

# Union Calendar No. 98

108TH CONGRESS  
1ST SESSION

# H. R. 2122

**[Report No. 108–147, Parts I, II, and III]**

To enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2003

Mr. TAUZIN (for himself, Mr. DINGELL, Mr. COX, Mr. TOM DAVIS of Virginia, Mr. MARKEY, Mr. BILIRAKIS, Mr. DAVIS of Florida, Mr. UPTON, Mr. STEARNS, Mr. GREENWOOD, Mr. SHADEGG, Mr. ISSA, Mr. LINCOLN DIAZ-BALART of Florida, and Ms. ESHOO) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Government Reform, and Select Homeland Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

JUNE 10, 2003

Reported from the Committee on Energy and Commerce

JUNE 10, 2003

Referral to the Committee on Government Reform and the Select Committee on Homeland Security extended for a period ending not later than June 13, 2003

JUNE 10, 2003

Referred to the Committee on Armed Services for a period ending not later than June 11, 2003 pursuant to clause 1(c), rule X

JUNE 11, 2003

The Committee on Armed Services discharged

JUNE 12, 2003

Reported from the Committee on Government Reform with an amendment

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

JUNE 13, 2003

Referral to the Select Committee on Homeland Security extended for a period ending not later than June 27, 2003

JUNE 27, 2003

Referral to the Select Committee on Homeland Security extended for a period ending not later than July 8, 2003

JULY 8, 2003

Additional sponsors: Mr. BURR and Mr. HALL

JULY 8, 2003

Reported from the Select Committee on Homeland Security with an amendment, committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in boldface roman]

[For text of introduced bill, see copy of bill as introduced on May 15, 2003]

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## A BILL

To enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Project BioShield Act  
5 of 2003”.

1 **SEC. 2. BIOMEDICAL COUNTERMEASURE RESEARCH AND**  
 2 **DEVELOPMENT —AUTHORITIES.**

3 (a) **IN GENERAL.**—Part B of title III of the Public  
 4 Health Service Act (42 U.S.C. 243 et seq.) is amended  
 5 by inserting after section 319F the following section:

6 **“SEC. 319F-1. AUTHORITY FOR USE OF CERTAIN PROCE-**  
 7 **DURES REGARDING BIOMEDICAL COUNTER-**  
 8 **MEASURE RESEARCH AND DEVELOPMENT**  
 9 **ACTIVITIES.**

10 **“(a) IN GENERAL.—**

11 **“(1) AUTHORITY.**—In conducting and sup-  
 12 porting research and development activities regard-  
 13 ing biomedical countermeasures under section  
 14 319F(h), the Secretary may conduct and support  
 15 such activities in accordance with this section if the  
 16 activities concern qualified countermeasures.

17 **“(2) QUALIFIED COUNTERMEASURE.**—For pur-  
 18 poses of this section, the term ‘qualified counter-  
 19 measure’ means a priority countermeasure (as de-  
 20 fined in section 319F(h)) that affects national secu-  
 21 rity.

22 **“(3) INTERAGENCY COOPERATION.—**

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

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

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

7           “(4) AVAILABILITY OF FACILITIES TO THE SEC-  
8           RETARY.—In any grant or cooperative agreement  
9           entered into under the authority provided in this  
10          section with respect to a biocontainment laboratory  
11          or other related or ancillary specialized research fa-  
12          cility that the Secretary determines necessary for the  
13          purpose of performing, administering, and sup-  
14          porting qualified countermeasure research and devel-  
15          opment, the Secretary may provide that the facility  
16          that is the object of such grant or cooperative agree-  
17          ment shall be available as needed to the Secretary  
18          to respond to public health emergencies affecting na-  
19          tional security.

20          “(b) EXPEDITED PROCUREMENT AUTHORITY.—

21                 “(1) INCREASED SIMPLIFIED ACQUISITION  
22                 THRESHOLD FOR BIOMEDICAL COUNTERMEASURE  
23                 PROCUREMENTS.—

24                 “(A) IN GENERAL.—For any procurement  
25                 by the Secretary of property or services for use

1 (as determined by the Secretary) in performing,  
2 administering, or supporting qualified counter-  
3 measure research or development activities  
4 under this section that the Secretary deter-  
5 mines necessary to respond to pressing research  
6 and development needs under this section; the  
7 amount specified in section 4(11) of the Office  
8 of Federal Procurement Policy Act (41 U.S.C.  
9 403(11)); as applicable pursuant to section  
10 302A(a) of the Federal Property and Adminis-  
11 trative Services Act of 1949 (41 U.S.C.  
12 252a(a)), shall be deemed to be \$25,000,000 in  
13 the administration, with respect to such pro-  
14 curement, of—

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

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

22 “(B) APPLICATION OF CERTAIN PROVI-  
23 SIONS.—Notwithstanding subparagraph (A)  
24 and the provision of law and regulations re-  
25 ferred to in such subparagraph, each of the fol-

1           lowing provisions shall apply to procurements  
2           described in this paragraph to the same extent  
3           that such provisions would apply to such pro-  
4           curements in the absence of subparagraph (A):

5                   “(i) Chapter 37 of title 40, United  
6                   States Code (relating to contract work  
7                   hours and safety standards):

8                   “(ii) Subsections (a) and (b) of Sec-  
9                   tion 7 of the Anti-Kickback Act of 1986  
10                   (41 U.S.C. 57(a) and (b)):

11                   “(iii) Section 304C of the Federal  
12                   Property and Administrative Services Act  
13                   of 1949 (41 U.S.C. 254d) (relating to the  
14                   — examination of contractor records):

15                   “(C) INTERNAL CONTROLS TO BE INSTI-  
16                   TUTED.—The Secretary shall institute appro-  
17                   priate internal controls for procurements that  
18                   are under this paragraph, including require-  
19                   ments with regard to documenting the justifica-  
20                   tion for use of the authority in this paragraph:

21                   “(2) USE OF NONCOMPETITIVE PROCEDURES.—

22           In addition to any other authority to use procedures  
23           other than competitive procedures, the Secretary  
24           may use such other procedures when—

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

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

9           ~~“(3) INCREASED MICROPURCHASE THRESH-~~  
10 ~~OLD.—~~

11           ~~“(A) IN GENERAL.—For a procurement~~  
12 ~~described by paragraph (1), the amount speci-~~  
13 ~~fied in subsections (c), (d), and (f) of section 32~~  
14 ~~of the Office of Federal Procurement Policy Act~~  
15 ~~(41 U.S.C. 428) shall be deemed to be \$15,000~~  
16 ~~in the administration of that section with re-~~  
17 ~~spect to such procurement.~~

18           ~~“(B) INTERNAL CONTROLS TO BE INSTI-~~  
19 ~~TUTED.—The Secretary shall institute appro-~~  
20 ~~priate internal controls for purchases that are~~  
21 ~~under this paragraph and that are greater than~~  
22 ~~\$2,500.~~

23           ~~“(C) EXCEPTION TO PREFERENCE FOR~~  
24 ~~PURCHASE CARD MECHANISM.—No provision of~~  
25 ~~law establishing a preference for using a Gov-~~

1           ernment purchase card method for purchases  
2           shall apply to purchases that are under this  
3           paragraph and that are greater than ~~\$2,500.~~

4           ~~“(c) AUTHORITY TO EXPEDITE PEER REVIEW.—~~

5           ~~“(1) IN GENERAL.—The Secretary may, as the~~  
6           ~~Secretary determines necessary to respond to press-~~  
7           ~~ing qualified countermeasure research and develop-~~  
8           ~~ment needs under this section, employ such exped-~~  
9           ~~ited peer review procedures (including consultation~~  
10          ~~with appropriate scientific experts) as the Secretary,~~  
11          ~~in consultation with the Director of NIH, deems ap-~~  
12          ~~propriate to obtain assessment of scientific and tech-~~  
13          ~~nical merit and likely contribution to the field of~~  
14          ~~qualified countermeasure research, in place of the~~  
15          ~~peer review and advisory council review procedures~~  
16          ~~that would be required under sections 301(a)(3),~~  
17          ~~405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and~~  
18          ~~494, as applicable to a grant, contract, or coopera-~~  
19          ~~tive agreement—~~

20                   ~~“(A) that is for performing, administering,~~  
21                   ~~or supporting qualified countermeasure research~~  
22                   ~~and development activities; and~~

23                   ~~“(B) the amount of which is not greater~~  
24                   ~~than \$1,500,000.~~

1           “(2) SUBSEQUENT PHASES OF RESEARCH.—

2           The Secretary’s determination of whether to employ  
3           expedited peer review with respect to subsequent  
4           phases of a research grant or cooperative agreement  
5           under this section shall be determined without re-  
6           gard to the peer review procedures used for any  
7           prior peer review of that same grant or cooperative  
8           agreement.

9           “(d) AUTHORITY FOR PERSONAL SERVICES CON-  
10          TRACTS.—

11           “(1) IN GENERAL.—For the purpose of per-  
12           forming, administering, and supporting qualified  
13           countermeasure research and development activities,  
14           the Secretary may, as the Secretary determines nec-  
15           essary to respond to pressing qualified counter-  
16           measure research and development needs under this  
17           section, obtain by contract (in accordance with sec-  
18           tion 3109 of title 5, United States Code, but without  
19           regard to the limitations in such section on the pe-  
20           riod of service and on pay) the personal services of  
21           experts or consultants who have scientific or other  
22           professional qualifications, except that in no case  
23           shall the compensation provided to any such expert  
24           or consultant exceed the daily equivalent of the an-  
25           nual rate of compensation for the President.

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

2           “(A) IN GENERAL.—A person carrying out  
3 a contract under paragraph (1), and an officer,  
4 employee, or governing board member of such  
5 person, shall be deemed to be an employee of  
6 the Department of Health and Human Services  
7 for purposes of claims under sections 1346(b)  
8 and 2672 of title 28, United States Code, for  
9 money damages for personal injury, including  
10 death, resulting from performance of functions  
11 under such contract.

12           “(B) EXCLUSIVITY OF REMEDY.—The  
13 remedy provided by subparagraph (A) shall be  
14 exclusive of any other civil action or proceeding  
15 by reason of the same subject matter against  
16 the person, officer, employee, or governing  
17 board member.

18           “(3) INTERNAL CONTROLS TO BE INSTI-  
19 TUTED.—

20           “(A) IN GENERAL.—The Secretary shall  
21 institute appropriate internal controls for con-  
22 tracts under this subsection, including proce-  
23 dures for the Secretary to make a determina-  
24 tion of whether a person, or an officer, em-  
25 ployee, or governing board member of a person,

1 is deemed to be an employee of the Department  
2 of Health and Human Services pursuant to  
3 paragraph (2).

4 “(B) DETERMINATION OF EMPLOYEE STA-  
5 TUS TO BE FINAL.—A determination by the  
6 Secretary under subparagraph (A) that a per-  
7 son, or an officer, employee, or governing board  
8 member of a person, is or is not deemed to be  
9 an employee of the Department of Health and  
10 Human Services shall be final and binding on  
11 the Secretary and the Attorney General and  
12 other parties to any civil action or proceeding.

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

17 “(e) STREAMLINED PERSONNEL AUTHORITY.—

18 “(1) IN GENERAL.—In addition to any other  
19 personnel authorities, the Secretary may, as the Sec-  
20 retary determines necessary to respond to pressing  
21 qualified countermeasure research and development  
22 needs under this section, without regard to such pro-  
23 visions of title 5, United States Code, governing ap-  
24 pointments in the competitive service, and without  
25 regard to the provisions of chapter 51 and sub-

1 chapter III of chapter 53 of such title relating to  
2 classification and General Schedule pay rates; ap-  
3 point professional and technical employees, not to  
4 exceed 30 such employees at any time; to positions  
5 in the National Institutes of Health to perform, ad-  
6 minister, or support qualified countermeasure re-  
7 search and development activities in carrying out  
8 this section.

9 “(2) INTERNAL CONTROLS TO BE INSTI-  
10 TUTED.—The Secretary shall institute appropriate  
11 internal controls for appointments under this sub-  
12 section.

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

16 (b) TECHNICAL AMENDMENT.—Section 481A of the  
17 Public Health Service Act (42 U.S.C. 287a-2) is amend-  
18 ed—

19 (1) in subsection (a)(1), by inserting “or the  
20 Director of the National Institute of Allergy and In-  
21 fectionous Diseases” after “Director of the Center”;

22 (2) in subsection (c)—

23 (A) in paragraph (1), by inserting “or the  
24 Director of the National Institute of Allergy

1 and Infectious Diseases” after “Director of the  
2 Center”; and

3 (B) in paragraph (2), in the matter pre-  
4 ceeding subparagraph (A), by striking “sub-  
5 section (i)” and inserting “subsection (i)(1)”;

6 (3) in subsection (d), by inserting “or the Di-  
7 rector of the National Institute of Allergy and Infec-  
8 tious Diseases” after “Director of the Center”;

9 (4) in subsection (e)—

10 (A) in paragraph (1)—

11 (i) in the matter preceding subpara-  
12 graph (A), by inserting “or the Director of  
13 the National Institute of Allergy and Infec-  
14 tious Diseases” after “Director of the Cen-  
15 ter”;

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

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

22 (B) in paragraph (2), by inserting “or the  
23 Director of the National Institute of Allergy  
24 and Infectious Diseases” after “Director of the  
25 Center”; and

1           (C) in paragraph (4), by inserting “of the  
2           Center or the Director of the National Institute  
3           of Allergy and Infectious Diseases” after “Di-  
4           rector”;

5           (5) in subsection (f)—

6           (A) in paragraph (1), by inserting “in the  
7           case of an award by the Director of the Cen-  
8           ter,” before “the applicant”; and

9           (B) in paragraph (2), by inserting “of the  
10          Center or the Director of the National Institute  
11          of Allergy and Infectious Diseases” after “Di-  
12          rector”; and

13          (6) in subsection (i)—

14          (A) by striking “APPROPRIATIONS.—For  
15          the purpose of carrying out this section,” and  
16          inserting the following: “APPROPRIATIONS.—

17          “(1) CENTER.—For the purpose of carrying out  
18          this section with respect to the Center,”; and

19          (B) by adding at the end the following:

20          “(2) NATIONAL INSTITUTE OF ALLERGY AND  
21          INFECTIOUS DISEASES.—For the purpose of ear-  
22          rying out this section with respect to the National  
23          Institute of Allergy and Infectious Diseases, there  
24          are authorized to be appropriated such sums as may  
25          be necessary for fiscal year 2003.”.

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

2 (a) IN GENERAL.—Part B of title III of the Public  
3 Health Service Act, as amended by section 2 of this Act,  
4 is amended by inserting after section 319F–1 the fol-  
5 lowing section:

6 **“SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE.**

7 “(a) STRATEGIC NATIONAL STOCKPILE.—

8 “(1) IN GENERAL.—The Secretary of Homeland  
9 Security (referred to in this section as the ‘Home-  
10 land Security Secretary’), in coordination with the  
11 Secretary and the Secretary of Veterans Affairs,  
12 shall maintain a stockpile or stockpiles of drugs, vac-  
13 cines and other biological products, medical devices,  
14 and other supplies in such numbers, types, and  
15 amounts as are determined by the Secretary to be  
16 appropriate and practicable, taking into account  
17 other available sources, to provide for the emergency  
18 health security of the United States, including the  
19 emergency health security of children and other vul-  
20 nerable populations, in the event of a bioterrorist at-  
21 tack or other public health emergency.

22 “(2) PROCEDURES.—The Secretary, in man-  
23 aging the stockpile under paragraph (1), shall—

24 “(A) consult with the working group under  
25 section 319F(a);

1           “(B) ensure that adequate procedures are  
2 followed with respect to such stockpile for in-  
3 ventory management and accounting, and for  
4 the physical security of the stockpile;

5           “(C) in consultation with Federal, State,  
6 and local officials, take into consideration the  
7 timing and location of special events;

8           “(D) review and revise, as appropriate, the  
9 contents of the stockpile on a regular basis to  
10 ensure that emerging threats, advanced tech-  
11 nologies, and new countermeasures are ade-  
12 quately considered;

13           “(E) devise plans for the effective and  
14 timely supply-chain management of the stock-  
15 pile, in consultation with appropriate Federal,  
16 State and local agencies, and the public and  
17 private health care infrastructure; and

18           “(F) ensure the adequate physical security  
19 of the stockpile.

20           “(b) SMALLPOX VACCINE DEVELOPMENT.—

21           “(1) IN GENERAL.—The Secretary shall award  
22 contracts, enter into cooperative agreements, or  
23 carry out such other activities as may reasonably be  
24 required in order to ensure that the stockpile under  
25 subsection (a) includes an amount of vaccine against

1 smallpox as determined by such Secretary to be suf-  
 2 ficient to meet the health security needs of the  
 3 United States.

4 “(2) RULE OF CONSTRUCTION.—Nothing in  
 5 this section shall be construed to limit the private  
 6 distribution, purchase, or sale of vaccines from  
 7 sources other than the stockpile described in sub-  
 8 section (a).

9 “(c) ADDITIONAL AUTHORITY REGARDING PRO-  
 10 CUREMENT OF CERTAIN BIOMEDICAL COUNTER-  
 11 MEASURES; AVAILABILITY OF SPECIAL RESERVE  
 12 FUND.—

13 “(1) IN GENERAL.—

14 “(A) USE OF FUND.—A security counter-  
 15 measure may, in accordance with this sub-  
 16 section, be procured with amounts in the special  
 17 reserve fund under paragraph (10).

18 “(B) SECURITY COUNTERMEASURE.—For  
 19 purposes of this subsection, the term ‘security  
 20 countermeasure’ means a priority counter-  
 21 measure (as defined in section 319F(h))—

22 “(i) that affects national security;

23 “(ii) that is determined under para-  
 24 graph (2)(B)(ii) to be a necessary counter-  
 25 measure; and

1           “~~(iii)(I)~~ that is approved or cleared  
2           under chapter V of the Federal Food,  
3           Drug, and Cosmetic Act, or licensed under  
4           section 351 of this Act, for use as a coun-  
5           termeasure to a chemical, biological, radio-  
6           logical, or nuclear agent identified as a  
7           material threat under paragraph ~~(2)(A)(ii)~~;  
8           or

9           “~~(II)~~ for which the Secretary deter-  
10          mines that sufficient and satisfactory clin-  
11          ical experience or research data (including  
12          data, if available, from pre-clinical and  
13          clinical trials) support a reasonable conclu-  
14          sion that the countermeasure will qualify  
15          for approval or licensing after the date of  
16          a determination under paragraph ~~(5)~~.

17          “~~(2)~~ DETERMINATION OF MATERIAL  
18          THREATS.—

19          “~~(A)~~ MATERIAL THREAT.—The Homeland  
20          Security Secretary, in consultation with the  
21          heads of other agencies as appropriate, shall on  
22          an ongoing basis—

23                 “~~(i)~~ assess current and emerging  
24                 threats of chemical, biological, radiological,  
25                 and nuclear agents; and

1           “(ii) determine which of such agents  
2           present a material threat against the  
3           United States population.

4           “(B) PUBLIC HEALTH IMPACT; NECESSARY  
5           COUNTERMEASURES.—The Secretary shall on  
6           an ongoing basis—

7           “(i) assess the potential public health  
8           consequences of use against the United  
9           States population of agents identified  
10          under subparagraph (A)(ii); and

11          “(ii) determine, on the basis of such  
12          assessment, the agents for which priority  
13          countermeasures are necessary to protect  
14          the public health from a material threat.

15          “(3) ASSESSMENT OF AVAILABILITY AND AP-  
16          PROPRIATENESS OF COUNTERMEASURES.—The Sec-  
17          retary, in consultation with the Homeland Security  
18          Secretary, shall assess on an ongoing basis the avail-  
19          ability and appropriateness of specific counter-  
20          measures to address specific threats identified under  
21          paragraph (2).

22          “(4) CALL FOR SECURITY COUNTERMEASURES;  
23          COMMITMENT FOR RECOMMENDATION FOR PRO-  
24          CUREMENT.—

1           “(A) PROPOSAL TO THE PRESIDENT.—If,  
2           pursuant to an assessment under paragraph  
3           (3), the Homeland Security Secretary and the  
4           Secretary make a determination that a security  
5           countermeasure would be appropriate, such Sec-  
6           retaries may jointly submit to the President a  
7           proposal to—

8                   “(i) issue a call for the development of  
9                   such security countermeasure; and

10                   “(ii) make a commitment that, upon  
11                   the first development of such security  
12                   countermeasure that meets the conditions  
13                   for procurement under paragraph (5), the  
14                   Secretaries will, based in part on informa-  
15                   tion obtained pursuant to such call, make  
16                   a recommendation under paragraph (6)  
17                   that the special reserve fund under para-  
18                   graph (10) be made available for the pro-  
19                   curement of such security countermeasure.

20           “(B) COUNTERMEASURE SPECIFICA-  
21           TIONS.—The Homeland Security Secretary and  
22           the Secretary shall, to the extent practicable,  
23           include in the proposal under subparagraph  
24           (A)—

1           “(i) estimated quantity of purchase  
2           (in the form of number of doses or number  
3           of effective courses of treatments regard-  
4           less of dosage form);

5           “(ii) necessary measures of minimum  
6           safety and effectiveness;

7           “(iii) estimated price for each dose or  
8           effective course of treatment regardless of  
9           dosage form; and

10          “(iv) other information that may be  
11          necessary to encourage and facilitate re-  
12          search, development, and manufacture of  
13          the countermeasure or to provide specifica-  
14          tions for the countermeasure.

15          “(C) **PRESIDENTIAL APPROVAL.**—If the  
16          President approves a proposal under subpara-  
17          graph (A), the Homeland Security Secretary  
18          and the Secretary shall make known to persons  
19          who may respond to a call for the security  
20          countermeasure involved—

21                 “(i) the call for the countermeasure;

22                 “(ii) specifications for the counter-  
23                 measure under subparagraph (B); and

24                 “(iii) a commitment described in sub-  
25                 paragraph (A)(ii).

1           “(5) SECRETARY’S DETERMINATION OF COUN-  
2           TERMEASURES APPROPRIATE FOR FUNDING FROM  
3           SPECIAL RESERVE FUND.—

4           “(A) IN GENERAL.—The Secretary, in ac-  
5           cordance with the provisions of this paragraph,  
6           shall identify specific security countermeasures  
7           that the Secretary determines, in consultation  
8           with the Homeland Security Secretary, to be  
9           appropriate for inclusion in the stockpile under  
10          subsection (a) pursuant to procurements made  
11          with amounts in the special reserve fund under  
12          paragraph (10) (referred to in this subsection  
13          individually as a ‘procurement under this sub-  
14          section’).

15          “(B) REQUIREMENTS.—In making a deter-  
16          mination under subparagraph (A) with respect  
17          to a security countermeasure, the Secretary  
18          shall determine and consider the following:

19                 “(i) The quantities of the product  
20                 that will be needed to meet the needs of  
21                 the stockpile.

22                 “(ii) The feasibility of production and  
23                 delivery within five years of sufficient  
24                 quantities of the product.

1                   “(iii) Whether there is a lack of a sig-  
2                   nificant commercial market for the product  
3                   at the time of procurement, other than as  
4                   a security countermeasure.

5                   “~~(6)~~ RECOMMENDATION FOR PRESIDENT’S AP-  
6                   PROVAL.—

7                   “~~(A)~~ RECOMMENDATION FOR PROCURE-  
8                   MENT.—In the case of a security counter-  
9                   measure that the Secretary has, in accordance  
10                  with paragraphs ~~(2)~~, ~~(3)~~, and ~~(5)~~, determined  
11                  to be appropriate for procurement under this  
12                  subsection, the Homeland Security Secretary  
13                  and the Secretary shall jointly submit to the  
14                  President, in coordination with the Director of  
15                  the Office of Management and Budget, a rec-  
16                  ommendation that the special reserve fund  
17                  under paragraph ~~(10)~~ be made available for the  
18                  procurement of such countermeasure.

19                  “~~(B)~~ PRESIDENTIAL APPROVAL.—The spe-  
20                  cial reserve fund under paragraph ~~(10)~~ is avail-  
21                  able for a procurement of a security counter-  
22                  measure only if the President has approved a  
23                  recommendation under subparagraph ~~(A)~~ re-  
24                  garding the countermeasure.

1           “(C) NOTICE TO CONGRESS.—The Sec-  
2           retary and the Homeland Security Secretary  
3           shall notify the Congress of each decision of the  
4           President to approve a recommendation under  
5           subparagraph (A). Such notice shall include an  
6           explanation of the decision to make available  
7           the special reserve fund under paragraph (10)  
8           for procurement of such a countermeasure, in-  
9           cluding, where available, the identification of  
10          the potential supplier or suppliers of such coun-  
11          termeasure, and whether other potential sup-  
12          pliers of the same or similar countermeasures  
13          were considered and rejected for procurement  
14          under this section and the reasons therefor.

