

**Calendar No. 53**108<sup>TH</sup> CONGRESS  
1<sup>ST</sup> 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.

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**IN THE SENATE OF THE UNITED STATES**

MARCH 11, 2003

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

MARCH 25, 2003

Reported by Mr. GREGG, with an amendment

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

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**A BILL**

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

**★(Star Print)**

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

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

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

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

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

Sec. 1. Short title; table of contents.

**TITLE I—PROTECTION FOR SMALLPOX EMERGENCY PERSONNEL**

Sec. 101. Short title.

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

**TITLE II—PROJECT BIOSHIELD**

Sec. 201. Short title.

Sec. 202. Biomedical countermeasure research and development authorities.

Sec. 203. Biomedical countermeasures procurement.

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

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

**TITLE III—IMPROVED VACCINE AFFORDABILITY AND AVAILABILITY**

Sec. 301. Short title.

**Subtitle A—State Vaccine Grants**

Sec. 311. Availability of influenza vaccine.

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

Sec. 313. Immunization awareness.

Sec. 314. Supply of vaccines.

Sec. 315. Communication.

Sec. 316. Fast track.

Sec. 317. Study.

**Subtitle B—Vaccine Injury Compensation Program**

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

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

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

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

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

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

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

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

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

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

7                   “(A) who is—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14           “(b) DETERMINATION OF ELIGIBILITY.—

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

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

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

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

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

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

17 “(3) DETERMINATION OF CAUSATION.—

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

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

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

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

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

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

22          “(5) REVIEW OF DETERMINATION.—

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

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

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

9           “(c) COUNTERMEASURE INJURY TABLE.—

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

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

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

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

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

3 “(d) ~~MEDICAL BENEFITS.~~—

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

14 “(2) ~~LIMITATIONS.~~—

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

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

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

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

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

12          “(2) AMOUNT OF COMPENSATION.—

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

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

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

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

5           ~~“(3) LIMITATIONS.—~~

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

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

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

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

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

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

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

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

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

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

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

24       “(5) LIMITATIONS.—

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

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

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

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

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

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

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

9 “(g) ADMINISTRATION.—

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

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

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

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

4 “(i) RELATIONSHIP TO OTHER LAWS.—

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

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

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

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

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

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

## 17 **TITLE II—PROJECT BIOSHIELD**

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

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

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

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

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

3 **“(a) IN GENERAL.—**

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

8 **“(2) IMPLEMENTATION.—**

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

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

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

1           ~~“(3) INTERAGENCY COOPERATION.—~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22           “(d) ~~FACILITIES AUTHORITY.~~—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 “(f) STREAMLINED PERSONNEL AUTHORITY.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 “(A) INTERAGENCY AGREEMENTS.—

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

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

8           “(ii) FOR ADMINISTRATIVE COSTS.—

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

18          “(B) PROCUREMENT.—

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

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

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

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

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

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

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

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

12 “(III) STORAGE BY VENDOR.—

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

1                   “(IV) CONTRACT DURATION.—

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

6                   “(V) TERMINATION FOR NON-

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

20                  “(iii) AVAILABILITY OF SIMPLIFIED

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4           ~~“(6) INTERAGENCY COOPERATION.—~~

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

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

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

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

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

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

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

16 “(B) BIOMEDICAL COUNTERMEASURE.—

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

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

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

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

10 ~~“(8) APPROPRIATIONS.—~~

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

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

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

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

10           “(iii) administrative costs.”

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

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

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

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

1 “(b) DECLARATION OF EMERGENCY.—

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

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

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

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

23 “(2) TERMINATION OF DECLARATION.—

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

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

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

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

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

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

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

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

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

10           “(i) such disease or condition; or

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

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

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

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

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

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

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

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

16       “(e) CONDITIONS OF AUTHORIZATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(f) DURATION OF AUTHORIZATION.—

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

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

21 “(g) REVOCATION OF AUTHORIZATION.—

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

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

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

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

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

12          “(i) RECORDKEEPING.—

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

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

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

1 a regulation promulgated under this section;  
2 and

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

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

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

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

22 “(j) CIVIL MONETARY PENALTIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13           (1) in subsection (c)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14           “(4) LIMITED ANTITRUST EXEMPTION.—

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

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

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

5           “(C) APPLICATION OF LAWS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(1) DEFINITIONS.—In this section:

