

108TH 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, and Mr. GRAHAM of South Carolina) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to 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.

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 counter-
 measures 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 adoles-
 cents; 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 adminis-
 tration 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:

15 “(1) COVERED COUNTERMEASURE.—The term
 16 ‘covered countermeasure’ means a covered counter-

1 measure as specified in article III of the Declara-
2 tion.

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

5 “(A) who is—

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

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

20 “(B) to whom a vaccine is administered
21 during the period in which the Declaration is
22 effective (including the portion of such period
23 before the date of enactment of this section)
24 and ending on the later of—

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

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

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

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

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

23 “(B) an injury, disability, illness, condi-
24 tion, or death determined, pursuant to the pro-
25 cedures established under subsection (b), to

1 have been sustained as the direct result of acci-
2 dental vaccinia inoculation through contact with
3 an individual who is (or who was accidentally
4 inoculated by) an individual in a category speci-
5 fied in Article IV of the Declaration to whom
6 vaccinia vaccine has been administered during
7 the effective period of the Declaration.

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

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

18 “(A) a covered individual who sustains a
19 covered injury as the direct result of adminis-
20 tration of a covered countermeasure; or

21 “(B) any individual who contracts vaccinia
22 during the effective period of the Declaration or
23 within 30 days after the end of such period—

24 “(i) to whom vaccinia vaccine was not
25 administered;

1 “(ii) who has resided with, or has
2 been in close contact with, a covered indi-
3 vidual; and

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

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

9 “(b) DETERMINATION OF ELIGIBILITY.—

10 “(1) IN GENERAL.—The Secretary, in consulta-
11 tion with the Attorney General and the Secretary of
12 Labor, shall establish administrative procedures for
13 determining, as applicable with respect to an indi-
14 vidual—

15 “(A) whether the individual is an eligible
16 individual;

17 “(B) whether the individual has sustained
18 a covered injury or injuries for which medical
19 benefits and employment income-loss compensa-
20 tion may be available under subsections (d) and
21 (e), and the amount of such benefits or com-
22 pensation; and

23 “(C) whether the covered injury or injuries
24 of the individual constitute a compensable dis-

1 ability, or caused the individual's death, for
2 purposes of benefits under subsection (f).

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

13 “(3) DETERMINATION OF CAUSATION.—

14 “(A) INJURIES SPECIFIED IN INJURY
15 TABLE.—In any case where an injury or other
16 adverse effect specified in the injury table es-
17 tablished under subsection (c) as a known effect
18 of a covered countermeasure manifests in an in-
19 dividual within the time period specified in such
20 table, such injury or other effect shall be
21 rebuttably presumed to have resulted from ad-
22 ministration of such covered countermeasure.

23 “(B) OTHER DETERMINATIONS.—In mak-
24 ing determinations other than those described
25 in subparagraph (A) as to the causation or se-

1 verity of an injury, the Secretary shall take into
2 consideration all relevant medical and scientific
3 evidence presented for consideration, and may
4 obtain and consider the views of qualified med-
5 ical experts.

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

10 “(A) the date a covered countermeasure
11 was administered to the individual; or

12 “(B) in the case of a claim based on con-
13 tact vaccination (as described in subsection
14 (a)(5)(B)), the date of the first symptom or
15 manifestation of onset of an adverse effect of
16 such vaccination.

17 “(5) REVIEW OF DETERMINATION.—

18 “(A) SECRETARY’S REVIEW AUTHORITY.—
19 The Secretary may review a determination
20 under this subsection at any time on the Sec-
21 retary’s own motion or on application, and may
22 affirm, vacate, or modify such determination.

23 “(B) SECRETARY’S ACTION NOT JUDI-
24 CIALLY REVIEWABLE.—The determinations of
25 the Secretary under this subsection shall not be

1 subject to review by another official of the
2 United States or by a court by mandamus or
3 otherwise.

4 “(c) COUNTERMEASURE INJURY TABLE.—

5 “(1) SMALLPOX COUNTERMEASURE INJURY
6 TABLE.—The Secretary shall establish by interim
7 final regulation a table identifying—

8 “(A) adverse effects (including injuries,
9 disabilities, illnesses, conditions, and deaths)
10 that shall be presumed to result from the ad-
11 ministration of (or exposure to) a covered coun-
12 termeasure; and

13 “(B) the time periods in which the first
14 symptom, or manifestation of onset of each
15 such adverse effect, must manifest in order for
16 such presumption to apply.

17 “(2) AMENDMENTS.—The Secretary may
18 amend by regulation the table established under
19 paragraph (1). Such amendments shall apply retro-
20 actively to claims filed or pending at the time of the
21 promulgation of final amending regulations and to
22 claims filed after such promulgation.

23 “(d) MEDICAL BENEFITS.—

24 “(1) IN GENERAL.—Subject to paragraph (2),
25 an eligible individual shall be entitled to payment by

1 the Secretary for medical items and services as rea-
2 sonable and necessary to treat a covered injury. The
3 Secretary may consider the provisions of chapter 81
4 of title 5, United States Code, (and the imple-
5 menting regulations with respect to such chapter) in
6 determining the amount of such payment and the
7 circumstances under which such payments are rea-
8 sonable and necessary.

9 “(2) LIMITATIONS.—

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

19 “(B) NO BENEFITS FOR MEDICARE-ELIGI-
20 BLE INDIVIDUAL.—No benefits shall be avail-
21 able to an individual under this subsection with
22 respect to any period in which the individual is
23 eligible for benefits under title XVIII of the So-
24 cial Security section (42 U.S.C. 1395 et seq.).

1 “(e) COMPENSATION FOR LOST EMPLOYMENT IN-
2 COME.—

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

8 “(2) AMOUNT OF COMPENSATION.—

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

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

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

22 “(ii) for purposes of computation of
23 pay and determination of wage-earning ca-
24 pacity under subparagraph (A), self-em-
25 ployment income shall be treated as wages.

1 “(3) LIMITATIONS.—

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

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

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

20 “(D) WAITING PERIOD.—An eligible indi-
21 vidual is not entitled to compensation under
22 this subsection for the first 5 work days of dis-
23 ability.

24 “(f) PAYMENT FOR DEATH AND PERMANENT, TOTAL
25 DISABILITY.—

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

16 “(2) DEATH BENEFIT.—Subject to the suc-
17 ceeding provisions of this subsection, in the case of
18 an eligible individual whose death is determined, in
19 accordance with the procedures established under
20 subsection (b), to have directly resulted from a cov-
21 ered injury or injuries a death benefit in the amount
22 determined under paragraph (3) shall be payable by
23 the Secretary to the survivor or survivors in the
24 same manner as death benefits are paid pursuant to
25 the Public Safety Officers’ Benefits Program under

1 subpart 1 of part L of title I of the Omnibus Crime
2 Control and Safe Streets Act of 1968 (42 U.S.C.
3 3796 et seq.) with respect to an eligible deceased
4 public safety officer.

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

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

20 “(5) LIMITATIONS.—

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

24 “(i) a disability benefit is paid or pay-
25 able with respect to such individual under

1 Public Safety Officers' Benefits Program
2 under subpart 1 of part L of title I of the
3 Omnibus Crime Control and Safe Streets
4 Act of 1968 (42 U.S.C. 3796 et seq.); or

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

12 “(B) DEATH BENEFITS.—No benefit is
13 payable under paragraph (2) with respect to the
14 death of an eligible individual if—

15 “(i) a disability benefit is paid with
16 respect to such individual under paragraph
17 (1) or the Public Safety Officers' Benefits
18 Program under subpart 1 of part L of title
19 I of the Omnibus Crime Control and Safe
20 Streets Act of 1968 (42 U.S.C. 3796 et
21 seq.); or

22 “(ii) a death benefit is paid or payable
23 with respect to such individual under the
24 Public Safety Officers' Benefits Program
25 under subpart 1 of part L of title I of the

1 Omnibus Crime Control and Safe Streets
2 Act of 1968 (42 U.S.C. 3796 et seq.).

3 “(g) ADMINISTRATION.—

4 “(1) ADMINISTRATION BY AGREEMENT WITH
5 OTHER AGENCY OR AGENCIES.—The Secretary may
6 administer any or all of the provisions of this section
7 through Memorandum of Agreement with the Attor-
8 ney General or the Secretary of Labor.

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

17 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
18 are authorized to be appropriated such sums as may be
19 necessary for fiscal year 2003 and each succeeding fiscal
20 year to carry out this section, to remain available until
21 expended, including administrative costs and costs of pro-
22 vision and payment of benefits.

23 “(i) RELATIONSHIP TO OTHER LAWS.—

24 “(1) NO PREEMPTION OF INDIVIDUAL
25 RIGHTS.—Except as otherwise provided in this sec-

1 tion, nothing in this section shall be construed to
2 override or limit any rights an individual may have
3 to seek compensation, benefits, or redress under any
4 other provision of Federal or State law.

5 “(2) RELATIONSHIP TO THE FEDERAL TORT
6 CLAIMS ACT.—

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

17 “(B) OFFSET OF COMPENSATION AGAINST
18 FEDERAL TORT CLAIMS ACT RECOVERY.—The
19 value of any compensation or benefits paid to
20 an individual, or the survivor or survivors of
21 such an individual, or the estate of the indi-
22 vidual pursuant to a claim under this section
23 shall be offset against any amount to which
24 such individual or the individual’s survivor, sur-

1 vivors, or estate are entitled under section
2 224(p).

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

12 **TITLE II—PROJECT BIOSHIELD**

13 **SEC. 201. SHORT TITLE.**

14 This title may be cited as the “Project BioShield Act
15 of 2003”.

16 **SEC. 202. BIOMEDICAL COUNTERMEASURE RESEARCH AND** 17 **DEVELOPMENT AUTHORITIES.**

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

21 **“SEC. 409I. BIOMEDICAL COUNTERMEASURE RESEARCH** 22 **AND DEVELOPMENT.**

23 “(a) IN GENERAL.—

24 “(1) AUTHORITY.—In carrying out research re-
25 sponsibilities under this Act, the Secretary may con-

1 duct and support research and development with re-
2 spect to biomedical countermeasures.

3 “(2) IMPLEMENTATION.—

4 “(A) IN GENERAL.—Except as provided in
5 subparagraph (C), authorities assigned by this
6 section to the Secretary shall be carried out
7 through the Director of NIH and the Director
8 of the National Institute of Allergy and Infec-
9 tious Diseases.

10 “(B) LEAD INSTITUTE.—The National In-
11 stitute of Allergy and Infectious Diseases shall
12 be the lead institute for biomedical counter-
13 measure research and development under this
14 section.