15          “(D) SUBSEQUENT SPECIFIC COUNTER-  
16          MEASURES.—Procurement under this sub-  
17          section of a security countermeasure for a par-  
18          ticular purpose does not preclude the subse-  
19          quent procurement under this subsection of any  
20          other security countermeasure for such purpose  
21          if the Secretary has determined under para-  
22          graph (5)(A) that such countermeasure is ap-  
23          propriate for inclusion in the stockpile and if,  
24          as determined by the Secretary, such counter-  
25          measure provides improved safety or effective-

1           ness, or for other reasons enhances prepared-  
2           ness to respond to threats of use of a biological,  
3           chemical, radiological, or nuclear agent. Such a  
4           determination by the Secretary is committed to  
5           agency discretion.

6           “(E) RULE OF CONSTRUCTION.—Rec-  
7           ommendations and approvals under this para-  
8           graph apply solely to determinations that the  
9           special reserve fund under paragraph (10) will  
10          be made available for a procurement of a secu-  
11          rity countermeasure, and not to the substance  
12          of contracts for such procurement or other mat-  
13          ters relating to awards of such contracts.

14          “(7) PROCUREMENT.—

15                 “(A) IN GENERAL.—For purposes of a  
16                 procurement under this subsection that is ap-  
17                 proved by the President under paragraph (6),  
18                 the Homeland Security Secretary and the Sec-  
19                 retary shall have responsibilities in accordance  
20                 with subparagraphs (B) and (C).

21                 “(B) INTERAGENCY AGREEMENTS.—

22                         “(i) FOR PROCUREMENT.—The  
23                         Homeland Security Secretary shall enter  
24                         into an agreement with the Secretary for  
25                         procurement of a security countermeasure

1 in accordance with the provisions of this  
2 paragraph. The special reserve fund under  
3 paragraph (10) shall be available for the  
4 Secretary's costs of such procurement,  
5 other than as provided in clause (ii).

6 “(ii) FOR ADMINISTRATIVE COSTS.—

7 The agreement entered into between the  
8 Homeland Security Secretary and the Sec-  
9 retary for managing the stockpile under  
10 subsection (a) shall provide for reimburse-  
11 ment of the Secretary's administrative  
12 costs relating to procurements under this  
13 subsection.

14 “(C) PROCUREMENT.—

15 “(i) IN GENERAL.—The Secretary  
16 shall be responsible for—

17 “(I) arranging for procurement  
18 of a security countermeasure, includ-  
19 ing negotiating terms (including quan-  
20 tity, production schedule, and price)  
21 of, and entering into, contracts and  
22 cooperative agreements, and for ear-  
23 rying out such other activities as may  
24 reasonably be required, in accordance

1 with the provisions of this subpara-  
2 graph; and

3 “(H) promulgating regulations to  
4 implement clauses (v), (vi), and (vii);  
5 and any other provisions of this sub-  
6 section.

7 “(ii) CONTRACT TERMS.—A contract  
8 for procurements under this subsection  
9 shall (or, as specified below, may) include  
10 the following terms:

11 “(I) PAYMENT CONDITIONED ON  
12 SUBSTANTIAL DELIVERY.—The con-  
13 tract shall provide that no payment  
14 may be made until delivery has been  
15 made of a substantial portion (as de-  
16 termined by the Secretary) of the  
17 total number of units contracted for,  
18 except that, notwithstanding any  
19 other provision of law, the contract  
20 may provide that, if the Secretary de-  
21 termines (in the Secretary’s discre-  
22 tion) that an advance payment is nec-  
23 essary to ensure success of a project,  
24 the Secretary may pay an amount, not  
25 to exceed 10 percent of the contract

1 amount, in advance of delivery. The  
2 contract shall provide that such ad-  
3 vance payment is required to be re-  
4 paid if there is a failure to perform  
5 under the contract, except in special  
6 circumstances as determined by the  
7 Secretary on a contract by contract  
8 basis.

9 “(II) CONTRACT DURATION.—

10 The contract shall be for a period not  
11 to exceed five years, except that, in  
12 first awarding the contract, the Sec-  
13 retary may provide for a longer dura-  
14 tion, not exceeding eight years, if the  
15 Secretary determines that complexities  
16 or other difficulties in performance  
17 under the contract justify such a pe-  
18 riod. The contract shall be renewable  
19 for additional periods, none of which  
20 shall exceed five years.

21 “(III) STORAGE BY VENDOR.—

22 The contract may provide that the  
23 vendor will provide storage for stocks  
24 of a product delivered to the owner-  
25 ship of the Federal Government under

1 the contract, for such period and  
2 under such terms and conditions as  
3 the Secretary may specify, and in  
4 such case amounts from the special  
5 reserve fund under paragraph (10)  
6 shall be available for costs of ship-  
7 ping, handling, storage, and related  
8 costs for such product.

9 “(iii) AVAILABILITY OF SIMPLIFIED  
10 ACQUISITION PROCEDURES.—

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

22 “(aa) section 303(g)(1)(A)  
23 of the Federal Property and Ad-  
24 ministrative Services Act of 1949

1           ~~(41 U.S.C. 253(g)(1)(A))~~ and its  
2           implementing regulations; and

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

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

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

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

24           ~~“(cc) Section 304C of the~~  
25           ~~Federal Property and Adminis-~~

1                   trative Services Act of 1949 (41  
2                   U.S.C. 254d) (relating to the —  
3                   — examination of contractor  
4                   records).

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

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

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

1                   “(aa) identifies an increment  
2                   of the total quantity of security  
3                   countermeasure required, wheth-  
4                   er by percentage or by numbers  
5                   of units; and

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

14                  “(II) DETERMINATION OF GOV-  
15                  ERNMENT’S REQUIREMENT NOT RE-  
16                  VIEWABLE.—If the Secretary includes  
17                  in each of a set of contracts a provi-  
18                  sion as described in subclause (I),  
19                  such Secretary’s determination of the  
20                  total quantity of security counter-  
21                  measure required, and any amend-  
22                  ment of such determination, is com-  
23                  mitted to agency discretion.

24                  “(vi) EXTENSION OF CLOSING DATE  
25                  FOR RECEIPT OF PROPOSALS NOT REVIEW-

1           ABLE.—A decision by the Secretary to ex-  
2           tend the closing date for receipt of pro-  
3           posals for a procurement under this sub-  
4           section is committed to agency discretion.

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

16          “(8) INTERAGENCY COOPERATION.—

17                 “(A) IN GENERAL.—In carrying out activi-  
18                 ties under this section, the Homeland Security  
19                 Secretary and the Secretary are authorized,  
20                 subject to subparagraph (B), to enter into  
21                 interagency agreements and other collaborative  
22                 undertakings with other agencies of the United  
23                 States Government.

24                 “(B) LIMITATION.—An agreement or un-  
25                 dertaking under this paragraph shall not au-

1           thorize another agency to exercise the authori-  
2           ties provided by this section to the Homeland  
3           Security Secretary or to the Secretary.

4           “(9) RESTRICTIONS ON USE OF FUNDS.—  
5           Amounts in the special reserve fund under para-  
6           graph (10) shall not be used to pay—

7                   “(A) costs for the purchase of vaccines  
8                   under procurement contracts entered into be-  
9                   fore the date of the enactment of the Project  
10                  BioShield Act of 2003; or

11                   “(B) administrative costs.

12           “(10) SPECIAL RESERVE FUND.—For purposes  
13           of this subsection, the term ‘special reserve fund’  
14           has the meaning given such term in section 510 of  
15           the Homeland Security Act of 2002.

16           “(d) DISCLOSURES.—No Federal agency shall dis-  
17           close under section 552, United States Code, any informa-  
18           tion identifying the location at which materials in the  
19           stockpile under subsection (a) are stored.

20           “(e) DEFINITION.—For purposes of subsection (a),  
21           the term ‘stockpile’ includes—

22                   “(1) a physical accumulation (at one or more  
23                   locations) of the supplies described in subsection (a);  
24                   or

1           “(2) a contractual agreement between the  
2           Homeland Security Secretary and a vendor or ven-  
3           dors under which such vendor or vendors agree to  
4           provide to such Secretary supplies described in sub-  
5           section (a).”

6           “(f) AUTHORIZATION OF APPROPRIATIONS.—

7           “(1) STRATEGIC NATIONAL STOCKPILE.—For  
8           the purpose of carrying out subsection (a), there are  
9           authorized to be appropriated \$640,000,000 for fis-  
10          cal year 2002, and such sums as may be necessary  
11          for each of fiscal years 2003 through 2006. Such  
12          authorization is in addition to amounts in the special  
13          reserve fund under subsection (c)(10).”

14          “(2) SMALLPOX VACCINE DEVELOPMENT.—For  
15          the purpose of carrying out subsection (b), there are  
16          authorized to be appropriated \$509,000,000 for fis-  
17          cal year 2002, and such sums as may be necessary  
18          for each of fiscal years 2003 through 2006.”

19          (b) AMENDMENT TO HOMELAND SECURITY ACT OF  
20          2002.—Title V of the Homeland Security Act of 2002  
21          (116 Stat. 2212; 6 U.S.C. 311 et seq.) is amended by add-  
22          ing at the end the following:

1 **“SEC. 510. PROCUREMENT OF SECURITY COUNTER-**  
2 **MEASURES FOR STRATEGIC NATIONAL**  
3 **STOCKPILE.**

4 “(a) AUTHORIZATION OF APPROPRIATIONS.—For  
5 procurement of security countermeasures under section  
6 319F–2(c) of the Public Health Service Act (referred to  
7 in this section as the ‘security countermeasures program’),  
8 there is authorized to be appropriated up to  
9 \$5,593,000,000 for the fiscal years 2004 through 2013.  
10 Of the amounts appropriated under the preceding sen-  
11 tence, not to exceed \$3,418,000,000 may be obligated dur-  
12 ing the fiscal years 2004 through 2008, of which not to  
13 exceed \$890,000,000 may be obligated during fiscal year  
14 2004.

15 “(b) SPECIAL RESERVE FUND.—For purposes of the  
16 security countermeasures program, the term ‘special re-  
17 serve fund’ means the appropriations account established  
18 as a result of any appropriations made under subsection  
19 (a).

20 “(c) AVAILABILITY.—

21 “(1) DURATION OF AVAILABILITY FOR OBLIGA-  
22 TION.—Subject to paragraph (2), all amounts appro-  
23 priated under subsection (a) are available for obliga-  
24 tion through the end of fiscal year 2013, provided  
25 that any portion of such amount that remains unob-  
26 ligated for such purposes on the expiration of such

1 term shall be returned to the United States Treas-  
2 ury and shall not be available for subsequent obliga-  
3 tion for any purpose.

4 “(2) INITIAL AVAILABILITY FOR PARTICULAR  
5 PROCUREMENTS.—Amounts appropriated under sub-  
6 section (a) become available for a procurement  
7 under the security countermeasures program only  
8 upon the approval by the President of such avail-  
9 ability for the procurement in accordance with para-  
10 graph (6)(B) of such program.”.

11 (c) CONFORMING AMENDMENT.—Section 121 of the  
12 Public Health Security and Bioterrorism Preparedness  
13 and Response Act of 2002 (116 Stat. 611; 42 U.S.C.  
14 300hh–12) is repealed. With respect to the program estab-  
15 lished under former section 121 of such Act, the repeal  
16 of such section under the preceding sentence applies as  
17 a modification of the program in accordance with the  
18 amendment made by subsection (a) of this section, and  
19 not as the termination of the program and the establish-  
20 ment of a different program.

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

23 Subchapter E of chapter V of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is  
25 amended by adding at the end the following section:

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

3 **“(a) IN GENERAL.—**

4 **“(1) EMERGENCY USES.—**Notwithstanding sec-  
5 tions 505, 510(k), and 515 of this Act and section  
6 351 of the Public Health Service Act, and subject to  
7 the provisions of this section, the Secretary may au-  
8 thorize the introduction into interstate commerce,  
9 during the effective period of a declaration under  
10 subsection (b), of a drug or device intended for use  
11 in an actual or potential emergency (referred to in  
12 this section as an ‘emergency use’).

13 **“(2) APPROVAL STATUS OF PRODUCT.—**An au-  
14 thorization under paragraph (1) may authorize an  
15 emergency use of a product that—

16 **“(A)** is not approved, licensed, or cleared  
17 for commercial distribution under a provision of  
18 law referred to in such paragraph (referred to  
19 in this section as an ‘unapproved product’); or

20 **“(B)** is approved, licensed, or cleared  
21 under such a provision, but which use is not  
22 under such provision an approved, licensed, or  
23 cleared use of the product (referred to in this  
24 section as an ‘unapproved use of an approved  
25 product’).

1           “(3) RELATION TO OTHER USES.—An emer-  
2           gency use authorized under paragraph (1) for a  
3           product is in addition to any other use that is au-  
4           thorized for the product under a provision of law re-  
5           ferred to in such paragraph.

6           “(4) DEFINITIONS.—For purposes of this sec-  
7           tion:

8                   “(A) The term ‘emergency use’ has the  
9                   meaning indicated for such term in paragraph  
10                  (1).

11                  “(B) The term ‘product’ means a drug or  
12                  device.

13                  “(C) The term ‘unapproved product’ has  
14                  the meaning indicated for such term in para-  
15                  graph (2)(A).

16                  “(D) The term ‘unapproved use of an ap-  
17                  proved product’ has the meaning indicated for  
18                  such term in paragraph (2)(B).

19           “(b) DECLARATION OF EMERGENCY.—

20                   “(1) IN GENERAL.—The Secretary may declare  
21                   an emergency justifying the authorization under this  
22                   subsection for a product on the basis of—

23                           “(A) a determination by the Secretary of  
24                           Homeland Security that there is a national  
25                           emergency, or a significant potential for a na-

1 tional emergency, involving a heightened risk of  
2 attack with a specified biological, chemical, ra-  
3 diological, or nuclear agent or agents;

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

11 “(C) a determination by the Secretary of a  
12 public health emergency under section 319 of  
13 the Public Health Service Act, affecting na-  
14 tional security and involving a specified biologi-  
15 cal, chemical, radiological, or nuclear agent or  
16 agents, or a specified disease or condition that  
17 may be attributable to such agent or agents.

18 “(2) TERMINATION OF DECLARATION.—

19 “(A) IN GENERAL.—A declaration under  
20 this subsection shall terminate upon the earlier  
21 of—

22 “(i) a determination by the Secretary,  
23 in consultation as appropriate with the  
24 Secretary of Homeland Security or the  
25 Secretary of Defense, that the cir-

1           circumstances described in paragraph (1)  
2           have ceased to exist; or

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

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

10          “(3) ADVANCE NOTICE OF TERMINATION.—In  
11          terminating a declaration under this section, the  
12          Secretary shall provide advance notice that the dec-  
13          laration will be terminated. The period of advance  
14          notice shall be a period reasonably determined to  
15          provide—

16                 “(A) in the case of an unapproved product,  
17                 a sufficient period for disposition of shipments  
18                 of the product, including the return of such  
19                 shipments to the manufacturer (in the case of  
20                 a manufacturer that chooses to have the ship-  
21                 ments returned); and

22                 “(B) in the case of unapproved uses of ap-  
23                 proved products, a sufficient period for the dis-  
24                 position of any labeling that was provided with  
25                 respect to the emergency use involved.

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

5           “(e) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—  
6 The Secretary may issue an authorization under this sec-  
7 tion with respect to the emergency use of a product only  
8 if, after consultation with the Director of the National In-  
9 stitutes of Health and the Director of the Centers for Dis-  
10 ease Control and Prevention, to the extent feasible and  
11 appropriate given the circumstances of the emergency in-  
12 volved, the Secretary concludes—

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

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

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

22           “(i) such disease or condition; or

23           “(ii) a serious or life-threatening dis-  
24 ease or condition caused by a product au-  
25 thorized under this section or approved

1           under this Act or the Public Health Serv-  
2           ice Act, for detecting, diagnosing, treating,  
3           or preventing such a disease or condition  
4           caused by such an agent; and

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

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

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

16          “(d) SCOPE OF AUTHORIZATION.—

17                 “(1) IN GENERAL.—An authorization of a prod-  
18                 uct under this section shall state—

19                         “(A) each disease or condition that the  
20                         product may be used to detect, diagnose, pre-  
21                         vent, or treat within the scope of the authoriza-  
22                         tion;

23                         “(B) the Secretary’s conclusions, made  
24                         under subsection (c)(2)(B), that the known and  
25                         potential benefits of the product, when used to

1 detect, diagnose, prevent, or treat such disease  
2 or condition; outweigh the known and potential  
3 risks of the product; and

4 “(C) the Secretary’s conclusions, made  
5 under subsection (e), concerning the safety and  
6 potential effectiveness of the product in detect-  
7 ing, diagnosing, preventing, or treating such  
8 diseases or conditions, including an assessment  
9 of the available scientific evidence.

10 “(2) CONFIDENTIAL INFORMATION.—Nothing  
11 in this section alters or amends section 1905 of title  
12 18, United States Code, or section 552(b)(4) of title  
13 5 of such Code.

14 “(e) CONDITIONS OF AUTHORIZATION.—

15 “(1) UNAPPROVED PRODUCT.—

16 “(A) REQUIRED CONDITIONS.—With re-  
17 spect to the emergency use of an unapproved  
18 product, the Secretary, to the extent feasible  
19 given the circumstances of the emergency, shall,  
20 for persons who choose to carry out one or  
21 more activities for which the authorization is  
22 issued, establish such conditions on an author-  
23 ization under this section as the Secretary finds  
24 necessary or appropriate to protect the public  
25 health, including the following:

1           “(i) Appropriate conditions designed  
2 to ensure that, to the extent feasible given  
3 the circumstances of the emergency, health  
4 care professionals administering the prod-  
5 uct are informed—

6                   “(I) that the Secretary has au-  
7 thorized the emergency use of the  
8 product;

9                   “(II) of the significant known  
10 and potential benefits and risks of the  
11 emergency use of the product, and of  
12 the extent to which such benefits and  
13 risks are unknown; and

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

17           “(ii) Appropriate conditions designed  
18 to ensure that, to the extent feasible given  
19 the circumstances of the emergency, indi-  
20 viduals to whom the product is adminis-  
21 tered are informed—

22                   “(I) that the Secretary has au-  
23 thorized the emergency use of the  
24 product;

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

6                   “(III) of the option to accept or  
7                   refuse administration of the product;  
8                   of the consequences, if any, of refus-  
9                   ing administration of the product, and  
10                  of the alternatives to the product that  
11                  are available and of their benefits and  
12                  risks.

13                  “(iii) Appropriate conditions for the  
14                  monitoring and reporting of adverse events  
15                  associated with the emergency use of the  
16                  product.

17                  “(iv) For manufacturers of the prod-  
18                  uct, appropriate conditions concerning rec-  
19                  ordkeeping and reporting, including  
20                  records access by the Secretary, with re-  
21                  spect to the emergency use of the product.

22                  “(B) AUTHORITY FOR ADDITIONAL CONDI-  
23                  TIONS.—With respect to the emergency use of  
24                  an unapproved product, the Secretary, to the  
25                  extent feasible given the circumstances of the

1 emergency, may, for persons who choose to  
2 carry out one or more activities for which the  
3 authorization is issued, establish such condi-  
4 tions on an authorization under this section as  
5 the Secretary finds necessary or appropriate to  
6 protect the public health, including the fol-  
7 lowing:

8 “(i) Appropriate conditions on which  
9 entities may distribute the product with re-  
10 spect to the emergency use of the product  
11 (including limitation to distribution by gov-  
12 ernment entities), and on how distribution  
13 is to be performed.

14 “(ii) Appropriate conditions on who  
15 may administer the product with respect to  
16 the emergency use of the product, and on  
17 the categories of individuals to whom, and  
18 the circumstances under which, the prod-  
19 uct may be administered with respect to  
20 such use.

21 “(iii) For persons other than manu-  
22 facturers of the product, appropriate con-  
23 ditions concerning recordkeeping and re-  
24 porting, including records access by the

1 Secretary, with respect to the emergency  
2 use of the product.

3 ~~“(iv) With respect to the emergency~~  
4 ~~use of the product, waive or limit, to the~~  
5 ~~extent appropriate given the circumstances~~  
6 ~~of the emergency, conditions regarding~~  
7 ~~current good manufacturing practice other-~~  
8 ~~wise applicable to the manufacture, proe-~~  
9 ~~cessing, packing, or holding of products~~  
10 ~~subject to regulation under this Act, in-~~  
11 ~~cluding such requirements established in~~  
12 ~~section 501.~~

13 ~~“(2) UNAPPROVED USE.—With respect to the~~  
14 ~~emergency use of a product that is an unapproved~~  
15 ~~use of an approved product:~~

16 ~~“(A) The Secretary may, for manufactur-~~  
17 ~~ers of the product who choose to carry out one~~  
18 ~~or more activities for which the authorization is~~  
19 ~~issued, establish any of the conditions described~~  
20 ~~in clauses (i) through (iv) of paragraph (1)(A).~~

21 ~~“(B)(i) If the authorization under this sec-~~  
22 ~~tion regarding the emergency use authorizes a~~  
23 ~~change in the labeling of the product, but the~~  
24 ~~manufacturer of the product chooses not to~~  
25 ~~make such change, such authorization may not~~

1 authorize distributors of the product or any  
2 other person to alter or obscure the labeling  
3 provided by the manufacturer.

4 “(ii) In the circumstances described in  
5 clause (i), an authorization under this section  
6 regarding the emergency use may, for persons  
7 who do not manufacture the product and who  
8 choose to act under this clause, authorize such  
9 persons to provide information on the product  
10 in addition to the labeling provided by the man-  
11 ufacturer, subject to compliance with clause (i).  
12 Such additional information shall not be consid-  
13 ered labeling for purposes of section 502.

14 “(f) DURATION OF AUTHORIZATION.—

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

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

1 “(g) REVOCATION OF AUTHORIZATION.—

2 “(1) REVIEW.—The Secretary shall periodically  
3 review the circumstances and the appropriateness of  
4 an authorization under this section.

5 “(2) REVOCATION.—The Secretary may revoke  
6 an authorization under this section if, in the Sec-  
7 retary’s unreviewable discretion, the criteria under  
8 subsection (e) for issuance of such authorization are  
9 no longer met.

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

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

20 “(j) RULES OF CONSTRUCTION.—Nothing in this sec-  
21 tion shall be construed to impair or otherwise affect—

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

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; or

5           “(3) the authority of the Secretary under sec-  
6 tion ~~319F-2~~ to manage the stockpile under such  
7 section.

8           “(k) APPLICATION TO MEMBERS OF ARMED  
9 FORCES.—

10           “(1) WAIVER OF REQUIREMENT RELATING TO  
11 OPTION TO REFUSE.—In the case of administration  
12 of a countermeasure to members of the armed  
13 forces, a requirement, under subsection  
14 (e)(1)(A)(ii)(III), designed to ensure that individuals  
15 are informed of an option to accept or refuse admin-  
16 istration of a product, may be waived by the Presi-  
17 dent if the President determines, in writing, that  
18 complying with such requirement is not feasible, is  
19 contrary to the best interests of the members af-  
20 fected, or is not in the interests of national security.

21           “(2) PROVISION OF INFORMATION TO MEMBER  
22 OF THE ARMED FORCES.—If the Secretary makes a  
23 determination that it is not feasible for the informa-  
24 tion required by subsection (e)(1)(A)(ii) to be pro-  
25 vided to a member of the armed forces prior to the

1 administration of the product, such information shall  
2 be provided to such member of the armed forces (or  
3 next-of-kin in the case of the death of a member) to  
4 whom the product was administered as soon as pos-  
5 sible, but not later than 30 days, after such adminis-  
6 tration. Information concerning the administration  
7 of the product shall be recorded in the medical  
8 record of the member.

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

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

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

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

1       “(m) DISCRETION REGARDING USE OF AUTHORIZA-  
2 TION.—Nothing in this section provides the Secretary any  
3 authority to require any person to carry out any activity  
4 that becomes lawful pursuant to an authorization under  
5 this section, and no person is required to inform the Sec-  
6 retary that the person will not be carrying out such activ-  
7 ity, except that a manufacturer of a sole-source unap-  
8 proved product authorized for emergency use shall notify  
9 the Secretary within a reasonable period of time after the  
10 issuance by the Secretary of such authorization if such  
11 manufacturer does not intend to carry out an activity or  
12 activities under the authorization. This section does not  
13 have any legal effect on a person who does not carry out  
14 any activity for which an authorization under this section  
15 is issued, or who carries out such an activity pursuant to  
16 other provisions of this Act or section 351 of the Public  
17 Health Service Act.

18       “(n) ENFORCEMENT.—A person who carries out an  
19 activity pursuant to an authorization under this section,  
20 but who fails to comply with applicable conditions under  
21 subsection (c), is with respect to that act of noncompliance  
22 subject to the provisions of law specified in subsection (a)  
23 and to the enforcement of such provisions under section  
24 301.”

