

108TH CONGRESS  
2D SESSION

# S. 15

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## AN ACT

To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures.

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 2004”.

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 QUALIFIED 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 countermeasures under section 319F(h), the  
14 Secretary may conduct and support such activities in  
15 accordance with this section and, in consultation  
16 with the Director of the National Institutes of  
17 Health, as part of the program under section 446,  
18 if the activities concern qualified countermeasures.

19 “(2) QUALIFIED COUNTERMEASURE.—For pur-  
20 poses of this section, the term ‘qualified counter-  
21 measure’ means a drug (as that term is defined by  
22 section 201(g)(1) of the Federal Food, Drug, and  
23 Cosmetic Act (21 U.S.C. 321(g)(1))), biological  
24 product (as that term is defined by section 351(i) of  
25 this Act (42 U.S.C. 262(i))), or device (as that term  
26 is defined by section 201(h) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 321(h))) that  
2 the Secretary determines to be a priority (consistent  
3 with sections 302(2) and 304(a) of the Homeland  
4 Security Act of 2002) to—

5 “(A) treat, identify, or prevent harm from  
6 any biological, chemical, radiological, or nuclear  
7 agent that may cause a public health emergency  
8 affecting national security; or

9 “(B) treat, identify, or prevent harm from  
10 a condition that may result in adverse health  
11 consequences or death and may be caused by  
12 administering a drug, biological product, or de-  
13 vice that is used as described in subparagraph  
14 (A).

15 “(3) INTERAGENCY COOPERATION.—

16 “(A) IN GENERAL.—In carrying out activi-  
17 ties under this section, the Secretary is author-  
18 ized, 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-  
25 ties provided by this section.

1           “(4) AVAILABILITY OF FACILITIES TO THE SEC-  
2           RETARY.—In any grant, contract, or cooperative  
3           agreement entered into under the authority provided  
4           in this section with respect to a biocontainment lab-  
5           oratory or other related or ancillary specialized re-  
6           search facility that the Secretary determines nec-  
7           essary for the purpose of performing, administering,  
8           or supporting qualified countermeasure research and  
9           development, the Secretary may provide that the fa-  
10          cility that is the object of such grant, contract, or  
11          cooperative agreement shall be available as needed to  
12          the Secretary to respond to public health emer-  
13          gencies affecting national security.

14           “(5) TRANSFERS OF QUALIFIED COUNTER-  
15          MEASURES.—Each agreement for an award of a  
16          grant, contract, or cooperative agreement under sec-  
17          tion 319F(h) for the development of a qualified  
18          countermeasure shall provide that the recipient of  
19          the award will comply with all applicable export-re-  
20          lated controls with respect to such countermeasure.

21          “(b) EXPEDITED PROCUREMENT AUTHORITY.—

22           “(1) INCREASED SIMPLIFIED ACQUISITION  
23          THRESHOLD FOR QUALIFIED COUNTERMEASURE  
24          PROCUREMENTS.—

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

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

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

24           “(B) APPLICATION OF CERTAIN PROVI-  
25 SIONS.—Notwithstanding subparagraph (A)

1 and the provision of law and regulations re-  
2 ferred to in such subparagraph, each of the fol-  
3 lowing provisions shall apply to procurements  
4 described in this paragraph to the same extent  
5 that such provisions would apply to such pro-  
6 curements in the absence of subparagraph (A):

7 “(i) Chapter 37 of title 40, United  
8 States Code (relating to contract work  
9 hours and safety standards).

10 “(ii) Subsections (a) and (b) of sec-  
11 tion 7 of the Anti-Kickback Act of 1986  
12 (41 U.S.C. 57(a) and (b)).

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

17 “(iv) Section 3131 of title 40, United  
18 States Code (relating to bonds of contrac-  
19 tors of public buildings or works).

20 “(v) Subsection (a) of section 304 of  
21 the Federal Property and Administrative  
22 Services Act of 1949 (41 U.S.C. 254(a))  
23 (relating to contingent fees to middlemen).

24 “(vi) Section 6002 of the Solid Waste  
25 Disposal Act (42 U.S.C. 6962).

1           “(vii) Section 1354 of title 31, United  
2           States Code (relating to the limitation on  
3           the use of appropriated funds for contracts  
4           with entities not meeting veterans employ-  
5           ment reporting requirements).

6           “(C) INTERNAL CONTROLS TO BE INSTI-  
7           TUTED.—The Secretary shall institute appro-  
8           priate internal controls for procurements that  
9           are under this paragraph, including require-  
10          ments with regard to documenting the justifica-  
11          tion for use of the authority in this paragraph  
12          with respect to the procurement involved.

13          “(D) AUTHORITY TO LIMIT COMPETI-  
14          TION.—In conducting a procurement under this  
15          paragraph, the Secretary may not use the au-  
16          thority provided for under subparagraph (A) to  
17          conduct a procurement on a basis other than  
18          full and open competition unless the Secretary  
19          determines that the mission of the BioShield  
20          Program under the Project BioShield Act of  
21          2004 would be seriously impaired without such  
22          a limitation.

