I) section 303(g)(1)(A) of the
7 Federal Property and Administrative
8 Services Act of 1949 (41 U.S.C.
9 253(g)(1)(A)) and its implementing
10 regulations; and

11 “(II) section 302A(b) of such Act
12 (41 U.S.C. 252a(b)) and its imple-
13 menting regulations.

14 “(iv) USE OF NONCOMPETITIVE PRO-
15 CEDURES.—In addition to any other au-
16 thority to use procedures other than com-
17 petitive procedures, the Secretary of
18 Health and Human Services may use such
19 other procedures for a procurement under
20 this subsection if the product is available
21 from only one responsible source or only
22 from a limited number of responsible
23 sources, and no other type of product will
24 satisfy such Secretary’s needs.

1 “(v) PREMIUM PROVISION IN MUL-
2 TIPLE AWARD CONTRACTS.—

3 “(I) IN GENERAL.—If, under this
4 subsection, the Secretary of Health
5 and Human Services enters into con-
6 tracts with more than one person to
7 procure a countermeasure, such Sec-
8 retary may, notwithstanding any other
9 provision of law, include in each of
10 such contracts a provision that—

11 “(aa) identifies an increment
12 of the total quantity of counter-
13 measure required, whether by
14 percentage or by numbers of
15 units; and

16 “(bb) promises to pay one or
17 more specified premiums based
18 on the priority of such persons’
19 production and delivery of the in-
20 crement identified under item
21 (aa); in accordance with the
22 terms and conditions of the con-
23 tract.

24 “(II) DETERMINATION OF GOV-
25 ERNMENT’S REQUIREMENT NOT RE-

1 VIEWABLE.—If the Secretary of
2 Health and Human Services includes
3 in each of a set of contracts a provi-
4 sion as described in clause (I), such
5 Secretary’s determination of the total
6 quantity of countermeasure required,
7 and any amendment of such deter-
8 mination, is committed to agency dis-
9 cretion.

10 “(vi) EXTENSION OF CLOSING DATE
11 FOR RECEIPT OF PROPOSALS NOT REVIEW-
12 ABLE.—A decision by the Secretary of
13 Health and Human Services to extend the
14 closing date for receipt of proposals for a
15 procurement under this subsection is com-
16 mitted to agency discretion.

17 “(vii) LIMITING COMPETITION TO
18 SOURCES RESPONDING TO REQUEST FOR
19 INFORMATION.—In conducting a procure-
20 ment under this subsection, the Secretary
21 of Health and Human Services may ex-
22 clude a source that has not responded to a
23 request for information under section
24 303A(a)(1)(B) of the Federal Property
25 and Administrative Services Act of 1949

1 ~~(41 U.S.C. 253a(a)(1)(B))~~ if such request
2 has given notice that such Secretary may
3 so exclude such a source.

4 ~~“(6) INTERAGENCY COOPERATION.—~~

5 ~~“(A) IN GENERAL.—~~In carrying out activi-
6 ties under this section, the Secretary and the
7 Secretary of Health and Human Services are
8 authorized, subject to subparagraph (B), to
9 enter into interagency agreements and other
10 collaborative undertakings with other agencies
11 of the United States Government.

12 ~~“(B) LIMITATION.—~~An agreement or un-
13 dertaking under this paragraph shall not au-
14 thorize another agency to exercise the authori-
15 ties provided by this section to the Secretary or
16 to the Secretary of Health and Human Serv-
17 ices.

18 ~~“(7) DEFINITIONS.—~~In this subsection:

19 ~~“(A) QUALIFIED COUNTERMEASURE.—~~The
20 term ‘qualified countermeasure’ means a bio-
21 medical countermeasure—

22 ~~“(i) that is approved under section~~
23 505(a) of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 355) or licensed
25 under section 351 of the Public Health

1 Service Act (42 U.S.C. 262) for use as
2 such a countermeasure to a chemical, bio-
3 logical, radiological, or nuclear agent iden-
4 tified as a material threat under paragraph
5 (1); or

6 “(ii) for which the Secretary of
7 Health and Human Services determines
8 that sufficient and satisfactory clinical ex-
9 perience or research data (including data,
10 if available, from preclinical and clinical
11 trials) support a reasonable conclusion that
12 the product will qualify for approval or li-
13 censing as such a countermeasure within 5
14 years after the date of a determination
15 under paragraph (3).

16 “(B) BIOMEDICAL COUNTERMEASURE.—

17 The term ‘biomedical countermeasure’ means a
18 drug (as that term is defined by section
19 201(g)(1) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 321(g)(1))) or biological
21 product (as that term is defined by section
22 351(i) of the Public Health Service Act (42
23 U.S.C. 262(i))) that is used—

24 “(i) to treat, identify, or prevent harm
25 from any biological, chemical, radiological,

1 or nuclear agent that may cause a public
2 health emergency affecting national secu-
3 rity; or

4 “(ii) to treat, identify, or prevent
5 harm from a condition that may result in
6 adverse health consequences or death and
7 may be caused by administering a drug or
8 biological product that is used as described
9 in clause (i).

10 ~~“(8) APPROPRIATIONS.—~~

11 ~~“(A) IN GENERAL.— There are appro-~~
12 ~~riated, out of any moneys in the Treasury not~~
13 ~~otherwise appropriated, for fiscal year 2003 and~~
14 ~~for each fiscal year thereafter, such sums as~~
15 ~~may be necessary for the costs incurred by the~~
16 ~~Secretary in the procurement of counter-~~
17 ~~measures under this subsection as approved by~~
18 ~~the President under paragraph (4) (other than~~
19 ~~costs specified in subparagraph (B)).~~

20 ~~“(B) RESTRICTIONS.—Amounts appro-~~
21 ~~riated under this paragraph shall not be avail-~~
22 ~~able to pay—~~

23 ~~“(i) costs for the purchase of vaccines~~
24 ~~under procurement contracts entered into~~
25 ~~before January 1, 2003;~~

1 “(ii) costs under new contracts, or
 2 costs of new obligations under contracts
 3 previously entered into, for procurement of
 4 a countermeasure after the date of a deter-
 5 mination under paragraph (3)(B)(iii) that
 6 there is a significant commercial market
 7 for the countermeasure other than as a
 8 homeland security threat countermeasure;
 9 or
 10 “(iii) administrative costs.”

11 **SEC. 204. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
 12 **USE IN EMERGENCIES.**

13 (a) IN GENERAL.—Subchapter E of Chapter V of the
 14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 15 360bbb, et seq.) is amended by adding at the end the fol-
 16 lowing:

17 **“SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
 18 **USE IN EMERGENCIES.**

19 “(a) IN GENERAL.—Notwithstanding sections 505
 20 and 515 of this Act and section 351 of the Public Health
 21 Service Act, and subject to the provisions of this section,
 22 the Secretary may authorize the introduction into inter-
 23 state commerce, during the effective period of a declara-
 24 tion under subsection (b), of a drug or device intended
 25 solely for use in an actual or potential emergency.

1 “(b) DECLARATION OF EMERGENCY.—

2 “(1) IN GENERAL.—The Secretary may declare
3 an emergency justifying the authorization of a drug
4 or device under this subsection on the basis of a de-
5 termination—

6 “(A) by the Secretary of Homeland Secu-
7 rity, that there is a national emergency (or a
8 significant potential of a national emergency)
9 involving a heightened risk of attack with a
10 specified biological, chemical, radiological, or
11 nuclear agent or agents;

12 “(B) by the Secretary of Defense, that
13 there is a military emergency (or a significant
14 potential of a military emergency) involving a
15 heightened risk to United States military forces
16 of attack with a biological, chemical, radio-
17 logical, or nuclear agent or agents; or

18 “(C) by the Secretary of a public health
19 emergency under section 319 of the Public
20 Health Service Act, involving a specified disease
21 or condition or a specified biological, chemical,
22 radiological, or nuclear agent or agents.

23 “(2) TERMINATION OF DECLARATION.—

1 “(A) IN GENERAL.—A declaration under
2 this subsection shall terminate upon the earlier
3 of—

4 “(i) a determination by the Secretary,
5 in consultation as appropriate with the
6 Secretary of Homeland Security or the
7 Secretary of Defense, that the cir-
8 cumstances described in paragraph (1)
9 have ceased to exist; or

10 “(ii) the expiration of the 1-year pe-
11 riod beginning on the date on which the
12 declaration is made.

13 “(B) RENEWAL.—Notwithstanding sub-
14 paragraph (A), the Secretary may renew a dec-
15 laration under this subsection, and this para-
16 graph shall apply to any such renewal.

17 “(3) PUBLICATION.—The Secretary shall
18 promptly publish in the Federal Register each dec-
19 laration, determination, and renewal under this sub-
20 section.

21 “(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—
22 The Secretary may issue an authorization under this sec-
23 tion with respect to a product if the Secretary concludes—

1 “(1) that an agent specified in a declaration
2 under subsection (b) can cause a serious or life-
3 threatening disease or condition;

4 “(2) that, based on the totality of scientific evi-
5 dence available to the Secretary, including data from
6 adequate and well-controlled clinical trials, if avail-
7 able, it is reasonable to believe that—

8 “(A) the product may be effective in de-
9 tecting, diagnosing, treating, or preventing—

10 “(i) such disease or condition; or

11 “(ii) a serious or life-threatening dis-
12 ease or condition caused by a product au-
13 thorized under this section or approved
14 under this Act or the Public Health Serv-
15 ice Act, for detecting, diagnosing, treating,
16 or preventing such a disease or condition
17 caused by such an agent; and

18 “(B) the known and potential benefits of
19 the product, when used to detect, diagnose, pre-
20 vent, or treat such disease or condition, out-
21 weigh the known and potential risks of the
22 product;

23 “(3) that there is no adequate, approved, and
24 available alternative to the product for detecting, di-

1 agnosing, preventing, or treating such disease or
2 condition; and

3 “(4) that such other criteria as the Secretary
4 may by regulation prescribe are satisfied.

5 “(d) SCOPE OF AUTHORIZATION.—An authorization
6 of a product under this section shall state—

7 “(1) each disease or condition that the product
8 may be used to detect, diagnose, prevent, or treat
9 within the scope of the authorization; and

10 “(2) the Secretary’s conclusions, under sub-
11 section (c), concerning the safety and potential effec-
12 tiveness of the product in detecting, diagnosing, pre-
13 venting, or treating such diseases or conditions, in-
14 cluding an assessment of the available scientific evi-
15 dence.

16 “(e) CONDITIONS OF AUTHORIZATION.—

17 “(1) IN GENERAL.—The Secretary is author-
18 ized, by order or regulation, to impose such condi-
19 tions on an authorization under this section as the
20 Secretary determines are necessary or appropriate to
21 protect the public health, including the following:

22 “(A) The Secretary shall impose require-
23 ments (including requirements concerning prod-
24 uct labeling and the provision of information)
25 designed to ensure that, to the maximum extent

1 feasible given the circumstances of the emer-
2 gency, health care professionals administering
3 the product are informed—

4 “(i) that the Secretary has authorized
5 the product solely for emergency use;

6 “(ii) of the significant known and po-
7 tential benefits and risks of use of the
8 product, and of the extent to which such
9 benefits and risks are unknown; and

10 “(iii) of the alternatives to the prod-
11 uct that are available, and of their benefits
12 and risks.

13 “(B) The Secretary shall impose require-
14 ments (including requirements concerning prod-
15 uct labeling and the provision of information)
16 designed to ensure that, to the maximum extent
17 feasible given the circumstances of the emer-
18 gency, individuals to whom the product is ad-
19 ministered are informed—

20 “(i) that the Secretary has authorized
21 the product solely for emergency use;

22 “(ii) of the significant known and po-
23 tential benefits and risks of use of the
24 product, and of the extent to which such
25 benefits and risks are unknown; and

1 “(iii) of any option to accept or refuse
2 administration of the product, and of the
3 alternatives to the product that are avail-
4 able and of their benefits and risks.

5 “(C) The Secretary may impose limitations
6 on which entities may distribute the product
7 (including limitation to distribution by govern-
8 ment entities), and on how distribution is to be
9 performed.

10 “(D) The Secretary may impose limita-
11 tions on who may administer the product, and
12 on the categories of individuals to whom, and
13 the circumstances under which, the product
14 may be administered.

15 “(E) The Secretary may condition the au-
16 thorization on the performance of studies, clin-
17 ical trials, or other research needed to support
18 marketing approval of the product.

19 “(F) The Secretary may impose require-
20 ments concerning recordkeeping and reporting,
21 including records access by the Secretary and
22 publication of data.

23 “(G) The Secretary may impose (or waive)
24 requirements, with respect to the product, of
25 current good manufacturing practice otherwise

1 applicable to the manufacture, processing, pack-
2 ing, or holding of products subject to regulation
3 under this Act.

4 “(H) The Secretary may impose require-
5 ments for the monitoring and reporting of ad-
6 verse events associated with use of the product.

7 “(2) WAIVER.—The Secretary may waive any
8 condition imposed under this subsection.

9 “(f) DURATION OF AUTHORIZATION.—

10 “(1) IN GENERAL.—Except as provided in para-
11 graph (2), an authorization under this section shall
12 be effective until the earlier of the termination of the
13 declaration under subsection (b) or a revocation
14 under subsection (g).

15 “(2) CONTINUED USE AFTER END OF EFPEC-
16 TIVE PERIOD.—An authorization shall continue to be
17 effective for continued use with respect to patients
18 to whom it was administered during the period de-
19 scribed by paragraph (1), to the extent found nec-
20 essary by such patients’ attending physicians.

21 “(g) REVOCATION OF AUTHORIZATION.—

22 “(1) REVIEW.—The Secretary shall periodically
23 review the circumstances and the appropriateness of
24 an authorization under this section.

1 “(2) REVOCATION.—The Secretary may revoke
2 an authorization under this section if, in the Sec-
3 retary’s unreviewable discretion—

4 “(A) the conditions for such an authoriza-
5 tion are no longer met; or

6 “(B) other circumstances make such rev-
7 ocation appropriate.

8 “(h) PUBLICATION.—The Secretary shall promptly
9 publish in the Federal Register a notice of each authoriza-
10 tion, and each termination or revocation of an authoriza-
11 tion, under this section.

12 “(i) RECORDKEEPING.—

13 “(1) IN GENERAL.—The Secretary may by
14 order or regulation require persons, including a per-
15 son who holds an authorization under this section,
16 or who manufactures, distributes, prescribes, or ad-
17 ministers a product that is the subject of such an
18 authorization, to establish and maintain—

19 “(A) data that is obtained from such activ-
20 ity and that pertains to the effectiveness or
21 safety of such product;

22 “(B) such records as are necessary to de-
23 termine, or facilitate a determination, whether
24 there may be any violation of this section or of

1 a regulation promulgated under this section;
2 and

3 “(C) such additional records as the Sec-
4 retary may determine necessary.

5 “(2) ACCESS TO RECORDS BY SECRETARY.—

6 “(A) SAFETY AND EFFECTIVENESS INFOR-
7 MATION.—The Secretary may by order or regu-
8 lation require a person who holds an authoriza-
9 tion under this section, or who manufactures,
10 distributes, prescribes, or administers a product
11 that is the subject of such an authorization to
12 provide to the Secretary all data that is ob-
13 tained from such activity and that pertains to
14 the safety or effectiveness of such product.

15 “(B) OTHER INFORMATION.—Every person
16 required under this section to establish or main-
17 tain records, and every person in charge or cus-
18 tody of such records, shall, upon request by the
19 Secretary, permit the Secretary at all reason-
20 able times to have access to, to copy, and to
21 verify such records.

22 “(j) CIVIL MONETARY PENALTIES.—

23 “(1) IN GENERAL.—A person who violates a re-
24 quirement of this section or of a regulation or order
25 promulgated pursuant to this section shall be subject

1 to a civil money penalty of not more than \$100,000
2 in the case of an individual, and not more than
3 \$250,000 in the case of any other person, for each
4 violation, not to exceed \$1,000,000 for all such viola-
5 tions adjudicated in a single proceeding.