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

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

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

17 “(2) COVERED ACTIVITIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 **Subtitle A—State Vaccine Grants**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22           (A) is—

23                   (i) a college or university; or

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

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

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

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

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

17                 (A) is—

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

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

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

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

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

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

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

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

7 **SEC. 315. COMMUNICATION.**

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

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

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

21 **SEC. 317. STUDY.**

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

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

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

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

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

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

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

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

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

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

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

#### 7           **TABLE.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4           (1) in paragraph (1)—

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

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

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

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

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

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

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

22           (2) in paragraph (2)—

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

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

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

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

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

12          “(d) DERIVATIVE PETITIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20       “(b) DERIVATIVE PETITIONS.—

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

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

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

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

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

21 “(2), (3), (4), (5), and (6)”; and

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

23 after “(a),”;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(A) the petitioner expressly consents; or

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

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

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

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

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

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

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

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

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

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

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

2  
3 “(2) either—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3           (2) by inserting “or relief” after “which dam-  
4           ages”.

5           (e) **PAST OR PRESENT PHYSICAL INJURY.**—Section  
6           2122 of the Public Health Service Act (42 U.S.C. 300aa-  
7           22) is amended—

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

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

12          “(d) **PAST OR PRESENT PHYSICAL INJURY.**—No vac-  
13          cine manufacturer or vaccine administrator shall be liable  
14          in a civil action brought after October 1, 1988, for equi-  
15          table or monetary relief absent proof of past or present  
16          physical injury from the administration of a vaccine; nor  
17          shall any vaccine manufacturer or vaccine administrator  
18          be liable in any such civil action for claims of medical mon-  
19          itoring, or increased risk of harm.”.

20          **SEC. 334. CLARIFICATION OF DEFINITION OF MANUFAC-**  
21          **TURER.**

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

24          (1) in the first sentence, by striking “under its  
25          label any vaccine set forth in the Vaccine Injury

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2 **DATA.**

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

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

7 **DATA.**

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

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

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

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

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

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

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

16 **SEC. 340. REPORT.**

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

1 **SECTION 1. SHORT TITLE.**

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

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

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

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

11 *“(a) IN GENERAL.—*

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

16 *“(2) IMPLEMENTATION.—*

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

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

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

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

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

24            “(3) *INTERAGENCY COOPERATION.—*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6                   (2) in subsection (c)—

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

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

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

17                   (4) in subsection (e)—

18                           (A) in paragraph (1)—

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

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

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

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

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

15                  (5) in subsection (f)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21           “(g) *INTERAGENCY COOPERATION.*—

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

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

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

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

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

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

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

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

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

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

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

23           “(i) *APPROPRIATIONS.*—

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

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

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

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

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

19            “(C) *administrative costs.*”

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

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

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

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

11 “(b) *DECLARATION OF EMERGENCY.*—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7           “(8) *The Secretary shall, to the extent feasible*  
8           *and appropriate given the circumstances of the emer-*  
9           *gency, impose requirements for the monitoring and*  
10           *reporting of adverse events associated with use of the*  
11           *product.*

12           “(f) *DURATION OF AUTHORIZATION.—*

13           “(1) *IN GENERAL.—Except as provided in para-*  
14           *graph (2), an authorization under this section shall*  
15           *be effective until the earlier of the termination of the*  
16           *declaration under subsection (b) or a revocation*  
17           *under subsection (g).*

18           “(2) *CONTINUED USE AFTER END OF EFFECTIVE*  
19           *PERIOD.—An authorization shall continue to be effec-*  
20           *tive for continued use with respect to patients to*  
21           *whom it was administered during the period de-*  
22           *scribed by paragraph (1), to the extent found nec-*  
23           *essary by such patients’ attending physicians.*

24           “(g) *REVOCATION OF AUTHORIZATION.—*

1           “(1) *REVIEW.*—*The Secretary shall periodically*  
2           *review the circumstances and the appropriateness of*  
3           *an authorization under this section.*

4           “(2) *REVOCAION.*—*The Secretary may revoke*  
5           *an authorization under this section if, in the Sec-*  
6           *retary’s unreviewable discretion—*

7                   “(A) *the conditions for such an authoriza-*  
8                   *tion are no longer met; or*

9                   “(B) *other circumstances make such revoca-*  
10                  *tion appropriate.*