1 **SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS**  
2 **ACT.**

3 (a) SECRETARY OF HEALTH AND HUMAN SERV-  
4 ICES.—

5 (1) ANNUAL REPORTS ON PARTICULAR EXER-  
6 CISES OF AUTHORITY.—

7 (A) RELEVANT AUTHORITIES.—The Sec-  
8 retary of Health and Human Services (referred  
9 to in this subsection as the “Secretary”) shall  
10 submit reports in accordance with subpara-  
11 graph (B) regarding the exercise of authority  
12 under the following provisions of law:

13 (i) With respect to section 319F–1 of  
14 the Public Health Service Act (as added by  
15 section 2 of this Act):

16 (I) Subsection (b)(1) (relating to  
17 increased simplified acquisition  
18 threshold):

19 (II) Subsection (b)(2) (relating to  
20 use of noncompetitive procedures):

21 (III) Subsection (c) (relating to  
22 expedited peer review procedures):

23 (ii) With respect to section 319F–2 of  
24 the Public Health Service Act (as added by  
25 section 3 of this Act):

1                   (I) Subsection (e)(7)(C)(iii) (re-  
2 relating to simplified acquisition proce-  
3 dures).

4                   (II) Subsection (e)(7)(C)(iv) (re-  
5 relating to use of noncompetitive proce-  
6 dures).

7                   (III) Subsection (e)(7)(C)(v) (re-  
8 relating to premium provision in mul-  
9 tiple-award contracts).

10                   (iii) With respect to section 564 of the  
11 Federal Food, Drug, and Cosmetic Act (as  
12 added by section 4 of this Act):

13                   (I) Subsection (a)(1) (relating to  
14 emergency uses of certain drugs and  
15 devices).

16                   (II) Subsection (b)(1) (relating to  
17 a declaration of an emergency).

18                   (III) Subsection (c) (relating to  
19 conditions on authorization).

20                   (B) CONTENTS OF REPORTS.—The Sec-  
21 retary shall annually submit to the Congress a  
22 report that summarizes—

23                   (i) the particular actions that were  
24 taken under the authorities specified in  
25 subparagraph (A), including, as applicable,

1 the identification of the threat agent,  
2 emergency, or the biomedical counter-  
3 measure with respect to which the author-  
4 ity was used;

5 (ii) the reasons underlying the deci-  
6 sion to use such authorities, including, as  
7 applicable, the options that were consid-  
8 ered and rejected with respect to the use of  
9 such authorities; and

10 (iii) the identification of each person  
11 or entity that received, or was considered  
12 and rejected for, grants, cooperative agree-  
13 ments, or contracts pursuant to the use of  
14 such authorities.

15 ~~(2) ANNUAL SUMMARIES REGARDING CERTAIN~~  
16 ~~ACTIVITY.~~—The Secretary shall annually submit to  
17 the Congress a report that summarizes the activity  
18 undertaken pursuant to the following authorities  
19 under section 319F–1 of the Public Health Service  
20 Act (as added by section 2 of this Act):

21 (A) Subsection (b)(3) (relating to in-  
22 creased micropurchase threshold).

23 (B) Subsection (d) (relating to authority  
24 for personal services contracts).

1                   (C) Subsection (e) (relating to streamlined  
2                   personnel authority):

3                   With respect to subparagraph (B), the report shall  
4                   include a provision specifying, for the one-year pe-  
5                   riod for which the report is submitted, the number  
6                   of persons who were paid amounts greater than  
7                   \$100,000 and the number of persons who were paid  
8                   amounts between \$50,000 and \$100,000.

9                   (b) NATIONAL ACADEMY OF SCIENCES REVIEW.—

10 Not later than three years after the date of the enactment  
11 of this Act, the Secretary of Health and Human Services  
12 shall request the National Academy of Sciences to enter  
13 into an agreement for a review of the biomedical counter-  
14 measure research and development authorities established  
15 in this Act to determine whether and to what extent activi-  
16 ties undertaken pursuant to such authorities have en-  
17 hanced the development of biomedical countermeasures af-  
18 fecting national security, and to recommend any legislative  
19 or administrative changes necessary to improve the ability  
20 of the Secretary to carry out these activities in the future.  
21 The Secretary shall ensure that the results of the study  
22 are submitted to the Congress not later than five years  
23 after such date of enactment.

24                   (c) GENERAL ACCOUNTING OFFICE REVIEW.—Four  
25 years after the date of the enactment of this Act, the

1 Comptroller General of the United States shall initiate a  
2 study—

3           (1)(A) to review the Secretary of Health and  
4           Human Services' utilization of the authorities grant-  
5           ed under this Act with respect to simplified acquisi-  
6           tion procedures; use of noncompetitive procedures;  
7           increased micropurchase thresholds; personal serv-  
8           ices contracts; streamlined personnel authority; and  
9           the purchase of security countermeasures under the  
10          special reserve fund; and

11          (B) to recommend any legislative or administra-  
12          tive changes necessary to improve the utilization or  
13          effectiveness of such authorities in the future;

14          (2)(A) to review the internal controls instituted  
15          by such Secretary with respect to such authorities;  
16          where required by this Act; and

17          (B) to recommend any legislative or administra-  
18          tive changes necessary to improve the effectiveness  
19          of such controls; and

20          (3)(A) to review such Secretary's utilization of  
21          the authority granted under this Act to authorize an  
22          emergency use of a biomedical countermeasure; in-  
23          cluding the means by which the Secretary deter-  
24          mines whether and under what conditions any such  
25          authorizations should be granted and the benefits

1 and adverse impacts, if any, resulting from the use  
2 of such authority; and

3 ~~(B)~~ to recommend any legislative or administra-  
4 tive changes necessary to improve the utilization or  
5 effectiveness of such authority and to enhance pro-  
6 tection of the public health.

7 The results of the study shall be submitted to the Con-  
8 gress not later than five years after the date of the enact-  
9 ment of this Act.

10 **SECTION 1. SHORT TITLE.**

11 *This Act may be cited as the “Project BioShield Act*  
12 *of 2003”.*

13 **SEC. 2. BIOMEDICAL COUNTERMEASURE RESEARCH AND**  
14 **DEVELOPMENT AUTHORITIES.**

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

18 **“SEC. 319F-1. AUTHORITY FOR USE OF CERTAIN PROCE-**  
19 **DURES REGARDING BIOMEDICAL COUNTER-**  
20 **MEASURE RESEARCH AND DEVELOPMENT AC-**  
21 **TIVITIES.**

22 *“(a) IN GENERAL.—*

23 *“(1) AUTHORITY.—In conducting and sup-*  
24 *porting research and development activities regarding*  
25 *biomedical countermeasures under section 319F(h),*

1        *the Secretary may conduct and support such activi-*  
2        *ties in accordance with this section if the activities*  
3        *concern qualified countermeasures.*

4            “(2) *QUALIFIED COUNTERMEASURE.—For pur-*  
5        *poses of this section, the term ‘qualified counter-*  
6        *measure’ means a priority countermeasure (as defined*  
7        *in section 319F(h)) that affects national security.*

8            “(3) *INTERAGENCY COOPERATION.—*

9            “(A) *IN GENERAL.—In carrying out activi-*  
10        *ties under this section, the Secretary is author-*  
11        *ized, subject to subparagraph (B), to enter into*  
12        *interagency agreements and other collaborative*  
13        *undertakings with other agencies of the United*  
14        *States Government.*

15            “(B) *LIMITATION.—An agreement or under-*  
16        *taking under this paragraph shall not authorize*  
17        *another agency to exercise the authorities pro-*  
18        *vided by this section.*

19            “(4) *AVAILABILITY OF FACILITIES TO THE SEC-*  
20        *RETARY.—In any grant or cooperative agreement en-*  
21        *tered into under the authority provided in this section*  
22        *with respect to a biocontainment laboratory or other*  
23        *related or ancillary specialized research facility that*  
24        *the Secretary determines necessary for the purpose of*  
25        *performing, administering, and supporting qualified*

1        *countermeasure research and development, the Sec-*  
2        *retary may provide that the facility that is the object*  
3        *of such grant or cooperative agreement shall be avail-*  
4        *able as needed to the Secretary to respond to public*  
5        *health emergencies affecting national security.*

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

7                *“(1) INCREASED SIMPLIFIED ACQUISITION*  
8        *THRESHOLD FOR BIOMEDICAL COUNTERMEASURE*  
9        *PROCUREMENTS.—*

10                *“(A) IN GENERAL.—For any procurement*  
11        *by the Secretary of property or services for use*  
12        *(as determined by the Secretary) in performing,*  
13        *administering, or supporting qualified counter-*  
14        *measure research or development activities under*  
15        *this section that the Secretary determines nec-*  
16        *essary to respond to pressing research and devel-*  
17        *opment needs under this section, the amount*  
18        *specified in section 4(11) of the Office of Federal*  
19        *Procurement Policy Act (41 U.S.C. 403(11)), as*  
20        *applicable pursuant to section 302A(a) of the*  
21        *Federal Property and Administrative Services*  
22        *Act of 1949 (41 U.S.C. 252a(a)), shall be deemed*  
23        *to be \$25,000,000 in the administration, with re-*  
24        *spect to such procurement, of—*

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

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

8           “(B) APPLICATION OF CERTAIN PROVI-  
9           SIONS.—Notwithstanding subparagraph (A) and  
10          the provision of law and regulations referred to  
11          in such subparagraph, each of the following pro-  
12          visions shall apply to procurements described in  
13          this paragraph to the same extent that such pro-  
14          visions would apply to such procurements in the  
15          absence of subparagraph (A):

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

19          “(ii) Subsections (a) and (b) of section  
20          7 of the Anti-Kickback Act of 1986 (41  
21          U.S.C. 57(a) and (b)).

22          “(iii) Section 304C of the Federal  
23          Property and Administrative Services Act  
24          of 1949 (41 U.S.C. 254d) (relating to the  
25          examination of contractor records).

1           “(C) *INTERNAL CONTROLS TO BE INSTI-*  
2           *TUTED.—The Secretary shall institute appro-*  
3           *priate internal controls for procurements that*  
4           *are under this paragraph, including require-*  
5           *ments with regard to documenting the justifica-*  
6           *tion for use of the authority in this paragraph.*

7           “(2) *OTHER THAN FULL AND OPEN COMPETI-*  
8           *TION.—(A) In using the authority provided in section*  
9           *303(c)(1) of title III of the Federal Property and Ad-*  
10           *ministrative Services Act of 1949 (41 U.S.C.*  
11           *253(c)(1)) to use procedures other than competitive*  
12           *procedures in the case of a procurement described in*  
13           *paragraph (1) of this subsection, the phrase ‘available*  
14           *from only one responsible source’ in such section*  
15           *303(c)(1) shall be deemed to mean ‘available from*  
16           *only one responsible source or only from a limited*  
17           *number of responsible sources’.*

18           “(B) *The authority under subparagraph (A) is*  
19           *in addition to any other authority to use procedures*  
20           *other than competitive procedures.*

21           “(C) *The Secretary shall implement this para-*  
22           *graph in accordance with applicable government-wide*  
23           *regulations, including requirements that offers be so-*  
24           *licitated from as many potential sources as is prac-*

1        *licable under the circumstances, that required notices*  
2        *be published, and that submitted offers be considered.*

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

5            “(A) *IN GENERAL.—For a procurement de-*  
6        *scribed by paragraph (1), the amount specified*  
7        *in subsections (c), (d), and (f) of section 32 of the*  
8        *Office of Federal Procurement Policy Act (41*  
9        *U.S.C. 428) shall be deemed to be \$15,000 in the*  
10       *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 purchases that are*  
15        *under this paragraph and that are greater than*  
16        *\$2,500.*

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

23        “(c) *AUTHORITY TO EXPEDITE PEER REVIEW.—*

24           “(1) *IN GENERAL.—The Secretary may, as the*  
25        *Secretary determines necessary to respond to pressing*

1        *qualified countermeasure research and development*  
2        *needs under this section, employ such expedited peer*  
3        *review procedures (including consultation with ap-*  
4        *propriate scientific experts) as the Secretary, in con-*  
5        *sultation with the Director of NIH, deems appro-*  
6        *priate to obtain assessment of scientific and technical*  
7        *merit and likely contribution to the field of qualified*  
8        *countermeasure research, in place of the peer review*  
9        *and advisory council review procedures that would be*  
10       *required under sections 301(a)(3), 405(b)(1)(B),*  
11       *405(b)(2), 406(a)(3)(A), 492, and 494, as applicable*  
12       *to a grant, contract, or cooperative agreement—*

13                *“(A) that is for performing, administering,*  
14                *or supporting qualified countermeasure research*  
15                *and development activities; and*

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

18                *“(2) SUBSEQUENT PHASES OF RESEARCH.—The*  
19        *Secretary’s determination of whether to employ expe-*  
20        *ditated peer review with respect to subsequent phases of*  
21        *a research grant or cooperative agreement under this*  
22        *section shall be determined without regard to the peer*  
23        *review procedures used for any prior peer review of*  
24        *that same grant or cooperative agreement.*

1       “(d) *AUTHORITY FOR PERSONAL SERVICES CON-*  
2 *TRACTS.*—

3               “(1) *IN GENERAL.*—*For the purpose of per-*  
4 *forming, administering, and supporting qualified*  
5 *countermeasure research and development activities,*  
6 *the Secretary may, as the Secretary determines nec-*  
7 *essary to respond to pressing qualified counter-*  
8 *measure research and development needs under this*  
9 *section, obtain by contract (in accordance with sec-*  
10 *tion 3109 of title 5, United States Code, but without*  
11 *regard to the limitations in such section on the period*  
12 *of service and on pay) the personal services of experts*  
13 *or consultants who have scientific or other profes-*  
14 *sional qualifications, except that in no case shall the*  
15 *compensation provided to any such expert or consult-*  
16 *ant exceed the daily equivalent of the annual rate of*  
17 *compensation for the President.*

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.*

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

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

19           “(B) *DETERMINATION OF EMPLOYEE STA-*  
20           *TUS TO BE FINAL.*—*A determination by the Sec-*  
21           *retary under subparagraph (A) that a person, or*  
22           *an officer, employee, or governing board member*  
23           *of a person, is or is not deemed to be an em-*  
24           *ployee of the Department of Health and Human*  
25           *Services shall be final and binding on the Sec-*

1           *retary and the Attorney General and other par-*  
2           *ties to any civil action or proceeding.*

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

7           “(e) *STREAMLINED PERSONNEL AUTHORITY.—*

8           “(1) *IN GENERAL.—In addition to any other*  
9           *personnel authorities, the Secretary may, as the Sec-*  
10          *retary determines necessary to respond to pressing*  
11          *qualified countermeasure research and development*  
12          *needs under this section, without regard to such pro-*  
13          *visions of title 5, United States Code, governing ap-*  
14          *pointments in the competitive service, and without re-*  
15          *gard to the provisions of chapter 51 and subchapter*  
16          *III of chapter 53 of such title relating to classification*  
17          *and General Schedule pay rates, appoint professional*  
18          *and technical employees, not to exceed 30 such em-*  
19          *ployees at any time, to positions in the National In-*  
20          *stitutes of Health to perform, administer, or support*  
21          *qualified countermeasure research and development*  
22          *activities in carrying out this section.*

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

1           “(f) *ACTIONS COMMITTED TO AGENCY DISCRETION.*—  
2 *Actions by the Secretary under the authority of this section*  
3 *are committed to agency discretion.*

4           “(g) *EFFECT ON RIGHT TO FILE PROTEST.*—*Nothing*  
5 *in this section shall affect the right of an interested party*  
6 *to file a protest with the contracting agency, to file a protest*  
7 *with the Comptroller General under subchapter V of chapter*  
8 *35 of title 31, United States Code, or to file an action in*  
9 *the United States Court of Federal Claims under section*  
10 *1491(b) of title 28, United States Code.”.*

11           (b) *TECHNICAL AMENDMENT.*—*Section 481A of the*  
12 *Public Health Service Act (42 U.S.C. 287a–2) is amend-*  
13 *ed—*

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

17                   (2) *in subsection (c)—*

18                           (A) *in paragraph (1), by inserting “or the*  
19 *Director of the National Institute of Allergy and*  
20 *Infectious Diseases” after “Director of the Cen-*  
21 *ter”;* *and*

22                           (B) *in paragraph (2), in the matter pre-*  
23 *ceding subparagraph (A), by striking “subsection*  
24 *(i)” and inserting “subsection (i)(1)”;*

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

4           (4) in subsection (e)—

5                 (A) in paragraph (1)—

6                     (i) in the matter preceding subpara-  
7                     graph (A), by inserting “or the Director of  
8                     the National Institute of Allergy and Infec-  
9                     tious Diseases” after “Director of the Cen-  
10                    ter”;

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

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

17                 (B) in paragraph (2), by inserting “or the  
18                 Director of the National Institute of Allergy and  
19                 Infectious Diseases” after “Director of the Cen-  
20                 ter”; and

21                 (C) in paragraph (4), by inserting “of the  
22                 Center or the Director of the National Institute  
23                 of Allergy and Infectious Diseases” after “Direc-  
24                 tor”;

25           (5) in subsection (f)—

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

4           (B) in paragraph (2), by inserting “of the  
5 Center or the Director of the National Institute  
6 of Allergy and Infectious Diseases” after “Direc-  
7 tor”; and

8           (6) in subsection (i)—

9           (A) by striking “APPROPRIATIONS.—For the  
10 purpose of carrying out this section,” and insert-  
11 ing the following: “APPROPRIATIONS.—

12           “(1) CENTER.—For the purpose of carrying out  
13 this section with respect to the Center,”; and

14           (B) by adding at the end the following:

15           “(2) NATIONAL INSTITUTE OF ALLERGY AND IN-  
16 FECTIOUS DISEASES.—For the purpose of carrying  
17 out this section with respect to the National Institute  
18 of Allergy and Infectious Diseases, there are author-  
19 ized to be appropriated such sums as may be nec-  
20 essary for fiscal year 2003.”.

21 **SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

22           (a) *IN GENERAL.*—Part B of title III of the Public  
23 Health Service Act, as amended by section 2 of this Act,  
24 is amended by inserting after section 319F–1 the following  
25 section:

1 **“SEC. 319F-2. STRATEGIC NATIONAL STOCKPILE.**

2 “(a) *STRATEGIC NATIONAL STOCKPILE.*—

3 “(1) *IN GENERAL.*—*The Secretary of Homeland*  
4 *Security (referred to in this section as the ‘Homeland*  
5 *Security Secretary’), in coordination with the Sec-*  
6 *retary and the Secretary of Veterans Affairs, shall*  
7 *maintain a stockpile or stockpiles of drugs, vaccines*  
8 *and other biological products, medical devices, and*  
9 *other supplies in such numbers, types, and amounts*  
10 *as are determined by the Secretary to be appropriate*  
11 *and practicable, taking into account other available*  
12 *sources, to provide for the emergency health security*  
13 *of the United States, including the emergency health*  
14 *security of children and other vulnerable populations,*  
15 *in the event of a bioterrorist attack or other public*  
16 *health emergency.*

17 “(2) *PROCEDURES.*—*The Secretary, in man-*  
18 *aging the stockpile under paragraph (1), shall—*

19 “(A) *consult with the working group under*  
20 *section 319F(a);*

21 “(B) *ensure that adequate procedures are*  
22 *followed with respect to such stockpile for inven-*  
23 *tory management and accounting, and for the*  
24 *physical security of the stockpile;*

1           “(C) *in consultation with Federal, State,*  
2           *and local officials, take into consideration the*  
3           *timing and location of special events;*

4           “(D) *review and revise, as appropriate, the*  
5           *contents of the stockpile on a regular basis to en-*  
6           *sure that emerging threats, advanced tech-*  
7           *nologies, and new countermeasures are ade-*  
8           *quately considered;*

9           “(E) *devise plans for the effective and time-*  
10           *ly supply-chain management of the stockpile, in*  
11           *consultation with appropriate Federal, State*  
12           *and local agencies, and the public and private*  
13           *health care infrastructure; and*

14           “(F) *ensure the adequate physical security*  
15           *of the stockpile.*

16           “(b) *SMALLPOX VACCINE DEVELOPMENT.—*

17           “(1) *IN GENERAL.—The Secretary shall award*  
18           *contracts, enter into cooperative agreements, or carry*  
19           *out such other activities as may reasonably be re-*  
20           *quired in order to ensure that the stockpile under sub-*  
21           *section (a) includes an amount of vaccine against*  
22           *smallpox as determined by such Secretary to be suffi-*  
23           *cient to meet the health security needs of the United*  
24           *States.*

1           “(2) *RULE OF CONSTRUCTION.*—*Nothing in this*  
2           *section shall be construed to limit the private dis-*  
3           *tribution, purchase, or sale of vaccines from sources*  
4           *other than the stockpile described in subsection (a).*

5           “(c) *ADDITIONAL AUTHORITY REGARDING PROCURE-*  
6           *MENT OF CERTAIN BIOMEDICAL COUNTERMEASURES;*  
7           *AVAILABILITY OF SPECIAL RESERVE FUND.*—

8           “(1) *IN GENERAL.*—

9           “(A) *USE OF FUND.*—*A security counter-*  
10           *measure may, in accordance with this subsection,*  
11           *be procured with amounts in the special reserve*  
12           *fund under paragraph (10).*

13           “(B) *SECURITY COUNTERMEASURE.*—*For*  
14           *purposes of this subsection, the term ‘security*  
15           *countermeasure’ means a priority counter-*  
16           *measure (as defined in section 319F(h))—*

17           “(i) *that affects national security;*

18           “(ii) *that is determined under para-*  
19           *graph (2)(B)(ii) to be a necessary counter-*  
20           *measure; and*

21           “(iii)(I) *that is approved or cleared*  
22           *under chapter V of the Federal Food, Drug,*  
23           *and Cosmetic Act, or licensed under section*  
24           *351 of this Act, for use as a countermeasure*  
25           *to a chemical, biological, radiological, or*

1 nuclear agent identified as a material  
2 threat under paragraph (2)(A)(ii); or

3 “(II) for which the Secretary deter-  
4 mines that sufficient and satisfactory clin-  
5 ical experience or research data (including  
6 data, if available, from pre-clinical and  
7 clinical trials) support a reasonable conclu-  
8 sion that the countermeasure will qualify  
9 for approval or licensing after the date of a  
10 determination under paragraph (5).

11 “(2) DETERMINATION OF MATERIAL THREATS.—

12 “(A) MATERIAL THREAT.—The Homeland  
13 Security Secretary, in consultation with the  
14 heads of other agencies as appropriate, shall on  
15 an ongoing basis—

16 “(i) assess current and emerging  
17 threats of chemical, biological, radiological,  
18 and nuclear agents; and

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

22 “(B) PUBLIC HEALTH IMPACT; NECESSARY  
23 COUNTERMEASURES.—The Secretary shall on an  
24 ongoing basis—

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

5           “(ii) determine, on the basis of such as-  
6           sessment, the agents for which priority  
7           countermeasures are necessary to protect the  
8           public health from a material threat.

9           “(3) ASSESSMENT OF AVAILABILITY AND APPRO-  
10          PRIATENESS OF COUNTERMEASURES.—The Secretary,  
11          in consultation with the Homeland Security Sec-  
12          retary, shall assess on an ongoing basis the avail-  
13          ability and appropriateness of specific counter-  
14          measures to address specific threats identified under  
15          paragraph (2).

16          “(4) CALL FOR SECURITY COUNTERMEASURES;  
17          COMMITMENT FOR RECOMMENDATION FOR PROCURE-  
18          MENT.—

19                 “(A) PROPOSAL TO THE PRESIDENT.—If,  
20                 pursuant to an assessment under paragraph (3),  
21                 the Homeland Security Secretary and the Sec-  
22                 retary make a determination that a security  
23                 countermeasure would be appropriate, such Sec-  
24                 retaries may jointly submit to the President a  
25                 proposal to—

1           “(i) issue a call for the development of  
2           such security countermeasure; and

3           “(ii) make a commitment that, upon  
4           the first development of such security coun-  
5           termeasure that meets the conditions for  
6           procurement under paragraph (5), the Sec-  
7           retaries will, based in part on information  
8           obtained pursuant to such call, make a rec-  
9           ommendation under paragraph (6) that the  
10          special reserve fund under paragraph (10)  
11          be made available for the procurement of  
12          such security countermeasure.

13          “(B) COUNTERMEASURE SPECIFICATIONS.—  
14          The Homeland Security Secretary and the Sec-  
15          retary shall, to the extent practicable, include in  
16          the proposal under subparagraph (A)—

17                 “(i) estimated quantity of purchase (in  
18                 the form of number of doses or number of ef-  
19                 fective courses of treatments regardless of  
20                 dosage form);

21                 “(ii) necessary measures of minimum  
22                 safety and effectiveness;

23                 “(iii) estimated price for each dose or  
24                 effective course of treatment regardless of  
25                 dosage form; and

1           “(iv) other information that may be  
2           necessary to encourage and facilitate re-  
3           search, development, and manufacture of the  
4           countermeasure or to provide specifications  
5           for the countermeasure.