6 “(2) ASSESSMENT OF CIVIL PENALTIES.—Para-
7 graphs (3), (4), and (5) of section 303(g) shall apply
8 to a civil penalty under this subsection, and ref-
9 erences in such paragraphs to ‘paragraph (1) or (2)’
10 shall, for purposes of this subsection, be deemed to
11 refer to paragraph (1) of this subsection.

12 “(k) ACTIONS COMMITTED TO AGENCY DISCRE-
13 TION.—Actions under the authority of this section by the
14 Secretary, by the Secretary of Defense, or by the Sec-
15 retary of Homeland Security are committed to agency dis-
16 cretion.

17 “(l) REGULATIONS.—The Secretary may promulgate
18 regulations to implement this section.

19 “(m) CONSTRUCTION.—Nothing in this section shall
20 be construed to impair or otherwise affect—

21 “(1) the authority of the President as Com-
22 mander in Chief of the Armed Forces of the United
23 States under article II, section 2 of the United
24 States Constitution; or

1 “(2) the authority of the Secretary of Defense
2 with respect to the Department of Defense, includ-
3 ing the armed forces, under other provisions of Fed-
4 eral law.

5 “(n) APPLICATION TO MEMBERS OF ARMED
6 FORCES.—

7 “(1) WAIVER OF REQUIREMENT RELATING TO
8 OPTION TO REFUSE.—In the case of the administra-
9 tion of a countermeasure to members of the armed
10 forces, a requirement, under subsection (e)(2)(C),
11 designed to ensure that individuals are informed of
12 an option to accept or refuse administration of a
13 product, may be waived by the President if the
14 President determines, in writing, that complying
15 with such requirement is not feasible, is contrary to
16 the best interests of the members affected, or is not
17 in the interests of national security.

18 “(2) EFFECT ON STATUTE PERTAINING TO IN-
19 VESTIGATIONAL NEW DRUGS.—In the case of an au-
20 thorization based on a determination by the Sec-
21 retary of Defense under subsection (b)(1)(B), sec-
22 tion 1107 of title 10, United States Code, shall not
23 apply to use of a product that is the subject of such
24 authorization, within the scope of such authorization
25 and while such authorization is effective.

1 “(o) **RELATION TO OTHER PROVISIONS.**—If a prod-
 2 uct is the subject of an authorization under this section,
 3 the use of such product within the scope of the authoriza-
 4 tion—

5 “(1) shall not be subject to any requirements
 6 pursuant to section 505(i) or 520(g); and

7 “(2) shall not be subject to any requirements
 8 otherwise applicable to clinical investigations pursu-
 9 ant to other provisions of this Act.”.

10 (b) **PROHIBITED ACTS.**—Section 301 of the Federal
 11 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
 12 ed—

13 (1) in subsection (c)—

14 (A) by striking “504, 703” and inserting
 15 “504, 564, 703”; and

16 (B) by striking “or 519” and inserting
 17 “519, or 564”; and

18 (2) by adding at the end the following:

19 “(hh)(1) Promotion or use of a product that is the
 20 subject of an authorization under section 564 other than
 21 as stated in the authorization, or other than during the
 22 period described by section 564(g), unless such promotion
 23 or use is permitted under another provision of this Act.

24 “(2) Failure to comply with an information require-
 25 ment under section 564(e)(1).”.

1 **SEC. 205. DEVELOPING NEW COUNTERMEASURES AND PRO-**
2 **TECTING EXISTING COUNTERMEASURES**
3 **AGAINST BIOTERRORISM.**

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

7 ~~“(k) LIMITED ANTITRUST EXEMPTION.—~~

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

10 ~~“(A) COUNTERMEASURES DEVELOPMENT~~
11 ~~MEETINGS AND CONSULTATIONS.—The Sec-~~
12 ~~retary may conduct meetings and consultations~~
13 ~~with parties involved in the development of~~
14 ~~countermeasures for the purpose of the develop-~~
15 ~~ment, manufacture, distribution, or sale of pri-~~
16 ~~ority countermeasures consistent with the pur-~~
17 ~~poses of this title. The Secretary shall give no-~~
18 ~~tice of such meetings and consultations to the~~
19 ~~Attorney General and the Chairperson of the~~
20 ~~Federal Trade Commission (referred to in this~~
21 ~~subsection as the ‘Chairperson’).~~

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

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

4 “(ii) be open to parties involved in the
5 development, manufacture, distribution,
6 purchase, or sale of priority counter-
7 measures, as determined by the Secretary;

8 “(iii) be open to the Attorney General
9 and the Chairperson;

10 “(iv) be limited to discussions involv-
11 ing the development, manufacture, dis-
12 tribution, or sale of priority counter-
13 measures, consistent with the purposes of
14 this title; and

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

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

24 “(D) EXEMPTION.—The antitrust laws
25 shall not apply to meetings and consultations

1 under this paragraph, except that any agree-
2 ment that results from a meeting or consulta-
3 tion and that has been denied an exemption
4 pursuant to this subsection shall be subject to
5 the antitrust laws.

6 ~~“(2) WRITTEN AGREEMENTS OR CONDUCT.—~~

7 The Secretary or any party to an agreement or other
8 conduct regarding covered activities entered into or
9 undertaken pursuant to meetings or consultations
10 conducted under paragraph (1), and that is con-
11 sistent with this paragraph, shall file such written
12 agreement or a description of the conduct involved
13 with the Attorney General and the Chairperson for
14 a determination of whether such agreement or con-
15 duct should be exempt from the antitrust laws. In
16 addition to the proposed agreement or description of
17 conduct itself, any such filing shall include—

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

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

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

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

5 “(E) any other relevant information rea-
6 sonably requested by the Attorney General, in
7 consultation with the Chairperson and the Sec-
8 retary.

9 “(3) DETERMINATION.—The Attorney General,
10 in consultation with the Chairperson, shall determine
11 whether an agreement or description of conduct sub-
12 mitted under paragraph (2) should be exempt from
13 the antitrust laws.

14 “(4) LIMITED ANTITRUST EXEMPTION.—

15 “(A) IN GENERAL.—The Attorney General,
16 in consultation with the Chairperson, may,
17 within 30 days of the receipt of a notification
18 pursuant to paragraph (2), revoke in whole or
19 in part, the scope of any exemption granted by
20 the Attorney General under a determination
21 under paragraph (3).

22 “(B) EXTENSION.—The Attorney General
23 may extend the 35-day period referred to in
24 subparagraph (A) for an additional period of
25 not to exceed 20 days. Such additional period

1 may be further extended only by the United
2 States district court, upon an application by the
3 Attorney General after notice to the Secretary
4 and the parties involved.

5 “(C) APPLICATION OF LAWS.—

6 “(i) IN GENERAL.—The antitrust laws
7 shall not apply to an agreement or conduct
8 (described in a description of conduct) that
9 is submitted for review pursuant to para-
10 graph (2) until such time as the Attorney
11 General determines, pursuant to subpara-
12 graph (D), that such agreement or conduct
13 should not, in whole or in part, be exempt
14 from the antitrust laws.

15 “(ii) LIMITED LIABILITY.—No party
16 to an agreement or conduct referred to in
17 clause (i) shall be liable under the antitrust
18 laws for any actions reasonably necessary
19 to carry out the agreement or for conduct
20 taken after the agreement or description
21 has been submitted pursuant to paragraph
22 (2) and prior to any revocation of the ex-
23 emption by the Attorney General pursuant
24 to subparagraph (D).

1 “(D) DETERMINATION.—In making a de-
2 termination under this subparagraph, the At-
3 torney General, in consultation with the Chair-
4 person and the Secretary shall consider—

5 “(i) whether the agreement or conduct
6 involved would facilitate the availability of
7 priority countermeasures;

8 “(ii) whether the exemption from the
9 antitrust laws would promote the public in-
10 terest;

11 “(iii) the competitive impact to areas
12 not directly related to the purposes of the
13 agreement or conduct; and

14 “(iv) any other factors determined rel-
15 evant by the Attorney General and the
16 Chairperson.

17 “(5) LIMITATION ON AND RENEWAL OF EXEMP-
18 TIONS.—An exemption provided under paragraphs
19 (3) or (4) shall be limited to covered activities, and
20 shall expire on the date that is 3 years after the date
21 on which the exemption becomes effective (and at 3
22 year intervals thereafter, if renewed) unless the At-
23 torney General in consultation with the Chairperson
24 determines that the exemption should be renewed

1 (with modifications, as appropriate) considering the
2 factors described in paragraph (4).

3 “(6) LIMITATION ON PARTIES.—Any exemption
4 from the antitrust laws provided under this sub-
5 section shall not apply to the use of any information
6 acquired in conducting exempted activities for any
7 purposes other than those expressly specified in the
8 antitrust exemption provided for by this subsection.

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

12 “(8) REPORT.—Not later than 1 year after the
13 date of enactment of this subsection, and annually
14 thereafter, the Attorney General and the Chair-
15 person shall report to the Committee on Health,
16 Education, Labor, and Pensions and the Committee
17 on the Judiciary of the Senate and the Committee
18 on Energy and Commerce and the Committee on the
19 Judiciary of the House of Representatives on the use
20 and continuing need for the exemption from the
21 antitrust laws provided by this subsection.

22 “(9) SUNSET.—The authority of any party to
23 apply for or to obtain a limited antitrust exemption
24 under this subsection shall expire at the end of the

1 6-year period that begins on the date of enactment
2 of this subsection.

3 “(1) DEFINITIONS.—In this section:

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

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

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

17 “(2) COVERED ACTIVITIES.—

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

24 “(i) theoretical analysis; experimen-
25 tation; or the systematic study of phe-

1 nomena or observable facts related to the
2 development of priority countermeasures;
3 “(ii) the development or testing of
4 basic engineering techniques related to the
5 development of priority countermeasures;
6 “(iii) the extension of investigative
7 findings or theory of a scientific or tech-
8 nical nature into practical application for
9 experimental and demonstration purposes,
10 including the experimental production and
11 testing of models, prototypes, equipment,
12 materials, and processes related to the de-
13 velopment of priority countermeasures;
14 “(iv) the production, distribution, or
15 marketing of a product, process, or service
16 related to the development of priority
17 countermeasures;
18 “(v) the testing in connection with the
19 production of a product, process, or service
20 related to the development of priority
21 countermeasures;
22 “(vi) the collection, exchange, and
23 analysis of research or production informa-
24 tion related to the development of priority
25 countermeasures; or

1 “(vii) any combination of the purposes
2 described in clauses (i) through (vi);
3 and such term may include the establishment
4 and operation of facilities for the conduct of
5 covered activities described in clauses (i)
6 through (vi); the conduct of such covered activi-
7 ties on a protracted and proprietary basis; and
8 the processing of applications for patents and
9 the granting of licenses for the results of such
10 covered activities.

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

14 “(i) Exchanging information among
15 competitors relating to costs, sales, profit-
16 ability, prices, marketing, or distribution of
17 any product, process, or service if such in-
18 formation is not reasonably necessary to
19 carry out the purposes of covered activi-
20 ties.

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

23 “(I) to restrict or require the
24 sale, licensing, or sharing of inven-
25 tions, developments, products, proc-

1 esses, or services not developed
2 through, produced by, or distributed
3 or sold through such covered activi-
4 ties; or

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

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

21 “(iv) Exchanging information among
22 competitors relating to production (other
23 than production by such covered activities)
24 of a product, process, or service if such in-
25 formation is not reasonably necessary to

1 carry out the purpose of such covered ac-
2 tivities.

3 “(v) Except as otherwise provided in
4 this subsection or subsection (k), entering
5 into any agreement or engaging in any
6 other conduct to restrict or require partici-
7 pation by any person who is a party to
8 such activities, in any unilateral or joint
9 activity that is not reasonably necessary to
10 carry out the purpose of such covered ac-
11 tivities.

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

18 “(4) PERSON.—The term ‘person’ has the
19 meaning given such term in subsection (a) of the
20 first section of the Clayton Act (15 U.S.C. 12(a)).

21 “(5) PRIORITY COUNTERMEASURE.—The term
22 ‘priority countermeasure’ means a countermeasure,
23 including a drug, medical device, biological product,
24 or diagnostic test to treat, identify, or prevent infec-
25 tion by a biological agent or toxin on the list devel-

1 oped under section 351A(a)(1) and prioritized under
 2 subsection (a)(1).”.

3 **TITLE III—IMPROVED VACCINE**
 4 **AFFORDABILITY AND AVAIL-**
 5 **ABILITY**

6 **SEC. 301. SHORT TITLE.**

7 This title may be cited as the “Improved Vaccine Af-
 8 fordability and Availability Act”.

9 **Subtitle A—State Vaccine Grants**

10 **SEC. 311. AVAILABILITY OF INFLUENZA VACCINE.**

11 Section 317(j) of the Public Health Service Act (42
 12 U.S.C. 247b(j)) is amended by adding at the end the fol-
 13 lowing:

14 “(3)(A) For the purpose of carrying out activities re-
 15 lating to influenza vaccine under the immunization pro-
 16 gram under this subsection, there are authorized to be ap-
 17 propriated such sums as may be necessary for each of fis-
 18 cal years 2003 and 2004. Such authorization shall be in
 19 addition to amounts available under paragraphs (1) and
 20 (2) for such purpose.

21 “(B) The authorization of appropriations established
 22 in subparagraph (A) shall not be effective for a fiscal year
 23 unless the total amount appropriated under paragraphs
 24 (1) and (2) for the fiscal year is not less than such total
 25 for fiscal year 2000.

1 “(C) The purposes for which amounts appropriated
2 under subparagraph (A) are available to the Secretary in-
3 clude providing for improved State and local infrastruc-
4 ture for influenza immunizations under this subsection in
5 accordance with the following:

6 “(i) Increasing influenza immunization rates in
7 populations considered by the Secretary to be at
8 high risk for influenza-related complications and in
9 their contacts.

10 “(ii) Recommending that health care providers
11 actively target influenza vaccine that is available in
12 September, October, and November to individuals
13 who are at increased risk for influenza-related com-
14 plications and to their contacts.

15 “(iii) Providing for the continued availability of
16 influenza immunizations through December of such
17 year, and for additional periods to the extent that
18 influenza vaccine remains available.

19 “(iv) Encouraging States, as appropriate, to de-
20 velop contingency plans (including plans for public
21 and professional educational activities) for maxi-
22 mizing influenza immunizations for high-risk popu-
23 lations in the event of a delay or shortage of influ-
24 enza vaccine.

1 “(D) The Secretary shall submit to the Committee
 2 on Energy and Commerce of the House of Representa-
 3 tives, and the Committee on Health, Education, Labor,
 4 and Pensions of the Senate, periodic reports describing the
 5 activities of the Secretary under this subsection regarding
 6 influenza vaccine. The first such report shall be submitted
 7 not later than June 6, 2003, the second report shall be
 8 submitted not later than June 6, 2004, and subsequent
 9 reports shall be submitted biennially thereafter.”.

10 **SEC. 312. PROGRAM FOR INCREASING IMMUNIZATION**
 11 **RATES FOR ADULTS AND ADOLESCENTS; COL-**
 12 **LECTION OF ADDITIONAL IMMUNIZATION**
 13 **DATA.**

14 (a) ACTIVITIES OF CENTERS FOR DISEASE CONTROL
 15 AND PREVENTION.—Section 317(j) of the Public Health
 16 Service Act (42 U.S.C. 247b(j)), as amended by section
 17 311, is further amended by adding at the end the fol-
 18 lowing:

19 “(4)(A) For the purpose of carrying out activities to
 20 increase immunization rates for adults and adolescents
 21 through the immunization program under this subsection,
 22 and for the purpose of carrying out subsection (k)(2),
 23 there are authorized to be appropriated \$50,000,000 for
 24 fiscal year 2003, and such sums as may be necessary for
 25 each of the fiscal years 2004 through 2006. Such author-

1 ization is in addition to amounts available under para-
2 graphs (1), (2), and (3) for such purposes.

3 “(B) In expending amounts appropriated under sub-
4 paragraph (A), the Secretary shall give priority to adults
5 and adolescents who are medically underserved and are
6 at risk for vaccine-preventable diseases, including as ap-
7 propriate populations identified through projects under
8 subsection (k)(2)(E).