11          “(h) *PUBLICATION.*—*The Secretary shall promptly*  
12          *publish in the Federal Register, and provide to the appro-*  
13          *priate committees of Congress, a notice of each authoriza-*  
14          *tion, and each termination or revocation of an authoriza-*  
15          *tion, under this section.*

16          “(i) *RECORDKEEPING.*—

17                  “(1) *IN GENERAL.*—*The Secretary may require*  
18                  *persons, including a person who holds an authoriza-*  
19                  *tion under this section, or who manufactures, distrib-*  
20                  *utes, prescribes, or administers a product that is the*  
21                  *subject of such an authorization, to establish and*  
22                  *maintain—*

23                          “(A) *data that is obtained from such activ-*  
24                          *ity and that pertains to the effectiveness or safety*  
25                          *of such product;*

1           “(B) *such records as are necessary to deter-*  
2 *mine, or facilitate a determination, whether*  
3 *there may be any violation of this section or of*  
4 *a regulation promulgated under this section; and*

5           “(C) *such additional records as the Sec-*  
6 *retary may determine necessary.*

7           “(2) *ACCESS TO RECORDS BY SECRETARY.—*

8           “(A) *SAFETY AND EFFECTIVENESS INFOR-*  
9 *MATION.—The Secretary may require a person*  
10 *who holds an authorization under this section, or*  
11 *who manufactures, distributes, prescribes, or ad-*  
12 *ministers a product that is the subject of such an*  
13 *authorization to provide to the Secretary all*  
14 *data that is obtained from such activity and that*  
15 *pertains to the safety or effectiveness of such*  
16 *product.*

17           “(B) *OTHER INFORMATION.—Every person*  
18 *required under this section to establish or main-*  
19 *tain records, and every person in charge or cus-*  
20 *tody of such records, shall, upon request by the*  
21 *Secretary, permit the Secretary at all reasonable*  
22 *times to have access to, to copy, and to verify*  
23 *such records.*

24           “(j) *CIVIL MONETARY PENALTIES.—*

1           “(1) *IN GENERAL.*—A person who violates a re-  
2           *quirement of this section or of a regulation or order*  
3           *promulgated pursuant to this section shall be subject*  
4           *to a civil money penalty of not more than \$100,000*  
5           *in the case of an individual, and not more than*  
6           *\$250,000 in the case of any other person, for each vio-*  
7           *lation, not to exceed \$1,000,000 for all such violations*  
8           *adjudicated in a single proceeding.*

9           “(2) *ASSESSMENT OF CIVIL PENALTIES.*—Para-  
10          *graphs (3), (4), and (5) of section 303(g) shall apply*  
11          *to a civil penalty under this subsection, and ref-*  
12          *erences in such paragraphs to ‘paragraph (1) or (2)’*  
13          *shall, for purposes of this subsection, be deemed to*  
14          *refer to paragraph (1) of this subsection.*

15          “(k) *ACTIONS COMMITTED TO AGENCY DISCRETION.*—  
16          *Actions under the authority of this section by the Secretary,*  
17          *by the Secretary of Defense, or by the Secretary of Home-*  
18          *land Security are committed to agency discretion.*

19          “(l) *REGULATIONS.*—The Secretary may promulgate  
20          *regulations to implement this section.*

21          “(m) *CONSTRUCTION.*—Nothing in this section shall be  
22          *construed to impair or otherwise affect—*

23                  “(1) *the authority of the President as Com-*  
24          *mander in Chief of the Armed Forces of the United*

1 *States under article II, section 2 of the United States*  
2 *Constitution; or*

3 *“(2) the authority of the Secretary of Defense*  
4 *with respect to the Department of Defense, including*  
5 *the armed forces, under other provisions of Federal*  
6 *law.*

7 *“(n) APPLICATION TO MEMBERS OF ARMED*  
8 *FORCES.—*

9 *“(1) WAIVER OF REQUIREMENT RELATING TO*  
10 *OPTION TO REFUSE.—In the case of the administra-*  
11 *tion of a countermeasure to members of the armed*  
12 *forces, a requirement, under subsection (e)(2), de-*  
13 *signed to ensure that individuals are informed of an*  
14 *option to accept or refuse administration of a prod-*  
15 *uct, may be waived by the President if the President*  
16 *determines, in writing, that complying with such re-*  
17 *quirement is not feasible, is contrary to the best inter-*  
18 *ests of the members affected, or is not in the interests*  
19 *of national security.*