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

22 “(3) INTERAGENCY COOPERATION.—

23 “(A) IN GENERAL.—In carrying out activi-
24 ties under this section, the Secretary is author-
25 ized, subject to subparagraph (B), to enter into

1 interagency agreements and other collaborative
2 undertakings with other agencies of the Federal
3 Government and to use other agencies of the
4 Department of Health and Human Services.

5 “(B) LIMITATION.—An agreement or un-
6 dertaking under this paragraph may not au-
7 thorize another agency to exercise the authori-
8 ties provided to the Secretary by this section.

9 “(b) EXPEDITED PROCUREMENT AUTHORITY.—

10 “(1) INCREASED SIMPLIFIED ACQUISITION
11 THRESHOLD FOR BIOMEDICAL COUNTERMEASURE
12 PROCUREMENTS.—

13 “(A) IN GENERAL.—For any procurement
14 by the Secretary, of property or services for use
15 (as determined by the Secretary) in performing,
16 administering, or supporting biomedical coun-
17 termeasure research or development, the
18 amount specified in section 4(11) of the Office
19 of Federal Procurement Policy Act (41 U.S.C.
20 403(11)), as applicable pursuant to section
21 302A(a) of the Federal Property and Adminis-
22 trative Services Act of 1949 (41 U.S.C.
23 252a(a)), shall be deemed to be \$25,000,000 in
24 the administration, with respect to such pro-
25 curement, of—

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

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

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

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

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

22 “(B) the property or services needed by
23 the Secretary are available from only one re-
24 sponsible source or only from a limited number
25 of responsible sources, and no other type of

1 property or services will meet the needs of the
2 Secretary.

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

5 “(A) IN GENERAL.—For a procurement
6 described by paragraph (1)(A), the amount
7 specified in subsections (c), (d), and (f) of sec-
8 tion 32 of the Office of Federal Procurement
9 Policy Act (41 U.S.C. 428) shall be deemed to
10 be \$15,000 in the administration of that section
11 with respect to 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
18 PURCHASE CARD MECHANISM.—No provision of
19 law establishing a preference for using a Fed-
20 eral Government purchase card method for pur-
21 chases shall apply to procurements made under
22 this paragraph and that are greater than
23 \$2,500.

24 “(c) AUTHORITY TO EXPEDITE PEER REVIEW.—The
25 Secretary may, as the Secretary determines necessary to

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

13 “(1) that is for performing, administering, or
14 supporting biomedical countermeasure research and
15 development; and

16 “(2) the amount of which is not greater than
17 \$1,500,000.

18 “(d) FACILITIES AUTHORITY.—

19 “(1) AGENCY FACILITIES.—In addition to any
20 similar authority provided under any other provision
21 of law, in carrying out this section, the Secretary
22 may—

23 “(A) acquire, lease, construct, improve,
24 renovate, remodel, repair, operate, and maintain
25 laboratories, other research facilities and equip-

1 ment, and other real or personal property as
2 the Secretary determines necessary for the pur-
3 pose of performing, administering, and sup-
4 porting biomedical countermeasure research
5 and development; and

6 “(B) acquire, without regard to section
7 8141 of title 40, United States Code, by lease
8 or otherwise, through the Administrator of Gen-
9 eral Services, buildings or parts of buildings in
10 the District of Columbia.

11 “(2) FACILITIES OF GRANTEE OR COOPERATIVE
12 AGREEMENT PARTNER.—

13 “(A) IN GENERAL.—The Secretary may
14 exercise the authorities described in section
15 481A with respect to biocontainment labora-
16 tories and other related or ancillary specialized
17 research facilities as the Secretary determines
18 necessary for the purpose of performing, admin-
19 istering, and supporting biomedical counter-
20 measure research and development.

21 “(B) AVAILABILITY OF FACILITY TO SEC-
22 RETARY.—A grant or cooperative agreement
23 under subparagraph (A) may provide that the
24 facility that is the object of such grant or coop-
25 erative agreement shall be available as needed

1 to the Secretary to respond to public health
2 emergencies affecting national security.

3 “(C) TWENTY YEAR USE REQUIREMENT.—

4 A grant or cooperative agreement under this
5 paragraph shall include an agreement by the
6 grantee or cooperative agreement partner that,
7 for not less than 20 years after the completion
8 of the acquisition, construction, or other work
9 described in subparagraph (A), the facility will
10 be used for the purposes of the research and
11 development for which it is to be acquired, con-
12 structed, or otherwise improved.

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

17 “(i) authorities exercised under that
18 section by the Director of the National
19 Center for Research Resources shall, for
20 purposes of this paragraph, be exercised by
21 the Secretary; and

22 “(ii) for purposes of this paragraph,
23 each of the percentages in subparagraphs
24 (A) and (B) of section 481A(e)(1) shall be
25 deemed to be 75 percent.

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

21 “(e) AUTHORITY FOR PERSONAL SERVICES CON-
22 TRACTS.—

23 “(1) IN GENERAL.—For the purpose of per-
24 forming, administering, and supporting biomedical
25 countermeasure research and development, the Sec-

1 retary may, as the Secretary determines necessary to
2 respond to pressing research and development needs
3 under this section, obtain by contract (in accordance
4 with section 3109 of title 5, United States Code, but
5 without regard to the limitations in such section on
6 the period of service and on pay) the personal serv-
7 ices of experts or consultants who have scientific or
8 other professional qualifications.

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

10 “(A) IN GENERAL.—A person carrying out
11 a contract under paragraph (1), and an officer,
12 employee, or governing board member of such
13 person, shall be deemed to be an employee of
14 the Department of Health and Human Services
15 for purposes of claims under sections 1346(b)
16 and 2672 of title 28, United States Code, for
17 money damages for personal injury, including
18 death, resulting from performance of functions
19 under such contract.

20 “(B) EXCLUSIVITY OF REMEDY.—The
21 remedy provided by subparagraph (A) shall be
22 exclusive of any other civil action or proceeding
23 by reason of the same subject matter against
24 the person, officer, employee, or governing
25 board member.

1 “(3) INTERNAL CONTROLS TO BE INSTI-
2 TUTED.—

3 “(A) IN GENERAL.—The Secretary shall
4 institute appropriate internal controls for con-
5 tracts under this subsection, including proce-
6 dures for the Secretary to make a determina-
7 tion of whether a person, or an officer, em-
8 ployee, or governing board member of a person,
9 is deemed to be an employee of the Department
10 of Health and Human Services pursuant to
11 paragraph (2).

12 “(B) DETERMINATION OF EMPLOYEE STA-
13 TUS TO BE FINAL.—A determination by the
14 Secretary under subparagraph (A) that a per-
15 son, or an officer, employee, or governing board
16 member of a person, is or is not deemed to be
17 an employee of the Department of Health and
18 Human Services shall be final and binding on
19 the Secretary and the Attorney General and
20 other parties to any civil action or proceeding.

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

25 “(f) STREAMLINED PERSONNEL AUTHORITY.—

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

16 “(2) INTERNAL CONTROLS TO BE INSTI-
17 TUTED.—The Secretary shall institute appropriate
18 internal controls for appointments under this sub-
19 section.

20 “(g) DEFINITION.—As used in this section, the term
21 ‘biomedical countermeasure’ means a drug (as that term
22 is defined by section 201(g)(1) of the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 321(g)(1))), biological prod-
24 uct (as that term is defined by section 351(i) of this Act
25 (42 U.S.C. 262(i))), or device (as that term is defined by

1 section 201(h) of the Federal Food, Drug, and Cosmetic
2 Act (21 U.S.C. 321(h)) that is used—

3 “(1) to treat, identify, or prevent harm from
4 any biological, chemical, radiological, or nuclear
5 agent that may cause a public health emergency af-
6 fecting national security; or

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

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

15 **SEC. 203. BIOMEDICAL COUNTERMEASURES PROCURE-**
16 **MENT.**

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

20 (1) by redesignating subsections (e) through (e)
21 as subsections (d) through (f), respectively; and

22 (2) by inserting after subsection (b) the fol-
23 lowing:

24 “(c) BIOMEDICAL COUNTERMEASURES PROCURE-
25 MENT.—

1 “(1) DETERMINATION OF MATERIAL
2 THREATS.—

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

6 “(i) assess current and emerging
7 threats of use of chemical, biological, radi-
8 ological, and nuclear agents; and

9 “(ii) determine which of such agents
10 present a material risk of use against the
11 United States population.

12 “(B) PUBLIC HEALTH IMPACT.—The Sec-
13 retary of Health and Human Services, in con-
14 sultation with the Secretary, shall on an ongo-
15 ing basis—

16 “(i) assess the potential public health
17 consequences of use against the United
18 States population of agents identified
19 under subparagraph (A)(ii); and

20 “(ii) determine, on the basis of such
21 assessment, the agents for which counter-
22 measures are necessary to protect the pub-
23 lic health.

24 “(2) ASSESSMENT OF AVAILABILITY AND AP-
25 PROPRIATENESS OF COUNTERMEASURES.—The Sec-

1 retary of Health and Human Services, in consulta-
2 tion with the Secretary, shall assess on an ongoing
3 basis the availability and appropriateness of specific
4 countermeasures to address specific threats identi-
5 fied under paragraph (1).

6 “(3) SECRETARY’S DETERMINATION OF COUN-
7 TERMEASURES APPROPRIATE FOR PROCUREMENT
8 UNDER THIS SUBSECTION.—

9 “(A) IN GENERAL.—The Secretary of
10 Health and Human Services, in accordance
11 with this paragraph, shall identify specific coun-
12 termeasures to threats identified under para-
13 graph (1) that such Secretary determines, in
14 consultation with the Secretary of Homeland
15 Security, to be appropriate for procurement
16 with appropriations under this subsection for
17 inclusion in the stockpile under subsection (a).

18 “(B) REQUIREMENTS.—In order for the
19 Secretary of Health and Human Services to
20 make the determination under subparagraph
21 (A) with respect to a countermeasure, the fol-
22 lowing requirements must be met:

23 “(i) DETERMINATION OF QUALIFIED
24 COUNTERMEASURE.—Such Secretary must
25 determine that the product is a qualified

1 countermeasure (as defined in paragraph
2 (7)).

3 “(ii) DETERMINATION OF QUANTITIES
4 NEEDED AND FEASIBILITY OF PRODUC-
5 TION AND DISTRIBUTION.—Such Secretary
6 must determine—

7 “(I) the quantities of the product
8 that will be needed to meet the needs
9 of the stockpile; and

10 “(II) that production and deliv-
11 ery within 5 years of sufficient quan-
12 tities of the product, as so deter-
13 mined, is reasonably expected to be
14 feasible.