23          “(2) PROCEDURES OTHER THAN FULL AND  
24          OPEN COMPETITION.—

1           “(A) IN GENERAL.—In using the authority  
2 provided in section 303(c)(1) of title III of the  
3 Federal Property and Administrative Services  
4 Act of 1949 (41 U.S.C. 253(c)(1)) to use proce-  
5 dures other than competitive procedures in the  
6 case of a procurement described in paragraph  
7 (1) of this subsection, the phrase ‘available  
8 from only one responsible source’ in such sec-  
9 tion 303(c)(1) shall be deemed to mean ‘avail-  
10 able from only one responsible source or only  
11 from a limited number of responsible sources’.

12           “(B) RELATION TO OTHER AUTHORI-  
13 TIES.—The authority under subparagraph (A)  
14 is in addition to any other authority to use pro-  
15 cedures other than competitive procedures.

16           “(C) APPLICABLE GOVERNMENT-WIDE  
17 REGULATIONS.—The Secretary shall implement  
18 this paragraph in accordance with government-  
19 wide regulations implementing such section  
20 303(c)(1) (including requirements that offers be  
21 solicited from as many potential sources as is  
22 practicable under the circumstances, that re-  
23 quired notices be published, and that submitted  
24 offers be considered), as such regulations apply  
25 to procurements for which an agency has au-

1           thority to use procedures other than competitive  
2           procedures when the property or services need-  
3           ed by the agency are available from only one re-  
4           sponsible source or only from a limited number  
5           of responsible sources and no other type of  
6           property or services will satisfy the needs of the  
7           agency.

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

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

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

22           “(C) EXCEPTION TO PREFERENCE FOR  
23           PURCHASE CARD MECHANISM.—No provision of  
24           law establishing a preference for using a Gov-  
25           ernment purchase card method for purchases

1 shall apply to purchases that are under this  
2 paragraph and that are greater than \$2,500.

3 “(4) REVIEW.—

4 “(A) REVIEW ALLOWED.—Notwithstanding  
5 subsection (f), section 1491 of title 28, United  
6 States Code, and section 3556 of title 31 of  
7 such Code, review of a contracting agency deci-  
8 sion relating to a procurement described in  
9 paragraph (1) may be had only by filing a  
10 protest—

11 “(i) with a contracting agency; or

12 “(ii) with the Comptroller General  
13 under subchapter V of chapter 35 of title  
14 31, United States Code.

15 “(B) OVERRIDE OF STAY OF CONTRACT  
16 AWARD OR PERFORMANCE COMMITTED TO  
17 AGENCY DISCRETION.—Notwithstanding section  
18 1491 of title 28, United States Code, and sec-  
19 tion 3553 of title 31 of such Code, the following  
20 authorizations by the head of a procuring activ-  
21 ity are committed to agency discretion:

22 “(i) An authorization under section  
23 3553(c)(2) of title 31, United States Code,  
24 to award a contract for a procurement de-  
25 scribed in paragraph (1) of this subsection.

1                   “(ii) An authorization under section  
2                   3553(d)(3)(C) of such title to perform a  
3                   contract for a procurement described in  
4                   paragraph (1) of this subsection.

5                   “(c) AUTHORITY TO EXPEDITE PEER REVIEW.—

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

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

24                  “(B) the amount of which is not greater  
25                  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 any subsequent  
4           phases of a research grant, contract, or cooperative  
5           agreement under this section shall be determined  
6           without regard to the peer review procedures used  
7           for any prior peer review of that same grant, con-  
8           tract, or cooperative agreement. Nothing in the pre-  
9           ceding sentence may be construed to impose any re-  
10          quirement with respect to peer review not otherwise  
11          required under any other law or regulation.

12          “(d) AUTHORITY FOR PERSONAL SERVICES CON-  
13          TRACTS.—

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

1 shall the compensation provided to any such expert  
2 or consultant exceed the daily equivalent of the an-  
3 nual rate of compensation for the President.

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

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

16 “(B) EXCLUSIVITY OF REMEDY.—The  
17 remedy provided by subparagraph (A) shall be  
18 exclusive of any other civil action or proceeding  
19 by reason of the same subject matter against  
20 the entity involved (person, officer, employee, or  
21 governing board member) for any act or omis-  
22 sion within the scope of the Federal Tort  
23 Claims Act.