20 *“(2) EFFECT ON STATUTE PERTAINING TO INVES-*  
21 *TIGATIONAL NEW DRUGS.—In the case of an author-*  
22 *ization based on a determination by the Secretary of*  
23 *Defense under subsection (b)(1)(B), section 1107 of*  
24 *title 10, United States Code, shall not apply to use*  
25 *of a product that is the subject of such authorization,*

1        *within the scope of such authorization and while such*  
2        *authorization is effective.*

3        “(o) *RELATION TO OTHER PROVISIONS.—If a product*  
4        *is the subject of an authorization under this section, the*  
5        *use of such product within the scope of the authorization—*

6                *“(1) shall not be subject to any requirements*  
7                *pursuant to section 505(i) or 520(g); and*

8                *“(2) shall not be subject to any requirements oth-*  
9                *erwise applicable to clinical investigations pursuant*  
10               *to other provisions of this Act.”.*

11        (b) *PROHIBITED ACTS.—Section 301 of the Federal*  
12        *Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-*  
13        *ed—*

14                (1) *in subsection (e)—*

15                        (A) *by striking “504, 703” and inserting*  
16                        *“504, 564, 703”; and*

17                        (B) *by striking “or 519” and inserting*  
18                        *“519, or 564”; and*

19                (2) *by adding at the end the following:*

20                *“(hh)(1) Promotion or use of a product that is the sub-*  
21        *ject of an authorization under section 564 other than as*  
22        *stated in the authorization, or other than during the period*  
23        *described by section 564(g), unless such promotion or use*  
24        *is permitted under another provision of this Act.*



1 *Health Service Act (42 U.S.C. 233(p)(2)) is amended by*  
2 *adding at the end the following:*

3                   “(D) *ACTS AND OMISSIONS DEEMED TO BE*  
4                   *WITHIN SCOPE OF EMPLOYMENT.—*

5                   “(i) *IN GENERAL.—In the case of a*  
6                   *claim arising out of alleged transmission of*  
7                   *vaccinia from an individual described in*  
8                   *clause (ii), acts or omissions by such indi-*  
9                   *vidual shall be deemed to have been taken*  
10                   *within the scope of such individual’s office*  
11                   *or employment for purposes of—*

12                   “(I) *subsection (a); and*

13                   “(II) *section 1346(b) and chapter*  
14                   *171 of title 28, United States Code.*

15                   “(ii) *INDIVIDUALS TO WHOM DEEMING*  
16                   *APPLIES.—An individual is described by*  
17                   *this clause if—*

18                   “(I) *vaccinia vaccine was admin-*  
19                   *istered to such individual as provided*  
20                   *by paragraph (2)(B); and*

21                   “(II) *such individual was within*  
22                   *a category of individuals covered by a*  
23                   *declaration under paragraph*  
24                   *(2)(A)(i)(I).”.*



1           “(II) a determination was made  
2           as to whether, or under what cir-  
3           cumstances, an individual should re-  
4           ceive a covered countermeasure;

5           “(III) the immediate site of ad-  
6           ministration of a covered counter-  
7           measure was monitored, managed, or  
8           cared for; or

9           “(IV) an evaluation was made of  
10          whether the administration of a cov-  
11          ered countermeasure was effective;”;

12          (3) in clause (iii) by striking “or”;

13          (4) by striking clause (iv) and inserting the fol-  
14          lowing:

15               “(iv) a State, a political subdivision of  
16               a State, or an agency or official of a State  
17               or of such a political subdivision, if such  
18               State, subdivision, agency, or official has es-  
19               tablished requirements, provided policy  
20               guidance, or supplied technical or scientific  
21               advice or assistance with respect to admin-  
22               istration of such countermeasures;

23               “(v) in the case of a claim arising out  
24               of alleged transmission of vaccinia from an  
25               individual—

1           “(I) the individual who allegedly  
2 transmitted the vaccinia, if vaccinia  
3 vaccine was administered to such indi-  
4 vidual as provided by paragraph  
5 (2)(B) and such individual was within  
6 a category of individuals covered by a  
7 declaration under paragraph  
8 (2)(A)(i)(I); or

9           “(II) an entity that employs an  
10 individual described by clause (I) or  
11 where such individual has privileges to  
12 provide health care;

13           “(vi) an official, agent, or employee of  
14 a person described in clause (i), (ii), (iii),  
15 or (iv);

16           “(vii) a contractor of, or a volunteer  
17 working for, a person described in clause  
18 (i), (ii), or (iv), if the contractor or volun-  
19 teer performs a function for which a person  
20 described in clause (i), (ii), or (iv) is a cov-  
21 ered person; or

22           “(viii) an individual who has privi-  
23 leges to provide health care under the aus-  
24 pices of an entity described in clause (ii) or  
25 (v)(II).”.