6           “(C) *PRESIDENTIAL APPROVAL.*—If the  
7           President approves a proposal under subpara-  
8           graph (A), the Homeland Security Secretary and  
9           the Secretary shall make known to persons who  
10          may respond to a call for the security counter-  
11          measure involved—

12                   “(i) the call for the countermeasure;

13                   “(ii) specifications for the counter-  
14                   measure under subparagraph (B); and

15                   “(iii) a commitment described in sub-  
16                   paragraph (A)(ii).

17          “(5) *SECRETARY’S DETERMINATION OF COUN-*  
18          *TERMEASURES APPROPRIATE FOR FUNDING FROM*  
19          *SPECIAL RESERVE FUND.*—

20                   “(A) *IN GENERAL.*—The Secretary, in ac-  
21                   cordance with the provisions of this paragraph,  
22                   shall identify specific security countermeasures  
23                   that the Secretary determines, in consultation  
24                   with the Homeland Security Secretary, to be ap-  
25                   propriate for inclusion in the stockpile under

1            *subsection (a) pursuant to procurements made*  
2            *with amounts in the special reserve fund under*  
3            *paragraph (10) (referred to in this subsection in-*  
4            *dividually as a ‘procurement under this sub-*  
5            *section’).*

6            *“(B) REQUIREMENTS.—In making a deter-*  
7            *mination under subparagraph (A) with respect*  
8            *to a security countermeasure, the Secretary shall*  
9            *determine and consider the following:*

10            *“(i) The quantities of the product that*  
11            *will be needed to meet the needs of the stock-*  
12            *pile.*

13            *“(ii) The feasibility of production and*  
14            *delivery within five years of sufficient*  
15            *quantities of the product.*

16            *“(iii) Whether there is a lack of a sig-*  
17            *nificant commercial market for the product*  
18            *at the time of procurement, other than as a*  
19            *security countermeasure.*

20            *“(6) RECOMMENDATION FOR PRESIDENT’S AP-*  
21            *PROVAL.—*

22            *“(A) RECOMMENDATION FOR PROCURE-*  
23            *MENT.—In the case of a security countermeasure*  
24            *that the Secretary has, in accordance with para-*  
25            *graphs (2), (3), and (5), determined to be appro-*

1            *priate for procurement under this subsection, the*  
2            *Homeland Security Secretary and the Secretary*  
3            *shall jointly submit to the President, in coordi-*  
4            *nation with the Director of the Office of Manage-*  
5            *ment and Budget, a recommendation that the*  
6            *special reserve fund under paragraph (10) be*  
7            *made available for the procurement of such coun-*  
8            *termeasure.*

9            *“(B) PRESIDENTIAL APPROVAL.—The spe-*  
10           *cial reserve fund under paragraph (10) is avail-*  
11           *able for a procurement of a security counter-*  
12           *measure only if the President has approved a*  
13           *recommendation under subparagraph (A) re-*  
14           *garding the countermeasure.*

15           *“(C) NOTICE TO CONGRESS.—The Secretary*  
16           *and the Homeland Security Secretary shall no-*  
17           *tify the Congress of each decision of the President*  
18           *to approve a recommendation under subpara-*  
19           *graph (A). Such notice shall include an expla-*  
20           *nation of the decision to make available the spe-*  
21           *cial reserve fund under paragraph (10) for pro-*  
22           *curement of such a countermeasure, including,*  
23           *where available, the identification of the poten-*  
24           *tial supplier or suppliers of such counter-*  
25           *measure, and whether other potential suppliers*

1           *of the same or similar countermeasures were con-*  
2           *sidered and rejected for procurement under this*  
3           *section and the reasons therefor.*

4           “(D) *SUBSEQUENT SPECIFIC COUNTER-*  
5           *MEASURES.—Procurement under this subsection*  
6           *of a security countermeasure for a particular*  
7           *purpose does not preclude the subsequent pro-*  
8           *curement under this subsection of any other secu-*  
9           *rity countermeasure for such purpose if the Sec-*  
10          *retary has determined under paragraph (5)(A)*  
11          *that such countermeasure is appropriate for in-*  
12          *clusion in the stockpile and if, as determined by*  
13          *the Secretary, such countermeasure provides im-*  
14          *proved safety or effectiveness, or for other reasons*  
15          *enhances preparedness to respond to threats of*  
16          *use of a biological, chemical, radiological, or nu-*  
17          *clear agent. Such a determination by the Sec-*  
18          *retary is committed to agency discretion.*

19          “(E) *RULE OF CONSTRUCTION.—Rec-*  
20          *ommendations and approvals under this para-*  
21          *graph apply solely to determinations that the*  
22          *special reserve fund under paragraph (10) will*  
23          *be made available for a procurement of a secu-*  
24          *rity countermeasure, and not to the substance of*

1           *contracts for such procurement or other matters*  
2           *relating to awards of such contracts.*

3           “(7) *PROCUREMENT.*—

4                   “(A) *IN GENERAL.*—*For purposes of a pro-*  
5                   *urement under this subsection that is approved*  
6                   *by the President under paragraph (6), the*  
7                   *Homeland Security Secretary and the Secretary*  
8                   *shall have responsibilities in accordance with*  
9                   *subparagraphs (B) and (C).*

10                   “(B) *INTERAGENCY AGREEMENTS.*—

11                           “(i) *FOR PROCUREMENT.*—*The Home-*  
12                           *land Security Secretary shall enter into an*  
13                           *agreement with the Secretary for procure-*  
14                           *ment of a security countermeasure in ac-*  
15                           *cordance with the provisions of this para-*  
16                           *graph. The special reserve fund under para-*  
17                           *graph (10) shall be available for the Sec-*  
18                           *retary’s costs of such procurement, other*  
19                           *than as provided in clause (ii).*

20                           “(ii) *FOR ADMINISTRATIVE COSTS.*—

21                           *The agreement entered into between the*  
22                           *Homeland Security Secretary and the Sec-*  
23                           *retary for managing the stockpile under*  
24                           *subsection (a) shall provide for reimburse-*  
25                           *ment of the Secretary’s administrative costs*

1 relating to procurements under this sub-  
2 section.

3 “(C) *PROCUREMENT.*—

4 “(i) *IN GENERAL.*—*The Secretary shall*  
5 *be responsible for—*

6 “(I) *arranging for procurement of*  
7 *a security countermeasure, including*  
8 *negotiating terms (including quantity,*  
9 *production schedule, and price) of, and*  
10 *entering into, contracts and coopera-*  
11 *tive agreements, and for carrying out*  
12 *such other activities as may reasonably*  
13 *be required, in accordance with the*  
14 *provisions of this subparagraph; and*

15 “(II) *promulgating regulations to*  
16 *implement clauses (v), (vi), and (vii),*  
17 *and any other provisions of this sub-*  
18 *section.*

19 “(ii) *CONTRACT TERMS.*—*A contract*  
20 *for procurements under this subsection shall*  
21 *(or, as specified below, may) include the fol-*  
22 *lowing terms:*

23 “(I) *PAYMENT CONDITIONED ON*  
24 *SUBSTANTIAL DELIVERY.*—*The contract*  
25 *shall provide that no payment may be*

1           *made until delivery has been made of*  
2           *a substantial portion (as determined*  
3           *by the Secretary) of the total number*  
4           *of units contracted for, except that,*  
5           *notwithstanding any other provision of*  
6           *law, the contract may provide that, if*  
7           *the Secretary determines (in the Sec-*  
8           *retary's discretion) that an advance*  
9           *payment is necessary to ensure success*  
10           *of a project, the Secretary may pay an*  
11           *amount, not to exceed 10 percent of the*  
12           *contract amount, in advance of deliv-*  
13           *ery. The contract shall provide that*  
14           *such advance payment is required to be*  
15           *repaid if there is a failure to perform*  
16           *under the contract, except in special*  
17           *circumstances as determined by the*  
18           *Secretary on a contract by contract*  
19           *basis.*

20           “(II) *CONTRACT DURATION.*—*The*  
21           *contract shall be for a period not to ex-*  
22           *ceed five years, except that, in first*  
23           *awarding the contract, the Secretary*  
24           *may provide for a longer duration, not*  
25           *exceeding eight years, if the Secretary*

1 *determines that complexities or other*  
2 *difficulties in performance under the*  
3 *contract justify such a period. The con-*  
4 *tract shall be renewable for additional*  
5 *periods, none of which shall exceed five*  
6 *years.*

7 *“(III) STORAGE BY VENDOR.—*  
8 *The contract may provide that the ven-*  
9 *dor will provide storage for stocks of a*  
10 *product delivered to the ownership of*  
11 *the Federal Government under the con-*  
12 *tract, for such period and under such*  
13 *terms and conditions as the Secretary*  
14 *may specify, and in such case amounts*  
15 *from the special reserve fund under*  
16 *paragraph (10) shall be available for*  
17 *costs of shipping, handling, storage,*  
18 *and related costs for such product.*

19 *“(iii) AVAILABILITY OF SIMPLIFIED AC-*  
20 *QUISITION PROCEDURES.—*

21 *“(I) IN GENERAL.—If the Sec-*  
22 *retary determines that there is a press-*  
23 *ing need for a procurement of a spe-*  
24 *cific countermeasure, the amount of the*  
25 *procurement under this subsection*

1 shall be deemed to be below the thresh-  
2 old amount specified in section 4(11)  
3 of the Office of Federal Procurement  
4 Policy Act (41 U.S.C. 403(11)), for  
5 purposes of application to such pro-  
6 curement, pursuant to section 302A(a)  
7 of the Federal Property and Adminis-  
8 trative Services Act of 1949 (41 U.S.C.  
9 252a(a)), of—

10 “(aa) section 303(g)(1)(A) of  
11 the Federal Property and Admin-  
12 istrative Services Act of 1949 (41  
13 U.S.C. 253(g)(1)(A)) and its im-  
14 plementing regulations; and

15 “(bb) section 302A(b) of such  
16 Act (41 U.S.C. 252a(b)) and its  
17 implementing regulations.

18 “(II) APPLICATION OF CERTAIN  
19 PROVISIONS.—Notwithstanding sub-  
20 clause (I) and the provision of law and  
21 regulations referred to in such clause,  
22 each of the following provisions shall  
23 apply to procurements described in  
24 this clause to the same extent that such  
25 provisions would apply to such pro-

1                   *curements in the absence of subclause*  
2                   *(I):*

3                   “*(aa) Chapter 37 of title 40,*  
4                   *United States Code (relating to*  
5                   *contract work hours and safety*  
6                   *standards).*

7                   “*(bb) Subsections (a) and (b)*  
8                   *of section 7 of the Anti-Kickback*  
9                   *Act of 1986 (41 U.S.C. 57(a) and*  
10                  *(b)).*

11                  “*(cc) Section 304C of the*  
12                  *Federal Property and Adminis-*  
13                  *trative Services Act of 1949 (41*  
14                  *U.S.C. 254d) (relating to the ex-*  
15                  *amination of contractor records).*

16                  “*(iv) OTHER THAN FULL AND OPEN*  
17                  *COMPETITION.—(I) In using the authority*  
18                  *provided in section 303(c)(1) of title III of*  
19                  *the Federal Property and Administrative*  
20                  *Services Act of 1949 (41 U.S.C. 253(c)(1))*  
21                  *to use procedures other than competitive*  
22                  *procedures in the case of a procurement*  
23                  *under this subsection, the phrase ‘available*  
24                  *from only one responsible source’ in such*  
25                  *section 303(c)(1) shall be deemed to mean*

1           *‘available from only one responsible source*  
2           *or only from a limited number of respon-*  
3           *sible sources’.*

4           *“(II) The authority under subclause (I)*  
5           *is in addition to any other authority to use*  
6           *procedures other than competitive proce-*  
7           *dures.*

8           *“(III) The Secretary shall implement*  
9           *this clause in accordance with applicable*  
10           *government-wide regulations, including re-*  
11           *quirements that offers be solicited from as*  
12           *many potential sources as is practicable*  
13           *under the circumstances, that required no-*  
14           *tices be published, and that submitted offers*  
15           *be considered.*

16           *“(v) PREMIUM PROVISION IN MULTIPLE*  
17           *AWARD CONTRACTS.—*

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

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

6                   “(bb) promises to pay one or  
7                   more specified premiums based on  
8                   the priority of such vendors’ pro-  
9                   duction and delivery of the incre-  
10                  ment identified under item (aa),  
11                  in accordance with the terms and  
12                  conditions of the contract.

13                  “(II) DETERMINATION OF GOV-  
14                  ERNMENT’S REQUIREMENT NOT RE-  
15                  VIEWABLE.—If the Secretary includes  
16                  in each of a set of contracts a provision  
17                  as described in subclause (I), such Sec-  
18                  retary’s determination of the total  
19                  quantity of security countermeasure re-  
20                  quired, and any amendment of such  
21                  determination, is committed to agency  
22                  discretion.

23                  “(vi) EXTENSION OF CLOSING DATE  
24                  FOR RECEIPT OF PROPOSALS NOT REVIEW-  
25                  ABLE.—A decision by the Secretary to ex-

1           *tend the closing date for receipt of proposals*  
2           *for a procurement under this subsection is*  
3           *committed to agency discretion.*

4           “(vii) *LIMITING COMPETITION TO*  
5           *SOURCES RESPONDING TO REQUEST FOR IN-*  
6           *FORMATION.—In conducting a procurement*  
7           *under this subsection, the Secretary may ex-*  
8           *clude a source that has not responded to a*  
9           *request for information under section*  
10           *303A(a)(1)(B) of the Federal Property and*  
11           *Administrative Services Act of 1949 (41*  
12           *U.S.C. 253a(a)(1)(B)) if such request has*  
13           *given notice that the Secretary may so ex-*  
14           *clude such a source.*

15           “(8) *INTERAGENCY COOPERATION.—*

16           “(A) *IN GENERAL.—In carrying out activi-*  
17           *ties under this section, the Homeland Security*  
18           *Secretary and the Secretary are authorized, sub-*  
19           *ject to subparagraph (B), to enter into inter-*  
20           *agency agreements and other collaborative under-*  
21           *takings with other agencies of the United States*  
22           *Government.*

23           “(B) *LIMITATION.—An agreement or under-*  
24           *taking under this paragraph shall not authorize*  
25           *another agency to exercise the authorities pro-*

1            *vided by this section to the Homeland Security*  
2            *Secretary or to the Secretary.*

3            “(9) *RESTRICTIONS ON USE OF FUNDS.—*  
4            *Amounts in the special reserve fund under paragraph*  
5            *(10) shall not be used to pay—*

6                    “(A) *costs for the purchase of vaccines*  
7                    *under procurement contracts entered into before*  
8                    *the date of the enactment of the Project Bio-*  
9                    *Shield Act of 2003; or*

10                    “(B) *administrative costs.*

11            “(10) *SPECIAL RESERVE FUND.—For purposes of*  
12            *this subsection, the term ‘special reserve fund’ has the*  
13            *meaning given such term in section 510 of the Home-*  
14            *land Security Act of 2002.*

15            “(d) *DISCLOSURES.—No Federal agency shall disclose*  
16            *under section 552, United States Code, any information*  
17            *identifying the location at which materials in the stockpile*  
18            *under subsection (a) are stored.*

19            “(e) *DEFINITION.—For purposes of subsection (a), the*  
20            *term ‘stockpile’ includes—*

21                    “(1) *a physical accumulation (at one or more lo-*  
22                    *cations) of the supplies described in subsection (a); or*

23                    “(2) *a contractual agreement between the Home-*  
24                    *land Security Secretary and a vendor or vendors*

1        *under which such vendor or vendors agree to provide*  
 2        *to such Secretary supplies described in subsection (a).*

3        “(f) *AUTHORIZATION OF APPROPRIATIONS.*—

4                “(1) *STRATEGIC NATIONAL STOCKPILE.*—*For the*  
 5        *purpose of carrying out subsection (a), there are au-*  
 6        *thorized to be appropriated \$640,000,000 for fiscal*  
 7        *year 2002, and such sums as may be necessary for*  
 8        *each of fiscal years 2003 through 2006. Such author-*  
 9        *ization is in addition to amounts in the special re-*  
 10        *serve fund under subsection (c)(10).*

11                “(2) *SMALLPOX VACCINE DEVELOPMENT.*—*For*  
 12        *the purpose of carrying out subsection (b), there are*  
 13        *authorized to be appropriated \$509,000,000 for fiscal*  
 14        *year 2002, and such sums as may be necessary for*  
 15        *each of fiscal years 2003 through 2006.”.*

16        (b) *AMENDMENT TO HOMELAND SECURITY ACT OF*  
 17        *2002.*—*Title V of the Homeland Security Act of 2002 (116*  
 18        *Stat. 2212; 6 U.S.C. 311 et seq.) is amended by adding at*  
 19        *the end the following:*

20        **“SEC. 510. PROCUREMENT OF SECURITY COUNTER-**  
 21                        **MEASURES FOR STRATEGIC NATIONAL**  
 22                        **STOCKPILE.**

23                “(a) *AUTHORIZATION OF APPROPRIATIONS.*—*For pro-*  
 24        *curement of security countermeasures under section 319F-*  
 25        *2(c) of the Public Health Service Act (referred to in this*

1 *section as the ‘security countermeasures program’), there is*  
2 *authorized to be appropriated up to \$5,593,000,000 for the*  
3 *fiscal years 2004 through 2013. Of the amounts appro-*  
4 *priated under the preceding sentence, not to exceed*  
5 *\$3,418,000,000 may be obligated during the fiscal years*  
6 *2004 through 2008, of which not to exceed \$890,000,000*  
7 *may be obligated during fiscal year 2004.*

8       “(b) *SPECIAL RESERVE FUND.*—*For purposes of the*  
9 *security countermeasures program, the term ‘special reserve*  
10 *fund’ means the appropriations account established as a re-*  
11 *sult of any appropriations made under subsection (a).*

12       “(c) *AVAILABILITY.*—

13               “(1) *DURATION OF AVAILABILITY FOR OBLIGA-*  
14 *TION.*—*Subject to paragraph (2), all amounts appro-*  
15 *priated under subsection (a) are available for obliga-*  
16 *tion through the end of fiscal year 2013, provided*  
17 *that any portion of such amount that remains unobli-*  
18 *gated for such purposes on the expiration of such term*  
19 *shall be returned to the United States Treasury and*  
20 *shall not be available for subsequent obligation for*  
21 *any purpose.*

22               “(2) *INITIAL AVAILABILITY FOR PARTICULAR*  
23 *PROCUREMENTS.*—*Amounts appropriated under sub-*  
24 *section (a) become available for a procurement under*  
25 *the security countermeasures program only upon the*

1 approval by the President of such availability for the  
2 procurement in accordance with paragraph (6)(B) of  
3 such program.”.

4 (c) *CONFORMING AMENDMENTS.*—(1) Section 121 of  
5 the Public Health Security and Bioterrorism Preparedness  
6 and Response Act of 2002 (116 Stat. 611; 42 U.S.C. 300hh–  
7 12) is repealed.

8 (2) The item relating to section 121 in the table of  
9 contents (contained in section 1(b)) of such Act is repealed.

10 (3) With respect to the program established under  
11 former section 121 of such Act, the repeal of such section  
12 under paragraph (1) applies as a modification of the pro-  
13 gram in accordance with the amendment made by sub-  
14 section (a) of this section, and not as the termination of  
15 the program and the establishment of a different program.

16 **SEC. 4. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE**  
17 **IN EMERGENCIES.**

18 Subchapter E of chapter V of the Federal Food, Drug,  
19 and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended  
20 by adding at the end the following section:

21 **“SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**  
22 **USE IN EMERGENCIES.**

23 “(a) *IN GENERAL.*—

24 “(1) *EMERGENCY USES.*—Notwithstanding sec-  
25 tions 505, 510(k), and 515 of this Act and section 351

1       of the Public Health Service Act, and subject to the  
2       provisions of this section, the Secretary may authorize  
3       the introduction into interstate commerce, during the  
4       effective period of a declaration under subsection (b),  
5       of a drug or device intended for use in an actual or  
6       potential emergency (referred to in this section as an  
7       ‘emergency use’).

8               “(2) APPROVAL STATUS OF PRODUCT.—An au-  
9       thorization under paragraph (1) may authorize an  
10      emergency use of a product that—

11               “(A) is not approved, licensed, or cleared  
12      for commercial distribution under a provision of  
13      law referred to in such paragraph (referred to in  
14      this section as an ‘unapproved product’); or

15               “(B) is approved, licensed, or cleared under  
16      such a provision, but which use is not under  
17      such provision an approved, licensed, or cleared  
18      use of the product (referred to in this section as  
19      an ‘unapproved use of an approved product’).

20               “(3) RELATION TO OTHER USES.—An emergency  
21      use authorized under paragraph (1) for a product is  
22      in addition to any other use that is authorized for the  
23      product under a provision of law referred to in such  
24      paragraph.

25               “(4) DEFINITIONS.—For purposes of this section:

1           “(A) The term ‘emergency use’ has the  
2 meaning indicated for such term in paragraph  
3 (1).

4           “(B) The term ‘product’ means a drug or  
5 device.

6           “(C) The term ‘unapproved product’ has the  
7 meaning indicated for such term in paragraph  
8 (2)(A).

9           “(D) The term ‘unapproved use of an ap-  
10 proved product’ has the meaning indicated for  
11 such term in paragraph (2)(B).

12       “(b) *DECLARATION OF EMERGENCY.*—

13           “(1) *IN GENERAL.*—The Secretary may declare  
14 an emergency justifying the authorization under this  
15 subsection for a product on the basis of—

16           “(A) a determination by the Secretary of  
17 Homeland Security that there is a national  
18 emergency, or a significant potential for a na-  
19 tional emergency, involving a heightened risk of  
20 attack with a specified biological, chemical, radi-  
21 ological, or nuclear agent or agents;

22           “(B) a determination by the Secretary of  
23 Defense that there is a military emergency, or a  
24 significant potential for a military emergency,  
25 involving a heightened risk to United States

1           *military forces of attack with a biological, chem-*  
2           *ical, radiological, or nuclear agent or agents; or*

3           “(C) *a determination by the Secretary of a*  
4           *public health emergency under section 319 of the*  
5           *Public Health Service Act, affecting national se-*  
6           *curity and involving a specified biological, chem-*  
7           *ical, radiological, or nuclear agent or agents, or*  
8           *a specified disease or condition that may be at-*  
9           *tributable to such agent or agents.*

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 one-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) *ADVANCE NOTICE OF TERMINATION.*—*In*  
4            *terminating a declaration under this section, the Sec-*  
5            *retary shall provide advance notice that the declara-*  
6            *tion will be terminated. The period of advance notice*  
7            *shall be a period reasonably determined to provide—*

8                    *“(A) in the case of an unapproved product,*  
9                    *a sufficient period for disposition of shipments of*  
10                   *the product, including the return of such ship-*  
11                   *ments to the manufacturer (in the case of a man-*  
12                   *ufacturer that chooses to have the shipments re-*  
13                   *turned); and*

14                   *“(B) in the case of unapproved uses of ap-*  
15                   *proved products, a sufficient period for the dis-*  
16                   *position of any labeling that was provided with*  
17                   *respect to the emergency use involved.*

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

22            “(c) *CRITERIA FOR ISSUANCE OF AUTHORIZATION.*—  
23            *The Secretary may issue an authorization under this sec-*  
24            *tion with respect to the emergency use of a product only*  
25            *if, after consultation with the Director of the National Insti-*

1 *tutes of Health and the Director of the Centers for Disease*  
2 *Control and Prevention, to the extent feasible and appro-*  
3 *priate given the circumstances of the emergency involved,*  
4 *the Secretary concludes—*

5           “(1) that an agent specified in a declaration  
6           under subsection (b) can cause a serious or life-threat-  
7           ening disease or condition;

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

12                  “(A) the product may be effective in detect-  
13                  ing, diagnosing, treating, or preventing—

14                          “(i) such disease or condition; or

15                          “(ii) a serious or life-threatening dis-  
16                          ease or condition caused by a product au-  
17                          thorized under this section or approved  
18                          under this Act or the Public Health Service  
19                          Act, for detecting, diagnosing, treating, or  
20                          preventing such a disease or condition  
21                          caused by such an agent; and

22                  “(B) the known and potential benefits of the  
23                  product, when used to detect, diagnose, prevent,  
24                  or treat such disease or condition, outweigh the  
25                  known and potential risks of the product;

1           “(3) that there is no adequate, approved, and  
2           available alternative to the product for detecting, di-  
3           agnosing, preventing, or treating such disease or con-  
4           dition; and

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

7           “(d) SCOPE OF AUTHORIZATION.—

8           “(1) IN GENERAL.—An authorization of a prod-  
9           uct under this section shall state—

10           “(A) each disease or condition that the  
11           product may be used to detect, diagnose, prevent,  
12           or treat within the scope of the authorization;

13           “(B) the Secretary’s conclusions, made  
14           under subsection (c)(2)(B), that the known and  
15           potential benefits of the product, when used to  
16           detect, diagnose, prevent, or treat such disease or  
17           condition, outweigh the known and potential  
18           risks of the product; and

19           “(C) the Secretary’s conclusions, made  
20           under subsection (c), concerning the safety and  
21           potential effectiveness of the product in detecting,  
22           diagnosing, preventing, or treating such diseases  
23           or conditions, including an assessment of the  
24           available scientific evidence.