15 “(iii) DETERMINATION OF NO SIG-
16 NIFICANT COMMERCIAL MARKET.—Such
17 Secretary shall—

18 “(I) determine that, at the time
19 of the initial determination under this
20 paragraph, there is not a significant
21 commercial market for the product
22 other than as a homeland security
23 threat countermeasure; and

24 “(II) annually redetermine and
25 report to the President, while a deter-

1 mination under subparagraph (A) re-
2 mains in effect with respect to the
3 product, whether a significant com-
4 mercial market exists for the product
5 other than as a homeland security
6 threat countermeasure.

7 “(4) RECOMMENDATION FOR PRESIDENT’S AP-
8 PROVAL.—

9 “(A) RECOMMENDATION FOR PROCURE-
10 MENT.—In the case of a countermeasure that
11 the Secretary and the Secretary of Health and
12 Human Services have determined is appropriate
13 for procurement under this subsection for inclu-
14 sion in the stockpile, in accordance with the
15 preceding provisions of this subsection, the Sec-
16 retary and the Secretary of Health and Human
17 Services shall jointly submit to the President, in
18 coordination with the Director of the Office of
19 Management and Budget, a recommendation
20 for procurement under this subsection.

21 “(B) PRESIDENTIAL APPROVAL.—A coun-
22 termeasure may be procured under this sub-
23 section only if the President has approved a
24 recommendation under subparagraph (A) with
25 respect to such countermeasure.

1 “(C) NOTICE TO CONGRESS.—The Sec-
2 retary shall notify Congress of each decision of
3 the President to approve a recommendation
4 under subparagraph (A).

5 “(5) PROCUREMENT.—The Secretary of Health
6 and Human Services and the Secretary shall be re-
7 sponsible for the following, for purposes of procure-
8 ment of qualified countermeasures for the stockpile
9 under subsection (a), as approved by the President
10 under paragraph (4):

11 “(A) INTERAGENCY AGREEMENTS.—

12 “(i) FOR PROCUREMENT.—The Sec-
13 retary shall enter into an agreement with
14 the Secretary of Health and Human Serv-
15 ices for the procurement of the counter-
16 measure in accordance with the provisions
17 of this paragraph. Amounts appropriated
18 under paragraph (8) shall be available for
19 the Secretary of Health and Human Serv-
20 ice’s costs of such procurement, other than
21 as provided in clause (ii).

22 “(ii) FOR ADMINISTRATIVE COSTS.—
23 The agreement entered into between the
24 Secretary and the Secretary of Health and
25 Human Services for managing the stock-

1 pile under subsection (a) shall provide for
2 reimbursement of the Secretary of Health
3 and Human Service's administrative costs
4 relating to procurements under this sub-
5 section from appropriations to carry out
6 such subsection (a).

7 “(B) PROCUREMENT.—

8 “(i) IN GENERAL.—The Secretary of
9 Health and Human Services shall be re-
10 sponsible for—

11 “(I) arranging for procurement
12 of the countermeasure, including ne-
13 gotiating terms (including quantity,
14 production schedule, and price) of,
15 and entering into, contracts and coop-
16 erative agreements, and for carrying
17 out such other activities as may rea-
18 sonably be required, in accordance
19 with the provisions of this subpara-
20 graph; and

21 “(II) promulgating regulations to
22 implement clauses (v), (vi), and (vii),
23 and any other provisions of this sub-
24 section.

1 “(ii) CONTRACT TERMS.—A contract
2 for procurements under this subsection
3 shall (or, as otherwise specified in this
4 clause, may) include the following terms:

5 “(I) PAYMENT CONDITIONED ON
6 SUBSTANTIAL DELIVERY.—The con-
7 tract shall provide that no payment
8 may be made until delivery has been
9 made of a substantial portion (as de-
10 termined by the Secretary of Health
11 and Human Services) of the total
12 number of units contracted for.

13 “(II) DISCOUNTED PAYMENT
14 FOR UNLICENSED PRODUCT.—The
15 contract may provide for a discounted
16 price per unit of a product that is not
17 licensed or approved as described in
18 paragraph (7)(A) at the time of deliv-
19 ery, and may provide for payment of
20 an additional amount per unit if the
21 product becomes so licensed or ap-
22 proved before the expiration date of
23 the contract (including an additional
24 amount per unit of product delivered

1 before the effective date of such li-
2 censing or approval).

3 “(III) STORAGE BY VENDOR.—

4 The contract may provide that the
5 vendor will provide storage for stocks
6 of a product delivered to the owner-
7 ship of the Government under the
8 contract, for such period and under
9 such terms and conditions as the Sec-
10 retary of Health and Human Services
11 may specify, and in such case
12 amounts appropriated under para-
13 graph (8) shall be available for costs
14 of shipping, handling, storage, and re-
15 lated costs for such product.

16 “(IV) CONTRACT DURATION.—

17 The contract shall be for a period not
18 to exceed 5 years, renewable for addi-
19 tional periods none of which shall ex-
20 ceed 5 years.

21 “(V) TERMINATION FOR NON-

22 DELIVERY.—In addition to any other
23 rights of the Secretary of Health and
24 Human Services to terminate the con-
25 tract, the contract may provide that

1 such Secretary may terminate the
2 contract for failure to deliver a rea-
3 sonable number (as determined by
4 such Secretary) of units of the prod-
5 uct by 3 years after the date the con-
6 tract is entered into, and may further
7 provide that in such case the vendor
8 shall not be entitled to any payment
9 under the contract.

10 “(iii) AVAILABILITY OF SIMPLIFIED
11 ACQUISITION PROCEDURES.—The amount
12 of any procurement under this subsection
13 shall be deemed to be below the threshold
14 amount specified in section 4(11) of the
15 Office of Federal Procurement Policy Act
16 (41 U.S.C. 403(11)), for purposes of appli-
17 cation to such procurement, pursuant to
18 section 302A(a) of the Federal Property
19 and Administrative Services Act of 1949
20 (41 U.S.C. 252a(a)), of—

21 “(I) section 303(g)(1)(A) of the
22 Federal Property and Administrative
23 Services Act of 1949 (41 U.S.C.
24 253(g)(1)(A)) and its implementing
25 regulations; and

1 “(II) section 302A(b) of such Act
2 (41 U.S.C. 252a(b)) and its imple-
3 menting regulations.

4 “(iv) USE OF NONCOMPETITIVE PRO-
5 CEDURES.—In addition to any other au-
6 thority to use procedures other than com-
7 petitive procedures, the Secretary of
8 Health and Human Services may use such
9 other procedures for a procurement under
10 this subsection if the product is available
11 from only one responsible source or only
12 from a limited number of responsible
13 sources, and no other type of product will
14 satisfy such Secretary’s needs.

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

17 “(I) IN GENERAL.—If, under this
18 subsection, the Secretary of Health
19 and Human Services enters into con-
20 tracts with more than one person to
21 procure a countermeasure, such Sec-
22 retary may, notwithstanding any other
23 provision of law, include in each of
24 such contracts a provision that—

1 “(aa) identifies an increment
2 of the total quantity of counter-
3 measure required, whether by
4 percentage or by numbers of
5 units; and

6 “(bb) promises to pay one or
7 more specified premiums based
8 on the priority of such persons’
9 production and delivery of the in-
10 crement identified under item
11 (aa), in accordance with the
12 terms and conditions of the con-
13 tract.

14 “(II) DETERMINATION OF GOV-
15 ERNMENT’S REQUIREMENT NOT RE-
16 VIEWABLE.—If the Secretary of
17 Health and Human Services includes
18 in each of a set of contracts a provi-
19 sion as described in clause (I), such
20 Secretary’s determination of the total
21 quantity of countermeasure required,
22 and any amendment of such deter-
23 mination, is committed to agency dis-
24 cretion.

1 “(vi) EXTENSION OF CLOSING DATE
2 FOR RECEIPT OF PROPOSALS NOT REVIEW-
3 ABLE.—A decision by the Secretary of
4 Health and Human Services to extend the
5 closing date for receipt of proposals for a
6 procurement under this subsection is com-
7 mitted to agency discretion.

8 “(vii) LIMITING COMPETITION TO
9 SOURCES RESPONDING TO REQUEST FOR
10 INFORMATION.—In conducting a procure-
11 ment under this subsection, the Secretary
12 of Health and Human Services may ex-
13 clude a source that has not responded to a
14 request for information under section
15 303A(a)(1)(B) of the Federal Property
16 and Administrative Services Act of 1949
17 (41 U.S.C. 253a(a)(1)(B)) if such request
18 has given notice that such Secretary may
19 so exclude such a source.

20 “(6) INTERAGENCY COOPERATION.—

21 “(A) IN GENERAL.—In carrying out activi-
22 ties under this section, the Secretary and the
23 Secretary of Health and Human Services are
24 authorized, subject to subparagraph (B), to
25 enter into interagency agreements and other

1 collaborative undertakings with other agencies
2 of the United States Government.

3 “(B) LIMITATION.—An agreement or un-
4 dertaking under this paragraph shall not au-
5 thorize another agency to exercise the authori-
6 ties provided by this section to the Secretary or
7 to the Secretary of Health and Human Serv-
8 ices.

9 “(7) DEFINITIONS.—In this subsection:

10 “(A) QUALIFIED COUNTERMEASURE.—The
11 term ‘qualified countermeasure’ means a bio-
12 medical countermeasure—

13 “(i) that is approved under section
14 505(a) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355) or licensed
16 under section 351 of the Public Health
17 Service Act (42 U.S.C. 262) for use as
18 such a countermeasure to a chemical, bio-
19 logical, radiological, or nuclear agent iden-
20 tified as a material threat under paragraph
21 (1); or

22 “(ii) for which the Secretary of
23 Health and Human Services determines
24 that sufficient and satisfactory clinical ex-
25 perience or research data (including data,

1 if available, from preclinical and clinical
2 trials) support a reasonable conclusion that
3 the product will qualify for approval or li-
4 censing as such a countermeasure within 5
5 years after the date of a determination
6 under paragraph (3).

7 “(B) BIOMEDICAL COUNTERMEASURE.—

8 The term ‘biomedical countermeasure’ means a
9 drug (as that term is defined by section
10 201(g)(1) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 321(g)(1))) or biological
12 product (as that term is defined by section
13 351(i) of the Public Health Service Act (42
14 U.S.C. 262(i))) that is used—

15 “(i) to treat, identify, or prevent harm
16 from any biological, chemical, radiological,
17 or nuclear agent that may cause a public
18 health emergency affecting national secu-
19 rity; or

20 “(ii) to treat, identify, or prevent
21 harm from a condition that may result in
22 adverse health consequences or death and
23 may be caused by administering a drug or
24 biological product that is used as described
25 in clause (i).