9 “(C) The purposes for which amounts appropriated
10 under subparagraph (A) are available include (with re-
11 spect to immunizations for adults and adolescents) the
12 payment of the costs of storing vaccines, outreach activi-
13 ties to inform individuals of the availability of the immuni-
14 zations, and other program expenses necessary for the es-
15 tablishment or operation of immunization programs ear-
16 ried out or supported by States or other public entities
17 pursuant to this subsection.

18 “(5) The Secretary shall annually submit to Congress
19 a report that—

20 “(A) evaluates the extent to which the immuni-
21 zation system in the United States has been effective
22 in providing for adequate immunization rates for
23 adults and adolescents, taking into account the ap-
24 plicable year 2010 health objectives established by

1 the Secretary regarding the health status of the peo-
2 ple of the United States; and

3 “(B) describes any issues identified by the Sec-
4 retary that may affect such rates.

5 “(6) In carrying out this subsection and paragraphs
6 (1) and (2) of subsection (k), the Secretary shall consider
7 recommendations regarding immunizations that are made
8 in reports issued by the Institute of Medicine of the Na-
9 tional Academy of Sciences.”.

10 (b) RESEARCH, DEMONSTRATIONS, AND EDU-
11 CATION.—Section 317(k) of the Public Health Service Act
12 (42 U.S.C. 247b(k)) is amended—

13 (1) by redesignating paragraphs (2) through
14 (4) as paragraphs (3) through (5), respectively;

15 (2) by inserting after paragraph (1) the fol-
16 lowing:

17 “(2)(A) The Secretary, directly and through grants
18 under paragraph (1), shall provide for a program of re-
19 search, demonstration projects, and education in accord-
20 ance with the following:

21 “(i) The Secretary shall coordinate with public
22 and private entities (including nonprofit private enti-
23 ties); and develop and disseminate guidelines, toward
24 the goal of ensuring that immunizations are rou-

1 tinely offered to adults and adolescents by public
2 and private health care providers.

3 “(ii) The Secretary shall cooperate with public
4 and private entities to obtain information for the an-
5 nual evaluations required in subsection (j)(5)(A).

6 “(iii) The Secretary shall (relative to fiscal year
7 2003) increase the extent to which the Secretary col-
8 lects data on the incidence, prevalence, and cir-
9 cumstances of diseases and adverse events that are
10 experienced by adults and adolescents and may be
11 associated with immunizations, including collecting
12 data in cooperation with commercial laboratories.

13 “(iv) The Secretary shall ensure that the enti-
14 ties with which the Secretary cooperates for pur-
15 poses of subparagraphs (A) through (C) include
16 managed care organizations, community-based orga-
17 nizations that provide health services, and other
18 health care providers.

19 “(v) The Secretary shall provide for projects to
20 identify racial and ethnic minority groups and other
21 health disparity populations for which immunization
22 rates for adults and adolescents are below such rates
23 for the general population, and to determine the fac-
24 tors underlying such disparities.

1 “(B) AUTHORIZATION OF APPROPRIATIONS.—There
 2 are authorized to be appropriated to carry out this sub-
 3 section, such sums as may be necessary for each of fiscal
 4 years 2003 through 2007.”

5 **SEC. 313. IMMUNIZATION AWARENESS.**

6 (a) DEVELOPMENT OF INFORMATION CONCERNING
 7 MENINGITIS.—

8 (1) IN GENERAL.—The Secretary of Health and
 9 Human Services (in this title referred to as the
 10 “Secretary”), in consultation with the Director of
 11 the Centers for Disease Control and Prevention,
 12 shall develop and make available to entities de-
 13 scribed in paragraph (2) information concerning
 14 bacterial meningitis and the availability and effec-
 15 tiveness of vaccinations for populations targeted by
 16 the Advisory Committee on Immunization Practices
 17 (an advisory committee established by the Secretary,
 18 acting through the Director of the Centers for Dis-
 19 ease Control and Prevention).

20 (2) ENTITIES.—An entity is described in this
 21 paragraph if the entity—

22 (A) is—

23 (i) a college or university; or

24 (ii) any other facility with a setting
 25 similar to a dormitory that houses age-ap-

1 appropriate populations for whom the Advi-
2 sory Committee on Immunization Practices
3 recommends such a vaccination; and
4 (B) is determined appropriate by the Sec-
5 retary.

6 (b) DEVELOPMENT OF INFORMATION CONCERNING
7 HEPATITIS.—

8 (1) IN GENERAL.—The Secretary, in consulta-
9 tion with the Director of the Centers for Disease
10 Control and Prevention, shall develop and make
11 available to entities described in paragraph (2) infor-
12 mation concerning hepatitis A and B and the avail-
13 ability and effectiveness of vaccinations with respect
14 to such diseases.

15 (2) ENTITIES.—An entity is described in this
16 paragraph if the entity—

17 (A) is—

18 (i) a health care clinic that serves in-
19 dividuals diagnosed as being infected with
20 HIV or as having other sexually trans-
21 mitted diseases;

22 (ii) an organization or business that
23 counsels individuals about international
24 travel or who arranges for such travel;

- 1 (iii) a police, fire, or emergency med-
2 ical services organization that responds to
3 natural or man-made disasters or emer-
4 gencies;
- 5 (iv) a prison or other detention facil-
6 ity;
- 7 (v) a college or university; or
- 8 (vi) a public health authority or chil-
9 dren's health service provider in areas of
10 intermediate or high endemicity for hepa-
11 titis A as defined by the Centers for Dis-
12 ease Control and Prevention; and
- 13 (B) is determined appropriate by the Sec-
14 retary.

15 **SEC. 314. SUPPLY OF VACCINES.**

16 (a) **IN GENERAL.**—The Secretary of Health and
17 Human Services, acting through the Director of the Cen-
18 ters for Disease Control and Prevention, shall prioritize,
19 acquire, and maintain a supply of such prioritized vaccines
20 sufficient to provide vaccinations throughout a 6-month
21 period.

22 (b) **PROCEEDS.**—Any proceeds received by the Sec-
23 retary of Health and Human Services from the sale of vac-
24 cines contained in the supply described in subsection (a),
25 shall be available to the Secretary for the purpose of pur-

1 chasing additional vaccines for the supply. Such proceeds
2 shall remain available until expended.

3 (c) **AUTHORIZATION OF APPROPRIATIONS.**—There
4 are authorized to be appropriated for the purpose of ear-
5 rying out subsection (a) such sums as may be necessary
6 for each of fiscal years 2003 through 2008.

7 **SEC. 315. COMMUNICATION.**

8 The Commissioner of Food and Drugs shall ensure
9 that vaccine manufacturers receive all forms of compliance
10 guidelines for vaccines and that such guidelines are kept
11 up to date.

12 **SEC. 316. FAST TRACK.**

13 The Commissioner of Food and Drugs shall issue reg-
14 ulations to revise the policies of the Food and Drug Ad-
15 ministration regarding fast-tracking and priority review
16 approval of vaccine products currently under development,
17 to allow for the use of new forms of existing vaccines in
18 cases where a determination is made that applying such
19 approvals is in the public health interest to address the
20 unmet need of strengthening the overall vaccine supply.

21 **SEC. 317. STUDY.**

22 (a) **IN GENERAL.**—The Secretary shall contract with
23 the Institute of Medicine of the National Academy of
24 Sciences or another independent and competent authority,
25 to conduct a study of the statutes, regulations, guidelines,

1 and compliance, inspection, and enforcement practices and
2 policies of the Department of Health and Human Services
3 and of the Food and Drug Administration that are appli-
4 cable to vaccines intended for human use that are in peri-
5 odic short supply in the United States.

6 (b) REQUIREMENTS.—The study under subsection
7 (a) shall include a review of the regulatory requirements,
8 guidelines, practices, and policies—

9 (1) for the development and licensing of vac-
10 cines and the licensing of vaccine manufacturing fa-
11 cilities;

12 (2) for inspections and other activities for main-
13 taining compliance and enforcement of the require-
14 ments applicable to such vaccines and facilities; and

15 (3) that may have contributed to temporary or
16 long-term shortages of vaccines.

17 (c) REPORT.—Not later than 6 months after the date
18 of enactment of this Act, the Secretary shall submit to
19 the Committee on Health, Education, Labor, and Pen-
20 sions of the Senate and the Committee on Energy and
21 Commerce of the House of Representatives a report that
22 contains—

23 (1) the results of the study under subsection
24 (a); and

1 (2) recommendations for modifications to the
2 regulatory requirements, guidelines, practices, and
3 policies described in subsection (b).

4 **Subtitle B—Vaccine Injury** 5 **Compensation Program**

6 **SEC. 321. ADMINISTRATIVE REVISION OF VACCINE INJURY**

7 **TABLE.**

8 Section 2114 of the Public Health Service Act (42
9 U.S.C. 300aa-14) is amended—

10 (1) by striking subsection (c)(1) and inserting
11 the following:

12 “(1) The Secretary may promulgate regulations
13 to modify in accordance with paragraph (3) the Vac-
14 eine Injury Table. In promulgating such regulations,
15 the Secretary shall provide for notice and for at
16 least 60 days of public comment.”; and

17 (2) in subsection (d), by striking “90 days” and
18 inserting “60 days”.

19 **SEC. 322. EQUITABLE RELIEF.**

20 Section 2111(a)(2)(A) of the Public Health Service
21 Act (42 U.S.C. 300aa-11(a)(2)(A)) is amended by strik-
22 ing “No person” and all that follows through “and—” and
23 inserting the following: “No person may bring or maintain
24 a civil action against a vaccine administrator or manufac-
25 turer in a Federal or State court for damages arising

1 from, or equitable relief relating to, a vaccine-related in-
 2 jury or death associated with the administration of a vac-
 3 cine after October 1, 1988 and no such court may award
 4 damages or equitable relief for any such vaccine-related
 5 injury or death, unless the person proves past or present
 6 physical injury and a timely petition has been filed in ac-
 7 cordance with section 2116 for compensation under the
 8 Program for such injury or death and—”.

9 **SEC. 323. DERIVATIVE PETITIONS FOR COMPENSATION.**

10 (a) LIMITATIONS ON DERIVATIVE PETITIONS.—Sec-
 11 tion 2111(a)(2) of the Public Health Service Act (42
 12 U.S.C. 300aa-11(a)(2)) is amended—

13 (1) in subparagraph (B), by inserting “or (B)”
 14 after “subparagraph (A)”;

15 (2) by redesignating subparagraph (B) as sub-
 16 paragraph (C); and

17 (3) by inserting after subparagraph (A) the fol-
 18 lowing:

19 “(B)(i) No parent or other third party may
 20 bring or maintain a civil action against a vaccine ad-
 21 ministrator or manufacturer in a Federal or State
 22 court for damages or equitable relief relating to a
 23 vaccine-related injury or death, including without
 24 limitation damages for loss of consortium, society,
 25 companionship, or services, loss of earnings, medical

1 or other expenses, and emotional distress, and no
2 court may award damages or equitable relief in such
3 an action, unless—

4 “(I) the person who sustained the under-
5 lying vaccine-related injury or death upon which
6 such parent’s or other third party’s claim is
7 premised has timely filed a petition for com-
8 pensation in accordance with section 2111;

9 “(II) such parent or other third party is
10 the legal representative or spouse of the person
11 who sustained the underlying vaccine-related in-
12 jury or death, and such legal representative or
13 spouse has filed a timely derivative petition, in
14 accordance with section 2116; and

15 “(III)(aa) the United States Court of Fed-
16 eral Claims has issued judgment under section
17 2112 on the derivative petition, and such legal
18 representative or spouse elects under section
19 2121(a) to file a civil action; or

20 “(bb) such legal representative or spouse
21 elects to withdraw such derivative petition
22 under section 2121(b) or such petition is con-
23 sidered withdrawn under such section.

24 “(ii) Any civil action brought in accordance
25 with this subparagraph shall be subject to the stand-

1 ards and procedures set forth in sections ~~2122~~ and
2 ~~2123~~, regardless of whether the action arises directly
3 from a vaccine-related injury or death associated
4 with the administration of a vaccine. In a case in
5 which the person who sustained the underlying vac-
6 cine-related injury or death upon which such legal
7 representative's or spouse's civil action is premised
8 elects under section ~~2121(a)~~ to receive the com-
9 pensation awarded, such legal representative or
10 spouse may not bring a civil action for damages or
11 equitable relief, and no court may award damages or
12 equitable relief, for any injury or loss of the type set
13 forth in section ~~2115(a)~~ or that might in any way
14 overlap with or otherwise duplicate compensation of
15 the type available under section ~~2115(a)~~.”.

16 (b) ELIGIBLE PERSONS.—Section ~~2111(a)(9)~~ of the
17 Public Health Service Act (~~42 U.S.C. 300aa-11(a)(9)~~) is
18 amended by striking the period and inserting “and to a
19 parent or other third party to the extent such parent or
20 other third party seeks damages or equitable relief relating
21 to a vaccine-related injury or death sustained by a person
22 who is qualified to file a petition for compensation under
23 the Program.”.

1 (e) PETITIONERS.—Section 2111(b) of the Public
2 Health Service Act (42 U.S.C. 300aa-11(b)) is amend-
3 ed—

4 (1) in paragraph (1)—

5 (A) in subparagraph (A), by striking “(B)”
6 and inserting “(C)”;

7 (B) by redesignating subparagraph (B) as
8 subparagraph (C); and

9 (C) by inserting after subparagraph (A)
10 the following:

11 “(B) Except as provided in subparagraph (C),
12 any legal representative or spouse of a person—

13 “(i) who has sustained a vaccine-related in-
14 jury or death; and

15 “(ii) who has filed a petition for compensa-
16 tion under the Program (or whose legal rep-
17 resentative has filed such a petition as author-
18 ized in subparagraph (A));

19 may, if such legal representative or spouse meets the
20 requirements of subsection (d), file a derivative peti-
21 tion under this section.”; and

22 (2) in paragraph (2)—

23 (A) by inserting “by or on behalf of the
24 person who sustained the vaccine-related injury
25 or death” after “filed”; and

1 (B) by adding at the end the following: “A
 2 legal representative or spouse may file only 1
 3 derivative petition with respect to each under-
 4 lying petition.”.

5 (d) DERIVATIVE PETITION CONTENTS.—Section
 6 2111 of the Public Health Service Act (42 U.S.C. 300aa-
 7 11) is amended—

8 (1) by redesignating subsections (d) and (e) as
 9 subsections (e) and (f), respectively; and

10 (2) by inserting after subsection (e) the fol-
 11 lowing:

12 “(d) DERIVATIVE PETITIONS.—

13 “(1) If the legal representative or spouse of the
 14 person who sustained the vaccine-related injury or
 15 death seeks compensation under the Program, such
 16 legal representative or spouse shall file a timely de-
 17 rivative petition for compensation under the Pro-
 18 gram in accordance with this section.

19 “(2) Such a derivative petition shall contain—

20 “(A) except for records that are unavail-
 21 able as described in subsection (e)(3), an affi-
 22 davit, and supporting documentation, dem-
 23 onstrating that—

24 “(i) the child or spouse of such person
 25 has, in accordance with section 2111, time-

1 ly filed a petition for compensation for the
 2 underlying vaccine-related injury or death
 3 upon which such legal representative's or
 4 spouse's derivative petition is premised;

5 “(ii) the derivative petition was timely
 6 filed;

7 “(iii) such legal representative or
 8 spouse suffered a loss compensable under
 9 section 2115(b) as a result of the vaccine-
 10 related injury or death sustained by such
 11 person; and

12 “(iv) such legal representative or
 13 spouse has not previously collected an
 14 award or settlement of a civil action for
 15 damages for such loss; and

16 “(B) records establishing such legal rep-
 17 resentative's or spouse's relationship to the per-
 18 son who sustained the vaccine-related injury or
 19 death.”.

