

108TH CONGRESS  
1ST SESSION

# H. R. 2122

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

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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 expe-  
9           dited 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 car-  
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 car-  
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 “(II) 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 “(II) 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 ex-  
3                   amination of contractor records).

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

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

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

24                                  “(aa) identifies an increment  
25                                  of the total quantity of security

1 countermeasure required, wheth-  
2 er by percentage or by numbers  
3 of units; and

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

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

22 “(vi) EXTENSION OF CLOSING DATE  
23 FOR RECEIPT OF PROPOSALS NOT REVIEW-  
24 ABLE.—A decision by the Secretary to ex-  
25 tend the closing date for receipt of pro-

1           posals for a procurement under this sub-  
2           section is committed to agency discretion.

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

14          “(8) INTERAGENCY COOPERATION.—

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

22                 “(B) LIMITATION.—An agreement or un-  
23                 dertaking under this paragraph shall not au-  
24                 thorize another agency to exercise the authori-

1           ties provided by this section to the Homeland  
2           Security Secretary or to the Secretary.

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

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

10                   “(B) administrative costs.

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

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

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

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

24                   “(2) a contractual agreement between the  
25                   Homeland Security Secretary and a vendor or ven-

1       dors under which such vendor or vendors agree to  
 2       provide to such Secretary supplies described in sub-  
 3       section (a).

4       “(f) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

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

24       “(a) AUTHORIZATION OF APPROPRIATIONS.—For  
 25       procurement of security countermeasures under section

1 319F–2(c) of the Public Health Service Act (referred to  
2 in this section as the ‘security countermeasures program’),  
3 there is authorized to be appropriated up to  
4 \$5,593,000,000 for the fiscal years 2004 through 2013.  
5 Of the amounts appropriated under the preceding sen-  
6 tence, not to exceed \$3,418,000,000 may be obligated dur-  
7 ing the fiscal years 2004 through 2008, of which not to  
8 exceed \$890,000,000 may be obligated during fiscal year  
9 2004.

10 “(b) SPECIAL RESERVE FUND.—For purposes of the  
11 security countermeasures program, the term ‘special re-  
12 serve fund’ means the appropriations account established  
13 as a result of any appropriations made under subsection  
14 (a).

15 “(c) AVAILABILITY.—

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



1           “(1) EMERGENCY USES.—Notwithstanding sec-  
2           tions 505, 510(k), and 515 of this Act and section  
3           351 of the Public Health Service Act, and subject to  
4           the provisions of this section, the Secretary may au-  
5           thorize the introduction into interstate commerce,  
6           during the effective period of a declaration under  
7           subsection (b), of a drug or device intended for use  
8           in an actual or potential emergency (referred to in  
9           this section as an ‘emergency use’).

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

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

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

23           “(3) RELATION TO OTHER USES.—An emer-  
24           gency use authorized under paragraph (1) for a  
25           product is in addition to any other use that is au-

1       thorized for the product under a provision of law re-  
2       ferred to in such paragraph.

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

5                       “(A) The term ‘emergency use’ has the  
6       meaning indicated for such term in paragraph  
7       (1).

8                       “(B) The term ‘product’ means a drug or  
9       device.

10                      “(C) The term ‘unapproved product’ has  
11       the meaning indicated for such term in para-  
12       graph (2)(A).

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

16       “(b) DECLARATION OF EMERGENCY.—

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

20                               “(A) a determination by the Secretary of  
21       Homeland Security that there is a national  
22       emergency, or a significant potential for a na-  
23       tional emergency, involving a heightened risk of  
24       attack with a specified biological, chemical, ra-  
25       diological, or nuclear agent or agents;

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

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

15          “(2) TERMINATION OF DECLARATION.—

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

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

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

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

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

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

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

24                   “(4) PUBLICATION.—The Secretary shall  
25                   promptly publish in the Federal Register each dec-

1 laration, determination, and renewal under this sub-  
2 section.

3 “(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—

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

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

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

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

20 “(i) such disease or condition; or

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

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

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

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

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

14 “(d) SCOPE OF AUTHORIZATION.—

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

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

21 “(B) the Secretary’s conclusions, made  
22 under subsection (c)(2)(B), that the known and  
23 potential benefits of the product, when used to  
24 detect, diagnose, prevent, or treat such disease

1 or condition, outweigh the known and potential  
2 risks of the product; and

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

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

13 “(e) CONDITIONS OF AUTHORIZATION.—

14 “(1) UNAPPROVED PRODUCT.—

15 “(A) REQUIRED CONDITIONS.—With re-  
16 spect to the emergency use of an unapproved  
17 product, the Secretary, to the extent feasible  
18 given the circumstances of the emergency, shall,  
19 for persons who choose to carry out one or  
20 more activities for which the authorization is  
21 issued, establish such conditions on an author-  
22 ization under this section as the Secretary finds  
23 necessary or appropriate to protect the public  
24 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, proc-  
9 essing, 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 (c) 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 (e), 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 (c)(7)(C)(iii) (re-  
2 lating to simplified acquisition proce-  
3 dures).

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

7 (III) Subsection (c)(7)(C)(v) (re-  
8 lating 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 (e) (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.

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