1 “(8) APPROPRIATIONS.—

2 “(A) IN GENERAL.— There are appro-
3 priated, out of any moneys in the Treasury not
4 otherwise appropriated, for fiscal year 2003 and
5 for each fiscal year thereafter, such sums as
6 may be necessary for the costs incurred by the
7 Secretary in the procurement of counter-
8 measures under this subsection as approved by
9 the President under paragraph (4) (other than
10 costs specified in subparagraph (B)).

11 “(B) RESTRICTIONS.—Amounts appro-
12 priated under this paragraph shall not be avail-
13 able to pay—

14 “(i) costs for the purchase of vaccines
15 under procurement contracts entered into
16 before January 1, 2003;

17 “(ii) costs under new contracts, or
18 costs of new obligations under contracts
19 previously entered into, for procurement of
20 a countermeasure after the date of a deter-
21 mination under paragraph (3)(B)(iii) that
22 there is a significant commercial market
23 for the countermeasure other than as a
24 homeland security threat countermeasure;
25 or

1 “(iii) administrative costs.”.

2 **SEC. 204. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
3 **USE IN EMERGENCIES.**

4 (a) IN GENERAL.—Subchapter E of Chapter V of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 360bbb, et seq.) is amended by adding at the end the fol-
7 lowing:

8 **“SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
9 **USE IN EMERGENCIES.**

10 “(a) IN GENERAL.—Notwithstanding sections 505
11 and 515 of this Act and section 351 of the Public Health
12 Service Act, and subject to the provisions of this section,
13 the Secretary may authorize the introduction into inter-
14 state commerce, during the effective period of a declara-
15 tion under subsection (b), of a drug or device intended
16 solely for use in an actual or potential emergency.

17 “(b) DECLARATION OF EMERGENCY.—

18 “(1) IN GENERAL.—The Secretary may declare
19 an emergency justifying the authorization of a drug
20 or device under this subsection on the basis of a de-
21 termination—

22 “(A) by the Secretary of Homeland Secu-
23 rity, that there is a national emergency (or a
24 significant potential of a national emergency)
25 involving a heightened risk of attack with a

1 specified biological, chemical, radiological, or
2 nuclear agent or agents;

3 “(B) by the Secretary of Defense, that
4 there is a military emergency (or a significant
5 potential of a military emergency) involving a
6 heightened risk to United States military forces
7 of attack with a biological, chemical, radio-
8 logical, or nuclear agent or agents; or

9 “(C) by the Secretary of a public health
10 emergency under section 319 of the Public
11 Health Service Act, involving a specified disease
12 or condition or a specified biological, chemical,
13 radiological, or nuclear agent or agents.

14 “(2) TERMINATION OF DECLARATION.—

15 “(A) IN GENERAL.—A declaration under
16 this subsection shall terminate upon the earlier
17 of—

18 “(i) a determination by the Secretary,
19 in consultation as appropriate with the
20 Secretary of Homeland Security or the
21 Secretary of Defense, that the cir-
22 cumstances described in paragraph (1)
23 have ceased to exist; or

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

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

8 “(3) PUBLICATION.—The Secretary shall
9 promptly publish in the Federal Register each dec-
10 laration, determination, and renewal under this sub-
11 section.

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

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

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

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

24 “(i) such disease or condition; or

1 “(ii) a serious or life-threatening dis-
2 ease or condition caused by a product au-
3 thorized under this section or approved
4 under this Act or the Public Health Serv-
5 ice Act, for detecting, diagnosing, treating,
6 or preventing such a disease or condition
7 caused by such an agent; and

8 “(B) the known and potential benefits of
9 the product, when used to detect, diagnose, pre-
10 vent, or treat such disease or condition, out-
11 weigh the known and potential risks of the
12 product;

13 “(3) that there is no adequate, approved, and
14 available alternative to the product for detecting, di-
15 agnosing, preventing, or treating such disease or
16 condition; and

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

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

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

24 “(2) the Secretary’s conclusions, under sub-
25 section (c), concerning the safety and potential effec-

1 tiveness of the product in detecting, diagnosing, pre-
2 venting, or treating such diseases or conditions, in-
3 cluding an assessment of the available scientific evi-
4 dence.

5 “(e) CONDITIONS OF AUTHORIZATION.—

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

11 “(A) The Secretary shall impose require-
12 ments (including requirements concerning prod-
13 uct labeling and the provision of information)
14 designed to ensure that, to the maximum extent
15 feasible given the circumstances of the emer-
16 gency, health care professionals administering
17 the product are informed—

18 “(i) that the Secretary has authorized
19 the product solely for emergency use;

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

1 “(iii) of the alternatives to the prod-
2 uct that are available, and of their benefits
3 and risks.

4 “(B) The Secretary shall impose require-
5 ments (including requirements concerning prod-
6 uct labeling and the provision of information)
7 designed to ensure that, to the maximum extent
8 feasible given the circumstances of the emer-
9 gency, individuals to whom the product is ad-
10 ministered are informed—

11 “(i) that the Secretary has authorized
12 the product solely for emergency use;

13 “(ii) of the significant known and po-
14 tential benefits and risks of use of the
15 product, and of the extent to which such
16 benefits and risks are unknown; and

17 “(iii) of any option to accept or refuse
18 administration of the product, and of the
19 alternatives to the product that are avail-
20 able and of their benefits and risks.

21 “(C) The Secretary may impose limitations
22 on which entities may distribute the product
23 (including limitation to distribution by govern-
24 ment entities), and on how distribution is to be
25 performed.

1 “(D) The Secretary may impose limita-
2 tions on who may administer the product, and
3 on the categories of individuals to whom, and
4 the circumstances under which, the product
5 may be administered.

6 “(E) The Secretary may condition the au-
7 thorization on the performance of studies, clin-
8 ical trials, or other research needed to support
9 marketing approval of the product.

10 “(F) The Secretary may impose require-
11 ments concerning recordkeeping and reporting,
12 including records access by the Secretary and
13 publication of data.

14 “(G) The Secretary may impose (or waive)
15 requirements, with respect to the product, of
16 current good manufacturing practice otherwise
17 applicable to the manufacture, processing, pack-
18 ing, or holding of products subject to regulation
19 under this Act.

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

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

25 “(f) DURATION OF AUTHORIZATION.—

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

6 “(2) CONTINUED USE AFTER END OF EFFEC-
7 TIVE PERIOD.—An authorization shall continue to be
8 effective for continued use with respect to patients
9 to whom it was administered during the period de-
10 scribed by paragraph (1), to the extent found nec-
11 essary by such patients’ attending physicians.

12 “(g) REVOCATION OF AUTHORIZATION.—

13 “(1) REVIEW.—The Secretary shall periodically
14 review the circumstances and the appropriateness of
15 an authorization under this section.

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

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

21 “(B) other circumstances make such rev-
22 ocation appropriate.

23 “(h) PUBLICATION.—The Secretary shall promptly
24 publish in the Federal Register a notice of each authoriza-

1 tion, and each termination or revocation of an authoriza-
2 tion, under this section.

3 “(i) RECORDKEEPING.—

4 “(1) IN GENERAL.—The Secretary may by
5 order or regulation require persons, including a per-
6 son who holds an authorization under this section,
7 or who manufactures, distributes, prescribes, or ad-
8 ministers a product that is the subject of such an
9 authorization, to establish and maintain—

10 “(A) data that is obtained from such activ-
11 ity and that pertains to the effectiveness or
12 safety of such product;

13 “(B) such records as are necessary to de-
14 termine, or facilitate a determination, whether
15 there may be any violation of this section or of
16 a regulation promulgated under this section;
17 and

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

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

21 “(A) SAFETY AND EFFECTIVENESS INFOR-
22 MATION.—The Secretary may by order or regu-
23 lation require a person who holds an authoriza-
24 tion under this section, or who manufactures,
25 distributes, prescribes, or administers a product

1 that is the subject of such an authorization to
2 provide to the Secretary all data that is ob-
3 tained from such activity and that pertains to
4 the safety or effectiveness of such product.

5 “(B) OTHER INFORMATION.—Every person
6 required under this section to establish or main-
7 tain records, and every person in charge or cus-
8 tody of such records, shall, upon request by the
9 Secretary, permit the Secretary at all reason-
10 able times to have access to, to copy, and to
11 verify such records.

12 “(j) CIVIL MONETARY PENALTIES.—

13 “(1) IN GENERAL.—A person who violates a re-
14 quirement of this section or of a regulation or order
15 promulgated pursuant to this section shall be subject
16 to a civil money penalty of not more than \$100,000
17 in the case of an individual, and not more than
18 \$250,000 in the case of any other person, for each
19 violation, not to exceed \$1,000,000 for all such viola-
20 tions adjudicated in a single proceeding.

21 “(2) ASSESSMENT OF CIVIL PENALTIES.—Para-
22 graphs (3), (4), and (5) of section 303(g) shall apply
23 to a civil penalty under this subsection, and ref-
24 erences in such paragraphs to ‘paragraph (1) or (2)’

1 shall, for purposes of this subsection, be deemed to
2 refer to paragraph (1) of this subsection.

3 “(k) ACTIONS COMMITTED TO AGENCY DISCRE-
4 TION.—Actions under the authority of this section by the
5 Secretary, by the Secretary of Defense, or by the Sec-
6 retary of Homeland Security are committed to agency dis-
7 cretion.

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

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

12 “(1) the authority of the President as Com-
13 mander in Chief of the Armed Forces of the United
14 States under article II, section 2 of the United
15 States Constitution; or

16 “(2) the authority of the Secretary of Defense
17 with respect to the Department of Defense, includ-
18 ing the armed forces, under other provisions of Fed-
19 eral law.

20 “(n) APPLICATION TO MEMBERS OF ARMED
21 FORCES.—

22 “(1) WAIVER OF REQUIREMENT RELATING TO
23 OPTION TO REFUSE.—In the case of the administra-
24 tion of a countermeasure to members of the armed
25 forces, a requirement, under subsection (e)(2)(C),

1 designed to ensure that individuals are informed of
2 an option to accept or refuse administration of a
3 product, may be waived by the President if the
4 President determines, in writing, that complying
5 with such requirement is not feasible, is contrary to
6 the best interests of the members affected, or is not
7 in the interests of national security.