20 (e) DETERMINATION OF ELIGIBILITY FOR COM-
 21 PENSATION.—Section 2113(a)(1) of the Public Health
 22 Service Act (42 U.S.C. 300aa-13(a)(1)) is amended—

23 (1) in subparagraph (A), by striking “and” and
 24 inserting “or, as applicable, section 2111(d),”;

1 (2) in subparagraph (B), by striking the period
2 and inserting “, and”; and

3 (3) by inserting before the flush matter at the
4 end, the following:

5 “(C) in the case of a derivative petition,
6 that the person who sustained the underlying
7 vaccine-related injury or death upon which the
8 derivative petition is premised has timely filed
9 a petition for compensation in accordance with
10 section 2111 and that, with respect to such un-
11 derlying petition, the special master or court
12 has made the findings specified in subpara-
13 graphs (A) and (B) of this paragraph.”.

14 (f) COMPENSATION.—Section 2115 of the Public
15 Health Service Act (42 U.S.C. 300aa-15) is amended—

16 (1) by redesignating subsections (b) through (j)
17 as subsections (e) through (k), respectively;

18 (2) by inserting after subsection (a) the fol-
19 lowing:

20 “(b) DERIVATIVE PETITIONS.—

21 “(1) IN GENERAL.—Compensation awarded
22 under the Program to a legal representative or
23 spouse who files a derivative petition under section
24 2111 for a loss sustained as a result of a vaccine-
25 related injury or death sustained by such petitioner’s

1 child or spouse shall only include compensation for
 2 any loss of consortium, society, companionship, or
 3 services, in an amount not to exceed the lesser of
 4 \$250,000 or the total amount of compensation
 5 awarded to the person who sustained the underlying
 6 vaccine-related injury or death.

7 “(2) MULTIPLE INDIVIDUALS.—Where more
 8 than 1 person files a derivative petition under sec-
 9 tion ~~2111~~ for losses sustained as a result of the
 10 same underlying vaccine-related injury or death, the
 11 aggregate compensation to such persons shall not
 12 exceed the lesser of \$250,000, or the total amount
 13 of compensation awarded to the person who sus-
 14 tained the underlying vaccine-related injury or
 15 death. The special master or court shall apportion
 16 compensation among the derivative petitioners in
 17 proportion to their respective losses.”;

18 (3) in subsection (c)(2), as so redesignated by
 19 paragraph (1)—

20 (A) by striking “(2) and (3)” and inserting

21 “(2), (3), (4), (5), and (6)”; and

22 (B) by inserting “and subsection (b),”

23 after “(a),”;

1 (4) in subsection (g), as so redesignated by
2 paragraph (1), in paragraph (4)(B), by striking
3 “subsection (j)” and inserting “subsection (k)”;

4 (5) in subsection (j), as so redesignated by
5 paragraph (1)—

6 (A) in paragraph (1), by striking “sub-
7 section (j)” and inserting “subsection (k)”; and

8 (B) in paragraph (2), by inserting “, or to
9 a legal representative or spouse of a person who
10 sustained a vaccine-related injury or death,”
11 after “death”; and

12 (6) in subsection (k), as so redesignated by
13 paragraph (1), by striking “subsection (f)(4)(B)”
14 and inserting “subsection (g)(4)(B)”.

15 **SEC. 324. JURISDICTION TO DISMISS ACTIONS IMPROP-**
16 **ERLY BROUGHT.**

17 Section 2111(a)(3) of the Public Health Service Act
18 (~~42 U.S.C. 300aa-11(a)(3)~~) is amended by adding at the
19 end the following: “If any civil action which is barred
20 under subparagraph (A) or (B) of paragraph (2) is filed
21 or maintained in a State court, or any vaccine adminis-
22 trator or manufacturer is made a party to any civil action
23 brought in State court (other than a civil action which
24 may be brought under paragraph (2)) for damages or eq-
25 uitable relief for a vaccine-related injury or death associ-

1 ated with the administration of a vaccine after October
 2 1, 1988, the civil action may be removed at any time be-
 3 fore final judgment by the defendant or defendants to the
 4 United States Court of Federal Claims. Once removed, the
 5 United States Court of Federal Claims shall have jurisdic-
 6 tion solely for the purpose of adjudicating whether the civil
 7 action should be dismissed pursuant to this section. If the
 8 United States Court of Federal Claims determines that
 9 the civil action should not be dismissed, the court shall
 10 remand the action to the State Court. The notice required
 11 by section 1446 of title 28, United States Code, shall be
 12 filed with the United States Court of Federal Claims, and
 13 that court shall, except as otherwise provided in this sec-
 14 tion, proceed in accordance with sections 1446 through
 15 1451 of title 28, United States Code.”.

16 **SEC. 325. CLARIFICATION OF WHEN INJURY IS CAUSED BY**
 17 **FACTOR UNRELATED TO ADMINISTRATION**
 18 **OF VACCINE.**

19 Section 2113(a)(2)(B) of the Public Health Service
 20 Act (~~42 U.S.C. 300aa-13(a)(2)(B)~~) is amended—

21 (1) by inserting “structural lesions, genetic dis-
 22 orders,” after “and related anoxia),”;

23 (2) by inserting “(without regard to whether
 24 the cause of the infection, toxin, trauma, structural

1 lesion, genetic disorder, or metabolic disturbance is
 2 known)” after “metabolic disturbances”; and
 3 (3) by striking “but” and inserting “and”.

4 **SEC. 326. INCREASE IN AWARD IN THE CASE OF A VACCINE-**
 5 **RELATED DEATH AND FOR PAIN AND SUF-**
 6 **FERING.**

7 (a) IN GENERAL.—Section 2115(a) of the Public
 8 Health Service Act (42 U.S.C. 300aa–15(a)) is amend-
 9 ed—

10 (1) in paragraph (2), by striking “\$250,000”
 11 and inserting “\$350,000”; and

12 (2) in paragraph (4), by striking “\$250,000”
 13 and inserting “\$350,000”.

14 (b) DEATH AWARDS.—Section 2115(a)(2) of the
 15 Public Health Service Act (42 U.S.C. 300aa–15(a)(2)) is
 16 amended by inserting “(if the deceased incurred unreim-
 17 burstable expenses due to the vaccine-related injury prior
 18 to death in excess of \$50,000, the award shall also include
 19 reimbursement for those unreimbursable expenses that ex-
 20 ceed \$50,000)” before the period.

21 **SEC. 327. BASIS FOR CALCULATING PROJECTED LOST**
 22 **EARNINGS.**

23 Section 2115(a)(3)(B) of the Public Health Service
 24 Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by strik-
 25 ing “loss of earnings” and all that follows and inserting

1 the following: “loss of earnings determined on the basis
 2 of the annual estimate of the average (mean) gross weekly
 3 earnings of wage and salary workers age 18 and over (ex-
 4 cluding the incorporated self-employed) in the private non-
 5 farm sector (which includes all industries other than agri-
 6 cultural production crops and livestock); as calculated an-
 7 nually by the Bureau of Labor Statistics from the quarter
 8 sample data of the Current Population Survey, or as cal-
 9 culated by such similar method as the Secretary may pre-
 10 scribe by regulation; less appropriate taxes and the aver-
 11 age cost of a health insurance policy; as determined by
 12 the Secretary.”.

13 **SEC. 328. ALLOWING COMPENSATION FOR FAMILY COUN-**
 14 **SELING EXPENSES AND EXPENSES OF ESTAB-**
 15 **LISHING AND MAINTAINING GUARDIANSHIP.**

16 (a) FAMILY COUNSELING EXPENSES IN POST-1988
 17 CASES.—Section 2115(a) of the Public Health Service Act
 18 (~~42 U.S.C. 300aa-15(a)~~) is amended by adding at the end
 19 the following:

20 “(5) Actual unreimbursable expenses that have
 21 been or will be incurred for family counseling as is
 22 determined to be reasonably necessary and that re-
 23 sult from the vaccine-related injury from which the
 24 petitioner seeks compensation.”.

1 (b) ~~EXPENSES OF ESTABLISHING AND MAINTAINING~~
 2 ~~GUARDIANSHIPS IN POST-1988 CASES.~~—Section 2115(a)
 3 of the Public Health Service Act (42 U.S.C. 300aa-15(a)),
 4 as amended by subsection (a), is further amended by add-
 5 ing at the end the following:

6 “~~(6)~~ Actual unreimbursable expenses that have
 7 been, or will be reasonably incurred to establish and
 8 maintain a guardianship or conservatorship for an
 9 individual who has suffered a vaccine-related injury,
 10 including attorney fees and other costs incurred in
 11 a proceeding to establish and maintain such guard-
 12 ianship or conservatorship.”.

13 (c) ~~CONFORMING AMENDMENT FOR CASES FROM~~
 14 ~~1988 AND EARLIER.~~—Section 2115 of the Public Health
 15 Service Act (42 U.S.C. 300aa-15) is amended in sub-
 16 section (c), as so redesignated by section 323(f)—

17 (1) in paragraph (2), by striking “and” at the
 18 end;

19 (2) in paragraph (3), by striking “(c)” and in-
 20 serting “(f)”;

21 (3) by redesignating paragraph (3) as para-
 22 graph (5); and

23 (4) by inserting after paragraph (2), the fol-
 24 lowing:

1 ~~“(3) family counseling expenses (as provided for~~
2 ~~in paragraph (5) of subsection (a));~~

3 ~~“(4) expenses of establishing and maintaining~~
4 ~~guardianships (as provided for in paragraph (6) of~~
5 ~~subsection (a)); and”.~~

6 **SEC. 329. ALLOWING PAYMENT OF INTERIM COSTS.**

7 Section 2115 of the Public Health Service Act (42
8 U.S.C. 300aa-15) is amended in subsection (f), as so re-
9 designated by section 323(f), by adding at the end the fol-
10 lowing:

11 ~~“(4) A special master or court may make an in-~~
12 ~~terim award of costs subject to final adjustment if—~~

13 ~~“(A) the case involves a vaccine adminis-~~
14 ~~tered on or after October 1, 1988;~~

15 ~~“(B) the special master or court has deter-~~
16 ~~mined that the petitioner is entitled to com-~~
17 ~~penation under the Program;~~

18 ~~“(C) the award is limited to other costs~~
19 ~~(within the meaning of paragraph (1)(B)) in-~~
20 ~~curring in the proceeding;~~

21 ~~“(D) not more than 1 prior award has~~
22 ~~been made with respect to such petition; and~~

23 ~~“(E) the petitioner provides documentation~~
24 ~~verifying the expenditure of the amount for~~
25 ~~which compensation is sought.”.~~

1 **SEC. 330. PROCEDURE FOR PAYING ATTORNEYS' FEES.**

2 Section 2115 of the Public Health Service Act (42
3 U.S.C. 300aa-15), is amended in subsection (f), as so re-
4 designated by section 323(f) and amended by section 329,
5 by adding at the end the following:

6 “(5) When a special master or court awards at-
7 torney fees or costs under paragraph (1) or (4), it
8 may order that such fees or costs be payable solely
9 to the petitioner’s attorney if—

10 “(A) the petitioner expressly consents; or

11 “(B) the special master or court deter-
12 mines, after affording to the Secretary and to
13 all interested persons the opportunity to submit
14 relevant information, that—

15 “(i) the petitioner cannot be located
16 or refuses to respond to a request by the
17 special master or court for information,
18 and there is no practical alternative means
19 to ensure that the attorney will be reim-
20 bursed for such fees or costs expeditiously;
21 or

22 “(ii) there are otherwise exceptional
23 circumstances and good cause for paying
24 such fees or costs solely to the petitioner’s
25 attorney.”.

1 **SEC. 331. EXTENSION OF STATUTE OF LIMITATIONS.**

2 (a) **GENERAL RULE.**—Section 2116(a) of the Public
3 Health Service Act (42 U.S.C. 300aa-16(a)) is amend-
4 ed—

5 (1) in paragraph (2), by striking “36 months”
6 and inserting “6 years”; and

7 (2) in paragraph (3), by striking “48 months”
8 and inserting “6 years”.

9 (b) **CLAIMS BASED ON REVISIONS TO TABLE.**—Sec-
10 tion 2116 of the Public Health Service Act (42 U.S.C.
11 300aa-16) is amended by striking subsection (b) and in-
12 serting the following:

13 “(b) **EFFECT OF REVISED TABLE.**—If at any time
14 the Vaccine Injury Table is revised and the effect of such
15 revision is to make an individual eligible for compensation
16 under the program, where, before such revision, such indi-
17 vidual was not eligible for compensation under the pro-
18 gram, or to significantly increase the likelihood that an
19 individual will be able to obtain compensation under the
20 program, such person may, and shall before filing a civil
21 action for equitable relief or monetary damages, notwith-
22 standing section 2111(b)(2), file a petition for such com-
23 pensation if—

24 “(1) the vaccine-related death or injury with re-
25 spect to which the petition is filed occurred not more

1 than 10 years before the effective date of the revision of the table; and

2
3 “(2) either—

4 “(A) the petition satisfies the conditions described in subsection (a); or

5
6 “(B) the date of the occurrence of the first symptom or manifestation of onset of the injury occurred more than 4 years before the petition is filed, and the petition is filed not more than 7
8 2 years after the effective date of the revision of the table.”.

9
10 (c) DERIVATIVE PETITIONS.—Section 2116 of the Public Health Service Act (42 U.S.C. 300aa-16) is amended by adding at the end the following:

11
12 “(d) DERIVATIVE PETITIONS.—No derivative petition may be filed for compensation under the Program later than the earlier of—

13
14 “(1) the last day on which the petition for compensation for the underlying claim of the person who sustained the vaccine-related injury or death upon which the derivative petition is premised may be timely filed; or

15
16 “(2) 60 days after the date on which the special master has issued a decision pursuant to section 2112(d)(3) on the underlying claim of the person

1 who sustained the vaccine-related injury or death
2 upon which the derivative petition is premised.”.

3 (d) **TIMELY RESOLUTIONS OF CLAIMS.**—

4 (1) **SPECIAL MASTER DECISION.**—Section
5 2112(d)(3)(A) of the Public Health Service Act (42
6 U.S.C. 300aa-12(d)(3)(A)) is amended by adding at
7 the end the following: “For purposes of this sub-
8 paragraph, the petition shall be deemed to be filed
9 on the date on which the special master issues a cer-
10 tificate of completeness, indicating that all petition
11 contents and supporting documents required under
12 section 2111(e) and, when applicable, section
13 2111(d) and the Vaccine Rules of the United States
14 Court of Federal Claims, such as an affidavit and
15 supporting documentation, have been served on the
16 Secretary and filed with the clerk of the United
17 States Court of Federal Claims.”.

18 (2) **DERIVATIVE PETITIONS.**—Section
19 2112(d)(3)(C) of the Public Health Service Act (42
20 U.S.C. 300aa-12(d)(3)(C)) is amended by adding at
21 the end the following: “With respect to any deriva-
22 tive petition filed under section 2111, the period of
23 time during which the petition for compensation for
24 the underlying vaccine-related injury or death upon
25 which such derivative petition is premised is pending

1 shall be treated as a suspension for purposes of this
 2 subparagraph.”.

3 ~~(3) COURT OF FEDERAL CLAIMS DECISION.—~~

4 Section 2121(b) of the Public Health Service Act
 5 (42 U.S.C. 300aa-21(b)) is amended by adding at
 6 the end the following: “For purposes of this sub-
 7 section, the petition shall be deemed to be filed on
 8 the date on which the special master issues a certifi-
 9 cate of completeness, indicating that all petition con-
 10 tents and supporting documents required under sec-
 11 tion 2111(e) and, when applicable, section 2111(d)
 12 and the Vaccine Rules of the United States Court of
 13 Federal Claims, such as an affidavit and supporting
 14 documentation, have been served on the Secretary
 15 and filed with the clerk of the United States Court
 16 of Federal Claims.”.

17 **SEC. 332. ADVISORY COMMISSION ON CHILDHOOD VAC-**
 18 **CINES.**

19 (a) **SELECTION OF PERSONS INJURED BY VACCINES**
 20 **AS PUBLIC MEMBERS.—**Section 2119(a)(1)(B) of the
 21 Public Health Service Act (42 U.S.C. 300aa-19(a)(1)(B))
 22 is amended by striking “of whom” and all that follows
 23 and inserting the following: “of whom 1 shall be the legal
 24 representative of a child who has suffered a vaccine-re-
 25 lated injury or death, and at least 1 other shall be either

1 the legal representative of a child who has suffered a vac-
 2 cine-related injury or death or an individual who has per-
 3 sonally suffered a vaccine-related injury.”.