1           (g) *AMENDMENT TO DEFINITION OF QUALIFIED*  
 2 *PERSON.*—Section 224(p)(7)(C) of the Public Health Serv-  
 3 *ice Act (42 U.S.C. 233(p)(7)(C)) is amended—*

4                   (1) *by striking “who is authorized to” and in-*  
 5 *serting the following: “who—*

6                                   *“(i) is authorized to”;*

7                   (2) *by striking the period and inserting “; or”;*

8                   *and*

9                   (3) *by adding at the end the following:*

10                                   *“(ii) is otherwise authorized by the*  
 11                                   *Secretary to administer such counter-*  
 12                                   *measure.”.*

13           (h) *DEFINITION OF “ARISING OUT OF ADMINISTRA-*  
 14 *TION OF A COVERED COUNTERMEASURE”.*—Section  
 15 *224(p)(7) of the Public Health Service Act (42 U.S.C.*  
 16 *233(p)(7)) is amended by adding at the end the following:*

17                                   *“(D) ARISING OUT OF ADMINISTRATION OF*  
 18                                   *A COVERED COUNTERMEASURE.—*

19                                   *“(i) IN GENERAL.—The term ‘arising*  
 20                                   *out of administration of a covered counter-*  
 21                                   *measure’, when used with respect to a claim*  
 22                                   *or liability, includes, except as provided in*  
 23                                   *clause (ii), a claim or liability arising out*  
 24                                   *of—*

1           “(I) *determining whether, or*  
2           *under what conditions, an individual*  
3           *should receive a covered counter-*  
4           *measure;*

5           “(II) *obtaining informed consent*  
6           *of an individual to the administration*  
7           *of a covered countermeasure;*

8           “(III) *monitoring, management,*  
9           *or care of an immediate site of admin-*  
10           *istration of a covered countermeasure,*  
11           *or evaluation of whether the adminis-*  
12           *tration of the countermeasure has been*  
13           *effective; or*

14           “(IV) *transmission of vaccinia*  
15           *virus by an individual to whom*  
16           *vaccinia vaccine was administered as*  
17           *provided by paragraph (2)(B).*

18           “(ii) *EXCEPTION.—Such term shall not*  
19           *include a claim or liability arising out of*  
20           *care for or treatment of complications aris-*  
21           *ing out of the administration of the counter-*  
22           *measure.”.*

23           (i)           *TECHNICAL           CORRECTION.—Section*  
24           *224(p)(2)(A)(ii) of the Public Health Service Act (42*

1 *U.S.C. 233(p)(2)(A)(ii)* is amended by striking “para-  
2 *graph (8)(A)*” and inserting “*paragraph (7)(A)*”.

3 (j) *EFFECTIVE DATE.*—*This amendments made by this*  
4 *section shall take effect as if enacted on November 25, 2002.*

5 ***SEC. 6. GAO REPORT.***

6 *Not later than 4 years after the date of enactment of*  
7 *this Act, the Comptroller General of the United States shall*  
8 *submit to the appropriate committees of Congress a report*  
9 *that—*

10 (1) *describes the activities conducted under the*  
11 *authorities provided for in section 409J(b)(1) of the*  
12 *Public Health Service Act (as added by section 2) and*  
13 *section 319A-1(f)(3) and (4) of such Act (as added by*  
14 *section 3);*

15 (2) *identifies any procurements that would have*  
16 *been prohibited except for the authorities provided in*  
17 *the sections described in paragraph (1); and*

18 (3) *assesses the adequacy of the internal controls*  
19 *established by the Secretary of Health and Human*  
20 *Services regarding procurements made under the au-*  
21 *thorities provided for in the sections described in*  
22 *paragraph (1).*

**Calendar No. 53**

108TH CONGRESS  
1ST SESSION

**S. 15**

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**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.

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MARCH 25, 2003

Reported with an amendment