1           “(2) *CONFIDENTIAL INFORMATION.*—*Nothing in*  
2 *this section alters or amends section 1905 of title 18,*  
3 *United States Code, or section 552(b)(4) of title 5 of*  
4 *such Code.*

5           “(e) *CONDITIONS OF AUTHORIZATION.*—

6           “(1) *UNAPPROVED PRODUCT.*—

7           “(A) *REQUIRED CONDITIONS.*—*With respect*  
8 *to the emergency use of an unapproved product,*  
9 *the Secretary, to the extent feasible given the cir-*  
10 *cumstances of the emergency, shall, for persons*  
11 *who choose to carry out one or more activities for*  
12 *which the authorization is issued, establish such*  
13 *conditions on an authorization under this sec-*  
14 *tion as the Secretary finds necessary or appro-*  
15 *priate to protect the public health, including the*  
16 *following:*

17           “(i) *Appropriate conditions designed to*  
18 *ensure that, to the extent feasible given the*  
19 *circumstances of the emergency, health care*  
20 *professionals administering the product are*  
21 *informed—*

22           “(I) *that the Secretary has au-*  
23 *thorized the emergency use of the prod-*  
24 *uct;*

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

6           “(III) of the alternatives to the  
7           product that are available, and of their  
8           benefits and risks.

9           “(ii) Appropriate conditions designed  
10          to ensure that, to the extent feasible given  
11          the circumstances of the emergency, individ-  
12          uals to whom the product is administered  
13          are informed—

14               “(I) that the Secretary has au-  
15               thorized the emergency use of the prod-  
16               uct;

17               “(II) of the significant known and  
18               potential benefits and risks of such use,  
19               and of the extent to which such benefits  
20               and risks are unknown; and

21               “(III) of the option to accept or  
22               refuse administration of the product, of  
23               the consequences, if any, of refusing  
24               administration of the product, and of  
25               the alternatives to the product that are

1           *available and of their benefits and*  
2           *risks.*

3           “(iii) *Appropriate conditions for the*  
4           *monitoring and reporting of adverse events*  
5           *associated with the emergency use of the*  
6           *product.*

7           “(iv) *For manufacturers of the prod-*  
8           *uct, appropriate conditions concerning rec-*  
9           *ordkeeping and reporting, including records*  
10          *access by the Secretary, with respect to the*  
11          *emergency use of the product.*

12          “(B) *AUTHORITY FOR ADDITIONAL CONDI-*  
13          *TIONS.—With respect to the emergency use of an*  
14          *unapproved product, the Secretary, to the extent*  
15          *feasible given the circumstances of the emergency,*  
16          *may, for persons who choose to carry out one or*  
17          *more activities for which the authorization is*  
18          *issued, establish such conditions on an author-*  
19          *ization under this section as the Secretary finds*  
20          *necessary or appropriate to protect the public*  
21          *health, including the following:*

22               “(i) *Appropriate conditions on which*  
23               *entities may distribute the product with re-*  
24               *spect to the emergency use of the product*  
25               *(including limitation to distribution by*

1           *government entities), and on how distribu-*  
2           *tion is to be performed.*

3           “(ii) *Appropriate conditions on who*  
4           *may administer the product with respect to*  
5           *the emergency use of the product, and on*  
6           *the categories of individuals to whom, and*  
7           *the circumstances under which, the product*  
8           *may be administered with respect to such*  
9           *use.*

10          “(iii) *For persons other than manufac-*  
11          *turers of the product, appropriate condi-*  
12          *tions concerning recordkeeping and report-*  
13          *ing, including records access by the Sec-*  
14          *retary, with respect to the emergency use of*  
15          *the product.*

16          “(iv) *With respect to the emergency use*  
17          *of the product, waive or limit, to the extent*  
18          *appropriate given the circumstances of the*  
19          *emergency, conditions regarding current*  
20          *good manufacturing practice otherwise ap-*  
21          *plicable to the manufacture, processing,*  
22          *packing, or holding of products subject to*  
23          *regulation under this Act, including such*  
24          *requirements established in section 501.*

1           “(2) *UNAPPROVED USE.*—*With respect to the*  
2           *emergency use of a product that is an unapproved use*  
3           *of an approved product:*

4                   “(A) *The Secretary may, for manufacturers*  
5                   *of the product who choose to carry out one or*  
6                   *more activities for which the authorization is*  
7                   *issued, establish any of the conditions described*  
8                   *in clauses (i) through (iv) of paragraph (1)(A).*

9                   “(B)(i) *If the authorization under this sec-*  
10                   *tion regarding the emergency use authorizes a*  
11                   *change in the labeling of the product, but the*  
12                   *manufacturer of the product chooses not to make*  
13                   *such change, such authorization may not author-*  
14                   *ize distributors of the product or any other per-*  
15                   *son to alter or obscure the labeling provided by*  
16                   *the manufacturer.*

17                   “(i) *In the circumstances described in*  
18                   *clause (i), an authorization under this section*  
19                   *regarding the emergency use may, for persons*  
20                   *who do not manufacture the product and who*  
21                   *choose to act under this clause, authorize such*  
22                   *persons to provide information on the product in*  
23                   *addition to the labeling provided by the manu-*  
24                   *facturer, subject to compliance with clause (i).*

1           *Such additional information shall not be consid-*  
2           *ered labeling for purposes of section 502.*

3           “(f) *DURATION OF AUTHORIZATION.*—

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

9           “(2) *CONTINUED USE AFTER END OF EFFECTIVE*  
10          *PERIOD.*—*An authorization shall continue to be effec-*  
11          *tive for continued use with respect to patients to*  
12          *whom it was administered during the period de-*  
13          *scribed by paragraph (1), to the extent found nec-*  
14          *essary by such patients’ attending physicians.*

15          “(g) *REVOCAION OF AUTHORIZATION.*—

16          “(1) *REVIEW.*—*The Secretary shall periodically*  
17          *review the circumstances and the appropriateness of*  
18          *an authorization under this section.*

19          “(2) *REVOCAION.*—*The Secretary may revoke*  
20          *an authorization under this section if, in the Sec-*  
21          *retary’s unreviewable discretion, the criteria under*  
22          *subsection (c) for issuance of such authorization are*  
23          *no longer met.*

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

1 *tion, and each termination or revocation of an authoriza-*  
2 *tion, and an explanation of the reasons therefor, under this*  
3 *section.*

4 “(i) *ACTIONS COMMITTED TO AGENCY DISCRETION.—*  
5 *Actions under the authority of this section by the Secretary,*  
6 *by the Secretary of Defense, or by the Secretary of Home-*  
7 *land Security are committed to agency discretion.*

8 “(j) *RULES OF CONSTRUCTION.—Nothing in this sec-*  
9 *tion shall be construed to impair or otherwise affect—*

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

14 “(2) *the authority of the Secretary of Defense*  
15 *with respect to the Department of Defense, including*  
16 *the armed forces, under other provisions of Federal*  
17 *law; or*

18 “(3) *the authority of the Secretary under section*  
19 *319F–2 to manage the stockpile under such section.*

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

22 “(1) *WAIVER OF REQUIREMENT RELATING TO*  
23 *OPTION TO REFUSE.—In the case of administration of*  
24 *a countermeasure to members of the armed forces, a*  
25 *requirement, under subsection (e)(1)(A)(ii)(III), de-*

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

8 “(2) *PROVISION OF INFORMATION TO MEMBER OF*  
9 *THE ARMED FORCES.*—If the Secretary makes a deter-  
10 mination that it is not feasible for the information re-  
11 quired by subsection (e)(1)(A)(ii) to be provided to a  
12 member of the armed forces prior to the administra-  
13 tion of the product, such information shall be pro-  
14 vided to such member of the armed forces (or next-of-  
15 kin in the case of the death of a member) to whom  
16 the product was administered as soon as possible, but  
17 not later than 30 days, after such administration. In-  
18 formation concerning the administration of the prod-  
19 uct shall be recorded in the medical record of the  
20 member.

21 “(3) *EFFECT ON STATUTE PERTAINING TO INVES-*  
22 *TIGATIONAL NEW DRUGS.*—In the case of an author-  
23 ization based on a determination by the Secretary of  
24 Defense under subsection (b)(1)(B), section 1107 of  
25 title 10, United States Code, shall not apply to use

1       of a product that is the subject of such authorization,  
2       within the scope of such authorization and while such  
3       authorization is effective.

4       “(l) *RELATION TO OTHER PROVISIONS.*—If a product  
5       is the subject of an authorization under this section, the  
6       use of such product within the scope of the authorization—

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

9               “(2) shall not be subject to any requirements oth-  
10              erwise applicable to clinical investigations pursuant  
11              to other provisions of this Act.

12       “(m) *DISCRETION REGARDING USE OF AUTHORIZA-*  
13       *TION.*—Nothing in this section provides the Secretary any  
14       authority to require any person to carry out any activity  
15       that becomes lawful pursuant to an authorization under  
16       this section, and no person is required to inform the Sec-  
17       retary that the person will not be carrying out such activ-  
18       ity, except that a manufacturer of a sole-source unapproved  
19       product authorized for emergency use shall notify the Sec-  
20       retary within a reasonable period of time after the issuance  
21       by the Secretary of such authorization if such manufacturer  
22       does not intend to carry out an activity or activities under  
23       the authorization. This section does not have any legal effect  
24       on a person who does not carry out any activity for which  
25       an authorization under this section is issued, or who carries

1 *out such an activity pursuant to other provisions of this*  
 2 *Act or section 351 of the Public Health Service Act.*

3 “(n) *ENFORCEMENT.*—*A person who carries out an ac-*  
 4 *tivity pursuant to an authorization under this section, but*  
 5 *who fails to comply with applicable conditions under sub-*  
 6 *section (e), is with respect to that act of noncompliance sub-*  
 7 *ject to the provisions of law specified in subsection (a) and*  
 8 *to the enforcement of such provisions under section 301.”.*

9 **SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS**  
 10 **ACT.**

11 (a) *SECRETARY OF HEALTH AND HUMAN SERVICES.*—

12 (1) *ANNUAL REPORTS ON PARTICULAR EXER-*  
 13 *CISES OF AUTHORITY.*—

14 (A) *RELEVANT AUTHORITIES.*—*The Sec-*  
 15 *retary of Health and Human Services (referred*  
 16 *to in this subsection as the “Secretary”) shall*  
 17 *submit reports in accordance with subparagraph*  
 18 *(B) regarding the exercise of authority under the*  
 19 *following provisions of law:*

20 (i) *With respect to section 319F–1 of*  
 21 *the Public Health Service Act (as added by*  
 22 *section 2 of this Act):*

23 (I) *Subsection (b)(1) (relating to*  
 24 *increased simplified acquisition thresh-*  
 25 *old).*

1                   (II) Subsection (b)(2) (relating to  
2                   use of noncompetitive procedures).

3                   (III) Subsection (c) (relating to  
4                   expedited peer review procedures).

5                   (ii) With respect to section 319F–2 of  
6                   the Public Health Service Act (as added by  
7                   section 3 of this Act):

8                   (I) Subsection (c)(7)(C)(iii) (re-  
9                   lating to simplified acquisition proce-  
10                  dures).

11                  (II) Subsection (c)(7)(C)(iv) (re-  
12                  lating to use of noncompetitive proce-  
13                  dures).

14                  (III) Subsection (c)(7)(C)(v) (re-  
15                  lating to premium provision in mul-  
16                  tiple-award contracts).

17                  (iii) With respect to section 564 of the  
18                  Federal Food, Drug, and Cosmetic Act (as  
19                  added by section 4 of this Act):

20                  (I) Subsection (a)(1) (relating to  
21                  emergency uses of certain drugs and  
22                  devices).

23                  (II) Subsection (b)(1) (relating to  
24                  a declaration of an emergency).

1                   (III) *Subsection (e) (relating to*  
2                   *conditions on authorization).*

3                   (B) *CONTENTS OF REPORTS.—The Sec-*  
4                   *retary shall annually submit to the Congress a*  
5                   *report that summarizes—*

6                   (i) *the particular actions that were*  
7                   *taken under the authorities specified in sub-*  
8                   *paragraph (A), including, as applicable, the*  
9                   *identification of the threat agent, emer-*  
10                  *gency, or the biomedical countermeasure*  
11                  *with respect to which the authority was*  
12                  *used;*

13                  (ii) *the reasons underlying the decision*  
14                  *to use such authorities, including, as appli-*  
15                  *cable, the options that were considered and*  
16                  *rejected with respect to the use of such au-*  
17                  *thorities; and*

18                  (iii) *the identification of each person*  
19                  *or entity that received, or was considered*  
20                  *and rejected for, grants, cooperative agree-*  
21                  *ments, or contracts pursuant to the use of*  
22                  *such authorities.*

23                  (2) *ANNUAL SUMMARIES REGARDING CERTAIN*  
24                  *ACTIVITY.—The Secretary shall annually submit to*  
25                  *the Congress a report that summarizes the activity*

1        *undertaken pursuant to the following authorities*  
2        *under section 319F–1 of the Public Health Service*  
3        *Act (as added by section 2 of this Act):*

4                *(A) Subsection (b)(3) (relating to increased*  
5                *micropurchase threshold).*

6                *(B) Subsection (d) (relating to authority for*  
7                *personal services contracts).*

8                *(C) Subsection (e) (relating to streamlined*  
9                *personnel authority).*

10        *With respect to subparagraph (B), the report shall in-*  
11        *clude a provision specifying, for the one-year period*  
12        *for which the report is submitted, the number of per-*  
13        *sons who were paid amounts greater than \$100,000*  
14        *and the number of persons who were paid amounts*  
15        *between \$50,000 and \$100,000.*

16        *(b) NATIONAL ACADEMY OF SCIENCES REVIEW.—Not*  
17        *later than three years after the date of the enactment of*  
18        *this Act, the Secretary of Health and Human Services shall*  
19        *request the National Academy of Sciences to enter into an*  
20        *agreement for a review of the biomedical countermeasure*  
21        *research and development authorities established in this Act*  
22        *to determine whether and to what extent activities under-*  
23        *taken pursuant to such authorities have enhanced the devel-*  
24        *opment of biomedical countermeasures affecting national se-*  
25        *curity, and to recommend any legislative or administrative*

1 *changes necessary to improve the ability of the Secretary*  
2 *to carry out these activities in the future. The Secretary*  
3 *shall ensure that the results of the study are submitted to*  
4 *the Congress not later than five years after such date of*  
5 *enactment.*

6 (c) *GENERAL ACCOUNTING OFFICE REVIEW.—Four*  
7 *years after the date of the enactment of this Act, the Comp-*  
8 *troller General of the United States shall initiate a study—*

9 (1)(A) *to review the Secretary of Health and*  
10 *Human Services' utilization of the authorities grant-*  
11 *ed under this Act with respect to simplified acquisi-*  
12 *tion procedures, use of noncompetitive procedures, in-*  
13 *creased micropurchase thresholds, personal services*  
14 *contracts, streamlined personnel authority, and the*  
15 *purchase of security countermeasures under the spe-*  
16 *cial reserve fund; and*

17 (B) *to recommend any legislative or administra-*  
18 *tive changes necessary to improve the utilization or*  
19 *effectiveness of such authorities in the future;*

20 (2)(A) *to review the internal controls instituted*  
21 *by such Secretary with respect to such authorities,*  
22 *where required by this Act; and*

23 (B) *to recommend any legislative or administra-*  
24 *tive changes necessary to improve the effectiveness of*  
25 *such controls; and*

1           (3)(A) to review such Secretary’s utilization of  
2           the authority granted under this Act to authorize an  
3           emergency use of a biomedical countermeasure, in-  
4           cluding the means by which the Secretary determines  
5           whether and under what conditions any such author-  
6           izations should be granted and the benefits and ad-  
7           verse impacts, if any, resulting from the use of such  
8           authority; and

9           (B) to recommend any legislative or administra-  
10          tive changes necessary to improve the utilization or  
11          effectiveness of such authority and to enhance protec-  
12          tion of the public health.

13       The results of the study shall be submitted to the Congress  
14       not later than five years after the date of the enactment  
15       of this Act.

16       **SECTION 1. SHORT TITLE.**

17               **This Act may be cited as the “Project Bio-**  
18       **Shield Act of 2003”.**

19       **SEC. 2. BIOMEDICAL COUNTERMEASURE RESEARCH AND**  
20                       **DEVELOPMENT —AUTHORITIES.**

21               **(a) IN GENERAL.—Part B of title III of the**  
22       **Public Health Service Act (42 U.S.C. 243 et**  
23       **seq.) is amended by inserting after section**  
24       **319F the following section:**

1 “SEC. 319F-1. AUTHORITY FOR USE OF CERTAIN PROCE-  
2 DURES REGARDING BIOMEDICAL COUNTER-  
3 MEASURE RESEARCH AND DEVELOPMENT  
4 ACTIVITIES.

5 “(a) IN GENERAL.—

6 “(1) AUTHORITY.—In conducting and  
7 supporting research and development ac-  
8 tivities regarding biomedical counter-  
9 measures under section 319F(h), the Sec-  
10 retary may conduct and support such ac-  
11 tivities in accordance with this section if  
12 the activities concern qualified counter-  
13 measures.

14 “(2) QUALIFIED COUNTERMEASURE.—For  
15 purposes of this section, the term ‘quali-  
16 fied countermeasure’ means a priority  
17 countermeasure (as defined in section  
18 319F(h)) that affects national security.

19 “(3) INTERAGENCY COOPERATION.—

20 “(A) IN GENERAL.—In carrying out  
21 activities under this section, the Sec-  
22 retary is authorized, subject to sub-  
23 paragraph (B), to enter into inter-  
24 agency agreements and other collabo-  
25 rative undertakings with other agen-  
26 cies of the United States Government.

1           **“(B) LIMITATION.—An agreement**  
2           **or undertaking under this paragraph**  
3           **shall not authorize another agency to**  
4           **exercise the authorities provided by**  
5           **this section.**

6           **“(4) AVAILABILITY OF FACILITIES TO THE**  
7           **SECRETARY.—In any grant or cooperative**  
8           **agreement entered into under the author-**  
9           **ity provided in this section with respect**  
10          **to a biocontainment laboratory or other**  
11          **related or ancillary specialized research**  
12          **facility that the Secretary determines**  
13          **necessary for the purpose of performing,**  
14          **administering, and supporting qualified**  
15          **countermeasure research and develop-**  
16          **ment, the Secretary may provide that the**  
17          **facility that is the object of such grant or**  
18          **cooperative agreement shall be available**  
19          **as needed to the Secretary to respond to**  
20          **public health emergencies affecting na-**  
21          **tional security.**

22          **“(b) EXPEDITED PROCUREMENT AUTHOR-**  
23          **ITY.—**

1           **“(1) INCREASED SIMPLIFIED ACQUISITION**  
2           **THRESHOLD FOR BIOMEDICAL COUNTER-**  
3           **MEASURE PROCUREMENTS.—**

4           **“(A) IN GENERAL.—For any pro-**  
5           **urement by the Secretary of prop-**  
6           **erty or services for use (as deter-**  
7           **mined by the Secretary) in per-**  
8           **forming, administering, or supporting**  
9           **qualified countermeasure research or**  
10           **development activities under this sec-**  
11           **tion that the Secretary determines**  
12           **necessary to respond to pressing re-**  
13           **search and development needs under**  
14           **this section, the amount specified in**  
15           **section 4(11) of the Office of Federal**  
16           **Procurement Policy Act (41 U.S.C.**  
17           **403(11)), as applicable pursuant to**  
18           **section 302A(a) of the Federal Prop-**  
19           **erty and Administrative Services Act**  
20           **of 1949 (41 U.S.C. 252a(a)), shall be**  
21           **deemed to be \$25,000,000 in the ad-**  
22           **ministration, with respect to such**  
23           **procurement, of—**

24                   **“(i) section 303(g)(1)(A) of the**  
25                   **Federal Property and Administra-**

1           **tive Services Act of 1949 (41**  
2           **U.S.C. 253(g)(1)(A)) and its imple-**  
3           **menting regulations; and**

4           **“(ii) section 302A(b) of such**  
5           **Act (41 U.S.C. 252a(b)) and its im-**  
6           **plementing regulations.**

7           **“(B) APPLICATION OF CERTAIN PRO-**  
8           **VISIONS.—Notwithstanding subpara-**  
9           **graph (A) and the provision of law**  
10           **and regulations referred to in such**  
11           **subparagraph, each of the following**  
12           **provisions shall apply to procure-**  
13           **ments described in this paragraph to**  
14           **the same extent that such provisions**  
15           **would apply to such procurements in**  
16           **the absence of subparagraph (A):**

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

21           **“(ii) Subsections (a) and (b) of**  
22           **Section 7 of the Anti-Kickback Act**  
23           **of 1986 (41 U.S.C. 57(a) and (b)).**

24           **“(iii) Section 304C of the Fed-**  
25           **eral Property and Administrative**

1           **Services Act of 1949 (41 U.S.C.**  
2           **254d) (relating to the examination**  
3           **of contractor records).**

4           **“(C) INTERNAL CONTROLS TO BE IN-**  
5           **STITUTED.—The Secretary shall insti-**  
6           **tute appropriate internal controls for**  
7           **procurements that are under this**  
8           **paragraph, including requirements**  
9           **with regard to documenting the jus-**  
10          **tification for use of the authority in**  
11          **this paragraph.**

12          **“(2) USE OF NONCOMPETITIVE PROCE-**  
13          **DURES.—In addition to any other author-**  
14          **ity to use procedures other than competi-**  
15          **tive procedures, the Secretary may use**  
16          **such other procedures when—**

17               **“(A) the procurement is as de-**  
18               **scribed by paragraph (1); and**

19               **“(B) the property or services**  
20               **needed by the Secretary are available**  
21               **from only one responsible source or**  
22               **only from a limited number of re-**  
23               **sponsible sources, and no other type**  
24               **of property or services will satisfy the**  
25               **Secretary’s needs.**

1           **“(3) INCREASED MICROPURCHASE**  
2           **THRESHOLD.—**

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

12           **“(B) INTERNAL CONTROLS TO BE IN-**  
13           **STITUTED.—The Secretary shall insti-**  
14           **tute appropriate internal controls for**  
15           **purchases that are under this para-**  
16           **graph and that are greater than**  
17           **\$2,500.**

18           **“(C) EXCEPTION TO PREFERENCE**  
19           **FOR PURCHASE CARD MECHANISM.—No**  
20           **provision of law establishing a pref-**  
21           **erence for using a Government pur-**  
22           **chase card method for purchases**  
23           **shall apply to purchases that are**  
24           **under this paragraph and that are**  
25           **greater than \$2,500.**

1       **“(c) AUTHORITY TO EXPEDITE PEER RE-**  
2 **VIEW.—**

3           **“(1) IN GENERAL.—The Secretary may,**  
4 **as the Secretary determines necessary to**  
5 **respond to pressing qualified counter-**  
6 **measure research and development needs**  
7 **under this section, employ such exped-**  
8 **ited peer review procedures (including**  
9 **consultation with appropriate scientific**  
10 **experts) as the Secretary, in consultation**  
11 **with the Director of NIH, deems appro-**  
12 **priate to obtain assessment of scientific**  
13 **and technical merit and likely contribu-**  
14 **tion to the field of qualified counter-**  
15 **measure research, in place of the peer re-**  
16 **view and advisory council review proce-**  
17 **dures that would be required under sec-**  
18 **tions 301(a)(3), 405(b)(1)(B), 405(b)(2),**  
19 **406(a)(3)(A), 492, and 494, as applicable to**  
20 **a grant, contract, or cooperative agree-**  
21 **ment—**

22           **“(A) that is for performing, ad-**  
23 **ministering, or supporting qualified**  
24 **countermeasure research and devel-**  
25 **opment activities; and**

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

3           “(2) SUBSEQUENT PHASES OF RE-  
4           SEARCH.—The Secretary’s determination  
5           of whether to employ expedited peer re-  
6           view with respect to subsequent phases  
7           of a research grant or cooperative agree-  
8           ment under this section shall be deter-  
9           mined without regard to the peer review  
10          procedures used for any prior peer re-  
11          view of that same grant or cooperative  
12          agreement.