4 (b) MANDATORY MEETING SCHEDULE ELIMI-
 5 NATED.—Section 2119(e) of the Public Health Service Act
 6 (42 U.S.C. 300aa–19(e)) is amended by striking “not less
 7 often than four times per year and”.

8 **SEC. 333. CLARIFICATION OF STANDARDS OF RESPONSI-**
 9 **BILITY.**

10 (a) GENERAL RULE.—Section 2122(a) of the Public
 11 Health Service Act (42 U.S.C. 300aa–22(a)) is amended
 12 by striking “and (e) State law shall apply to a civil action
 13 brought for damages” and inserting “(d), and (f) State
 14 law shall apply to a civil action brought for damages or
 15 equitable relief”; and

16 (b) UNAVOIDABLE ADVERSE SIDE EFFECTS.—Sec-
 17 tion 2122(b)(1) of the Public Health Service Act (42
 18 U.S.C. 300aa–22(b)(1)) is amended by inserting “or equi-
 19 table relief” after “for damages”.

20 (c) DIRECT WARNINGS.—Section 2122(e) of the Pub-
 21 lie Health Service Act (42 U.S.C. 300aa–22(e)) is amend-
 22 ed by inserting “or equitable relief” after “for damages”.

23 (d) CONSTRUCTION.—Section 2122(d) of the Public
 24 Health Service Act (42 U.S.C. 300aa–22(d)) is amend-
 25 ed—

1 Table” and inserting “any vaccine set forth in the
 2 Vaccine Injury table, including any component or in-
 3 gredient of any such vaccine”; and

4 (2) in the second sentence, by inserting “includ-
 5 ing any component or ingredient of any such vac-
 6 cine” before the period.

7 **SEC. 335. CLARIFICATION OF DEFINITION OF VACCINE-RE-**
 8 **LATED INJURY OR DEATH.**

9 Section ~~2133(5)~~ of the Public Health Service Act (~~42~~
 10 ~~U.S.C. 300aa-33(5)~~) is amended by adding at the end the
 11 following: “For purposes of the preceding sentence, an
 12 adulterant or contaminant shall not include any compo-
 13 nent or ingredient listed in a vaccine’s product license ap-
 14 plication or product label.”.

15 **SEC. 336. CLARIFICATION OF DEFINITION OF VACCINE AND**
 16 **DEFINITION OF PHYSICAL INJURY.**

17 Section ~~2133~~ of the Public Health Service Act (~~42~~
 18 ~~U.S.C. 300aa-33~~) is amended by adding at the end the
 19 following:

20 “(7) The term ‘vaccine’ means any preparation or
 21 suspension, including a preparation or suspension con-
 22 taining an attenuated or inactive microorganism or
 23 subunit thereof or toxin, developed or administered to
 24 produce or enhance the body’s immune response to a dis-
 25 ease or diseases and includes all components and ingredi-

1 ents listed in the vaccine's product license application and
2 product label.

3 “(8) The term ‘physical injury’ means a manifest
4 physical illness, condition, or death, including a neuro-
5 logical disease or disorder.”.

6 **SEC. 337. AMENDMENTS TO VACCINE INJURY COMPENSA-**
7 **TION TRUST FUND.**

8 (a) EXPANSION OF COMPENSATED LOSS.—Section
9 9510(e)(1)(A) of the Internal Revenue Code of 1986 is
10 amended by inserting “, or related loss,” after “death”.

11 (b) INCREASE IN LIMIT ON ADMINISTRATIVE EX-
12 PENSES.—Subparagraph (B) of section 9510(e)(1) of the
13 Internal Revenue Code of 1986 is amended—

14 (1) by striking “(but not in excess of the base
15 amount of \$9,500,000 for any fiscal year)”; and

16 (2) by striking the period and inserting “, pro-
17 vided that such administrative costs shall not exceed
18 the greater of—

19 “(i) the base amount of \$9,500,000
20 for any fiscal year,

21 “(ii) 125 percent of the base amount
22 for any fiscal year in which the total num-
23 ber of claims pending under such subtitle
24 exceeds 150 percent of the average number
25 of claims pending in the preceding 5 years,

1 “~~(iii)~~ 175 percent of the base amount
2 for any fiscal year in which the total num-
3 ber of claims pending under such subtitle
4 exceeds 200 percent of the average number
5 of claims pending in the preceding 5 years;

6 “~~(iv)~~ 225 percent of the base amount
7 for any fiscal year in which the total num-
8 ber of claims pending under such subtitle
9 exceeds 250 percent of the average number
10 of claims pending in the preceding 5 years,
11 or

12 “~~(v)~~ 275 percent of the base amount
13 for any fiscal year in which the total num-
14 ber of claims pending under such subtitle
15 exceeds 300 percent of the average number
16 of claims pending in the preceding 5
17 years.”.

18 ~~(e)~~ CONFORMING AMENDMENT.—Section
19 9510(c)(1)(A) of the Internal Revenue Code of 1986 is
20 amended by striking “October 18, 2000” and inserting
21 “the date of enactment of the Improved Vaccine Afford-
22 ability and Availability Act”.

1 **SEC. 338. ONGOING REVIEW OF CHILDHOOD VACCINE**

2 **DATA.**

3 Part C of title XXI of the Public Health Service Act
4 (42 U.S.C. 300a–25 et seq.) is amended by adding at the
5 end the following:

6 **“SEC. 2129A. ONGOING REVIEW OF CHILDHOOD VACCINE**

7 **DATA.**

8 “(a) **IN GENERAL.**—Not later than 6 months after
9 the date of enactment of this section, the Secretary shall
10 enter into a contract with the Institute of Medicine of the
11 National Academy of Science under which the Institute
12 shall conduct an ongoing, comprehensive review of new sci-
13 entific data on childhood vaccines (according to priorities
14 agreed upon from time to time by the Secretary and the
15 Institute of Medicine).

16 “(b) **REPORTS.**—Not later than 3 years after the date
17 on which the contract is entered into under subsection (a),
18 the Institute of Medicine shall submit to the Secretary a
19 report on the findings of the studies conducted under such
20 contract, including findings as to any adverse events asso-
21 ciated with childhood vaccines, including conclusions con-
22 cerning causation of adverse events by such vaccines, and
23 other appropriate recommendations, based on such find-
24 ings and conclusions.

25 “(c) **FAILURE TO ENTER INTO CONTRACT.**—If the
26 Secretary and the Institute of Medicine are unable to

1 enter into the contract described in subsection (a); the
2 Secretary shall enter into a contract with another qualified
3 nongovernmental scientific organization for the purposes
4 described in subsections (a) and (b).

5 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
6 carry out this section, there are authorized to be appro-
7 priated such sums as may be necessary for each of fiscal
8 years 2003, 2004, 2005 and 2006.”.

9 **SEC. 339. PENDING ACTIONS.**

10 The amendments made by this title shall apply to all
11 actions or proceedings pending on or after the date of en-
12 actment of this Act, unless a court of competent jurisdic-
13 tion has entered judgment (regardless of whether the time
14 for appeal has expired) in such action or proceeding dis-
15 posing of the entire action or proceeding.

16 **SEC. 340. REPORT.**

17 Not later than 1 year after the date of enactment
18 of this Act, and annually thereafter, the Advisory Commis-
19 sion on Childhood Vaccines shall report to the Secretary
20 regarding the status of the Vaccine Injury Compensation
21 Trust Fund, and shall make recommendations to the Sec-
22 retary regarding the allocation of funds from the Vaccine
23 Injury Compensation Trust Fund.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Project BioShield Act*
3 *of 2003”.*

4 **SEC. 2. BIOMEDICAL COUNTERMEASURE RESEARCH AND**
5 **DEVELOPMENT AUTHORITIES.**

6 *(a) IN GENERAL.—Part B of title IV of the Public*
7 *Health Service Act (42 U.S.C. 284 et seq.) is amended by*
8 *adding at the end the following:*

9 **“SEC. 409J. BIOMEDICAL COUNTERMEASURE RESEARCH**
10 **AND DEVELOPMENT.**

11 *“(a) IN GENERAL.—*

12 *“(1) AUTHORITY.—In carrying out research re-*
13 *sponsibilities under this Act, the Secretary may con-*
14 *duct and support research and development with re-*
15 *spect to biomedical countermeasures.*

16 *“(2) IMPLEMENTATION.—*

17 *“(A) IN GENERAL.—Except as provided in*
18 *subparagraph (C), authorities assigned by this*
19 *section to the Secretary shall be carried out*
20 *through the Director of NIH.*

21 *“(B) LEAD INSTITUTE.—The National In-*
22 *stitute of Allergy and Infectious Diseases shall be*
23 *the lead institute for performing, administering,*
24 *or supporting biomedical countermeasure re-*
25 *search and development. The Director of NIH*
26 *may delegate to the Director of the Institute au-*

1 *thorities as are necessary to carry out this func-*
2 *tion.*

3 “(C) *CHEMICAL, RADIOLOGICAL, AND NU-*
4 *CLEAR AGENTS.—To the extent that an authority*
5 *described in subparagraph (A) is exercised with*
6 *respect to a chemical, radiological, or nuclear*
7 *agent, the Secretary may authorize the Director*
8 *of NIH to carry out the authority through any*
9 *national research institute.*

10 “(D) *AVAILABILITY OF FACILITIES TO THE*
11 *SECRETARY.—In any grant or cooperative agree-*
12 *ment entered into under the authority provided*
13 *in this section with respect to a biocontainment*
14 *laboratory or other related or ancillary special-*
15 *ized research facility that the Secretary deter-*
16 *mines necessary for the purpose of performing,*
17 *administering, and supporting biomedical coun-*
18 *termeasures research and development, the Sec-*
19 *retary may provide that the facility that is the*
20 *object of such grant or cooperative agreement*
21 *shall be available as needed to the Secretary to*
22 *respond to public health emergencies affecting*
23 *national security.*

24 “(3) *INTERAGENCY COOPERATION.—*

1 “(A) *IN GENERAL.*—*In carrying out activi-*
2 *ties under this section, the Secretary is author-*
3 *ized, subject to subparagraph (B), to enter into*
4 *interagency agreements and other collaborative*
5 *undertakings with other agencies of the Federal*
6 *Government and to use other agencies of the De-*
7 *partment of Health and Human Services.*

8 “(B) *LIMITATION.*—*An agreement or under-*
9 *taking under this paragraph may not authorize*
10 *another agency to exercise the authorities pro-*
11 *vided to the Secretary by this section.*

12 “(b) *EXPEDITED PROCUREMENT AUTHORITY.*—

13 “(1) *INCREASED SIMPLIFIED ACQUISITION*
14 *THRESHOLD FOR BIOMEDICAL COUNTERMEASURE*
15 *PROCUREMENTS.*—

16 “(A) *IN GENERAL.*—*For any procurement*
17 *by the Secretary, of property or services for use*
18 *(as determined by the Secretary) in performing,*
19 *administering, or supporting biomedical counter-*
20 *measure research or development, the amount*
21 *specified in section 4(11) of the Office of Federal*
22 *Procurement Policy Act (41 U.S.C. 403(11)), as*
23 *applicable pursuant to section 302A(a) of the*
24 *Federal Property and Administrative Services*
25 *Act of 1949 (41 U.S.C. 252a(a)), shall be deemed*

1 to be \$25,000,000 in the administration, with re-
2 spect to such procurement, of—

3 “(i) section 303(g)(1)(A) of the *Federal*
4 *Property and Administrative Services Act*
5 *of 1949 (41 U.S.C. 253(g)(1)(A)) and its*
6 *implementing regulations; and*

7 “(ii) section 302A(b) of such Act (41
8 *U.S.C. 252a(b)) and its implementing regu-*
9 *lations.*

10 “(B) *INTERNAL CONTROLS TO BE INSTI-*
11 *TUTED.—The Secretary shall institute appro-*
12 *priate internal controls for procurements made*
13 *under this paragraph, including requirements*
14 *with respect to documenting the justification for*
15 *use of the authority provided in this paragraph.*

16 “(2) *USE OF NONCOMPETITIVE PROCEDURES.—*
17 *In addition to any other authority to use procedures*
18 *other than competitive procedures for procurements,*
19 *the Secretary may use such other noncompetitive pro-*
20 *cedures when—*

21 “(A) *the procurement is as described by*
22 *paragraph (1)(A); and*

23 “(B) *the property or services needed by the*
24 *Secretary are available from only one responsible*
25 *source or only from a limited number of respon-*

1 sible sources, and no other type of property or
2 services will meet the needs of the Secretary.

3 “(3) *INCREASED MICROPURCHASE THRESH-*
4 *OLD.—*

5 “(A) *IN GENERAL.—*For a procurement de-
6 scribed by paragraph (1)(A), the amount speci-
7 fied in subsections (c), (d), and (f) of section 32
8 of the Office of Federal Procurement Policy Act
9 (41 U.S.C. 428) shall be deemed to be \$15,000 in
10 the administration of that section with respect to
11 such procurement.

12 “(B) *INTERNAL CONTROLS TO BE INSTI-*
13 *TUTED.—*The Secretary shall institute appro-
14 priate internal controls for procurements that
15 are made under this paragraph and that are
16 greater than \$2,500.

17 “(C) *EXCEPTION TO PREFERENCE FOR PUR-*
18 *CHASE CARD MECHANISM.—*No provision of law
19 establishing a preference for using a Federal
20 Government purchase card method for purchases
21 shall apply to procurements made under this
22 paragraph and that are greater than \$2,500.

23 “(c) *AUTHORITY TO EXPEDITE PEER REVIEW.—*The
24 Secretary may, as the Secretary determines necessary to re-
25 spond to pressing research and development needs under

1 *this section, employ such expedited peer review procedures*
2 *(including consultation with appropriate scientific experts)*
3 *as the Secretary, in consultation with the Director of NIH,*
4 *determines to be appropriate to obtain an assessment of sci-*
5 *entific and technical merit and likely contribution to the*
6 *field of biomedical countermeasure research, in place of the*
7 *peer review and advisory council review procedures that*
8 *would otherwise be required under sections 301(a)(3),*
9 *405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as ap-*
10 *plicable to a grant, contract, or cooperative agreement—*

11 *“(1) that is for performing, administering, or*
12 *supporting biomedical countermeasure research and*
13 *development; and*

14 *“(2) the amount of which is not greater than*
15 *\$1,500,000.*

16 *“(d) AGENCY FACILITIES.—In addition to any similar*
17 *authority provided under any other provision of law, in*
18 *carrying out this section, the Secretary may—*

19 *“(1) acquire, lease, construct, improve, renovate,*
20 *remodel, repair, operate, and maintain laboratories,*
21 *other research facilities and equipment, and other real*
22 *or personal property as the Secretary determines nec-*
23 *essary for the purpose of performing, administering,*
24 *and supporting biomedical countermeasure research*
25 *and development; and*

1 “(2) acquire, without regard to section 8141 of
2 title 40, United States Code, by lease or otherwise,
3 through the Administrator of General Services, build-
4 ings or parts of buildings in the District of Columbia.

5 “(e) *AUTHORITY FOR PERSONAL SERVICES CON-*
6 *TRACTS.*—

7 “(1) *IN GENERAL.*—For the purpose of per-
8 forming, administering, and supporting biomedical
9 countermeasure research and development, the Sec-
10 retary may, as the Secretary determines necessary to
11 respond to pressing research and development needs
12 under this section, obtain by contract (in accordance
13 with section 3109 of title 5, United States Code, but
14 without regard to the limitations in such section on
15 the period of service and on pay) the personal services
16 of experts or consultants who have scientific or other
17 professional qualifications.