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

16 “(o) RELATION TO OTHER PROVISIONS.—If a prod-
17 uct is the subject of an authorization under this section,
18 the use of such product within the scope of the authoriza-
19 tion—

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

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

1 (b) PROHIBITED ACTS.—Section 301 of the Federal
 2 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
 3 ed—

4 (1) in subsection (e)—

5 (A) by striking “504, 703” and inserting
 6 “504, 564, 703”; and

7 (B) by striking “or 519” and inserting
 8 “519, or 564”; and

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

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

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

17 **SEC. 205. DEVELOPING NEW COUNTERMEASURES AND PRO-**
 18 **TECTING EXISTING COUNTERMEASURES**
 19 **AGAINST BIOTERRORISM.**

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

23 “(k) LIMITED ANTITRUST EXEMPTION.—

24 “(1) COUNTERMEASURES DEVELOPMENT MEET-
 25 INGS.—

1 “(A) COUNTERMEASURES DEVELOPMENT
2 MEETINGS AND CONSULTATIONS.—The Sec-
3 retary may conduct meetings and consultations
4 with parties involved in the development of
5 countermeasures for the purpose of the develop-
6 ment, manufacture, distribution, or sale of pri-
7 ority countermeasures consistent with the pur-
8 poses of this title. The Secretary shall give no-
9 tice of such meetings and consultations to the
10 Attorney General and the Chairperson of the
11 Federal Trade Commission (referred to in this
12 subsection as the ‘Chairperson’).

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

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

19 “(ii) be open to parties involved in the
20 development, manufacture, distribution,
21 purchase, or sale of priority counter-
22 measures, as determined by the Secretary;

23 “(iii) be open to the Attorney General
24 and the Chairperson;

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

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

10 “(C) MINUTES.—The Secretary shall
11 maintain minutes of meetings and consultations
12 under this subsection, which shall not be dis-
13 closed under section 552 of title 5, United
14 States Code.

15 “(D) EXEMPTION.—The antitrust laws
16 shall not apply to meetings and consultations
17 under this paragraph, except that any agree-
18 ment that results from a meeting or consulta-
19 tion and that has been denied an exemption
20 pursuant to this subsection shall be subject to
21 the antitrust laws.

22 “(2) WRITTEN AGREEMENTS OR CONDUCT.—
23 The Secretary or any party to an agreement or other
24 conduct regarding covered activities entered into or
25 undertaken pursuant to meetings or consultations

1 conducted under paragraph (1), and that is con-
2 sistent with this paragraph, shall file such written
3 agreement or a description of the conduct involved
4 with the Attorney General and the Chairperson for
5 a determination of whether such agreement or con-
6 duct should be exempt from the antitrust laws. In
7 addition to the proposed agreement or description of
8 conduct itself, any such filing shall include—

9 “(A) an explanation of the intended pur-
10 pose of the agreement or conduct;

11 “(B) a specific statement of the substance
12 of the agreement or conduct;

13 “(C) a description of the methods that will
14 be utilized to achieve the objectives of the
15 agreement or conduct;

16 “(D) an explanation of the necessity of a
17 cooperative effort among the particular partici-
18 pating parties to achieve the objectives of the
19 agreement or conduct; and

20 “(E) any other relevant information rea-
21 sonably requested by the Attorney General, in
22 consultation with the Chairperson and the Sec-
23 retary.

24 “(3) DETERMINATION.—The Attorney General,
25 in consultation with the Chairperson, shall determine

1 whether an agreement or description of conduct sub-
2 mitted under paragraph (2) should be exempt from
3 the antitrust laws.

4 “(4) LIMITED ANTITRUST EXEMPTION.—

5 “(A) IN GENERAL.—The Attorney General,
6 in consultation with the Chairperson, may,
7 within 30 days of the receipt of a notification
8 pursuant to paragraph (2), revoke in whole or
9 in part, the scope of any exemption granted by
10 the Attorney General under a determination
11 under paragraph (3).

12 “(B) EXTENSION.—The Attorney General
13 may extend the 35-day period referred to in
14 subparagraph (A) for an additional period of
15 not to exceed 20 days. Such additional period
16 may be further extended only by the United
17 States district court, upon an application by the
18 Attorney General after notice to the Secretary
19 and the parties involved.

20 “(C) APPLICATION OF LAWS.—

21 “(i) IN GENERAL.—The antitrust laws
22 shall not apply to an agreement or conduct
23 (described in a description of conduct) that
24 is submitted for review pursuant to para-
25 graph (2) until such time as the Attorney

1 General determines, pursuant to subpara-
2 graph (D), that such agreement or conduct
3 should not, in whole or in part, be exempt
4 from the antitrust laws.

5 “(ii) LIMITED LIABILITY.—No party
6 to an agreement or conduct referred to in
7 clause (i) shall be liable under the antitrust
8 laws for any actions reasonably necessary
9 to carry out the agreement or for conduct
10 taken after the agreement or description
11 has been submitted pursuant to paragraph
12 (2) and prior to any revocation of the ex-
13 emption by the Attorney General pursuant
14 to subparagraph (D).

15 “(D) DETERMINATION.—In making a de-
16 termination under this subparagraph, the At-
17 torney General, in consultation with the Chair-
18 person and the Secretary shall consider—

19 “(i) whether the agreement or conduct
20 involved would facilitate the availability of
21 priority countermeasures;

22 “(ii) whether the exemption from the
23 antitrust laws would promote the public in-
24 terest;

1 “(iii) the competitive impact to areas
2 not directly related to the purposes of the
3 agreement or conduct; and

4 “(iv) any other factors determined rel-
5 evant by the Attorney General and the
6 Chairperson.

7 “(5) LIMITATION ON AND RENEWAL OF EXEMP-
8 TIONS.—An exemption provided under paragraphs
9 (3) or (4) shall be limited to covered activities, and
10 shall expire on the date that is 3 years after the date
11 on which the exemption becomes effective (and at 3
12 year intervals thereafter, if renewed) unless the At-
13 torney General in consultation with the Chairperson
14 determines that the exemption should be renewed
15 (with modifications, as appropriate) considering the
16 factors described in paragraph (4).

17 “(6) LIMITATION ON PARTIES.—Any exemption
18 from the antitrust laws provided under this sub-
19 section shall not apply to the use of any information
20 acquired in conducting exempted activities for any
21 purposes other than those expressly specified in the
22 antitrust exemption provided for by this subsection.

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

1 “(8) REPORT.—Not later than 1 year after the
2 date of enactment of this subsection, and annually
3 thereafter, the Attorney General and the Chair-
4 person shall report to the Committee on Health,
5 Education, Labor, and Pensions and the Committee
6 on the Judiciary of the Senate and the Committee
7 on Energy and Commerce and the Committee on the
8 Judiciary of the House of Representatives on the use
9 and continuing need for the exemption from the
10 antitrust laws provided by this subsection.

11 “(9) SUNSET.—The authority of any party to
12 apply for or to obtain a limited antitrust exemption
13 under this subsection shall expire at the end of the
14 6-year period that begins on the date of enactment
15 of this subsection.

16 “(1) DEFINITIONS.—In this section:

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

19 “(A) has the meaning given such term in
20 subsection (a) of the first section of the Clayton
21 Act (15 U.S.C. 12(a)), except that such term
22 includes the Act of June 19, 1936 (15 U.S.C.
23 13 et seq.) commonly known as the Robinson-
24 Patman Act), and section 5 of the Federal
25 Trade Commission Act (15 U.S.C. 45) to the

1 extent such section 5 applies to unfair methods
2 of competition; and

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

5 “(2) COVERED ACTIVITIES.—

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

12 “(i) theoretical analysis, experimen-
13 tation, or the systematic study of phe-
14 nomena or observable facts related to the
15 development of priority countermeasures;

16 “(ii) the development or testing of
17 basic engineering techniques related to the
18 development of priority countermeasures;

19 “(iii) the extension of investigative
20 findings or theory of a scientific or tech-
21 nical nature into practical application for
22 experimental and demonstration purposes,
23 including the experimental production and
24 testing of models, prototypes, equipment,

1 materials, and processes related to the de-
2 velopment of priority countermeasures;

3 “(iv) the production, distribution, or
4 marketing of a product, process, or service
5 related to the development of priority
6 countermeasures;

7 “(v) the testing in connection with the
8 production of a product, process, or service
9 related to the development of priority
10 countermeasures;

11 “(vi) the collection, exchange, and
12 analysis of research or production informa-
13 tion related to the development of priority
14 countermeasures; or

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

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

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

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

11 “(ii) Entering into any agreement or
12 engaging in any other conduct—

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

20 “(II) to restrict or require par-
21 ticipation by any person who is a
22 party to such covered activities in
23 other research and development activi-
24 ties, that is not reasonably necessary
25 to prevent the misappropriation of

1 proprietary information contributed
2 by any person who is a party to such
3 covered activities or of the results of
4 such covered activities.

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

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

18 “(v) Except as otherwise provided in
19 this subsection or subsection (k), entering
20 into any agreement or engaging in any
21 other conduct to restrict or require partici-
22 pation by any person who is a party to
23 such activities, in any unilateral or joint
24 activity that is not reasonably necessary to

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

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

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

12 “(5) PRIORITY COUNTERMEASURE.—The term
13 ‘priority countermeasure’ means a countermeasure,
14 including a drug, medical device, biological product,
15 or diagnostic test to treat, identify, or prevent infec-
16 tion by a biological agent or toxin on the list devel-
17 oped under section 351A(a)(1) and prioritized under
18 subsection (a)(1).”.

19 **TITLE III—IMPROVED VACCINE**
20 **AFFORDABILITY AND AVAIL-**
21 **ABILITY**

22 **SEC. 301. SHORT TITLE.**

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

1 **Subtitle A—State Vaccine Grants**

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

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

6 “(3)(A) For the purpose of carrying out activities re-
7 lating to influenza vaccine under the immunization pro-
8 gram under this subsection, there are authorized to be ap-
9 propriated such sums as may be necessary for each of fis-
10 cal years 2003 and 2004. Such authorization shall be in
11 addition to amounts available under paragraphs (1) and
12 (2) for such purpose.

13 “(B) The authorization of appropriations established
14 in subparagraph (A) shall not be effective for a fiscal year
15 unless the total amount appropriated under paragraphs
16 (1) and (2) for the fiscal year is not less than such total
17 for fiscal year 2000.

18 “(C) The purposes for which amounts appropriated
19 under subparagraph (A) are available to the Secretary in-
20 clude providing for improved State and local infrastruc-
21 ture for influenza immunizations under this subsection in
22 accordance with the following:

23 “(i) Increasing influenza immunization rates in
24 populations considered by the Secretary to be at

1 high risk for influenza-related complications and in
2 their contacts.

3 “(ii) Recommending that health care providers
4 actively target influenza vaccine that is available in
5 September, October, and November to individuals
6 who are at increased risk for influenza-related com-
7 plications and to their contacts.

8 “(iii) Providing for the continued availability of
9 influenza immunizations through December of such
10 year, and for additional periods to the extent that
11 influenza vaccine remains available.