13          “(d) AUTHORITY FOR PERSONAL SERVICES  
14          CONTRACTS.—

15                 “(1) IN GENERAL.—For the purpose of  
16                 performing, administering, and sup-  
17                 porting qualified countermeasure re-  
18                 search and development activities, the  
19                 Secretary may, as the Secretary deter-  
20                 mines necessary to respond to pressing  
21                 qualified countermeasure research and  
22                 development needs under this section,  
23                 obtain by contract (in accordance with  
24                 section 3109 of title 5, United States Code,  
25                 but without regard to the limitations in

1       **such section on the period of service and**  
2       **on pay) the personal services of experts**  
3       **or consultants who have scientific or**  
4       **other professional qualifications, except**  
5       **that in no case shall the compensation**  
6       **provided to any such expert or consult-**  
7       **ant exceed the daily equivalent of the an-**  
8       **ual rate of compensation for the Presi-**  
9       **dent.**

10           **“(2) FEDERAL TORT CLAIMS ACT COV-**  
11           **ERAGE.—**

12                   **“(A) IN GENERAL.—A person car-**  
13                   **rying out a contract under paragraph**  
14                   **(1), and an officer, employee, or gov-**  
15                   **erning board member of such person,**  
16                   **shall be deemed to be an employee of**  
17                   **the Department of Health and Human**  
18                   **Services for purposes of claims under**  
19                   **sections 1346(b) and 2672 of title 28,**  
20                   **United States Code, for money dam-**  
21                   **ages for personal injury, including**  
22                   **death, resulting from performance of**  
23                   **functions under such contract.**

24                   **“(B) EXCLUSIVITY OF REMEDY.—The**  
25                   **remedy provided by subparagraph**

1 (A) shall be exclusive of any other  
2 civil action or proceeding by reason  
3 of the same subject matter against  
4 the person, officer, employee, or gov-  
5 erning board member.

6 “(3) INTERNAL CONTROLS TO BE INSTI-  
7 TUTED.—

8 “(A) IN GENERAL.—The Secretary  
9 shall institute appropriate internal  
10 controls for contracts under this sub-  
11 section, including procedures for the  
12 Secretary to make a determination of  
13 whether a person, or an officer, em-  
14 ployee, or governing board member  
15 of a person, is deemed to be an em-  
16 ployee of the Department of Health  
17 and Human Services pursuant to  
18 paragraph (2).

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

1           **Health and Human Services shall be**  
2           **final and binding on the Secretary**  
3           **and the Attorney General and other**  
4           **parties to any civil action or pro-**  
5           **ceeding.**

6           **“(4) NUMBER OF PERSONAL SERVICES**  
7           **CONTRACTS LIMITED.—The number of ex-**  
8           **perts and consultants whose personal**  
9           **services are obtained under paragraph**  
10          **(1) shall not exceed 30 at any time.**

11          **“(e) STREAMLINED PERSONNEL AUTHORITY.—**

12           **“(1) IN GENERAL.—In addition to any**  
13          **other personnel authorities, the Sec-**  
14          **retary may, as the Secretary determines**  
15          **necessary to respond to pressing quali-**  
16          **fied countermeasure research and devel-**  
17          **opment needs under this section, without**  
18          **regard to such provisions of title 5,**  
19          **United States Code, governing appoint-**  
20          **ments in the competitive service, and**  
21          **without regard to the provisions of chap-**  
22          **ter 51 and subchapter III of chapter 53 of**  
23          **such title relating to classification and**  
24          **General Schedule pay rates, appoint pro-**  
25          **fessional and technical employees, not to**

1       **exceed 30 such employees at any time, to**  
2       **positions in the National Institutes of**  
3       **Health to perform, administer, or support**  
4       **qualified countermeasure research and**  
5       **development activities in carrying out**  
6       **this section.**

7               **“(2) INTERNAL CONTROLS TO BE INSTI-**  
8       **TUTED.—The Secretary shall institute ap-**  
9       **propriate internal controls for appoint-**  
10       **ments under this subsection.**

11               **“(f) ACTIONS COMMITTED TO AGENCY DIS-**  
12       **CRETION.—Actions by the Secretary under the**  
13       **authority of this section are committed to**  
14       **agency discretion.”.**

15               **(b) TECHNICAL AMENDMENT.—Section 481A**  
16       **of the Public Health Service Act (42 U.S.C.**  
17       **287a-2) is amended—**

18                       **(1) in subsection (a)(1), by inserting**  
19       **“or the Director of the National Institute**  
20       **of Allergy and Infectious Diseases” after**  
21       **“Director of the Center”;**

22                       **(2) in subsection (c)—**

23                               **(A) in paragraph (1), by inserting**  
24       **“or the Director of the National Insti-**  
25       **tute of Allergy and Infectious Dis-**

1           **eases” after “Director of the Center”;**  
2           **and**

3                   **(B) in paragraph (2), in the matter**  
4                   **preceding subparagraph (A), by strik-**  
5                   **ing “subsection (i)” and inserting**  
6                   **“subsection (i)(1)”;**

7                   **(3) in subsection (d), by inserting “or**  
8                   **the Director of the National Institute of**  
9                   **Allergy and Infectious Diseases” after**  
10                   **“Director of the Center”;**

11                   **(4) in subsection (e)—**

12                           **(A) in paragraph (1)—**

13                                   **(i) in the matter preceding**  
14                                   **subparagraph (A), by inserting**  
15                                   **“or the Director of the National**  
16                                   **Institute of Allergy and Infectious**  
17                                   **Diseases” after “Director of the**  
18                                   **Center”;**

19                                   **(ii) in subparagraph (A), by**  
20                                   **inserting “(or, in the case of the**  
21                                   **Institute, 75 percent)” after “50**  
22                                   **percent”; and**

23                                   **(iii) in subparagraph (B), by**  
24                                   **inserting “(or, in the case of the**

1           **Institute, 75 percent)” after “40**  
2           **percent”;**

3           **(B) in paragraph (2), by inserting**  
4           **“or the Director of the National Insti-**  
5           **tute of Allergy and Infectious Dis-**  
6           **eases” after “Director of the Center”;**  
7           **and**

8           **(C) in paragraph (4), by inserting**  
9           **“of the Center or the Director of the**  
10           **National Institute of Allergy and In-**  
11           **fectious Diseases” after “Director”;**  
12           **(5) in subsection (f)—**

13           **(A) in paragraph (1), by inserting**  
14           **“in the case of an award by the Direc-**  
15           **tor of the Center,” before “the appli-**  
16           **cant”;** and

17           **(B) in paragraph (2), by inserting**  
18           **“of the Center or the Director of the**  
19           **National Institute of Allergy and In-**  
20           **fectious Diseases” after “Director”;**  
21           **and**

22           **(6) in subsection (i)—**

23           **(A) by striking “APPROPRIA-**  
24           **TIONS.—For the purpose of carrying**

1           **out this section,” and inserting the**  
2           **following: “APPROPRIATIONS.—**

3           **“(1) CENTER.—For the purpose of car-**  
4           **rying out this section with respect to the**  
5           **Center,”; and**

6           **(B) by adding at the end the fol-**  
7           **lowing:**

8           **“(2) NATIONAL INSTITUTE OF ALLERGY**  
9           **AND INFECTIOUS DISEASES.—For the pur-**  
10          **pose of carrying out this section with re-**  
11          **spect to the National Institute of Allergy**  
12          **and Infectious Diseases, there are author-**  
13          **ized to be appropriated such sums as may**  
14          **be necessary for fiscal year 2003.”.**

15 **SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

16          **(a) IN GENERAL.—Part B of title III of the**  
17          **Public Health Service Act, as amended by sec-**  
18          **tion 2 of this Act, is amended by inserting**  
19          **after section 319F-1 the following section:**

20          **“SEC. 319F-2. STRATEGIC NATIONAL STOCKPILE.**

21                 **“(a) STRATEGIC NATIONAL STOCKPILE.—**

22                 **“(1) IN GENERAL.—The Secretary of**  
23                 **Homeland Security (referred to in this**  
24                 **section as the ‘Homeland Security Sec-**  
25                 **retary’), in coordination with the Sec-**

1       retary and the Secretary of Veterans Af-  
2       fairs, shall maintain a stockpile or stock-  
3       piles of drugs, vaccines and other biologi-  
4       cal products, medical devices, and other  
5       supplies in such numbers, types, and  
6       amounts as are determined by the Sec-  
7       retary to be appropriate and practicable,  
8       taking into account other available  
9       sources, to provide for the emergency  
10      health security of the United States, in-  
11      cluding the emergency health security of  
12      children and other vulnerable popu-  
13      lations, in the event of a bioterrorist at-  
14      tack or other public health emergency.

15           “(2) PROCEDURES.—The Secretary, in  
16      managing the stockpile under paragraph  
17      (1), shall—

18                   “(A) consult with the working  
19                   group under section 319F(a);

20                   “(B) ensure that adequate proce-  
21                   dures are followed with respect to  
22                   such stockpile for inventory manage-  
23                   ment and accounting, and for the  
24                   physical security of the stockpile;

1           **“(C) in consultation with Federal,**  
2           **State, and local officials, take into**  
3           **consideration the timing and location**  
4           **of special events;**

5           **“(D) review and revise, as appro-**  
6           **priate, the contents of the stockpile**  
7           **on a regular basis to ensure that**  
8           **emerging threats, advanced tech-**  
9           **nologies, and new countermeasures**  
10          **are adequately considered;**

11          **“(E) devise plans for the effective**  
12          **and timely supply-chain management**  
13          **of the stockpile, in consultation with**  
14          **appropriate Federal, State and local**  
15          **agencies, and the public and private**  
16          **health care infrastructure; and**

17          **“(F) ensure the adequate physical**  
18          **security of the stockpile.**

19          **“(b) SMALLPOX VACCINE DEVELOPMENT.—**

20                 **“(1) IN GENERAL.—The Secretary shall**  
21                 **award contracts, enter into cooperative**  
22                 **agreements, or carry out such other ac-**  
23                 **tivities as may reasonably be required in**  
24                 **order to ensure that the stockpile under**  
25                 **subsection (a) includes an amount of vac-**

1        **cine against smallpox as determined by**  
2        **such Secretary to be sufficient to meet**  
3        **the health security needs of the United**  
4        **States.**

5            **“(2) RULE OF CONSTRUCTION.—Nothing**  
6        **in this section shall be construed to limit**  
7        **the private distribution, purchase, or sale**  
8        **of vaccines from sources other than the**  
9        **stockpile described in subsection (a).**

10        **“(c) ADDITIONAL AUTHORITY REGARDING**  
11 **PROCUREMENT OF CERTAIN BIOMEDICAL COUN-**  
12 **TERMEASURES; AVAILABILITY OF SPECIAL RE-**  
13 **SERVE FUND.—**

14            **“(1) IN GENERAL.—**

15            **“(A) USE OF FUND.—A security**  
16        **countermeasure may, in accordance**  
17        **with this subsection, be procured**  
18        **with amounts in the special reserve**  
19        **fund under paragraph (10).**

20            **“(B) SECURITY COUNTERMEASURE.—**  
21        **For purposes of this subsection, the**  
22        **term ‘security countermeasure’**  
23        **means a priority countermeasure (as**  
24        **defined in section 319F(h))—**

1           “(i) against a chemical, bio-  
2           logical, radiological, or nuclear  
3           agent identified as a material  
4           threat under paragraph (2)(A)(ii);

5           “(ii) that is determined under  
6           paragraph (2)(B)(ii) to be a nec-  
7           essary countermeasure;

8           “(iii) that is designed, devel-  
9           oped, modified, or procured for  
10          the specific purpose of pre-  
11          venting, detecting, identifying,  
12          detering, or mitigating actual or  
13          potential acts of chemical, biologi-  
14          cal, radiological, or nuclear catas-  
15          trophe;

16          “(iv)(I) that is approved or  
17          cleared under chapter V of the  
18          Federal Food, Drug, and Cosmetic  
19          Act, or licensed under section 351  
20          of this Act, for use as a counter-  
21          measure to a chemical, biological,  
22          radiological, or nuclear agent  
23          identified as a material threat  
24          under paragraph (2)(A)(ii); or

1           “(II) for which the Secretary  
2           determines that sufficient and  
3           satisfactory clinical experience or  
4           research data (including data, if  
5           available, from pre-clinical and  
6           clinical trials) support a reason-  
7           able conclusion that the counter-  
8           measure will qualify for approval  
9           or licensing after the date of a de-  
10          termination under paragraph (5);  
11          and

12           “(v) that relates to an actual  
13          or potential act of terrorism or  
14          catastrophic event or to actual or  
15          potential warfare.

16           **“(2) DETERMINATION OF MATERIAL**  
17          **THREATS.—**

18           **“(A) MATERIAL THREAT.—The**  
19          **Homeland Security Secretary, in con-**  
20          **sultation with the heads of other**  
21          **agencies as appropriate, shall on an**  
22          **ongoing basis—**

23           **“(i) assess current and emerg-**  
24          **ing threats of chemical, biologi-**

1           cal, radiological, and nuclear  
2           agents; and

3           “(ii) determine which of such  
4           agents present a material threat  
5           against the United States popu-  
6           lation.

7           “(B) PUBLIC HEALTH IMPACT; NEC-  
8           CESSARY COUNTERMEASURES.—The Sec-  
9           retary shall on an ongoing basis—

10           “(i) assess the potential public  
11           health consequences of use  
12           against the United States popu-  
13           lation of agents identified under  
14           subparagraph (A)(ii); and

15           “(ii) determine, on the basis of  
16           such assessment, the agents for  
17           which priority countermeasures  
18           are necessary to protect the pub-  
19           lic health from a material threat.

20           “(C) NOTICE TO CONGRESS.—The  
21           Secretary and the Homeland Security  
22           Secretary shall promptly notify the  
23           designated congressional committees  
24           (as defined in paragraph (10)) of any  
25           determination made pursuant to sub-

1 paragraph (A) or (B). Such notice  
2 shall be in unclassified and, if nec-  
3 essary, classified form.

4 “(D) ASSURING ACCESS TO THREAT  
5 INFORMATION.—In making the assess-  
6 ment and determination required  
7 under subparagraph (A), the Home-  
8 land Security Secretary shall use all  
9 information to which such Secretary  
10 is entitled under section 202 of the  
11 Homeland Security Act of 2002, in-  
12 cluding but not limited to informa-  
13 tion, regardless of its level of classi-  
14 fication, relating to current and  
15 emerging threats of chemical, biologi-  
16 cal, radiological, and nuclear agents.

17 “(3) ASSESSMENT OF AVAILABILITY AND  
18 APPROPRIATENESS OF COUNTERMEASURES.—  
19 The Secretary, in consultation with the  
20 Homeland Security Secretary, shall as-  
21 sess on an ongoing basis the availability  
22 and appropriateness of specific counter-  
23 measures to address specific threats iden-  
24 tified under paragraph (2).

1           **“(4) CALL FOR DEVELOPMENT OF COUN-**  
2           **TERMEASURES; COMMITMENT FOR REC-**  
3           **COMMENDATION FOR PROCUREMENT.—**

4           **“(A) PROPOSAL TO THE PRESI-**  
5           **DENT.—If, pursuant to an assessment**  
6           **under paragraph (3), the Homeland**  
7           **Security Secretary and the Secretary**  
8           **make a determination that a counter-**  
9           **measure would be appropriate but is**  
10           **either currently unavailable for pro-**  
11           **curement or available under unsuit-**  
12           **able conditions, such Secretaries may**  
13           **jointly submit to the President a pro-**  
14           **posal to—**

15           **“(i) issue a call for the devel-**  
16           **opment of such countermeasure;**  
17           **and**

18           **“(ii) make a commitment that,**  
19           **upon the first development of**  
20           **such countermeasure that meets**  
21           **the conditions for procurement**  
22           **under paragraph (5), the Secre-**  
23           **taries will, based in part on infor-**  
24           **mation obtained pursuant to such**  
25           **call, make a recommendation**

1           under paragraph (6) that the spe-  
2           cial reserve fund under para-  
3           graph (10) be made available for  
4           the procurement of such counter-  
5           measure.

6           “(B) COUNTERMEASURE SPECIFICA-  
7           TIONS.—The Homeland Security Sec-  
8           retary and the Secretary shall, to the  
9           extent practicable, include in the pro-  
10          posal under subparagraph (A)—

11           “(i) estimated quantity of pur-  
12           chase (in the form of number of  
13           doses or number of effective  
14           courses of treatments regardless  
15           of dosage form);

16           “(ii) necessary measures of  
17           minimum safety and effective-  
18           ness;

19           “(iii) estimated price for each  
20           dose or effective course of treat-  
21           ment regardless of dosage form;  
22           and

23           “(iv) other information that  
24           may be necessary to encourage  
25           and facilitate research, develop-

1           **ment, and manufacture of the**  
2           **countermeasure or to provide**  
3           **specifications for the counter-**  
4           **measure.**

5           **“(C) PRESIDENTIAL APPROVAL.—If**  
6           **the President approves a proposal**  
7           **under subparagraph (A), the Home-**  
8           **land Security Secretary and the Sec-**  
9           **retary shall make known to persons**  
10          **who may respond to a call for the**  
11          **countermeasure involved—**

12               **“(i) the call for the counter-**  
13               **measure;**

14               **“(ii) specifications for the**  
15               **countermeasure under subpara-**  
16               **graph (B); and**

17               **“(iii) a commitment described**  
18               **in subparagraph (A)(ii).**

19           **“(5) SECRETARY’S DETERMINATION OF**  
20           **COUNTERMEASURES APPROPRIATE FOR FUND-**  
21           **ING FROM SPECIAL RESERVE FUND.—**

22               **“(A) IN GENERAL.—The Secretary,**  
23               **in accordance with the provisions of**  
24               **this paragraph, shall identify specific**  
25               **security countermeasures that the**

1           **Secretary determines, in consultation**  
2           **with the Homeland Security Sec-**  
3           **retary, to be appropriate for inclu-**  
4           **sion in the stockpile under subsection**  
5           **(a) pursuant to procurements made**  
6           **with amounts in the special reserve**  
7           **fund under paragraph (10) (referred**  
8           **to in this subsection individually as a**  
9           **‘procurement under this subsection’).**

10           **“(B) REQUIREMENTS.—In making a**  
11           **determination under subparagraph**  
12           **(A) with respect to a security counter-**  
13           **measure, the Secretary shall deter-**  
14           **mine and consider the following:**

15                   **“(i) The quantities of the**  
16                   **product that will be needed to**  
17                   **meet the needs of the stockpile.**

18                   **“(ii) The feasibility of produc-**  
19                   **tion and delivery within five**  
20                   **years of sufficient quantities of**  
21                   **the product.**

22                   **“(iii) Whether there is a lack**  
23                   **of a significant commercial mar-**  
24                   **ket for the product at the time of**

1           **procurement, other than as a se-**  
2           **curity countermeasure.**

3           **“(6) RECOMMENDATION FOR PRESIDENT’S**  
4           **APPROVAL.—**

5           **“(A) RECOMMENDATION FOR PRO-**  
6           **CUREMENT.—In the case of a security**  
7           **countermeasure that the Secretary**  
8           **has, in accordance with paragraphs**  
9           **(2), (3), and (5), determined to be ap-**  
10          **propriate for procurement under this**  
11          **subsection, the Homeland Security**  
12          **Secretary and the Secretary shall**  
13          **jointly submit to the President, in co-**  
14          **ordination with the Director of the**  
15          **Office of Management and Budget, a**  
16          **recommendation that the special re-**  
17          **serve fund under paragraph (10) be**  
18          **made available for the procurement**  
19          **of such countermeasure.**

20          **“(B) PRESIDENTIAL APPROVAL.—The**  
21          **special reserve fund under paragraph**  
22          **(10) is available for a procurement of**  
23          **a security countermeasure only if the**  
24          **President has approved a rec-**

1           **ommendation under subparagraph**  
2           **(A) regarding the countermeasure.**

3           **“(C) NOTICE TO CONGRESS.—The**  
4           **Secretary and the Homeland Security**  
5           **Secretary shall notify the designated**  
6           **congressional committees of each de-**  
7           **cision of the President to approve a**  
8           **recommendation under subparagraph**  
9           **(A). Such notice shall include an ex-**  
10           **planation of the decision to make**  
11           **available the special reserve fund**  
12           **under paragraph (10) for procure-**  
13           **ment of such a countermeasure, in-**  
14           **cluding, where available, the identi-**  
15           **fication of the potential supplier or**  
16           **suppliers of such countermeasure,**  
17           **and whether other potential sup-**  
18           **pliers of the same or similar counter-**  
19           **measures were considered and re-**  
20           **jected for procurement under this**  
21           **section and the reasons therefor.**

22           **“(D) SUBSEQUENT SPECIFIC COUN-**  
23           **TERMEASURES.—Procurement under**  
24           **this subsection of a security counter-**  
25           **measure for a particular purpose**

1 does not preclude the subsequent  
2 procurement under this subsection of  
3 any other security countermeasure  
4 for such purpose if the Secretary has  
5 determined under paragraph (5)(A)  
6 that such countermeasure is appro-  
7 priate for inclusion in the stockpile  
8 and if, as determined by the Sec-  
9 retary, such countermeasure provides  
10 improved safety or effectiveness, or  
11 for other reasons enhances prepared-  
12 ness to respond to threats of use of a  
13 biological, chemical, radiological, or  
14 nuclear agent. Such a determination  
15 by the Secretary is committed to  
16 agency discretion.

17 “(E) RULE OF CONSTRUCTION.—Rec-  
18 ommendations and approvals under  
19 this paragraph apply solely to deter-  
20 minations that the special reserve  
21 fund under paragraph (10) will be  
22 made available for a procurement of  
23 a security countermeasure, and not to  
24 the substance of contracts for such

1           **procurement or other matters relat-**  
2           **ing to awards of such contracts.**

3           **“(7) PROCUREMENT.—**

4                   **“(A) IN GENERAL.—For purposes of**  
5                   **a procurement under this subsection**  
6                   **that is approved by the President**  
7                   **under paragraph (6), the Homeland**  
8                   **Security Secretary and the Secretary**  
9                   **shall have responsibilities in accord-**  
10                   **ance with subparagraphs (B) and (C).**

11                   **“(B) INTERAGENCY AGREEMENTS.—**

12                           **“(i) FOR PROCUREMENT.—The**  
13                           **Homeland Security Secretary**  
14                           **shall enter into an agreement**  
15                           **with the Secretary for procure-**  
16                           **ment of a security counter-**  
17                           **measure in accordance with the**  
18                           **provisions of this paragraph. The**  
19                           **special reserve fund under para-**  
20                           **graph (10) shall be available for**  
21                           **the Secretary’s costs of such pro-**  
22                           **urement, other than as provided**  
23                           **in clause (ii).**

24                           **“(ii) FOR ADMINISTRATIVE**  
25                           **COSTS.—The agreement entered**

1           **into between the Homeland Secu-**  
2           **urity Secretary and the Secretary**  
3           **for managing the stockpile under**  
4           **subsection (a) shall provide for**  
5           **reimbursement of the Secretary’s**  
6           **administrative costs relating to**  
7           **procurements under this sub-**  
8           **section.**

9           **“(C) PROCUREMENT.—**

10           **“(i) IN GENERAL.—The Sec-**  
11           **retary shall be responsible for—**

12                   **“(I) arranging for procure-**  
13                   **ment of a security counter-**  
14                   **measure, including negoti-**  
15                   **ating terms (including quan-**  
16                   **tity, production schedule, and**  
17                   **price) of, and entering into,**  
18                   **contracts and cooperative**  
19                   **agreements, and for carrying**  
20                   **out such other activities as**  
21                   **may reasonably be required,**  
22                   **in accordance with the provi-**  
23                   **sions of this subparagraph;**  
24                   **and**

1           **“(II) promulgating regula-**  
2           **tions to implement clauses (v),**  
3           **(vi), and (vii), and any other**  
4           **provisions of this subsection.**

5           **“(ii) CONTRACT TERMS.—A con-**  
6           **tract for procurements under this**  
7           **subsection shall (or, as specified**  
8           **below, may) include the following**  
9           **terms:**

10           **“(I) PAYMENT CONDITIONED**  
11           **ON SUBSTANTIAL DELIVERY.—**  
12           **The contract shall provide**  
13           **that no payment may be made**  
14           **until delivery has been made**  
15           **of a substantial portion (as**  
16           **determined by the Secretary)**  
17           **of the total number of units**  
18           **contracted for, except that,**  
19           **notwithstanding any other**  
20           **provision of law, the contract**  
21           **may provide that, if the Sec-**  
22           **retary determines (in the Sec-**  
23           **retary’s discretion) that an**  
24           **advance payment is necessary**  
25           **to ensure success of a project,**

1           **the Secretary may pay an**  
2           **amount, not to exceed 10 per-**  
3           **cent of the contract amount,**  
4           **in advance of delivery. The**  
5           **contract shall provide that**  
6           **such advance payment is re-**  
7           **quired to be repaid if there is**  
8           **a failure to perform under the**  
9           **contract, except in special cir-**  
10          **cumstances as determined by**  
11          **the Secretary on a contract by**  
12          **contract basis.**