18 “(2) *FEDERAL TORT CLAIMS ACT COVERAGE.*—

19 “(A) *IN GENERAL.*—A person carrying out
20 a contract under paragraph (1), and an officer,
21 employee, or governing board member of such
22 person, shall be deemed to be an employee of the
23 Department of Health and Human Services for
24 purposes of claims under sections 1346(b) and
25 2672 of title 28, United States Code, for money

1 *damages for personal injury, including death, re-*
2 *sulting from performance of functions under such*
3 *contract.*

4 “(B) *EXCLUSIVITY OF REMEDY.*—*The rem-*
5 *edy provided by subparagraph (A) shall be exclu-*
6 *sive of any other civil action or proceeding by*
7 *reason of the same subject matter against the*
8 *person, officer, employee, or governing board*
9 *member for any act or omission within the scope*
10 *of the Federal Tort Claims Act.*

11 “(C) *RECOURSE IN CASE OF GROSS MIS-*
12 *CONDUCT OR CONTRACT VIOLATION.*—

13 “(i) *IN GENERAL.*—*Should payment be*
14 *made by the United States to any claimant*
15 *bringing a claim under this paragraph, ei-*
16 *ther by way of administrative determina-*
17 *tion, settlement, or court judgment, the*
18 *United States shall have, notwithstanding*
19 *any provision of State law, the right to re-*
20 *cover for that portion of the damages so*
21 *awarded or paid, as well as interest and*
22 *any costs of litigation, resulting from the*
23 *failure of any person, officer, employee, or*
24 *governing board member to carry out any*
25 *obligation or responsibility assumed by such*

1 *person, officer, employee, or governing board*
2 *member under a contract with the United*
3 *States or from any grossly negligent, reck-*
4 *less, or illegal conduct or willful misconduct*
5 *on the part of such person, officer, employee,*
6 *or governing board member.*

7 “(ii) *VENUE.—The United States may*
8 *maintain an action under this subpara-*
9 *graph against such person, officer, em-*
10 *ployee, or governing board member in the*
11 *district court of the United States in which*
12 *such person, officer, employee, or governing*
13 *board member resides or has its principal*
14 *place of business.*

15 “(3) *INTERNAL CONTROLS TO BE INSTITUTED.—*

16 “(A) *IN GENERAL.—The Secretary shall in-*
17 *stitute appropriate internal controls for con-*
18 *tracts under this subsection, including proce-*
19 *dures for the Secretary to make a determination*
20 *of whether a person, or an officer, employee, or*
21 *governing board member of a person, is deemed*
22 *to be an employee of the Department of Health*
23 *and Human Services pursuant to paragraph (2).*

24 “(B) *DETERMINATION OF EMPLOYEE STA-*
25 *TUS TO BE FINAL.—A determination by the Sec-*

1 *retary under subparagraph (A) that a person, or*
2 *an officer, employee, or governing board member*
3 *of a person, is or is not deemed to be an em-*
4 *ployee of the Department of Health and Human*
5 *Services shall be final and binding on the Sec-*
6 *retary and the Attorney General and other par-*
7 *ties to any civil action or proceeding.*

8 *“(4) NUMBER OF PERSONAL SERVICES CON-*
9 *TRACTS LIMITED.—The number of experts and con-*
10 *sultants whose personal services are obtained under*
11 *paragraph (1) shall not exceed 30 at any time.*

12 *“(f) STREAMLINED PERSONNEL AUTHORITY.—*

13 *“(1) IN GENERAL.—In addition to any other*
14 *personnel authorities, the Secretary may, as the Sec-*
15 *retary determines necessary to respond to pressing re-*
16 *search and development needs under this section,*
17 *without regard to such provisions of title 5, United*
18 *States Code, governing appointments in the competi-*
19 *tive service, and without regard to the provisions of*
20 *chapter 51 and subchapter III of chapter 53 of such*
21 *title relating to classification and General Schedule*
22 *pay rates, appoint professional and technical employ-*
23 *ees, not to exceed 30 such employees at any time, to*
24 *positions in the National Institutes of Health to per-*
25 *form, administer, or support biomedical counter-*

1 *measure research and development in carrying out*
2 *this section.*

3 “(2) *INTERNAL CONTROLS TO BE INSTITUTED.*—
4 *The Secretary shall institute appropriate internal*
5 *controls for appointments under this subsection.*

6 “(g) *DEFINITION.*—*As used in this section, the term*
7 *‘biomedical countermeasure’ means a drug (as that term is*
8 *defined by section 201(g)(1) of the Federal Food, Drug, and*
9 *Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as*
10 *that term is defined by section 351(i) of this Act (42 U.S.C.*
11 *262(i))), or device (as that term is defined by section 201(h)*
12 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
13 *321(h))) that is used—*

14 “(1) *to treat, identify, or prevent harm from any*
15 *biological, chemical, radiological, or nuclear agent*
16 *that may cause a public health emergency affecting*
17 *national security; or*

18 “(2) *to treat, identify, or prevent harm from a*
19 *condition that may result in adverse health con-*
20 *sequences or death and may be caused by admin-*
21 *istering a drug, biological product, or device that is*
22 *used as described in paragraph (1).*

23 “(h) *ACTIONS COMMITTED TO AGENCY DISCRETION.*—
24 *Actions by the Secretary under the authority of this section*
25 *are committed to agency discretion.”.*

1 (b) *TECHNICAL AMENDMENT.*—Section 481A of the
2 *Public Health Service Act (42 U.S.C. 287a-2)* is amended—

3 (1) in subsection (a)(1), by inserting “or the Di-
4 rector of the National Institute of Allergy and Infec-
5 tious Diseases” after “Director of the Center”;

6 (2) in subsection (c)—

7 (A) in paragraph (1), by inserting “or the
8 Director of the National Institute of Allergy and
9 Infectious Diseases” after “Director of the Cen-
10 ter”; and

11 (B) in paragraph (2), in the matter pre-
12 ceding subparagraph (A), by striking “subsection
13 (i)” and inserting “subsection (i)(1)”;

14 (3) in subsection (d), by inserting “or the Direc-
15 tor of the National Institute of Allergy and Infectious
16 Diseases” after “Director of the Center”;

17 (4) in subsection (e)—

18 (A) in paragraph (1)—

19 (i) in the matter preceding subpara-
20 graph (A), by inserting “or the Director of
21 the National Institute of Allergy and Infec-
22 tious Diseases” after “Director of the Cen-
23 ter”;

1 (ii) in subparagraph (A), by inserting
2 “(or, in the case of the Institute, 75 per-
3 cent)” after “50 percent”; and

4 (iii) in subparagraph (B), by inserting
5 “(or, in the case of the Institute, 75 per-
6 cent)” after “40 percent”;

7 (B) in paragraph (2), by inserting “or the
8 Director of the National Institute of Allergy and
9 Infectious Diseases” after “Director of the Cen-
10 ter”; and

11 (C) in paragraph (4), by inserting “of the
12 Center or the Director of the National Institute
13 of Allergy and Infectious Diseases” after “Direc-
14 tor”; and

15 (5) in subsection (f)—

16 (A) in paragraph (1), by inserting “in the
17 case of an award by the Director of the Center,”
18 before “the applicant”; and

19 (B) in paragraph (2), by inserting “of the
20 Center or the Director of the National Institute
21 of Allergy and Infectious Diseases” after “Direc-
22 tor”.

1 **SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

2 *Part B of title III of the Public Health Service Act*
3 *(42 U.S.C. 243 et seq.) is amended by inserting after section*
4 *319A, the following:*

5 **“SEC. 319A-1. BIOMEDICAL COUNTERMEASURES PROCURE-**
6 **MENT.**

7 *“(a) DETERMINATION OF MATERIAL THREATS.—*

8 *“(1) RISK OF USE.—The Secretary of Homeland*
9 *Security, in consultation with the heads of other*
10 *agencies as appropriate, shall on an ongoing basis—*

11 *“(A) assess current and emerging threats of*
12 *use of chemical, biological, radiological, and nu-*
13 *clear agents; and*

14 *“(B) determine which of such agents present*
15 *a material risk of use against the United States*
16 *population.*

17 *“(2) PUBLIC HEALTH IMPACT.—The Secretary,*
18 *in consultation with the Secretary of Homeland Secu-*
19 *urity, shall on an ongoing basis—*

20 *“(A) assess the potential public health con-*
21 *sequences of use against the United States popu-*
22 *lation of agents identified under paragraph*
23 *(1)(B); and*

24 *“(B) determine, on the basis of such assess-*
25 *ment, the agents for which countermeasures are*
26 *necessary to protect the public health.*

1 “(b) *ASSESSMENT OF AVAILABILITY AND APPRO-*
2 *PRIATENESS OF COUNTERMEASURES.*—*The Secretary, in*
3 *consultation with the Secretary of Homeland Security, shall*
4 *assess on an ongoing basis the availability and appro-*
5 *priateness of specific countermeasures to address specific*
6 *threats identified under subsection (a).*

7 “(c) *CALL FOR NECESSARY COUNTERMEASURES; COM-*
8 *MITMENT FOR RECOMMENDATION FOR PROCUREMENT.*—

9 “(1) *PROPOSAL TO THE PRESIDENT.*—*Based on*
10 *a determination of necessary countermeasures under*
11 *subsection (a), and the assessment of availability and*
12 *appropriateness of countermeasures under subsection*
13 *(b), the Secretary of Homeland Security and the Sec-*
14 *retary may jointly submit to the President a proposal*
15 *to—*

16 “(A) *call for a necessary countermeasure*
17 *that is not available; and*

18 “(B) *commit to make a recommendation for*
19 *procurement under subsection (e) of the first such*
20 *specific countermeasure that meets the conditions*
21 *for procurement under subsection (d).*

22 “(2) *COUNTERMEASURE SPECIFICATIONS.*—*The*
23 *Secretary of Homeland Security and the Secretary*
24 *shall, to the extent practicable, include in the rec-*
25 *ommendation under paragraph (1)—*

1 “(A) *estimated quantity of purchase (in the*
2 *form of number of doses or number of effective*
3 *courses of treatments regardless of dosage form);*

4 “(B) *necessary measures of minimum safety*
5 *and effectiveness;*

6 “(C) *estimated price for each dose or effec-*
7 *tive course of treatment regardless of dosage*
8 *form; and*

9 “(D) *other information that may be nec-*
10 *essary to encourage and facilitate research, devel-*
11 *opment, and manufacture of the countermeasure*
12 *or to provide specifications for the counter-*
13 *measure.*

14 “(3) *PRESIDENTIAL APPROVAL.—If the President*
15 *has approved a request under paragraph (1), the Sec-*
16 *retary of Homeland Security and the Secretary shall*
17 *make known to persons who may respond to a call for*
18 *the countermeasure—*

19 “(A) *the call for the countermeasure;*

20 “(B) *specifications for the countermeasure*
21 *under paragraph (2); and*

22 “(C) *a commitment for a recommendation*
23 *for procurement under subsection (e) of the first*
24 *such specific countermeasure that meets the con-*

1 *ditions for procurement under subsection (d) and*
2 *the specifications under paragraph (2).*

3 “(4) *SUBSEQUENT SPECIFIC COUNTER-*
4 *MEASURES.—Procurement under subsection (f) of the*
5 *first such specific countermeasure, or any other such*
6 *countermeasure, that meets the conditions for procure-*
7 *ment under subsection (d) and the specifications*
8 *under paragraph (2) shall not preclude the additional*
9 *procurement under subsection (f) of a subsequent such*
10 *countermeasure that meets the conditions of procure-*
11 *ment under subsection (d) if such a countermeasure*
12 *provides improved safety or effectiveness or for other*
13 *reasons enhances preparedness to respond to threats of*
14 *use of a biological, chemical, radiological, or nuclear*
15 *agent.*

16 “(d) *SECRETARY’S DETERMINATION OF COUNTER-*
17 *MEASURES APPROPRIATE FOR PROCUREMENT UNDER THIS*
18 *SECTION.—*

19 “(1) *IN GENERAL.—The Secretary, in accordance*
20 *with this section, shall identify specific counter-*
21 *measures to threats identified under subsection (a)*
22 *that the Secretary determines, in consultation with*
23 *the Secretary of Homeland Security, to be appro-*
24 *priate for procurement with appropriations under*
25 *this subsection for inclusion in the stockpile under*

1 *section 121(a) of the Public Health and Bioterrorism*
2 *Preparedness and Response Act of 2002 (42 U.S.C.*
3 *300hh-12(a)).*

4 “(2) *REQUIREMENTS.—In order for the Sec-*
5 *retary to make the determination under paragraph*
6 *(1) with respect to a countermeasure, the following re-*
7 *quirements must be met:*

8 “(A) *DETERMINATION OF QUALIFIED COUN-*
9 *TERMEASURE.—The Secretary must determine*
10 *that the product is a qualified countermeasure*
11 *(as defined in subsection (h)).*

12 “(B) *DETERMINATION OF QUANTITIES*
13 *NEEDED AND FEASIBILITY OF PRODUCTION AND*
14 *DISTRIBUTION.—The Secretary must deter-*
15 *mine—*

16 “(i) *the quantities of the product that*
17 *will be needed to meet the needs of the stock-*
18 *pile; and*

19 “(ii) *that production and delivery*
20 *within 5 years of sufficient quantities of the*
21 *product, as so determined, is reasonably ex-*
22 *pected to be feasible.*

23 “(C) *DETERMINATION OF NO SIGNIFICANT*
24 *COMMERCIAL MARKET.—The Secretary shall—*

1 “(i) determine that, at the time of the
2 initial determination under this subsection,
3 there is not a significant commercial mar-
4 ket for the product other than as a bio-
5 medical countermeasure; and

6 “(ii) annually redetermine and report
7 to the President, while a determination
8 under paragraph (1) remains in effect with
9 respect to the product, whether a significant
10 commercial market exists for the product
11 other than as a biomedical countermeasure.

12 “(e) *RECOMMENDATION FOR PRESIDENT’S AP-*
13 *PROVAL.—*

14 “(1) *RECOMMENDATION FOR PROCUREMENT.—In*
15 *the case of a countermeasure that the Secretary of*
16 *Homeland Security and the Secretary have deter-*
17 *mined is appropriate for procurement under this sec-*
18 *tion for inclusion in the stockpile, in accordance with*
19 *the preceding provisions of this section, the Secretary*
20 *of Homeland Security and the Secretary shall jointly*
21 *submit to the President, in coordination with the Di-*
22 *rector of the Office of Management and Budget, a rec-*
23 *ommendation for procurement under this section.*

24 “(2) *PRESIDENTIAL APPROVAL.—A counter-*
25 *measure may be procured under this section only if*

1 *the President has approved a recommendation under*
2 *paragraph (1) with respect to such countermeasure.*

3 “(3) *NOTICE TO CONGRESS.—The Secretary of*
4 *Homeland Security shall notify Congress of each deci-*
5 *sion of the President to approve a recommendation*
6 *under paragraph (1).*

7 “(f) *PROCUREMENT.—The Secretary and the Secretary*
8 *of Homeland Security shall be responsible for the following,*
9 *for purposes of procurement of qualified countermeasures*
10 *for the stockpile under section 121(a) of the Public Health*
11 *and Bioterrorism Preparedness and Response Act of 2002*
12 *(42 U.S.C. 300hh-12(a)), as approved by the President*
13 *under subsection (e):*

14 “(1) *IN GENERAL.—The Secretary shall be re-*
15 *sponsible for—*

16 “(A) *arranging for procurement of the coun-*
17 *termeasure, including negotiating terms (includ-*
18 *ing quantity, production schedule, and price) of,*
19 *and entering into, contracts and cooperative*
20 *agreements, and for carrying out such other ac-*
21 *tivities as may reasonably be required, in ac-*
22 *cordance with the provisions of this paragraph;*
23 *and*

1 “(B) promulgating regulations to imple-
2 ment subparagraphs (E), (F), and (G), and any
3 other provisions of this section.

4 “(2) *CONTRACT TERMS.*—A contract for procure-
5 ment under this section shall (or, as otherwise speci-
6 fied in this paragraph, may) include the following
7 terms:

8 “(A) *PAYMENT CONDITIONED ON SUBSTAN-*
9 *TIAL DELIVERY.*—The contract shall provide that
10 no payment may be made until delivery has been
11 made of a substantial portion (as determined by
12 the Secretary) of the total number of units con-
13 tracted for.