12 “(iv) Encouraging States, as appropriate, to de-
13 velop contingency plans (including plans for public
14 and professional educational activities) for maxi-
15 mizing influenza immunizations for high-risk popu-
16 lations in the event of a delay or shortage of influ-
17 enza vaccine.

18 “(D) The Secretary shall submit to the Committee
19 on Energy and Commerce of the House of Representa-
20 tives, and the Committee on Health, Education, Labor,
21 and Pensions of the Senate, periodic reports describing the
22 activities of the Secretary under this subsection regarding
23 influenza vaccine. The first such report shall be submitted
24 not later than June 6, 2003, the second report shall be

1 submitted not later than June 6, 2004, and subsequent
2 reports shall be submitted biennially thereafter.”.

3 **SEC. 312. PROGRAM FOR INCREASING IMMUNIZATION**
4 **RATES FOR ADULTS AND ADOLESCENTS; COL-**
5 **LECTION OF ADDITIONAL IMMUNIZATION**
6 **DATA.**

7 (a) ACTIVITIES OF CENTERS FOR DISEASE CONTROL
8 AND PREVENTION.—Section 317(j) of the Public Health
9 Service Act (42 U.S.C. 247b(j)), as amended by section
10 311, is further amended by adding at the end the fol-
11 lowing:

12 “(4)(A) For the purpose of carrying out activities to
13 increase immunization rates for adults and adolescents
14 through the immunization program under this subsection,
15 and for the purpose of carrying out subsection (k)(2),
16 there are authorized to be appropriated \$50,000,000 for
17 fiscal year 2003, and such sums as may be necessary for
18 each of the fiscal years 2004 through 2006. Such author-
19 ization is in addition to amounts available under para-
20 graphs (1), (2), and (3) for such purposes.

21 “(B) In expending amounts appropriated under sub-
22 paragraph (A), the Secretary shall give priority to adults
23 and adolescents who are medically underserved and are
24 at risk for vaccine-preventable diseases, including as ap-

1 appropriate populations identified through projects under
2 subsection (k)(2)(E).

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

12 “(5) The Secretary shall annually submit to Congress
13 a report that—

14 “(A) evaluates the extent to which the immuni-
15 zation system in the United States has been effective
16 in providing for adequate immunization rates for
17 adults and adolescents, taking into account the ap-
18 plicable year 2010 health objectives established by
19 the Secretary regarding the health status of the peo-
20 ple of the United States; and

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

23 “(6) In carrying out this subsection and paragraphs
24 (1) and (2) of subsection (k), the Secretary shall consider
25 recommendations regarding immunizations that are made

1 in reports issued by the Institute of Medicine of the Na-
2 tional Academy of Sciences.”.

3 (b) RESEARCH, DEMONSTRATIONS, AND EDU-
4 CATION.—Section 317(k) of the Public Health Service Act
5 (42 U.S.C. 247b(k)) is amended—

6 (1) by redesignating paragraphs (2) through
7 (4) as paragraphs (3) through (5), respectively;

8 (2) by inserting after paragraph (1) the fol-
9 lowing:

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

14 “(i) The Secretary shall coordinate with public
15 and private entities (including nonprofit private enti-
16 ties), and develop and disseminate guidelines, toward
17 the goal of ensuring that immunizations are rou-
18 tinely offered to adults and adolescents by public
19 and private health care providers.

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

23 “(iii) The Secretary shall (relative to fiscal year
24 2003) increase the extent to which the Secretary col-
25 lects data on the incidence, prevalence, and cir-

1 cumstances of diseases and adverse events that are
2 experienced by adults and adolescents and may be
3 associated with immunizations, including collecting
4 data in cooperation with commercial laboratories.

5 “(iv) The Secretary shall ensure that the enti-
6 ties with which the Secretary cooperates for pur-
7 poses of subparagraphs (A) through (C) include
8 managed care organizations, community-based orga-
9 nizations that provide health services, and other
10 health care providers.

11 “(v) The Secretary shall provide for projects to
12 identify racial and ethnic minority groups and other
13 health disparity populations for which immunization
14 rates for adults and adolescents are below such rates
15 for the general population, and to determine the fac-
16 tors underlying such disparities.

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

21 **SEC. 313. IMMUNIZATION AWARENESS.**

22 (a) DEVELOPMENT OF INFORMATION CONCERNING
23 MENINGITIS.—

24 (1) IN GENERAL.—The Secretary of Health and
25 Human Services (in this title referred to as the

1 “Secretary”), in consultation with the Director of
2 the Centers for Disease Control and Prevention,
3 shall develop and make available to entities de-
4 scribed in paragraph (2) information concerning
5 bacterial meningitis and the availability and effec-
6 tiveness of vaccinations for populations targeted by
7 the Advisory Committee on Immunization Practices
8 (an advisory committee established by the Secretary,
9 acting through the Director of the Centers for Dis-
10 ease Control and Prevention).

11 (2) ENTITIES.—An entity is described in this
12 paragraph if the entity—

13 (A) is—

14 (i) a college or university; or

15 (ii) any other facility with a setting
16 similar to a dormitory that houses age-ap-
17 propriate populations for whom the Advi-
18 sory Committee on Immunization Practices
19 recommends such a vaccination; and

20 (B) is determined appropriate by the Sec-
21 retary.

22 (b) DEVELOPMENT OF INFORMATION CONCERNING
23 HEPATITIS.—

24 (1) IN GENERAL.—The Secretary, in consulta-
25 tion with the Director of the Centers for Disease

1 Control and Prevention, shall develop and make
2 available to entities described in paragraph (2) infor-
3 mation concerning hepatitis A and B and the avail-
4 ability and effectiveness of vaccinations with respect
5 to such diseases.

6 (2) ENTITIES.—An entity is described in this
7 paragraph if the entity—

8 (A) is—

9 (i) a health care clinic that serves in-
10 dividuals diagnosed as being infected with
11 HIV or as having other sexually trans-
12 mitted diseases;

13 (ii) an organization or business that
14 counsels individuals about international
15 travel or who arranges for such travel;

16 (iii) a police, fire, or emergency med-
17 ical services organization that responds to
18 natural or man-made disasters or emer-
19 gencies;

20 (iv) a prison or other detention facil-
21 ity;

22 (v) a college or university; or

23 (vi) a public health authority or chil-
24 dren's health service provider in areas of
25 intermediate or high endemicity for hepa-

1 titis A as defined by the Centers for Dis-
2 ease Control and Prevention; and

3 (B) is determined appropriate by the Sec-
4 retary.

5 **SEC. 314. SUPPLY OF VACCINES.**

6 (a) IN GENERAL.—The Secretary of Health and
7 Human Services, acting through the Director of the Cen-
8 ters for Disease Control and Prevention, shall prioritize,
9 acquire, and maintain a supply of such prioritized vaccines
10 sufficient to provide vaccinations throughout a 6-month
11 period.

12 (b) PROCEEDS.—Any proceeds received by the Sec-
13 retary of Health and Human Services from the sale of vac-
14 cines contained in the supply described in subsection (a),
15 shall be available to the Secretary for the purpose of pur-
16 chasing additional vaccines for the supply. Such proceeds
17 shall remain available until expended.

18 (c) AUTHORIZATION OF APPROPRIATIONS.—There
19 are authorized to be appropriated for the purpose of car-
20 rying out subsection (a) such sums as may be necessary
21 for each of fiscal years 2003 through 2008.

22 **SEC. 315. COMMUNICATION.**

23 The Commissioner of Food and Drugs shall ensure
24 that vaccine manufacturers receive all forms of compliance

1 guidelines for vaccines and that such guidelines are kept
2 up to date.

3 **SEC. 316. FAST TRACK.**

4 The Commissioner of Food and Drugs shall issue reg-
5 ulations to revise the policies of the Food and Drug Ad-
6 ministration regarding fast-tracking and priority review
7 approval of vaccine products currently under development,
8 to allow for the use of new forms of existing vaccines in
9 cases where a determination is made that applying such
10 approvals is in the public health interest to address the
11 unmet need of strengthening the overall vaccine supply.

12 **SEC. 317. STUDY.**

13 (a) **IN GENERAL.**—The Secretary shall contract with
14 the Institute of Medicine of the National Academy of
15 Sciences or another independent and competent authority,
16 to conduct a study of the statutes, regulations, guidelines,
17 and compliance, inspection, and enforcement practices and
18 policies of the Department of Health and Human Services
19 and of the Food and Drug Administration that are appli-
20 cable to vaccines intended for human use that are in peri-
21 odic short supply in the United States.

22 (b) **REQUIREMENTS.**—The study under subsection
23 (a) shall include a review of the regulatory requirements,
24 guidelines, practices, and policies—

1 (1) for the development and licensing of vac-
 2 cines and the licensing of vaccine manufacturing fa-
 3 cilities;

4 (2) for inspections and other activities for main-
 5 taining compliance and enforcement of the require-
 6 ments applicable to such vaccines and facilities; and

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

9 (c) REPORT.—Not later than 6 months after the date
 10 of enactment of this Act, the Secretary shall submit to
 11 the Committee on Health, Education, Labor, and Pen-
 12 sions of the Senate and the Committee on Energy and
 13 Commerce of the House of Representatives a report that
 14 contains—

15 (1) the results of the study under subsection
 16 (a); and

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

20 **Subtitle B—Vaccine Injury**
 21 **Compensation Program**

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

23 **TABLE.**

24 Section 2114 of the Public Health Service Act (42
 25 U.S.C. 300aa–14) is amended—

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

3 “(1) The Secretary may promulgate regulations
4 to modify in accordance with paragraph (3) the Vac-
5 cine Injury Table. In promulgating such regulations,
6 the Secretary shall provide for notice and for at
7 least 60 days of public comment.”; and

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

10 **SEC. 322. EQUITABLE RELIEF.**

11 Section 2111(a)(2)(A) of the Public Health Service
12 Act (42 U.S.C. 300aa-11(a)(2)(A)) is amended by strik-
13 ing “No person” and all that follows through “and—” and
14 inserting the following: “No person may bring or maintain
15 a civil action against a vaccine administrator or manufac-
16 turer in a Federal or State court for damages arising
17 from, or equitable relief relating to, a vaccine-related in-
18 jury or death associated with the administration of a vac-
19 cine after October 1, 1988 and no such court may award
20 damages or equitable relief for any such vaccine-related
21 injury or death, unless the person proves past or present
22 physical injury and a timely petition has been filed in ac-
23 cordance with section 2116 for compensation under the
24 Program for such injury or death and—”.