13           **“(II) CONTRACT DURA-**  
14          **TION.—The contract shall be**  
15          **for a period not to exceed five**  
16          **years, except that, in first**  
17          **awarding the contract, the**  
18          **Secretary may provide for a**  
19          **longer duration, not exceed-**  
20          **ing eight years, if the Sec-**  
21          **retary determines that com-**  
22          **plexities or other difficulties**  
23          **in performance under the**  
24          **contract justify such a period.**  
25          **The contract shall be renew-**

1           **able for additional periods,**  
2           **none of which shall exceed**  
3           **five years.**

4           **“(III) STORAGE BY VEN-**  
5           **DOR.—The contract may pro-**  
6           **vide that the vendor will pro-**  
7           **vide storage for stocks of a**  
8           **product delivered to the own-**  
9           **ership of the Federal Govern-**  
10           **ment under the contract, for**  
11           **such period and under such**  
12           **terms and conditions as the**  
13           **Secretary may specify, and in**  
14           **such case amounts from the**  
15           **special reserve fund under**  
16           **paragraph (10) shall be avail-**  
17           **able for costs of shipping,**  
18           **handling, storage, and related**  
19           **costs for such product.**

20           **“(IV) NON-STOCKPILE SALES**  
21           **OF SECURITY COUNTER-**  
22           **MEASURES.—The contract may**  
23           **provide that the vendor will**  
24           **not at any time (including**  
25           **after performance under the**

1           **contract is otherwise com-**  
2           **pleted) sell or otherwise pro-**  
3           **vide such countermeasure to**  
4           **any domestic or foreign per-**  
5           **son, or transfer to any such**  
6           **person any quantity of such**  
7           **security countermeasure, or**  
8           **any intellectual property re-**  
9           **lating thereto that would en-**  
10          **able the development or pro-**  
11          **duction of the counter-**  
12          **measure, without certification**  
13          **by the Secretary, in consulta-**  
14          **tion with the Homeland Secu-**  
15          **rity Secretary, the Secretary**  
16          **of Defense, and the Secretary**  
17          **of State, that such sale or**  
18          **transfer, or category of sales**  
19          **or transfers, would not ad-**  
20          **versely affect the national se-**  
21          **curity; and that, for each vio-**  
22          **lation of this provision of the**  
23          **contract, the United States is**  
24          **entitled to recover from the**  
25          **person as liquidated damages**

1           **an amount equal to three**  
2           **times the sum of the pay-**  
3           **ments made to the vendor**  
4           **under the contract.**

5           **“(iii) AVAILABILITY OF SIM-**  
6           **PLIFIED ACQUISITION PROCE-**  
7           **DURES.—**

8           **“(I) IN GENERAL.—The**  
9           **amount of any procurement**  
10           **under this subsection shall be**  
11           **deemed to be below the**  
12           **threshold amount specified in**  
13           **section 4(11) of the Office of**  
14           **Federal Procurement Policy**  
15           **Act (41 U.S.C. 403(11)), for**  
16           **purposes of application to**  
17           **such procurement, pursuant**  
18           **to section 302A(a) of the Fed-**  
19           **eral Property and Administra-**  
20           **tive Services Act of 1949 (41**  
21           **U.S.C. 252a(a)), of—**

22                   **“(aa)                   section**  
23                   **303(g)(1)(A) of the Federal**  
24                   **Property and Administra-**  
25                   **tive Services Act of 1949**

1           **(41 U.S.C. 253(g)(1)(A)) and**  
2           **its implementing regula-**  
3           **tions; and**

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

8           **“(II) APPLICATION OF CER-**  
9           **TAIN PROVISIONS.—Notwith-**  
10          **standing subclause (I) and the**  
11          **provision of law and regula-**  
12          **tions referred to in such**  
13          **clause, each of the following**  
14          **provisions shall apply to pro-**  
15          **curements described in this**  
16          **clause to the same extent that**  
17          **such provisions would apply**  
18          **to such procurements in the**  
19          **absence of subclause (I):**

20          **“(aa) Chapter 37 of**  
21          **title 40, United States**  
22          **Code (relating to contract**  
23          **work hours and safety**  
24          **standards).**

1           “(bb) Subsections (a)  
2           and (b) of Section 7 of the  
3           **Anti-Kickback Act of 1986**  
4           (41 U.S.C. 57(a) and (b)).

5           “(cc) Section 304C of  
6           the **Federal Property and**  
7           **Administrative Services**  
8           **Act of 1949** (41 U.S.C.  
9           **254d**) (relating to the ex-  
10          amination of contractor  
11          records).

12          “(iv) **USE OF NONCOMPETITIVE**  
13          **PROCEDURES.—**In addition to any  
14          other authority to use procedures  
15          other than competitive proce-  
16          dures, the Secretary may use such  
17          other procedures for a procure-  
18          ment under this subsection if the  
19          product is available from only one  
20          responsible source or only from a  
21          limited number of responsible  
22          sources, and no other type of  
23          product will satisfy the Sec-  
24          retary’s needs.

1                   **“(v) PREMIUM PROVISION IN**  
2                   **MULTIPLE AWARD CONTRACTS.—**

3                   **“(I) IN GENERAL.—If, under**  
4                   **this subsection, the Secretary**  
5                   **enters into contracts with**  
6                   **more than one vendor to pro-**  
7                   **cure a security counter-**  
8                   **measure, such Secretary may,**  
9                   **notwithstanding any other**  
10                  **provision of law, include in**  
11                  **each of such contracts a pro-**  
12                  **vision that—**

13                  **“(aa) identifies an in-**  
14                  **crement of the total quan-**  
15                  **tity of security counter-**  
16                  **measure required, wheth-**  
17                  **er by percentage or by**  
18                  **numbers of units; and**

19                  **“(bb) promises to pays**  
20                  **one or more specified pre-**  
21                  **miums based on the pri-**  
22                  **ority of such vendors’ pro-**  
23                  **duction and delivery of**  
24                  **the increment identified**  
25                  **under item (aa), in accord-**

1                   **ance with the terms and**  
2                   **conditions of the contract.**

3                   **“(II) DETERMINATION OF**  
4                   **GOVERNMENT’S REQUIREMENT**  
5                   **NOT REVIEWABLE.—If the Sec-**  
6                   **retary includes in each of a**  
7                   **set of contracts a provision as**  
8                   **described in subclause (I),**  
9                   **such Secretary’s determina-**  
10                   **tion of the total quantity of**  
11                   **security countermeasure re-**  
12                   **quired, and any amendment**  
13                   **of such determination, is com-**  
14                   **mitted to agency discretion.**

15                   **“(vi) EXTENSION OF CLOSING**  
16                   **DATE FOR RECEIPT OF PROPOSALS**  
17                   **NOT REVIEWABLE.—A decision by**  
18                   **the Secretary to extend the clos-**  
19                   **ing date for receipt of proposals**  
20                   **for a procurement under this sub-**  
21                   **section is committed to agency**  
22                   **discretion.**

23                   **“(vii) LIMITING COMPETITION TO**  
24                   **SOURCES RESPONDING TO REQUEST**  
25                   **FOR INFORMATION.—In conducting**

1           a procurement under this sub-  
2           section, the Secretary may ex-  
3           clude a source that has not re-  
4           sponded to a request for informa-  
5           tion under section 303A(a)(1)(B)  
6           of the Federal Property and Ad-  
7           ministrative Services Act of 1949  
8           (41 U.S.C. 253a(a)(1)(B)) if such re-  
9           quest has given notice that the  
10          Secretary may so exclude such a  
11          source.

12          **“(8) INTERAGENCY COOPERATION.—**

13               **“(A) IN GENERAL.—**In carrying out  
14               activities under this section, the  
15               Homeland Security Secretary and the  
16               Secretary are authorized, subject to  
17               subparagraph (B), to enter into inter-  
18               agency agreements and other collabo-  
19               rative undertakings with other agen-  
20               cies of the United States Government.

21               **“(B) LIMITATION.—**An agreement  
22               or undertaking under this paragraph  
23               shall not authorize another agency to  
24               exercise the authorities provided by

1           **this section to the Homeland Security**  
2           **Secretary or to the Secretary.**

3           **“(9) RESTRICTIONS ON USE OF FUNDS.—**  
4           **Amounts in the special reserve fund**  
5           **under paragraph (10) shall not be used to**  
6           **pay—**

7                   **“(A) costs for the purchase of vac-**  
8                   **cines under procurement contracts**  
9                   **entered into before the date of the en-**  
10                   **actment of the Project BioShield Act**  
11                   **of 2003; or**

12                   **“(B) administrative costs.**

13           **“(10) DEFINITIONS.—**

14                   **“(A) SPECIAL RESERVE FUND.—For**  
15                   **purposes of this subsection, the term**  
16                   **‘special reserve fund’ has the mean-**  
17                   **ing given such term in section 510 of**  
18                   **the Homeland Security Act of 2002.**

19                   **“(B) DESIGNATED CONGRESSIONAL**  
20                   **COMMITTEES.—For purposes of this**  
21                   **section, the term ‘designated congress-**  
22                   **sional committees’ means the fol-**  
23                   **lowing committees of the Congress:**

24                           **“(i) In the House of Represent-**  
25                           **atives: the Committee on Energy**

1           **and Commerce, the Committee on**  
2           **Appropriations, the Committee on**  
3           **Government Reform, and the Se-**  
4           **lect Committee on Homeland Se-**  
5           **curity (or any successor to the Se-**  
6           **lect Committee).**

7           **“(ii) In the Senate: the Com-**  
8           **mittee on Health, Education,**  
9           **Labor, and Pensions, the Com-**  
10          **mittee on Appropriations, and the**  
11          **Committee on Government Af-**  
12          **fairs.**

13          **“(d) DISCLOSURES.—No Federal agency**  
14          **shall disclose under section 552 of title 5,**  
15          **United States Code, any information identi-**  
16          **fyng the location at which materials in the**  
17          **stockpile under subsection (a) are stored.**

18          **“(e) DEFINITION.—For purposes of sub-**  
19          **section (a), the term ‘stockpile’ includes—**

20               **“(1) a physical accumulation (at one**  
21               **or more locations) of the supplies de-**  
22               **scribed in subsection (a); or**

23               **“(2) a contractual agreement between**  
24               **the Homeland Security Secretary and a**  
25               **vendor or vendors under which such ven-**

1        **dor or vendors agree to provide to such**  
2        **Secretary supplies described in sub-**  
3        **section (a).**

4        **“(f) AUTHORIZATION OF APPROPRIATIONS.—**

5            **“(1) STRATEGIC NATIONAL STOCKPILE.—**

6        **For the purpose of carrying out sub-**  
7        **section (a), there are authorized to be ap-**  
8        **propriated \$640,000,000 for fiscal year**  
9        **2002, and such sums as may be necessary**  
10       **for each of fiscal years 2003 through 2006.**  
11       **Such authorization is in addition to**  
12       **amounts in the special reserve fund**  
13       **under subsection (c)(10).**

14           **“(2) SMALLPOX VACCINE DEVELOP-**  
15       **MENT.—For the purpose of carrying out**  
16       **subsection (b), there are authorized to be**  
17       **appropriated \$509,000,000 for fiscal year**  
18       **2002, and such sums as may be necessary**  
19       **for each of fiscal years 2003 through**  
20       **2006.”.**

21       **(b) AMENDMENT TO HOMELAND SECURITY**  
22 **ACT OF 2002.—Title V of the Homeland Secu-**  
23 **rity Act of 2002 (116 Stat. 2212; 6 U.S.C. 311 et**  
24 **seq.) is amended by adding at the end the fol-**  
25 **lowing:**

1 **“SEC. 510. PROCUREMENT OF SECURITY COUNTER-**  
2 **MEASURES FOR STRATEGIC NATIONAL**  
3 **STOCKPILE.**

4 **“(a) AUTHORIZATION OF APPROPRIATIONS.—**  
5 **For the procurement of security counter-**  
6 **measures under section 319F–2(c) of the Pub-**  
7 **lic Health Service Act (referred to in this sec-**  
8 **tion as the ‘security countermeasures pro-**  
9 **gram’), there is authorized to be appropriated**  
10 **up to \$5,593,000,000 for the fiscal years 2004**  
11 **through 2013. Of the amounts appropriated**  
12 **under the preceding sentence, not to exceed**  
13 **\$3,418,000,000 may be obligated during the fis-**  
14 **cal years 2004 through 2008, of which not to**  
15 **exceed \$890,000,000 may be obligated during**  
16 **fiscal year 2004.**

17 **“(b) SPECIAL RESERVE FUND.—For pur-**  
18 **poses of the security countermeasures pro-**  
19 **gram, the term ‘special reserve fund’ means**  
20 **the appropriations account established as a**  
21 **result of any appropriations made under sub-**  
22 **section (a).**

23 **“(c) AVAILABILITY.—**

24 **“(1) INTEGRITY OF SPECIAL RESERVE**  
25 **FUND; LIMITATION OF OBLIGATIONAL AU-**  
26 **THORITY TO FUND PURPOSES; INTENT OF**

1       **CONGRESS AGAINST REPROGRAMMING.—Sub-**  
2       **ject to paragraph (2), all amounts appro-**  
3       **priated under subsection (a) are available**  
4       **for obligation through the end of fiscal**  
5       **year 2013 and only for the specific pur-**  
6       **poses set forth in the security counter-**  
7       **measures program. It is the intent of the**  
8       **Congress that no portion of such amount**  
9       **that remains unobligated for such pur-**  
10       **poses shall be applied, through re-**  
11       **programming or otherwise, to any other**  
12       **purpose.**

13               **“(2) INITIAL AVAILABILITY FOR PAR-**  
14       **TICULAR PROCUREMENTS.—Amounts appro-**  
15       **priated under subsection (a) become**  
16       **available for a procurement under the se-**  
17       **curity countermeasures program only**  
18       **upon the approval by the President of**  
19       **such availability for the procurement in**  
20       **accordance with paragraph (6)(B) of such**  
21       **program.**

22               **“(d) RELATED AUTHORIZATIONS OF APPRO-**  
23       **PRIATIONS.—**

24               **“(1) THREAT ASSESSMENT CAPABILI-**  
25       **TIES.—For the purpose of carrying out the**

1       responsibilities of the Secretary for ter-  
2       ror threat assessment under the security  
3       countermeasures program, there are au-  
4       thorized to be appropriated \$5,000,000 for  
5       fiscal year 2004, and such sums as may be  
6       necessary for each of the fiscal years 2005  
7       and 2006, for the hiring of professional  
8       personnel within the Directorate for In-  
9       formation Analysis and Infrastructure  
10      Protection, who shall be analysts respon-  
11      sible for chemical, biological, radio-  
12      logical, and nuclear threat assessment  
13      (including but not limited to analysis of  
14      chemical, biological, radiological, and nu-  
15      clear agents, the means by which such  
16      agents could be weaponized or used in a  
17      terrorist attack, and the capabilities,  
18      plans, and intentions of terrorists and  
19      other non-state actors who may have or  
20      acquire such agents). All such analysts  
21      shall meet the applicable standards and  
22      qualifications for the performance of in-  
23      telligence activities promulgated by the  
24      Director of Central Intelligence pursuant

1 to section 104 of the National Security  
2 Act of 1947.

3 “(2) INTELLIGENCE SHARING INFRA-  
4 STRUCTURE.—For the purpose of carrying  
5 out the acquisition and deployment of se-  
6 cure facilities (including information  
7 technology and physical infrastructure,  
8 whether mobile and temporary, or per-  
9 manent) sufficient to permit the Sec-  
10 retary to receive, not later than Decem-  
11 ber 31, 2003, all classified information  
12 and products to which the Under Sec-  
13 retary for Information Analysis and In-  
14 frastructure Protection is entitled under  
15 subtitle A of title II, there are authorized  
16 to be appropriated such sums as may be  
17 necessary for each of the fiscal years 2003  
18 through 2006.

19 “(e) EMERGENCY DEVELOPMENT OF SECURITY  
20 COUNTERMEASURES.—If the Secretary of Home-  
21 land Security and the Secretary of Health and  
22 Human Services jointly determine that pro-  
23 curement of a security countermeasure that  
24 has been approved for procurement using the  
25 special reserve fund under subsection (a)—

1           **“(1) is not proceeding at a sufficiently**  
2           **rapid pace under 319F-2 of the Public**  
3           **Health Service Act to protect the national**  
4           **security; or**

5           **“(2) could be produced significantly**  
6           **less expensively by the government di-**  
7           **rectly than through procurements under**  
8           **such section;**

9           **then amounts in the special reserve fund may**  
10          **be used by the Secretary of Health and**  
11          **Human Services to produce security counter-**  
12          **measures for placement in the stockpile**  
13          **under subsection (a) of section 319F-2 of such**  
14          **Act if the joint determination is submitted to**  
15          **the President and the President approves**  
16          **such use of the special reserve fund. Amounts**  
17          **made available for such use in accordance**  
18          **with the preceding sentence are available for**  
19          **obligation as of the date on which the presi-**  
20          **dential approval is made, subject to applica-**  
21          **ble law regarding the apportionment of ap-**  
22          **propriations. This subsection applies notwith-**  
23          **standing other provisions of this section, and**  
24          **notwithstanding section 319F-2 of the Public**  
25          **Health Service Act. This subsection may not**

1 be construed as affecting the amounts speci-  
2 fied in subsection (a) as authorizations of ap-  
3 propriations or the obligation limits con-  
4 tained therein.”.

5 (c) CONFORMING AMENDMENT.—Section 121  
6 of the Public Health Security and Bioter-  
7 rorism Preparedness and Response Act of  
8 2002 (116 Stat. 611; 42 U.S.C. 300hh-12) is re-  
9 pealed. With respect to the program estab-  
10 lished under former section 121 of such Act,  
11 the repeal of such section under the pre-  
12 ceding sentence applies as a modification of  
13 the program in accordance with the amend-  
14 ment made by subsection (a) of this section,  
15 and not as the termination of the program  
16 and the establishment of a different program.

17 SEC. 4. AUTHORIZATION FOR MEDICAL PRODUCTS FOR  
18 USE IN EMERGENCIES.

19 Subchapter E of chapter V of the Federal  
20 Food, Drug, and Cosmetic Act (21 U.S.C.  
21 360bbb et seq.) is amended by adding at the  
22 end the following section:

23 “SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR  
24 USE IN EMERGENCIES.

25 “(a) IN GENERAL.—

1           **“(1) EMERGENCY USES.—Notwith-**  
2           **standing sections 505, 510(k), and 515 of**  
3           **this Act and section 351 of the Public**  
4           **Health Service Act, and subject to the**  
5           **provisions of this section, the Secretary**  
6           **may authorize the introduction into**  
7           **interstate commerce, during the effective**  
8           **period of a declaration under subsection**  
9           **(b), of a drug or device intended for use**  
10          **in an actual or potential emergency (re-**  
11          **ferred to in this section as an ‘emergency**  
12          **use’).**

13           **“(2) APPROVAL STATUS OF PRODUCT.—**  
14          **An authorization under paragraph (1)**  
15          **may authorize an emergency use of a**  
16          **product that—**

17                   **“(A) is not approved, licensed, or**  
18                   **cleared for commercial distribution**  
19                   **under a provision of law referred to**  
20                   **in such paragraph (referred to in this**  
21                   **section as an ‘unapproved product’);**  
22                   **or**

23                   **“(B) is approved, licensed, or**  
24                   **cleared under such a provision, but**  
25                   **which use is not under such provi-**

1           sion an approved, licensed, or cleared  
2           use of the product (referred to in this  
3           section as an ‘unapproved use of an  
4           approved product’).

5           “(3) **RELATION TO OTHER USES.**—An  
6           emergency use authorized under para-  
7           graph (1) for a product is in addition to  
8           any other use that is authorized for the  
9           product under a provision of law referred  
10          to in such paragraph.

11          “(4) **DEFINITIONS.**—For purposes of  
12          this section:

13                 “(A) The term ‘emergency use’ has  
14                 the meaning indicated for such term  
15                 in paragraph (1).

16                 “(B) The term ‘product’ means a  
17                 drug or device.

18                 “(C) The term ‘unapproved prod-  
19                 uct’ has the meaning indicated for  
20                 such term in paragraph (2)(A).

21                 “(D) The term ‘unapproved use of  
22                 an approved product’ has the mean-  
23                 ing indicated for such term in para-  
24                 graph (2)(B).

25          “(b) **DECLARATION OF EMERGENCY.**—

1           **“(1) IN GENERAL.—The Secretary may**  
2           **declare an emergency justifying the au-**  
3           **thorization under this subsection for a**  
4           **product on the basis of—**

5                   **“(A) a determination by the Sec-**  
6                   **retary of Homeland Security that**  
7                   **there is a national emergency, or a**  
8                   **significant potential for a national**  
9                   **emergency, involving a heightened**  
10                  **risk of attack with a specified biologi-**  
11                  **cal, chemical, radiological, or nuclear**  
12                  **agent or agents;**

13                   **“(B) a determination by the Sec-**  
14                   **retary of Defense that there is a mili-**  
15                   **tary emergency, or a significant po-**  
16                   **tential for a military emergency, in-**  
17                   **volving a heightened risk to United**  
18                   **States military forces of attack with a**  
19                   **biological, chemical, radiological, or**  
20                   **nuclear agent or agents; or**

21                   **“(C) a determination by the Sec-**  
22                   **retary of a public health emergency**  
23                   **under section 319 of the Public**  
24                   **Health Service Act, affecting national**  
25                   **security and involving a specified bio-**

1           **logical, chemical, radiological, or nu-**  
2           **clear agent or agents, or a specified**  
3           **disease or condition that may be at-**  
4           **tributable to such agent or agents.**

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

6                   **“(A) IN GENERAL.—A declaration**  
7                   **under this subsection shall terminate**  
8                   **upon the earlier of—**

9                           **“(i) a determination by the**  
10                           **Secretary, in consultation as ap-**  
11                           **propriate with the Secretary of**  
12                           **Homeland Security or the Sec-**  
13                           **retary of Defense, that the cir-**  
14                           **cumstances described in para-**  
15                           **graph (1) have ceased to exist; or**

16                           **“(ii) the expiration of the one-**  
17                           **year period beginning on the date**  
18                           **on which the declaration is made.**

19                   **“(B) RENEWAL.—Notwithstanding**  
20                   **subparagraph (A), the Secretary may**  
21                   **renew a declaration under this sub-**  
22                   **section, and this paragraph shall**  
23                   **apply to any such renewal.**

24                   **“(3) ADVANCE NOTICE OF TERMI-**  
25                   **NATION.—In terminating a declaration**

1 under this section, the Secretary shall  
2 provide advance notice that the declara-  
3 tion will be terminated. The period of ad-  
4 vance notice shall be a period reasonably  
5 determined to provide—

6 “(A) in the case of an unapproved  
7 product, a sufficient period for dis-  
8 position of shipments of the product,  
9 including the return of such ship-  
10 ments to the manufacturer (in the  
11 case of a manufacturer that chooses  
12 to have the shipments returned); and

13 “(B) in the case of unapproved  
14 uses of approved products, a suffi-  
15 cient period for the disposition of any  
16 labeling that was provided with re-  
17 spect to the emergency use involved.

18 “(4) PUBLICATION.—The Secretary  
19 shall promptly publish in the Federal  
20 Register each declaration, determination,  
21 and renewal under this subsection.