14 “(B) *DISCOUNTED PAYMENT FOR UNLI-*
15 *CENSED PRODUCT.*—The contract may provide
16 for a discounted price per unit of a product that
17 is not licensed or approved as described in sub-
18 section (h)(1) at the time of delivery, and may
19 provide for payment of an additional amount
20 per unit if the product becomes so licensed or ap-
21 proved before the expiration date of the contract
22 (including an additional amount per unit of
23 product delivered before the effective date of such
24 licensing or approval).

1 “(C) *STORAGE BY VENDOR.*—*The contract*
2 *may provide that the vendor will provide storage*
3 *for stocks of a product delivered to the ownership*
4 *of the Government under the contract, for such*
5 *period and under such terms and conditions as*
6 *the Secretary may specify, and in such case*
7 *amounts appropriated under subsection (i) shall*
8 *be available for costs of shipping, handling, stor-*
9 *age, and related costs for such product.*

10 “(D) *CONTRACT DURATION.*—*The contract*
11 *shall be for a period not to exceed 5 years, re-*
12 *newable for additional periods none of which*
13 *shall exceed 5 years.*

14 “(E) *TERMINATION FOR NONDELIVERY.*—*In*
15 *addition to any other rights of the Secretary to*
16 *terminate the contract, the contract may provide*
17 *that such Secretary may terminate the contract*
18 *for failure to deliver a reasonable number (as de-*
19 *termined by the Secretary) of units of the prod-*
20 *uct by 3 years after the date the contract is en-*
21 *tered into, and may further provide that in such*
22 *case the vendor shall not be entitled to any pay-*
23 *ment under the contract.*

24 “(F) *PRODUCT APPROVAL.*—*The contract*
25 *shall provide that the vendor seek approval,*

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

8 “(3) *AVAILABILITY OF SIMPLIFIED ACQUISITION*
9 *PROCEDURES.—The amount of any procurement*
10 *under this section shall be deemed to be below the*
11 *threshold amount specified in section 4(11) of the Of-*
12 *fice of Federal Procurement Policy Act (41 U.S.C.*
13 *403(11)), for purposes of application to such procure-*
14 *ment, pursuant to section 302A(a) of the Federal*
15 *Property and Administrative Services Act of 1949 (41*
16 *U.S.C. 252a(a)), of—*

17 “(A) *section 303(g)(1)(A) of the Federal*
18 *Property and Administrative Services Act of*
19 *1949 (41 U.S.C. 253(g)(1)(A)) and its imple-*
20 *menting regulations; and*

21 “(B) *section 302A(b) of such Act (41 U.S.C.*
22 *252a(b)) and its implementing regulations.*

23 “(4) *USE OF NONCOMPETITIVE PROCEDURES.—*
24 *In addition to any other authority to use procedures*
25 *other than competitive procedures, the Secretary may*

1 *use such other procedures for a procurement under*
2 *this section if the product is available from only one*
3 *responsible source or only from a limited number of*
4 *responsible sources, and no other type of product will*
5 *satisfy such Secretary's needs.*

6 *“(5) PREMIUM PROVISION IN MULTIPLE AWARD*
7 *CONTRACTS.—*

8 *“(A) IN GENERAL.—If, under this section,*
9 *the Secretary enters into contracts with more*
10 *than one person to procure a countermeasure,*
11 *such Secretary may, notwithstanding any other*
12 *provision of law, include in each of such con-*
13 *tracts a provision that—*

14 *“(i) identifies an increment of the total*
15 *quantity of countermeasure required, wheth-*
16 *er by percentage or by numbers of units;*
17 *and*

18 *“(ii) promises to pay one or more spec-*
19 *ified premiums based on the priority of*
20 *such persons' production and delivery of the*
21 *increment identified under clause (i), in ac-*
22 *cordance with the terms and conditions of*
23 *the contract.*

24 *“(B) DETERMINATION OF GOVERNMENT'S*
25 *REQUIREMENT NOT REVIEWABLE.—If the Sec-*

1 *retary includes in each of a set of contracts a*
2 *provision as described in subparagraph (A), such*
3 *Secretary's determination of the total quantity of*
4 *countermeasure required, and any amendment of*
5 *such determination, is committed to agency dis-*
6 *cretion.*

7 “(6) *EXTENSION OF CLOSING DATE FOR RECEIPT*
8 *OF PROPOSALS NOT REVIEWABLE.*—*A decision by the*
9 *Secretary to extend the closing date for receipt of pro-*
10 *posals for a procurement under this subsection is*
11 *committed to agency discretion.*

12 “(7) *LIMITING COMPETITION TO SOURCES RE-*
13 *SPONDING TO REQUEST FOR INFORMATION.*—*In con-*
14 *ducting a procurement under this section, the Sec-*
15 *retary may exclude a source that has not responded*
16 *to a request for information under section*
17 *303A(a)(1)(B) of the Federal Property and Adminis-*
18 *trative Services Act of 1949 (41 U.S.C.*
19 *253a(a)(1)(B)) if such request has given notice that*
20 *such Secretary may so exclude such a source.*

21 “(g) *INTERAGENCY COOPERATION.*—

22 “(1) *IN GENERAL.*—*In carrying out activities*
23 *under this section, the Secretary of Homeland Secu-*
24 *rity and the Secretary are authorized, subject to*
25 *paragraph (2), to enter into interagency agreements*

1 *and other collaborative undertakings with other agen-*
2 *cies of the United States Government.*

3 “(2) *LIMITATION.*—*An agreement or undertaking*
4 *under this subsection shall not authorize another*
5 *agency to exercise the authorities provided by this sec-*
6 *tion to the Secretary of Homeland Security or to the*
7 *Secretary.*

8 “(h) *DEFINITIONS.*—*In this section:*

9 “(1) *QUALIFIED COUNTERMEASURE.*—*The term*
10 *‘qualified countermeasure’ means a biomedical coun-*
11 *termeasure—*

12 “(A) *that is approved under section 505(a)*
13 *of the Federal Food, Drug, and Cosmetic Act (21*
14 *U.S.C. 355) or licensed under section 351 of this*
15 *Act (42 U.S.C. 262) or that is approved under*
16 *section 515 or cleared under section 510(k) of the*
17 *Federal Food, Drug, and Cosmetic Act (21*
18 *U.S.C. 360e and 360) for use as such a counter-*
19 *measure to a chemical, biological, radiological,*
20 *or nuclear agent identified as a material threat*
21 *under subsection (a); or*

22 “(B) *for which the Secretary determines*
23 *that sufficient and satisfactory clinical experi-*
24 *ence or research data (including data, if avail-*
25 *able, from preclinical and clinical trials) sup-*

1 *port a reasonable conclusion that the product*
2 *will qualify for approval or licensing as such a*
3 *countermeasure within 5 years after the date of*
4 *a determination under subsection (d).*

5 “(2) *BIOMEDICAL COUNTERMEASURE.*—*The term*
6 *‘biomedical countermeasure’ means a drug (as that*
7 *term is defined by section 201(g)(1) of the Federal*
8 *Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))),*
9 *device (as that term is defined by section 201(h) of the*
10 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
11 *321(h))), or biological product (as that term is de-*
12 *finied by section 351(i) of this Act (42 U.S.C. 262(i)))*
13 *that is used—*

14 “(A) *to treat, identify, or prevent harm*
15 *from any biological, chemical, radiological, or*
16 *nuclear agent that may cause a public health*
17 *emergency affecting national security; or*

18 “(B) *to treat, identify, or prevent harm*
19 *from a condition that may result in adverse*
20 *health consequences or death and may be caused*
21 *by administering a drug or biological product*
22 *that is used as described in subparagraph (A).*

23 “(i) *APPROPRIATIONS.*—

24 “(1) *IN GENERAL.*— *There are appropriated, out*
25 *of any moneys in the Treasury not otherwise appro-*

1 *appropriated, for fiscal year 2003 and for each fiscal year*
2 *thereafter, such sums as may be necessary for the costs*
3 *incurred by the Secretary in the procurement of coun-*
4 *termeasures under this subsection as approved by the*
5 *President under subsection (e) (other than costs speci-*
6 *fied in paragraph (2)).*

7 “(2) *RESTRICTIONS.—Amounts appropriated*
8 *under this subsection shall not be available to pay—*

9 “(A) *costs for the purchase of vaccines*
10 *under procurement contracts entered into before*
11 *January 1, 2003;*

12 “(B) *costs under new contracts, or costs of*
13 *new obligations under contracts previously en-*
14 *tered into, for procurement of a countermeasure*
15 *after the date of a determination under sub-*
16 *section (d)(2)(C) that there is a significant com-*
17 *mercial market for the countermeasure other*
18 *than as a biomedical countermeasure; or*

19 “(C) *administrative costs.*”

20 **SEC. 4. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE**
21 **IN EMERGENCIES.**

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

1 **“SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
2 **USE IN EMERGENCIES.**

3 “(a) *IN GENERAL.*—Notwithstanding sections 505,
4 510(k), and 515 of this Act and section 351 of the Public
5 Health Service Act, and subject to the provisions of this sec-
6 tion, the Secretary may authorize the introduction into
7 interstate commerce, during the effective period of a dec-
8 laration under subsection (b), of a drug, biological product,
9 or device intended solely for use in an actual or potential
10 emergency.

11 “(b) *DECLARATION OF EMERGENCY.*—

12 “(1) *IN GENERAL.*—The Secretary may declare
13 an emergency justifying the authorization of a drug,
14 biological product, or device under this subsection on
15 the basis of a determination—

16 “(A) *by the Secretary of Homeland Secu-*
17 *rity, that there is a domestic emergency (or a*
18 *significant potential of a domestic emergency)*
19 *involving a heightened risk of attack with a spec-*
20 *ified biological, chemical, radiological, or nuclear*
21 *agent;*

22 “(B) *by the Secretary of Defense, that there*
23 *is a military emergency (or a significant poten-*
24 *tial of a military emergency) involving a height-*
25 *ened risk to United States military forces of at-*

1 *tack with a biological, chemical, radiological, or*
2 *nuclear agent; or*

3 “(C) *by the Secretary of a public health*
4 *emergency under section 319 of the Public*
5 *Health Service Act, affecting national security*
6 *and involving a specified biological, chemical,*
7 *radiological, or nuclear agent or a specified dis-*
8 *ease or condition that may be attributable to*
9 *such agent.*

10 “(2) *TERMINATION OF DECLARATION.—*

11 “(A) *IN GENERAL.—A declaration under*
12 *this subsection shall terminate upon the earlier*
13 *of—*

14 “(i) *a determination by the Secretary,*
15 *in consultation as appropriate with the Sec-*
16 *retary of Homeland Security or the Sec-*
17 *retary of Defense, that the circumstances de-*
18 *scribed in paragraph (1) have ceased to*
19 *exist; or*

20 “(ii) *the expiration of the 1-year pe-*
21 *riod beginning on the date on which the*
22 *declaration is made.*

23 “(B) *RENEWAL.—Notwithstanding subpara-*
24 *graph (A), the Secretary may renew a declara-*

1 *tion under this subsection, and this paragraph*
2 *shall apply to any such renewal.*

3 “(3) *NOTIFICATION.*—*The Secretary shall*
4 *promptly publish in the Federal Register, and shall*
5 *notify the appropriate committees of Congress con-*
6 *cerning, each declaration, determination, and renewal*
7 *under this subsection.*

8 “(c) *CRITERIA FOR ISSUANCE OF AUTHORIZATION.*—
9 *The Secretary may issue an authorization under this sec-*
10 *tion with respect to a product if the Secretary concludes—*

11 “(1) *that an agent specified in a declaration*
12 *under subsection (b) can cause a serious or life-threat-*
13 *ening disease or condition;*

14 “(2) *that, based on the totality of scientific evi-*
15 *dence available to the Secretary, including data from*
16 *adequate and well-controlled clinical trials, if avail-*
17 *able, it is reasonable to believe that—*

18 “(A) *the product may be effective in detect-*
19 *ing, diagnosing, treating, or preventing—*

20 “(i) *such disease or condition; or*

21 “(ii) *a serious or life-threatening dis-*
22 *ease or condition caused by a product au-*
23 *thorized under this section or approved*
24 *under this Act or the Public Health Service*
25 *Act, for detecting, diagnosing, treating, or*

1 *preventing such a disease or condition*
2 *caused by such an agent; and*

3 *“(B) the known and potential benefits of the*
4 *product, when used to detect, diagnose, prevent,*
5 *or treat such disease or condition, outweigh the*
6 *known and potential risks of the product;*

7 *“(3) that there is no adequate, approved, and*
8 *available alternative to the product for detecting, di-*
9 *agnosing, preventing, or treating such disease or con-*
10 *dition; and*

11 *“(4) that such other criteria as the Secretary*
12 *may by regulation prescribe are satisfied.*

13 *“(d) SCOPE OF AUTHORIZATION.—An authorization of*
14 *a product under this section shall state—*

15 *“(1) each disease or condition and the intended*
16 *use of the product within the scope of the authoriza-*
17 *tion; and*

18 *“(2) the Secretary’s conclusions, under subsection*
19 *(c), concerning the safety and potential effectiveness of*
20 *the product in detecting, diagnosing, preventing, or*
21 *treating such diseases or conditions, including an as-*
22 *essment of the available scientific evidence.*

23 *“(e) CONDITIONS OF AUTHORIZATION.—The Secretary*
24 *is authorized to impose such conditions on an authorization*
25 *under this section as the Secretary determines are necessary*

1 *or appropriate to protect the public health, including the*
2 *following:*

3 “(1) *The Secretary shall impose requirements*
4 *(including requirements concerning product labeling*
5 *and the provision of information) designed to ensure*
6 *that, to the maximum extent feasible given the cir-*
7 *cumstances of the emergency, health care professionals*
8 *administering the product are informed—*

9 “(A) *that the Secretary has authorized the*
10 *product solely for emergency use;*

11 “(B) *of the significant known and potential*
12 *benefits and risks of use of the product, and of*
13 *the extent to which such benefits and risks are*
14 *unknown; and*

15 “(C) *of the alternatives to the product that*
16 *are available, and of their benefits and risks.*

17 “(2) *The Secretary shall impose requirements*
18 *(including requirements concerning product labeling*
19 *and the provision of information) designed to ensure*
20 *that, to the maximum extent feasible given the cir-*
21 *cumstances of the emergency, individuals to whom the*
22 *product is administered are informed—*

23 “(A) *that the Secretary has authorized the*
24 *product solely for emergency use;*

1 “(B) of the significant known and potential
2 benefits and risks of use of the product, and of
3 the extent to which such benefits and risks are
4 unknown; and

5 “(C) of any option to accept or refuse ad-
6 ministration of the product, and of the alter-
7 natives to the product that are available and of
8 their benefits and risks.

9 “(3) The Secretary may impose limitations on
10 which entities may distribute the product (including
11 limitation to distribution by government entities),
12 and on how distribution is to be performed.

13 “(4) The Secretary may impose limitations on
14 who may administer the product, and on the cat-
15 egories of individuals to whom, and the circumstances
16 under which, the product may be administered.

17 “(5) The Secretary may condition the authoriza-
18 tion on the performance of studies, clinical trials, or
19 other research needed to support marketing approval
20 of the product.

21 “(6) The Secretary shall impose, to the extent
22 feasible and appropriate given the circumstances of
23 the emergency, requirements concerning recordkeeping
24 and reporting, including records access by the Sec-
25 retary and publication of data.