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

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

5 (1) in subparagraph (B), by inserting “or (B)”
6 after “subparagraph (A)”;

7 (2) by redesignating subparagraph (B) as sub-
8 paragraph (C); and

9 (3) by inserting after subparagraph (A) the fol-
10 lowing:

11 “(B)(i) No parent or other third party may
12 bring or maintain a civil action against a vaccine ad-
13 ministrator or manufacturer in a Federal or State
14 court for damages or equitable relief relating to a
15 vaccine-related injury or death, including without
16 limitation damages for loss of consortium, society,
17 companionship, or services, loss of earnings, medical
18 or other expenses, and emotional distress, and no
19 court may award damages or equitable relief in such
20 an action, unless—

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

1 “(II) such parent or other third party is
2 the legal representative or spouse of the person
3 who sustained the underlying vaccine-related in-
4 jury or death, and such legal representative or
5 spouse has filed a timely derivative petition, in
6 accordance with section 2116; and

7 “(III)(aa) the United States Court of Fed-
8 eral Claims has issued judgment under section
9 2112 on the derivative petition, and such legal
10 representative or spouse elects under section
11 2121(a) to file a civil action; or

12 “(bb) such legal representative or spouse
13 elects to withdraw such derivative petition
14 under section 2121(b) or such petition is con-
15 sidered withdrawn under such section.

16 “(ii) Any civil action brought in accordance
17 with this subparagraph shall be subject to the stand-
18 ards and procedures set forth in sections 2122 and
19 2123, regardless of whether the action arises directly
20 from a vaccine-related injury or death associated
21 with the administration of a vaccine. In a case in
22 which the person who sustained the underlying vac-
23 cine-related injury or death upon which such legal
24 representative’s or spouse’s civil action is premised
25 elects under section 2121(a) to receive the com-

1 pensation awarded, such legal representative or
2 spouse may not bring a civil action for damages or
3 equitable relief, and no court may award damages or
4 equitable relief, for any injury or loss of the type set
5 forth in section 2115(a) or that might in any way
6 overlap with or otherwise duplicate compensation of
7 the type available under section 2115(a).”.

8 (b) ELIGIBLE PERSONS.—Section 2111(a)(9) of the
9 Public Health Service Act (42 U.S.C. 300aa–11(a)(9)) is
10 amended by striking the period and inserting “and to a
11 parent or other third party to the extent such parent or
12 other third party seeks damages or equitable relief relating
13 to a vaccine-related injury or death sustained by a person
14 who is qualified to file a petition for compensation under
15 the Program.”.

16 (c) PETITIONERS.—Section 2111(b) of the Public
17 Health Service Act (42 U.S.C. 300aa–11(b)) is amend-
18 ed—

19 (1) in paragraph (1)—

20 (A) in subparagraph (A), by striking “(B)”
21 and inserting “(C)”;

22 (B) by redesignating subparagraph (B) as
23 subparagraph (C); and

24 (C) by inserting after subparagraph (A)
25 the following:

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

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

5 “(ii) who has filed a petition for compensa-
6 tion under the Program (or whose legal rep-
7 resentative has filed such a petition as author-
8 ized in subparagraph (A));

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

12 (2) in paragraph (2)—

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

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

20 (d) DERIVATIVE PETITION CONTENTS.—Section
21 2111 of the Public Health Service Act (42 U.S.C. 300aa-
22 11) is amended—

23 (1) by redesignating subsections (d) and (e) as
24 subsections (e) and (f), respectively; and

1 (2) by inserting after subsection (c) the fol-
2 lowing:

3 “(d) DERIVATIVE PETITIONS.—

4 “(1) If the legal representative or spouse of the
5 person who sustained the vaccine-related injury or
6 death seeks compensation under the Program, such
7 legal representative or spouse shall file a timely de-
8 rivative petition for compensation under the Pro-
9 gram in accordance with this section.

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

11 “(A) except for records that are unavail-
12 able as described in subsection (c)(3), an affi-
13 davit, and supporting documentation, dem-
14 onstrating that—

15 “(i) the child or spouse of such person
16 has, in accordance with section 2111, time-
17 ly filed a petition for compensation for the
18 underlying vaccine-related injury or death
19 upon which such legal representative’s or
20 spouse’s derivative petition is premised;

21 “(ii) the derivative petition was timely
22 filed;

23 “(iii) such legal representative or
24 spouse suffered a loss compensable under
25 section 2115(b) as a result of the vaccine-

1 related injury or death sustained by such
2 person; and

3 “(iv) such legal representative or
4 spouse has not previously collected an
5 award or settlement of a civil action for
6 damages for such loss; and

7 “(B) records establishing such legal rep-
8 resentative’s or spouse’s relationship to the per-
9 son who sustained the vaccine-related injury or
10 death.”.

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

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

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

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

20 “(C) in the case of a derivative petition,
21 that the person who sustained the underlying
22 vaccine-related injury or death upon which the
23 derivative petition is premised has timely filed
24 a petition for compensation in accordance with
25 section 2111 and that, with respect to such un-

1 derlying petition, the special master or court
2 has made the findings specified in subpara-
3 graphs (A) and (B) of this paragraph.”.

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

6 (1) by redesignating subsections (b) through (j)
7 as subsections (c) through (k), respectively;

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

10 “(b) DERIVATIVE PETITIONS.—

11 “(1) IN GENERAL.—Compensation awarded
12 under the Program to a legal representative or
13 spouse who files a derivative petition under section
14 2111 for a loss sustained as a result of a vaccine-
15 related injury or death sustained by such petitioner’s
16 child or spouse shall only include compensation for
17 any loss of consortium, society, companionship, or
18 services, in an amount not to exceed the lesser of
19 \$250,000 or the total amount of compensation
20 awarded to the person who sustained the underlying
21 vaccine-related injury or death.

22 “(2) MULTIPLE INDIVIDUALS.—Where more
23 than 1 person files a derivative petition under sec-
24 tion 2111 for losses sustained as a result of the
25 same underlying vaccine-related injury or death, the

1 aggregate compensation to such persons shall not
2 exceed the lesser of \$250,000, or the total amount
3 of compensation awarded to the person who sus-
4 tained the underlying vaccine-related injury or
5 death. The special master or court shall apportion
6 compensation among the derivative petitioners in
7 proportion to their respective losses.”;

8 (3) in subsection (e)(2), as so redesignated by
9 paragraph (1)—

10 (A) by striking “(2) and (3)” and inserting
11 “(2), (3), (4), (5), and (6)”;

12 (B) by inserting “and subsection (b),”
13 after “(a),”;

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

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

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

21 (B) in paragraph (2), by inserting “, or to
22 a legal representative or spouse of a person who
23 sustained a vaccine-related injury or death,”
24 after “death”;

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

4 **SEC. 324. JURISDICTION TO DISMISS ACTIONS IMPROP-**
5 **ERLY BROUGHT.**

6 Section 2111(a)(3) of the Public Health Service Act
7 (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the
8 end the following: “If any civil action which is barred
9 under subparagraph (A) or (B) of paragraph (2) is filed
10 or maintained in a State court, or any vaccine adminis-
11 trator or manufacturer is made a party to any civil action
12 brought in State court (other than a civil action which
13 may be brought under paragraph (2)) for damages or eq-
14 uitable relief for a vaccine-related injury or death associ-
15 ated with the administration of a vaccine after October
16 1, 1988, the civil action may be removed at any time be-
17 fore final judgment by the defendant or defendants to the
18 United States Court of Federal Claims. Once removed, the
19 United States Court of Federal Claims shall have jurisdic-
20 tion solely for the purpose of adjudicating whether the civil
21 action should be dismissed pursuant to this section. If the
22 United States Court of Federal Claims determines that
23 the civil action should not be dismissed, the court shall
24 remand the action to the State Court. The notice required
25 by section 1446 of title 28, United States Code, shall be

1 filed with the United States Court of Federal Claims, and
 2 that court shall, except as otherwise provided in this sec-
 3 tion, proceed in accordance with sections 1446 through
 4 1451 of title 28, United States Code.”.

5 **SEC. 325. CLARIFICATION OF WHEN INJURY IS CAUSED BY**
 6 **FACTOR UNRELATED TO ADMINISTRATION**
 7 **OF VACCINE.**

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

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

12 (2) by inserting “(without regard to whether
 13 the cause of the infection, toxin, trauma, structural
 14 lesion, genetic disorder, or metabolic disturbance is
 15 known)” after “metabolic disturbances”; and

16 (3) by striking “but” and inserting “and”.

17 **SEC. 326. INCREASE IN AWARD IN THE CASE OF A VACCINE-**
 18 **RELATED DEATH AND FOR PAIN AND SUF-**
 19 **FERING.**

20 (a) IN GENERAL.—Section 2115(a) of the Public
 21 Health Service Act (42 U.S.C. 300aa-15(a)) is amend-
 22 ed—

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

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

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

10 **SEC. 327. BASIS FOR CALCULATING PROJECTED LOST**
11 **EARNINGS.**

12 Section 2115(a)(3)(B) of the Public Health Service
13 Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by strik-
14 ing “loss of earnings” and all that follows and inserting
15 the following: “loss of earnings determined on the basis
16 of the annual estimate of the average (mean) gross weekly
17 earnings of wage and salary workers age 18 and over (ex-
18 cluding the incorporated self-employed) in the private non-
19 farm sector (which includes all industries other than agri-
20 cultural production crops and livestock), as calculated an-
21 nually by the Bureau of Labor Statistics from the quarter
22 sample data of the Current Population Survey, or as cal-
23 culated by such similar method as the Secretary may pre-
24 scribe by regulation, less appropriate taxes and the aver-

1 age cost of a health insurance policy, as determined by
2 the Secretary.”.

3 **SEC. 328. ALLOWING COMPENSATION FOR FAMILY COUN-**
4 **SELING EXPENSES AND EXPENSES OF ESTAB-**
5 **LISHING AND MAINTAINING GUARDIANSHIP.**

6 (a) FAMILY COUNSELING EXPENSES IN POST-1988
7 CASES.—Section 2115(a) of the Public Health Service Act
8 (42 U.S.C. 300aa–15(a)) is amended by adding at the end
9 the following:

10 “(5) Actual unreimbursable expenses that have
11 been or will be incurred for family counseling as is
12 determined to be reasonably necessary and that re-
13 sult from the vaccine-related injury from which the
14 petitioner seeks compensation.”.

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

20 “(6) Actual unreimbursable expenses that have
21 been, or will be reasonably incurred to establish and
22 maintain a guardianship or conservatorship for an
23 individual who has suffered a vaccine-related injury,
24 including attorney fees and other costs incurred in

1 a proceeding to establish and maintain such guard-
2 ianship or conservatorship.”.