22 “(c) CRITERIA FOR ISSUANCE OF AUTHORIZA-  
23 TION.—The Secretary may issue an authoriza-  
24 tion under this section with respect to the  
25 emergency use of a product only if, after con-

1 **sultation with the Director of the National In-**  
2 **stitutes of Health and the Director of the Cen-**  
3 **ters for Disease Control and Prevention, to**  
4 **the extent feasible and appropriate given the**  
5 **circumstances of the emergency involved, the**  
6 **Secretary concludes—**

7           **“(1) that an agent specified in a dec-**  
8 **laration under subsection (b) can cause a**  
9 **serious or life-threatening disease or con-**  
10 **dition;**

11           **“(2) that, based on the totality of sci-**  
12 **entific evidence available to the Sec-**  
13 **retary, including data from adequate and**  
14 **well-controlled clinical trials, if available,**  
15 **it is reasonable to believe that—**

16           **“(A) the product may be effective**  
17 **in detecting, diagnosing, treating, or**  
18 **preventing—**

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

20           **or**

21           **“(ii) a serious or life-threat-**  
22 **ening disease or condition caused**  
23 **by a product authorized under**  
24 **this section or approved under**  
25 **this Act or the Public Health**

1           **Service Act, for detecting, diag-**  
2           **nosng, treating, or preventing**  
3           **such a disease or condition**  
4           **caused by such an agent; and**

5           **“(B) the known and potential ben-**  
6           **efits of the product, when used to de-**  
7           **tect, diagnose, prevent, or treat such**  
8           **disease or condition, outweigh the**  
9           **known and potential risks of the**  
10          **product;**

11          **“(3) that there is no adequate, ap-**  
12          **proved, and available alternative to the**  
13          **product for detecting, diagnosing, pre-**  
14          **venting, or treating such disease or con-**  
15          **dition; and**

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

19          **“(d) SCOPE OF AUTHORIZATION.—**

20               **“(1) IN GENERAL.—An authorization of**  
21               **a product under this section shall state—**

22                       **“(A) each disease or condition**  
23                       **that the product may be used to de-**  
24                       **tect, diagnose, prevent, or treat with-**  
25                       **in the scope of the authorization;**

1           **“(B) the Secretary’s conclusions,**  
2           **made under subsection (c)(2)(B), that**  
3           **the known and potential benefits of**  
4           **the product, when used to detect, di-**  
5           **agnose, prevent, or treat such disease**  
6           **or condition, outweigh the known**  
7           **and potential risks of the product;**  
8           **and**

9           **“(C) the Secretary’s conclusions,**  
10           **made under subsection (c), con-**  
11           **cerning the safety and potential effec-**  
12           **tiveness of the product in detecting,**  
13           **diagnosing, preventing, or treating**  
14           **such diseases or conditions, including**  
15           **an assessment of the available sci-**  
16           **entific evidence.**

17           **“(2) CONFIDENTIAL INFORMATION.—**

18           **Nothing in this section alters or amends**  
19           **section 1905 of title 18, United States**  
20           **Code, or section 552(b)(4) of title 5 of**  
21           **such Code.**

22           **“(e) CONDITIONS OF AUTHORIZATION.—**

23           **“(1) UNAPPROVED PRODUCT.—**

24           **“(A) REQUIRED CONDITIONS.—With**  
25           **respect to the emergency use of an**

1           unapproved product, the Secretary,  
2           to the extent feasible given the cir-  
3           cumstances of the emergency, shall,  
4           for persons who choose to carry out  
5           one or more activities for which the  
6           authorization is issued, establish such  
7           conditions on an authorization under  
8           this section as the Secretary finds  
9           necessary or appropriate to protect  
10          the public health, including the fol-  
11          lowing:

12                   “(i) Appropriate conditions  
13                   designed to ensure that, to the ex-  
14                   tent feasible given the cir-  
15                   cumstances of the emergency,  
16                   health care professionals admin-  
17                   istering the product are in-  
18                   formed—

19                           “(I) that the Secretary has  
20                           authorized the emergency use  
21                           of the product;

22                           “(II) of the significant  
23                           known and potential benefits  
24                           and risks of the emergency  
25                           use of the product, and of the

1 extent to which such benefits  
2 and risks are unknown; and

3 “(III) of the alternatives to  
4 the product that are avail-  
5 able, and of their benefits and  
6 risks.

7 “(ii) Appropriate conditions  
8 designed to ensure that, to the ex-  
9 tent feasible given the cir-  
10 cumstances of the emergency, in-  
11 dividuals to whom the product is  
12 administered are informed—

13 “(I) that the Secretary has  
14 authorized the emergency use  
15 of the product;

16 “(II) of the significant  
17 known and potential benefits  
18 and risks of such use, and of  
19 the extent to which such ben-  
20 efits and risks are unknown;  
21 and

22 “(III) of the option to ac-  
23 cept or refuse administration  
24 of the product, of the con-  
25 sequences, if any, of refusing

1           **administration of the product,**  
2           **and of the alternatives to the**  
3           **product that are available**  
4           **and of their benefits and**  
5           **risks.**

6           **“(iii) Appropriate conditions**  
7           **for the monitoring and reporting**  
8           **of adverse events associated with**  
9           **the emergency use of the product.**

10           **“(iv) For manufacturers of the**  
11           **product, appropriate conditions**  
12           **concerning recordkeeping and re-**  
13           **porting, including records access**  
14           **by the Secretary, with respect to**  
15           **the emergency use of the product.**

16           **“(B) AUTHORITY FOR ADDITIONAL**  
17           **CONDITIONS.—With respect to the**  
18           **emergency use of an unapproved**  
19           **product, the Secretary, to the extent**  
20           **feasible given the circumstances of**  
21           **the emergency, may, for persons who**  
22           **choose to carry out one or more ac-**  
23           **tivities for which the authorization is**  
24           **issued, establish such conditions on**  
25           **an authorization under this section**

1 as the Secretary finds necessary or  
2 appropriate to protect the public  
3 health, including the following:

4 “(i) Appropriate conditions on  
5 which entities may distribute the  
6 product with respect to the emer-  
7 gency use of the product (includ-  
8 ing limitation to distribution by  
9 government entities), and on how  
10 distribution is to be performed.

11 “(ii) Appropriate conditions  
12 on who may administer the prod-  
13 uct with respect to the emergency  
14 use of the product, and on the  
15 categories of individuals to  
16 whom, and the circumstances  
17 under which, the product may be  
18 administered with respect to such  
19 use.

20 “(iii) For persons other than  
21 manufacturers of the product, ap-  
22 propriate conditions concerning  
23 recordkeeping and reporting, in-  
24 cluding records access by the Sec-

1           retary, with respect to the emer-  
2           gency use of the product.

3           “(iv) With respect to the emer-  
4           gency use of the product, waive  
5           or limit, to the extent appropriate  
6           given the circumstances of the  
7           emergency, conditions regarding  
8           current good manufacturing prac-  
9           tice otherwise applicable to the  
10          manufacture, processing, packing,  
11          or holding of products subject to  
12          regulation under this Act, includ-  
13          ing such requirements estab-  
14          lished in section 501.

15          “(2) UNAPPROVED USE.—With respect  
16          to the emergency use of a product that is  
17          an unapproved use of an approved prod-  
18          uct:

19                 “(A) The Secretary may, for manu-  
20                 facturers of the product who choose  
21                 to carry out one or more activities for  
22                 which the authorization is issued, es-  
23                 tablish any of the conditions de-  
24                 scribed in clauses (i) through (iv) of  
25                 paragraph (1)(A).

1           **“(B)(i) If the authorization under**  
2           **this section regarding the emergency**  
3           **use authorizes a change in the label-**  
4           **ing of the product, but the manufac-**  
5           **turer of the product chooses not to**  
6           **make such change, such authoriza-**  
7           **tion may not authorize distributors of**  
8           **the product or any other person to**  
9           **alter or obscure the labeling provided**  
10           **by the manufacturer.**

11           **“(ii) In the circumstances de-**  
12           **scribed in clause (i), an authorization**  
13           **under this section regarding the**  
14           **emergency use may, for persons who**  
15           **do not manufacture the product and**  
16           **who choose to act under this clause,**  
17           **authorize such persons to provide in-**  
18           **formation on the product in addition**  
19           **to the labeling provided by the manu-**  
20           **facturer, subject to compliance with**  
21           **clause (i). Such additional informa-**  
22           **tion shall not be considered labeling**  
23           **for purposes of section 502.**

24           **“(f) DURATION OF AUTHORIZATION.—**

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

7           **“(2) CONTINUED USE AFTER END OF EF-**  
8 **FECTIVE PERIOD.—An authorization shall**  
9 **continue to be effective for continued use**  
10 **with respect to patients to whom it was**  
11 **administered during the period described**  
12 **by paragraph (1), to the extent found nec-**  
13 **essary by such patients’ attending physi-**  
14 **cians.**

15 **“(g) REVOCATION OF AUTHORIZATION.—**

16           **“(1) REVIEW.—The Secretary shall pe-**  
17 **riodically review the circumstances and**  
18 **the appropriateness of an authorization**  
19 **under this section.**

20           **“(2) REVOCATION.—The Secretary may**  
21 **revoke an authorization under this sec-**  
22 **tion if, in the Secretary’s unreviewable**  
23 **discretion, the criteria under subsection**  
24 **(c) for issuance of such authorization are**  
25 **no longer met.**

1       “(h) PUBLICATION.—The Secretary shall  
2 promptly publish in the Federal Register a  
3 notice of each authorization, and each termi-  
4 nation or revocation of an authorization, and  
5 an explanation of the reasons therefor, under  
6 this section.

7       “(i) ACTIONS COMMITTED TO AGENCY DIS-  
8 CRETION.—Actions under the authority of this  
9 section by the Secretary, by the Secretary of  
10 Defense, or by the Secretary of Homeland Se-  
11 curity are committed to agency discretion.

12       “(j) RULES OF CONSTRUCTION.—Nothing in  
13 this section shall be construed to impair or  
14 otherwise affect—

15               “(1) the authority of the President as  
16 Commander in Chief of the Armed Forces  
17 of the United States under article II, sec-  
18 tion 2 of the United States Constitution;

19               “(2) the authority of the Secretary of  
20 Defense with respect to the Department  
21 of Defense, including the armed forces,  
22 under other provisions of Federal law; or

23               “(3) the authority of the Secretary  
24 under section 319F-2 to manage the  
25 stockpile under such section.

1       **“(k) APPLICATION TO MEMBERS OF ARMED**  
2 **FORCES.—**

3           **“(1) WAIVER OF REQUIREMENT RELATING**  
4 **TO OPTION TO REFUSE.—In the case of ad-**  
5 **ministration of a countermeasure to**  
6 **members of the armed forces, a require-**  
7 **ment, under subsection (e)(1)(A)(ii)(III),**  
8 **designed to ensure that individuals are**  
9 **informed of an option to accept or refuse**  
10 **administration of a product, may be**  
11 **waived by the President if the President**  
12 **determines, in writing, that complying**  
13 **with such requirement is not feasible, is**  
14 **contrary to the best interests of the mem-**  
15 **bers affected, or is not in the interests of**  
16 **national security.**

17           **“(2) PROVISION OF INFORMATION TO**  
18 **MEMBER OF THE ARMED FORCES.—If the**  
19 **Secretary makes a determination that it**  
20 **is not feasible for the information re-**  
21 **quired by subsection (e)(1)(A)(ii) to be**  
22 **provided to a member of the armed**  
23 **forces prior to the administration of the**  
24 **product, such information shall be pro-**  
25 **vided to such member of the armed**

1 forces (or next-of-kin in the case of the  
2 death of a member) to whom the product  
3 was administered as soon as possible, but  
4 not later than 30 days, after such admin-  
5 istration. Information concerning the ad-  
6 ministration of the product shall be re-  
7 corded in the medical record of the mem-  
8 ber.

9 “(3) EFFECT ON STATUTE PERTAINING TO  
10 INVESTIGATIONAL NEW DRUGS.—In the case  
11 of an authorization based on a deter-  
12 mination by the Secretary of Defense  
13 under subsection (b)(1)(B), section 1107 of  
14 title 10, United States Code, shall not  
15 apply to use of a product that is the sub-  
16 ject of such authorization, within the  
17 scope of such authorization and while  
18 such authorization is effective.

19 “(1) RELATION TO OTHER PROVISIONS.—If a  
20 product is the subject of an authorization  
21 under this section, the use of such product  
22 within the scope of the authorization—

23 “(1) shall not be subject to any re-  
24 quirements pursuant to section 505(i) or  
25 520(g); and

1           “(2) shall not be subject to any re-  
2           quirements otherwise applicable to clin-  
3           ical investigations pursuant to other pro-  
4           visions of this Act.

5           “(m) DISCRETION REGARDING USE OF AU-  
6 THORIZATION.—Nothing in this section pro-  
7 vides the Secretary any authority to require  
8 any person to carry out any activity that be-  
9 comes lawful pursuant to an authorization  
10 under this section, and no person is required  
11 to inform the Secretary that the person will  
12 not be carrying out such activity, except that  
13 a manufacturer of a sole-source unapproved  
14 product authorized for emergency use shall  
15 notify the Secretary within a reasonable pe-  
16 riod of time after the issuance by the Sec-  
17 retary of such authorization if such manufac-  
18 turer does not intend to carry out an activity  
19 or activities under the authorization. This  
20 section does not have any legal effect on a  
21 person who does not carry out any activity for  
22 which an authorization under this section is  
23 issued, or who carries out such an activity  
24 pursuant to other provisions of this Act or  
25 section 351 of the Public Health Service Act.

1       “(n) ENFORCEMENT.—A person who carries  
2 out an activity pursuant to an authorization  
3 under this section, but who fails to comply  
4 with applicable conditions under subsection  
5 (e), is with respect to that act of noncompli-  
6 ance subject to the provisions of law specified  
7 in subsection (a) and to the enforcement of  
8 such provisions under section 301.”.

9 SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS  
10 ACT.

11       (a) SECRETARY OF HEALTH AND HUMAN  
12 SERVICES.—

13           (1) ANNUAL REPORTS ON PARTICULAR  
14 EXERCISES OF AUTHORITY.—

15           (A) RELEVANT AUTHORITIES.—The  
16 Secretary of Health and Human Serv-  
17 ices (referred to in this subsection as  
18 the “Secretary”) shall submit reports  
19 in accordance with subparagraph (B)  
20 regarding the exercise of authority  
21 under the following provisions of law:

22           (i) With respect to section  
23 319F-1 of the Public Health Serv-  
24 ice Act (as added by section 2 of  
25 this Act):

1           **(I) Subsection (b)(1) (relat-**  
2           **ing to increased simplified ac-**  
3           **quisition threshold).**

4           **(II) Subsection (b)(2) (re-**  
5           **lating to use of noncompeti-**  
6           **tive procedures).**

7           **(III) Subsection (c) (relat-**  
8           **ing to expedited peer review**  
9           **procedures).**

10           **(ii) With respect to section**  
11           **319F-2 of the Public Health Serv-**  
12           **ice Act (as added by section 3 of**  
13           **this Act):**

14           **(I) Subsection (c)(7)(C)(iii)**  
15           **(relating to simplified acquisi-**  
16           **tion procedures).**

17           **(II) Subsection**  
18           **(c)(7)(C)(iv) (relating to use of**  
19           **noncompetitive procedures).**

20           **(III) Subsection**  
21           **(c)(7)(C)(v) (relating to pre-**  
22           **mium provision in multiple-**  
23           **award contracts).**

24           **(iii) With respect to section**  
25           **564 of the Federal Food, Drug,**

1           **and Cosmetic Act (as added by**  
2           **section 4 of this Act):**

3                   **(I) Subsection (a)(1) (relat-**  
4                   **ing to emergency uses of cer-**  
5                   **tain drugs and devices).**

6                   **(II) Subsection (b)(1) (re-**  
7                   **lating to a declaration of an**  
8                   **emergency).**

9                   **(III) Subsection (e) (relat-**  
10                   **ing to conditions on author-**  
11                   **ization).**

12           **(B) CONTENTS OF REPORTS.—The**  
13           **Secretary shall annually submit to**  
14           **the designated congressional commit-**  
15           **tees (as defined in subsection (e)) a**  
16           **report that summarizes—**

17                   **(i) the particular actions that**  
18                   **were taken under the authorities**  
19                   **specified in subparagraph (A), in-**  
20                   **cluding, as applicable, the identi-**  
21                   **fication of the threat agent, emer-**  
22                   **gency, or the biomedical counter-**  
23                   **measure with respect to which**  
24                   **the authority was used;**

1           (ii) the reasons underlying the  
2           decision to use such authorities,  
3           including, as applicable, the op-  
4           tions that were considered and  
5           rejected with respect to the use of  
6           such authorities;

7           (iii) the identification of each  
8           person or entity that received, or  
9           was considered and rejected for,  
10          grants, cooperative agreements,  
11          or contracts pursuant to the use  
12          of such authorities; and

13          (iv) whether, with respect to  
14          each procurement that is ap-  
15          proved by the President under  
16          section 319F-2(c)(6) of the Public  
17          Health Service Act (as added by  
18          section 3 of this Act), a contract  
19          was not entered into within one  
20          year after such approval by the  
21          President.

22           (2) ANNUAL SUMMARIES REGARDING CER-  
23          TAIN ACTIVITY.—The Secretary shall annu-  
24          ally submit to the designated congres-  
25          sional committees a report that summa-

1       **rizes the activity undertaken pursuant to**  
2       **the following authorities under section**  
3       **319F-1 of the Public Health Service Act**  
4       **(as added by section 2 of this Act):**

5               **(A) Subsection (b)(3) (relating to**  
6               **increased micropurchase threshold).**

7               **(B) Subsection (d) (relating to au-**  
8               **thority for personal services con-**  
9               **tracts).**

10              **(C) Subsection (e) (relating to**  
11              **streamlined personnel authority).**

12       **With respect to subparagraph (B), the re-**  
13       **port shall include a provision specifying,**  
14       **for the one-year period for which the re-**  
15       **port is submitted, the number of persons**  
16       **who were paid amounts greater than**  
17       **\$100,000 and the number of persons who**  
18       **were paid amounts between \$50,000 and**  
19       **\$100,000.**

20       **(b) NATIONAL ACADEMY OF SCIENCES RE-**  
21       **VIEW.—**

22              **(1) IN GENERAL.—Not later than four**  
23       **years after the date of the enactment of**  
24       **this Act, the Secretary of Health and**  
25       **Human Services shall request the Na-**

1        **tional Academy of Sciences to enter into**  
2        **an agreement for a review of the bio-**  
3        **medical countermeasure research and de-**  
4        **velopment authorities established in this**  
5        **Act to determine whether and to what ex-**  
6        **tent activities undertaken pursuant to**  
7        **such authorities have enhanced the de-**  
8        **velopment of biomedical counter-**  
9        **measures affecting national security, and**  
10       **to recommend any legislative or adminis-**  
11       **trative changes necessary to improve the**  
12       **ability of the Secretary to carry out these**  
13       **activities in the future. The Secretary**  
14       **shall ensure that the results of the study**  
15       **are submitted to the designated congres-**  
16       **sional committees not later than five**  
17       **years after such date of enactment.**

18            **(2) CERTAIN CONTENTS.—The report**  
19        **under paragraph (1) shall include—**

20                    **(A) a summary of the most recent**  
21                    **analysis by the Department of Home-**  
22                    **land Security and the intelligence**  
23                    **community of the domestic threat**  
24                    **from chemical, biological, radio-**  
25                    **logical, and nuclear agents;**

1           **(B) the Academy’s assessment of**  
2           **the current availability of counter-**  
3           **measures to address such threats;**

4           **(C) the Academy’s assessment of**  
5           **the extent to which programs and ac-**  
6           **tivities under this Act will reduce any**  
7           **gap between the threat and the avail-**  
8           **ability of countermeasures to an ac-**  
9           **ceptable level of risk; and**

10           **(D)(i) the Academy’s assessment**  
11           **of threats to national security that**  
12           **are posed by technology that will en-**  
13           **able, during the 10-year period begin-**  
14           **ning on the date of the enactment of**  
15           **this Act, the development of anti-**  
16           **biotic resistant, mutated, and bioengi-**  
17           **neered strains of biological agents;**  
18           **and**

19           **(ii) recommendations on short-**  
20           **term and long-term governmental**  
21           **strategies for addressing such**  
22           **threats, including recommendations**  
23           **for Federal policies regarding re-**  
24           **search priorities, the development of**

1           **countermeasures, and investments in**  
2           **technology.**

3           **(c) GENERAL ACCOUNTING OFFICE REVIEW.—**

4           **Four years after the date of the enactment of**  
5           **this Act, the Comptroller General of the**  
6           **United States shall initiate a study—**

7                   **(1)(A) to review the Secretary of**  
8                   **Health and Human Services' utilization of**  
9                   **the authorities granted under this Act**  
10                   **with respect to simplified acquisition**  
11                   **procedures, use of noncompetitive proce-**  
12                   **dures, increased micropurchase thresh-**  
13                   **olds, personal services contracts, stream-**  
14                   **lined personnel authority, and the pur-**  
15                   **chase of security countermeasures under**  
16                   **the special reserve fund; and**

17                   **(B) to recommend any legislative or**  
18                   **administrative changes necessary to im-**  
19                   **prove the utilization or effectiveness of**  
20                   **such authorities in the future;**

21                   **(2)(A) to review the internal controls**  
22                   **instituted by such Secretary with respect**  
23                   **to such authorities, where required by**  
24                   **this Act; and**

1           **(B) to recommend any legislative or**  
2           **administrative changes necessary to im-**  
3           **prove the effectiveness of such controls;**  
4           **and**

5           **(3)(A) to review such Secretary's utili-**  
6           **zation of the authority granted under**  
7           **this Act to authorize an emergency use of**  
8           **a biomedical countermeasure, including**  
9           **the means by which the Secretary deter-**  
10          **mines whether and under what condi-**  
11          **tions any such authorizations should be**  
12          **granted and the benefits and adverse im-**  
13          **pacts, if any, resulting from the use of**  
14          **such authority; and**

15          **(B) to recommend any legislative or**  
16          **administrative changes necessary to im-**  
17          **prove the utilization or effectiveness of**  
18          **such authority and to enhance protection**  
19          **of the public health.**

20          **The results of the study shall be submitted to**  
21          **the designated congressional committees not**  
22          **later than five years after the date of the en-**  
23          **actment of this Act.**

24          **(d) REPORT REGARDING ADDITIONAL BAR-**  
25          **RIERS TO PROCUREMENT OF SECURITY COUNTER-**

1 **MEASURES.—Not later than 180 days after the**  
2 **date of the enactment of this Act, the Sec-**  
3 **retary of Homeland Security and the Sec-**  
4 **retary of Health and Human Services shall re-**  
5 **port to the designated congressional commit-**  
6 **tees any barriers to the procurement of secu-**  
7 **rity countermeasures that have not been ad-**  
8 **dressed by this Act.**

9       **(e) STATUS OF PROGRAM FOR CHEMICAL TER-**  
10 **RORISM PREPAREDNESS.—Not later than 180**  
11 **days after the date of the enactment of this**  
12 **Act, the Secretary of Homeland Security shall**  
13 **submit to the designated congressional com-**  
14 **mittees a report describing the status of the**  
15 **program carried out by the Secretary to en-**  
16 **hance the preparedness of the United States**  
17 **to respond to terrorist attacks involving**  
18 **chemical agents.**

19       **(f) DESIGNATED CONGRESSIONAL COMMIT-**  
20 **TEES.—For purposes of this section, the term**  
21 **“designated congressional committees” means**  
22 **the following committees of the Congress:**

23               **(1) In the House of Representatives:**  
24               **the Committee on Energy and Commerce,**  
25               **the Committee on Appropriations, the**

1       **Committee on Government Reform, and**  
2       **the Select Committee on Homeland Secu-**  
3       **urity (or any successor to the Select Com-**  
4       **mittee).**

5               **(2) In the Senate: the Committee on**  
6       **Health, Education, Labor, and Pensions,**  
7       **the Committee on Appropriations, and**  
8       **the Committee on Government Affairs.**

9       **SEC. 6. OUTREACH.**

10       **The Secretary of Health and Human Serv-**  
11       **ices shall develop outreach measures to en-**  
12       **sure to the extent practicable that diverse in-**  
13       **stitutions, including Historically Black Col-**  
14       **leges and Universities and those serving large**  
15       **proportions of Hispanics, Native Americans,**  
16       **Asian-Pacific Americans, or other underrep-**  
17       **resented populations, are meaningfully aware**  
18       **of available research and development grants**  
19       **and procurements conducted under sections 2**  
20       **and 3 of this Act.**

1 **SEC. 7. ENSURING COORDINATION, COOPERATION AND**  
2 **THE ELIMINATION OF UNNECESSARY DUPLI-**  
3 **CATION IN PROGRAMS DESIGNED TO PRO-**  
4 **TECT THE HOMELAND FROM BIOLOGICAL,**  
5 **CHEMICAL, RADIOLOGICAL, AND NUCLEAR**  
6 **AGENTS.**

7 **(a) ENSURING COORDINATION OF PRO-**  
8 **GRAMS.—The Secretary of Health and Human**  
9 **Services, the Secretary of Homeland Security,**  
10 **and the Secretary of Defense shall ensure the**  
11 **activities of their respective Departments co-**  
12 **ordinate, complement, and do not unneces-**  
13 **sarily duplicate programs to identify poten-**  
14 **tial domestic threats from biological, chem-**  
15 **ical, radiological or nuclear agents, detect**  
16 **such domestic incidents, analyze such inci-**  
17 **dents, and develop necessary counter-**  
18 **measures. The aforementioned Secretaries**  
19 **shall further ensure that information and**  
20 **technology possessed by the Departments rel-**  
21 **evant to these activities are shared with the**  
22 **other Departments.**

23 **(b) DESIGNATION OF AGENCY COORDINATION**  
24 **OFFICER.—The Secretary of Health and**  
25 **Human Services, the Secretary of Homeland**  
26 **Security, and the Secretary of Defense shall**

1 each designate an officer or employee of their  
2 respective Departments who shall coordinate,  
3 through regular meetings and communica-  
4 tions, with the other aforementioned Depart-  
5 ments such programs and activities carried  
6 out by their Departments.

**Union Calendar No. 98**

108TH CONGRESS  
1ST SESSION

**H. R. 2122**

**[Report No. 108–147, Parts I, II, and III]**

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**A BILL**

To enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes.

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JULY 8, 2003

Reported from the Select Committee on Homeland Security with an amendment; committed to the Committee of the Whole House on the State of the Union and ordered to be printed