1 “(7) *The Secretary may waive, to the extent ap-*
2 *propriate given the circumstances of the emergency,*
3 *requirements, with respect to the product, of current*
4 *good manufacturing practice otherwise applicable to*
5 *the manufacture, processing, packing, or holding of*
6 *products subject to regulation under this Act.*

7 “(8) *The Secretary shall, to the extent feasible*
8 *and appropriate given the circumstances of the emer-*
9 *gency, impose requirements for the monitoring and*
10 *reporting of adverse events associated with use of the*
11 *product.*

12 “(f) *DURATION OF AUTHORIZATION.—*

13 “(1) *IN GENERAL.—Except as provided in para-*
14 *graph (2), an authorization under this section shall*
15 *be effective until the earlier of the termination of the*
16 *declaration under subsection (b) or a revocation*
17 *under subsection (g).*

18 “(2) *CONTINUED USE AFTER END OF EFFECTIVE*
19 *PERIOD.—An authorization shall continue to be effec-*
20 *tive for continued use with respect to patients to*
21 *whom it was administered during the period de-*
22 *scribed by paragraph (1), to the extent found nec-*
23 *essary by such patients’ attending physicians.*

24 “(g) *REVOCAION OF AUTHORIZATION.—*

1 “(1) *REVIEW.*—*The Secretary shall periodically*
2 *review the circumstances and the appropriateness of*
3 *an authorization under this section.*

4 “(2) *REVOCAION.*—*The Secretary may revoke*
5 *an authorization under this section if, in the Sec-*
6 *retary’s unreviewable discretion—*

7 “(A) *the conditions for such an authoriza-*
8 *tion are no longer met; or*

9 “(B) *other circumstances make such revoca-*
10 *tion appropriate.*

11 “(h) *PUBLICATION.*—*The Secretary shall promptly*
12 *publish in the Federal Register, and provide to the appro-*
13 *priate committees of Congress, a notice of each authoriza-*
14 *tion, and each termination or revocation of an authoriza-*
15 *tion, under this section.*

16 “(i) *RECORDKEEPING.*—

17 “(1) *IN GENERAL.*—*The Secretary may require*
18 *persons, including a person who holds an authoriza-*
19 *tion under this section, or who manufactures, distrib-*
20 *utes, prescribes, or administers a product that is the*
21 *subject of such an authorization, to establish and*
22 *maintain—*

23 “(A) *data that is obtained from such activ-*
24 *ity and that pertains to the effectiveness or safety*
25 *of such product;*

1 “(B) *such records as are necessary to deter-*
2 *mine, or facilitate a determination, whether*
3 *there may be any violation of this section or of*
4 *a regulation promulgated under this section; and*

5 “(C) *such additional records as the Sec-*
6 *retary may determine necessary.*

7 “(2) *ACCESS TO RECORDS BY SECRETARY.—*

8 “(A) *SAFETY AND EFFECTIVENESS INFOR-*
9 *MATION.—The Secretary may require a person*
10 *who holds an authorization under this section, or*
11 *who manufactures, distributes, prescribes, or ad-*
12 *ministers a product that is the subject of such an*
13 *authorization to provide to the Secretary all*
14 *data that is obtained from such activity and that*
15 *pertains to the safety or effectiveness of such*
16 *product.*

17 “(B) *OTHER INFORMATION.—Every person*
18 *required under this section to establish or main-*
19 *tain records, and every person in charge or cus-*
20 *tody of such records, shall, upon request by the*
21 *Secretary, permit the Secretary at all reasonable*
22 *times to have access to, to copy, and to verify*
23 *such records.*

24 “(j) *CIVIL MONETARY PENALTIES.—*

1 “(1) *IN GENERAL.*—A person who violates a re-
2 *quirement of this section or of a regulation or order*
3 *promulgated pursuant to this section shall be subject*
4 *to a civil money penalty of not more than \$100,000*
5 *in the case of an individual, and not more than*
6 *\$250,000 in the case of any other person, for each vio-*
7 *lation, not to exceed \$1,000,000 for all such violations*
8 *adjudicated in a single proceeding.*

9 “(2) *ASSESSMENT OF CIVIL PENALTIES.*—Para-
10 *graphs (3), (4), and (5) of section 303(g) shall apply*
11 *to a civil penalty under this subsection, and ref-*
12 *erences in such paragraphs to ‘paragraph (1) or (2)’*
13 *shall, for purposes of this subsection, be deemed to*
14 *refer to paragraph (1) of this subsection.*

15 “(k) *ACTIONS COMMITTED TO AGENCY DISCRETION.*—
16 *Actions under the authority of this section by the Secretary,*
17 *by the Secretary of Defense, or by the Secretary of Home-*
18 *land Security are committed to agency discretion.*

19 “(l) *REGULATIONS.*—The Secretary may promulgate
20 *regulations to implement this section.*

21 “(m) *CONSTRUCTION.*—Nothing in this section shall be
22 *construed to impair or otherwise affect—*

23 “(1) *the authority of the President as Com-*
24 *mander in Chief of the Armed Forces of the United*

1 *States under article II, section 2 of the United States*
2 *Constitution; or*

3 “(2) *the authority of the Secretary of Defense*
4 *with respect to the Department of Defense, including*
5 *the armed forces, under other provisions of Federal*
6 *law.*

7 “(n) *APPLICATION TO MEMBERS OF ARMED*
8 *FORCES.—*

9 “(1) *WAIVER OF REQUIREMENT RELATING TO*
10 *OPTION TO REFUSE.—In the case of the administra-*
11 *tion of a countermeasure to members of the armed*
12 *forces, a requirement, under subsection (e)(2), de-*
13 *signed to ensure that individuals are informed of an*
14 *option to accept or refuse administration of a prod-*
15 *uct, may be waived by the President if the President*
16 *determines, in writing, that complying with such re-*
17 *quirement is not feasible, is contrary to the best inter-*
18 *ests of the members affected, or is not in the interests*
19 *of national security.*

20 “(2) *EFFECT ON STATUTE PERTAINING TO INVES-*
21 *TIGATIONAL NEW DRUGS.—In the case of an author-*
22 *ization based on a determination by the Secretary of*
23 *Defense under subsection (b)(1)(B), section 1107 of*
24 *title 10, United States Code, shall not apply to use*
25 *of a product that is the subject of such authorization,*

1 *within the scope of such authorization and while such*
2 *authorization is effective.*

3 “(o) *RELATION TO OTHER PROVISIONS.—If a product*
4 *is the subject of an authorization under this section, the*
5 *use of such product within the scope of the authorization—*

6 *“(1) shall not be subject to any requirements*
7 *pursuant to section 505(i) or 520(g); and*

8 *“(2) shall not be subject to any requirements oth-*
9 *erwise applicable to clinical investigations pursuant*
10 *to other provisions of this Act.”.*

11 (b) *PROHIBITED ACTS.—Section 301 of the Federal*
12 *Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-*
13 *ed—*

14 (1) *in subsection (e)—*

15 (A) *by striking “504, 703” and inserting*
16 *“504, 564, 703”; and*

17 (B) *by striking “or 519” and inserting*
18 *“519, or 564”; and*

19 (2) *by adding at the end the following:*

20 *“(hh)(1) Promotion or use of a product that is the sub-*
21 *ject of an authorization under section 564 other than as*
22 *stated in the authorization, or other than during the period*
23 *described by section 564(g), unless such promotion or use*
24 *is permitted under another provision of this Act.*

1 “(2) *Failure to comply with an information require-*
2 *ment under section 564(e).*”.

3 **SEC. 5. AMENDMENTS TO PROVISIONS OF THE HOMELAND**
4 **SECURITY ACT.**

5 (a) *DECLARATION RECOMMENDING MAKING COUNTER-*
6 *MEASURE AVAILABLE TO INDIVIDUALS.*—Section
7 *224(p)(2)(A)(i) of the Public Health Service Act (42 U.S.C.*
8 *233(p)(2)(A)(i)) is amended—*

9 (1) *by striking “advisable the administration”*
10 *and inserting the following: “advisable—*

11 *“(I) the administration”;*

12 (2) *by striking the period and inserting “; or”;*
13 *and*

14 (3) *by adding at the end the following:*

15 *“(II) making a covered counter-*
16 *measure available to a category or cat-*
17 *egories of individuals who may wish to*
18 *receive it.”.*

19 (b) *AMENDMENT TO ACCIDENTAL VACCINIA INOCULA-*
20 *TION PROVISION.*—Section *224(p)(2)(C)(ii)(II) of the Pub-*
21 *lic Health Service Act (42 U.S.C. 233(p)(2)(C)(ii)(II)) is*
22 *amended by striking “resides or has resided with” and in-*
23 *serting “has resided with, or has had close contact with,”.*

24 (c) *DEEMING ACTS AND OMISSIONS TO BE WITHIN*
25 *SCOPE OF EMPLOYMENT.*—Section *224(p)(2) of the Public*

1 *Health Service Act (42 U.S.C. 233(p)(2)) is amended by*
2 *adding at the end the following:*

3 “(D) *ACTS AND OMISSIONS DEEMED TO BE*
4 *WITHIN SCOPE OF EMPLOYMENT.—*

5 “(i) *IN GENERAL.—In the case of a*
6 *claim arising out of alleged transmission of*
7 *vaccinia from an individual described in*
8 *clause (ii), acts or omissions by such indi-*
9 *vidual shall be deemed to have been taken*
10 *within the scope of such individual’s office*
11 *or employment for purposes of—*

12 “(I) *subsection (a); and*

13 “(II) *section 1346(b) and chapter*
14 *171 of title 28, United States Code.*

15 “(ii) *INDIVIDUALS TO WHOM DEEMING*
16 *APPLIES.—An individual is described by*
17 *this clause if—*

18 “(I) *vaccinia vaccine was admin-*
19 *istered to such individual as provided*
20 *by paragraph (2)(B); and*

21 “(II) *such individual was within*
22 *a category of individuals covered by a*
23 *declaration under paragraph*
24 *(2)(A)(i)(I).”.*

1 (d) *REQUIREMENT TO COOPERATE WITH UNITED*
 2 *STATES.*—Section 224(p)(5) of the Public Health Service
 3 Act (42 U.S.C. 233(p)(5)) is amended in paragraph head-
 4 ing by striking “DEFENDANT” and inserting “COVERED
 5 PERSON”.

6 (e) *AMENDMENT TO DEFINITION OF COVERED COUN-*
 7 *TERMEASURE.*—Subclause (II) of section 224(p)(7)(A)(i) of
 8 the Public Health Service Act (42 U.S.C.
 9 233(p)(7)(A)(i)(II)) is amended to read as follows:

10 “(II) used to control or treat the
 11 adverse effects of vaccinia inoculation
 12 or of administration of another covered
 13 countermeasure; and”.

14 (f) *AMENDMENT TO DEFINITION OF COVERED PER-*
 15 *SON.*—Section 224(p)(7)(B) of the Public Health Service
 16 Act (42 U.S.C. 233(p)(7)(B)) is amended—

17 (1) in the matter preceding clause (i), by strik-
 18 ing “includes any person” and inserting “means a
 19 person”;

20 (2) in clause (ii)—

21 (A) by striking “auspices such” and insert-
 22 ing the following: “auspices—

23 “(I) such”; and

24 (B) by adding at the end the following:

1 “(II) a determination was made
2 as to whether, or under what cir-
3 cumstances, an individual should re-
4 ceive a covered countermeasure;

5 “(III) the immediate site of ad-
6 ministration of a covered counter-
7 measure was monitored, managed, or
8 cared for; or

9 “(IV) an evaluation was made of
10 whether the administration of a cov-
11 ered countermeasure was effective;”;

12 (3) in clause (iii) by striking “or”;

13 (4) by striking clause (iv) and inserting the fol-
14 lowing:

15 “(iv) a State, a political subdivision of
16 a State, or an agency or official of a State
17 or of such a political subdivision, if such
18 State, subdivision, agency, or official has es-
19 tablished requirements, provided policy
20 guidance, or supplied technical or scientific
21 advice or assistance with respect to admin-
22 istration of such countermeasures;

23 “(v) in the case of a claim arising out
24 of alleged transmission of vaccinia from an
25 individual—

1 “(I) the individual who allegedly
2 transmitted the vaccinia, if vaccinia
3 vaccine was administered to such indi-
4 vidual as provided by paragraph
5 (2)(B) and such individual was within
6 a category of individuals covered by a
7 declaration under paragraph
8 (2)(A)(i)(I); or

9 “(II) an entity that employs an
10 individual described by clause (I) or
11 where such individual has privileges to
12 provide health care;

13 “(vi) an official, agent, or employee of
14 a person described in clause (i), (ii), (iii),
15 or (iv);

16 “(vii) a contractor of, or a volunteer
17 working for, a person described in clause
18 (i), (ii), or (iv), if the contractor or volun-
19 teer performs a function for which a person
20 described in clause (i), (ii), or (iv) is a cov-
21 ered person; or

22 “(viii) an individual who has privi-
23 leges to provide health care under the aus-
24 pices of an entity described in clause (ii) or
25 (v)(II).”.

1 (g) *AMENDMENT TO DEFINITION OF QUALIFIED*
 2 *PERSON*.—Section 224(p)(7)(C) of the Public Health Serv-
 3 *ice Act (42 U.S.C. 233(p)(7)(C)) is amended—*

4 (1) *by striking “who is authorized to” and in-*
 5 *serting the following: “who—*

6 *“(i) is authorized to”;*

7 (2) *by striking the period and inserting “; or”;*

8 *and*

9 (3) *by adding at the end the following:*

10 *“(ii) is otherwise authorized by the*
 11 *Secretary to administer such counter-*
 12 *measure.”.*

13 (h) *DEFINITION OF “ARISING OUT OF ADMINISTRA-*
 14 *TION OF A COVERED COUNTERMEASURE”*.—Section
 15 *224(p)(7) of the Public Health Service Act (42 U.S.C.*
 16 *233(p)(7)) is amended by adding at the end the following:*

17 *“(D) ARISING OUT OF ADMINISTRATION OF*
 18 *A COVERED COUNTERMEASURE.—*

19 *“(i) IN GENERAL.—The term ‘arising*
 20 *out of administration of a covered counter-*
 21 *measure’, when used with respect to a claim*
 22 *or liability, includes, except as provided in*
 23 *clause (ii), a claim or liability arising out*
 24 *of—*

1 “(I) *determining whether, or*
 2 *under what conditions, an individual*
 3 *should receive a covered counter-*
 4 *measure;*

5 “(II) *obtaining informed consent*
 6 *of an individual to the administration*
 7 *of a covered countermeasure;*

8 “(III) *monitoring, management,*
 9 *or care of an immediate site of admin-*
 10 *istration of a covered countermeasure,*
 11 *or evaluation of whether the adminis-*
 12 *tration of the countermeasure has been*
 13 *effective; or*

14 “(IV) *transmission of vaccinia*
 15 *virus by an individual to whom*
 16 *vaccinia vaccine was administered as*
 17 *provided by paragraph (2)(B).*

18 “(ii) *EXCEPTION.—Such term shall not*
 19 *include a claim or liability arising out of*
 20 *care for or treatment of complications aris-*
 21 *ing out of the administration of the counter-*
 22 *measure.”.*

23 (i) *TECHNICAL CORRECTION.—Section*
 24 *224(p)(2)(A)(ii) of the Public Health Service Act (42*

1 *U.S.C. 233(p)(2)(A)(ii)* is amended by striking “para-
2 *graph (8)(A)*” and inserting “*paragraph (7)(A)*”.

3 (j) *EFFECTIVE DATE.*—*This amendments made by this*
4 *section shall take effect as if enacted on November 25, 2002.*

5 ***SEC. 6. GAO REPORT.***

6 *Not later than 4 years after the date of enactment of*
7 *this Act, the Comptroller General of the United States shall*
8 *submit to the appropriate committees of Congress a report*
9 *that—*

10 (1) *describes the activities conducted under the*
11 *authorities provided for in section 409J(b)(1) of the*
12 *Public Health Service Act (as added by section 2) and*
13 *section 319A-1(f)(3) and (4) of such Act (as added by*
14 *section 3);*

15 (2) *identifies any procurements that would have*
16 *been prohibited except for the authorities provided in*
17 *the sections described in paragraph (1); and*

18 (3) *assesses the adequacy of the internal controls*
19 *established by the Secretary of Health and Human*
20 *Services regarding procurements made under the au-*
21 *thorities provided for in the sections described in*
22 *paragraph (1).*

Calendar No. 53

108TH CONGRESS
1ST SESSION

S. 15

A BILL

To amend the Public Health Service Act to provide for the payment of compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures, to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States, and to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program.

MARCH 25, 2003

Reported with an amendment