3 (c) CONFORMING AMENDMENT FOR CASES FROM
4 1988 AND EARLIER.—Section 2115 of the Public Health
5 Service Act (42 U.S.C. 300aa–15) is amended in sub-
6 section (c), as so redesignated by section 323(f)—

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

9 (2) in paragraph (3), by striking “(e)” and in-
10 sserting “(f)”;

11 (3) by redesignating paragraph (3) as para-
12 graph (5); and

13 (4) by inserting after paragraph (2), the fol-
14 lowing:

15 “(3) family counseling expenses (as provided for
16 in paragraph (5) of subsection (a));

17 “(4) expenses of establishing and maintaining
18 guardianships (as provided for in paragraph (6) of
19 subsection (a)); and”.

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

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

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

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

5 “(B) the special master or court has deter-
6 mined that the petitioner is entitled to com-
7 pensation under the Program;

8 “(C) the award is limited to other costs
9 (within the meaning of paragraph (1)(B)) in-
10 curred in the proceeding;

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

13 “(E) the petitioner provides documentation
14 verifying the expenditure of the amount for
15 which compensation is sought.”.

16 **SEC. 330. PROCEDURE FOR PAYING ATTORNEYS’ FEES.**

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

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

25 “(A) the petitioner expressly consents; or

1 “(B) the special master or court deter-
2 mines, after affording to the Secretary and to
3 all interested persons the opportunity to submit
4 relevant information, that—

5 “(i) the petitioner cannot be located
6 or refuses to respond to a request by the
7 special master or court for information,
8 and there is no practical alternative means
9 to ensure that the attorney will be reim-
10 bursed for such fees or costs expeditiously;
11 or

12 “(ii) there are otherwise exceptional
13 circumstances and good cause for paying
14 such fees or costs solely to the petitioner’s
15 attorney.”.

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

17 (a) **GENERAL RULE.**—Section 2116(a) of the Public
18 Health Service Act (42 U.S.C. 300aa–16(a)) is amend-
19 ed—

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

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

24 (b) **CLAIMS BASED ON REVISIONS TO TABLE.**—Sec-
25 tion 2116 of the Public Health Service Act (42 U.S.C.

1 300aa–16) is amended by striking subsection (b) and in-
2 serting the following:

3 “(b) EFFECT OF REVISED TABLE.—If at any time
4 the Vaccine Injury Table is revised and the effect of such
5 revision is to make an individual eligible for compensation
6 under the program, where, before such revision, such indi-
7 vidual was not eligible for compensation under the pro-
8 gram, or to significantly increase the likelihood that an
9 individual will be able to obtain compensation under the
10 program, such person may, and shall before filing a civil
11 action for equitable relief or monetary damages, notwith-
12 standing section 2111(b)(2), file a petition for such com-
13 pensation if—

14 “(1) the vaccine-related death or injury with re-
15 spect to which the petition is filed occurred not more
16 than 10 years before the effective date of the revi-
17 sion of the table; and

18 “(2) either—

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

21 “(B) the date of the occurrence of the first
22 symptom or manifestation of onset of the injury
23 occurred more than 4 years before the petition
24 is filed, and the petition is filed not more than

1 2 years after the effective date of the revision
2 of the table.”.

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

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

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

14 “(2) 60 days after the date on which the special
15 master has issued a decision pursuant to section
16 2112(d)(3) on the underlying claim of the person
17 who sustained the vaccine-related injury or death
18 upon which the derivative petition is premised.”.

19 (d) TIMELY RESOLUTIONS OF CLAIMS.—

20 (1) SPECIAL MASTER DECISION.—Section
21 2112(d)(3)(A) of the Public Health Service Act (42
22 U.S.C. 300aa–12(d)(3)(A)) is amended by adding at
23 the end the following: “For purposes of this sub-
24 paragraph, the petition shall be deemed to be filed
25 on the date on which the special master issues a cer-

1 tificate of completeness, indicating that all petition
2 contents and supporting documents required under
3 section 2111(c) and, when applicable, section
4 2111(d) and the Vaccine Rules of the United States
5 Court of Federal Claims, such as an affidavit and
6 supporting documentation, have been served on the
7 Secretary and filed with the clerk of the United
8 States Court of Federal Claims.”.

9 (2) DERIVATIVE PETITIONS.—Section
10 2112(d)(3)(C) of the Public Health Service Act (42
11 U.S.C. 300aa–12(d)(3)(C)) is amended by adding at
12 the end the following: “With respect to any deriva-
13 tive petition filed under section 2111, the period of
14 time during which the petition for compensation for
15 the underlying vaccine-related injury or death upon
16 which such derivative petition is premised is pending
17 shall be treated as a suspension for purposes of this
18 subparagraph.”.

19 (3) COURT OF FEDERAL CLAIMS DECISION.—
20 Section 2121(b) of the Public Health Service Act
21 (42 U.S.C. 300aa–21(b)) is amended by adding at
22 the end the following: “For purposes of this sub-
23 section, the petition shall be deemed to be filed on
24 the date on which the special master issues a certifi-
25 cate of completeness, indicating that all petition con-

1 tents and supporting documents required under sec-
2 tion 2111(c) and, when applicable, section 2111(d)
3 and the Vaccine Rules of the United States Court of
4 Federal Claims, such as an affidavit and supporting
5 documentation, have been served on the Secretary
6 and filed with the clerk of the United States Court
7 of Federal Claims.”.

8 **SEC. 332. ADVISORY COMMISSION ON CHILDHOOD VAC-**
9 **CINES.**

10 (a) SELECTION OF PERSONS INJURED BY VACCINES
11 AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of the
12 Public Health Service Act (42 U.S.C. 300aa–19(a)(1)(B))
13 is amended by striking “of whom” and all that follows
14 and inserting the following: “of whom 1 shall be the legal
15 representative of a child who has suffered a vaccine-re-
16 lated injury or death, and at least 1 other shall be either
17 the legal representative of a child who has suffered a vac-
18 cine-related injury or death or an individual who has per-
19 sonally suffered a vaccine-related injury.”.

20 (b) MANDATORY MEETING SCHEDULE ELIMI-
21 NATED.—Section 2119(c) of the Public Health Service Act
22 (42 U.S.C. 300aa–19(c)) is amended by striking “not less
23 often than four times per year and”.

1 **SEC. 333. CLARIFICATION OF STANDARDS OF RESPONSI-**
2 **BILITY.**

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

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

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

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

19 (1) by inserting “or equitable relief” after “for
20 damages”; and

21 (2) by inserting “or relief” after “which dam-
22 ages”.

23 (e) PAST OR PRESENT PHYSICAL INJURY.—Section
24 2122 of the Public Health Service Act (42 U.S.C. 300aa–
25 22) is amended—

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

3 (2) by inserting after subsection (c) the fol-
4 lowing:

5 “(d) PAST OR PRESENT PHYSICAL INJURY.—No vac-
6 cine manufacturer or vaccine administrator shall be liable
7 in a civil action brought after October 1, 1988, for equi-
8 table or monetary relief absent proof of past or present
9 physical injury from the administration of a vaccine, nor
10 shall any vaccine manufacturer or vaccine administrator
11 be liable in any such civil action for claims of medical mon-
12 itoring, or increased risk of harm.”.

13 **SEC. 334. CLARIFICATION OF DEFINITION OF MANUFAC-**
14 **TURER.**

15 Section 2133(3) of the Public Health Service Act (42
16 U.S.C. 300aa-33(3)) is amended—

17 (1) in the first sentence, by striking “under its
18 label any vaccine set forth in the Vaccine Injury
19 Table” and inserting “any vaccine set forth in the
20 Vaccine Injury table, including any component or in-
21 gredient of any such vaccine”; and

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

1 **SEC. 335. CLARIFICATION OF DEFINITION OF VACCINE-RE-**
2 **LATED INJURY OR DEATH.**

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

9 **SEC. 336. CLARIFICATION OF DEFINITION OF VACCINE AND**
10 **DEFINITION OF PHYSICAL INJURY.**

11 Section 2133 of the Public Health Service Act (42
12 U.S.C. 300aa-33) is amended by adding at the end the
13 following:

14 “(7) The term ‘vaccine’ means any preparation or
15 suspension, including a preparation or suspension con-
16 taining an attenuated or inactive microorganism or
17 subunit thereof or toxin, developed or administered to
18 produce or enhance the body’s immune response to a dis-
19 ease or diseases and includes all components and ingredi-
20 ents listed in the vaccine’s product license application and
21 product label.

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

1 **SEC. 337. AMENDMENTS TO VACCINE INJURY COMPENSA-**
2 **TION TRUST FUND.**

3 (a) EXPANSION OF COMPENSATED LOSS.—Section
4 9510(c)(1)(A) of the Internal Revenue Code of 1986 is
5 amended by inserting “, or related loss,” after “death”.

6 (b) INCREASE IN LIMIT ON ADMINISTRATIVE EX-
7 PENSES.—Subparagraph (B) of section 9510(c)(1) of the
8 Internal Revenue Code of 1986 is amended—

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

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

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

16 “(ii) 125 percent of the base amount
17 for any fiscal year in which the total num-
18 ber of claims pending under such subtitle
19 exceeds 150 percent of the average number
20 of claims pending in the preceding 5 years,

21 “(iii) 175 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 200 percent of the average number
25 of claims pending in the preceding 5 years,

1 “(iv) 225 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 250 percent of the average number
5 of claims pending in the preceding 5 years,
6 or

7 “(v) 275 percent of the base amount
8 for any fiscal year in which the total num-
9 ber of claims pending under such subtitle
10 exceeds 300 percent of the average number
11 of claims pending in the preceding 5
12 years.”.

13 (c) CONFORMING AMENDMENT.—Section
14 9510(c)(1)(A) of the Internal Revenue Code of 1986 is
15 amended by striking “October 18, 2000” and inserting
16 “the date of enactment of the Improved Vaccine Afford-
17 ability and Availability Act”.

18 **SEC. 338. ONGOING REVIEW OF CHILDHOOD VACCINE**
19 **DATA.**

20 Part C of title XXI of the Public Health Service Act
21 (42 U.S.C. 300a–25 et seq.) is amended by adding at the
22 end the following:

1 **“SEC. 2129A. ONGOING REVIEW OF CHILDHOOD VACCINE**
2 **DATA.**

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

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

20 “(c) FAILURE TO ENTER INTO CONTRACT.—If the
21 Secretary and the Institute of Medicine are unable to
22 enter into the contract described in subsection (a), the
23 Secretary shall enter into a contract with another qualified
24 nongovernmental scientific organization for the purposes
25 described in subsections (a) and (b).

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

5 **SEC. 339. PENDING ACTIONS.**

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

12 **SEC. 340. REPORT.**

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

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