24 “(C) RECOURSE IN CASE OF GROSS MIS-  
25 CONDUCT OR CONTRACT VIOLATION.—

1           “(i) IN GENERAL.—Should payment  
2           be made by the United States to any  
3           claimant bringing a claim under this para-  
4           graph, either by way of administrative de-  
5           termination, settlement, or court judgment,  
6           the United States shall have, notwith-  
7           standing any provision of State law, the  
8           right to recover against any entity identi-  
9           fied in subparagraph (B) for that portion  
10          of the damages so awarded or paid, as well  
11          as interest and any costs of litigation, re-  
12          sulting from the failure of any such entity  
13          to carry out any obligation or responsibility  
14          assumed by such entity under a contract  
15          with the United States or from any grossly  
16          negligent or reckless conduct or intentional  
17          or willful misconduct on the part of such  
18          entity.

19          “(ii) VENUE.—The United States may  
20          maintain an action under this subpara-  
21          graph against such entity in the district  
22          court of the United States in which such  
23          entity resides or has its principal place of  
24          business.

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

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

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

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

25           “(e) STREAMLINED PERSONNEL AUTHORITY.—

1           “(1) IN GENERAL.—In addition to any other  
2 personnel authorities, the Secretary may, as the Sec-  
3 retary determines necessary to respond to pressing  
4 qualified countermeasure research and development  
5 needs under this section, without regard to those  
6 provisions of title 5, United States Code, governing  
7 appointments in the competitive service, and without  
8 regard to the provisions of chapter 51 and sub-  
9 chapter III of chapter 53 of such title relating to  
10 classification and General Schedule pay rates, ap-  
11 point professional and technical employees, not to  
12 exceed 30 such employees at any time, to positions  
13 in the National Institutes of Health to perform, ad-  
14 minister, or support qualified countermeasure re-  
15 search and development activities in carrying out  
16 this section.

17           “(2) LIMITATIONS.—The authority provided for  
18 under paragraph (1) shall be exercised in a manner  
19 that—

20                   “(A) recruits and appoints individuals  
21 based solely on their abilities, knowledge, and  
22 skills;

23                   “(B) does not discriminate for or against  
24 any applicant for employment on any basis de-

1 scribed in section 2302(b)(1) of title 5, United  
2 States Code;

3 “(C) does not allow an official to appoint  
4 an individual who is a relative (as defined in  
5 section 3110(a)(3) of such title) of such official;

6 “(D) does not discriminate for or against  
7 an individual because of the exercise of any ac-  
8 tivity described in paragraph (9) or (10) of sec-  
9 tion 2302(b) of such title; and

10 “(E) accords a preference, among equally  
11 qualified persons, to persons who are preference  
12 eligibles (as defined in section 2108(3) of such  
13 title).

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

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

21 (b) TECHNICAL AMENDMENT.—Section 481A of the  
22 Public Health Service Act (42 U.S.C. 287a–2) is  
23 amended—

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

4           (2) in subsection (c)—

5           (A) in paragraph (1), by inserting “or the  
6 Director of the National Institute of Allergy  
7 and Infectious Diseases” after “Director of the  
8 Center”; and

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

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

15           (4) in subsection (e)—

16           (A) in paragraph (1)—

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

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

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

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

8 (C) in paragraph (4), by inserting “of the  
9 Center or the Director of the National Institute  
10 of Allergy and Infectious Diseases” after “Di-  
11 rector”;

12 (5) in subsection (f)—

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

16 (B) in paragraph (2), by inserting “of the  
17 Center or the Director of the National Institute  
18 of Allergy and Infectious Diseases” after “Di-  
19 rector”; and

20 (6) in subsection (i)—

21 (A) by striking “APPROPRIATIONS.—For  
22 the purpose of carrying out this section,” and  
23 inserting the following: “APPROPRIATIONS.—

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

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

2 “(2) NATIONAL INSTITUTE OF ALLERGY AND  
3 INFECTIOUS DISEASES.—For the purpose of car-  
4 rying out this section with respect to the National  
5 Institute of Allergy and Infectious Diseases, there  
6 are authorized to be appropriated such sums as may  
7 be necessary for each of the fiscal years 2004 and  
8 2005.”.

9 (c) ADDITIONAL AUTHORIZATIONS OF APPROPRIA-  
10 TIONS.—Section 2106 of the Public Health Service Act  
11 (42 U.S.C. 300aa–6) is amended—

12 (1) in subsection (a), by striking “authorized to  
13 be appropriated” and all that follows and inserting  
14 the following: “authorized to be appropriated such  
15 sums as may be necessary for each of the fiscal  
16 years 2004 and 2005.”; and

17 (2) in subsection (b), by striking “authorized to  
18 be appropriated” and all that follows and inserting  
19 the following: “authorized to be appropriated such  
20 sums as may be necessary for each of the fiscal  
21 years 2004 and 2005.”.

22 (d) TECHNICAL AMENDMENTS.—Section 319F of the  
23 Public Health Service Act (42 U.S.C. 247d–6) is  
24 amended—

1 (1) in subsection (a), by inserting “the Sec-  
2 retary of Homeland Security,” after “Management  
3 Agency,”; and

4 (2) in subsection (h)(4)(B), by striking “to di-  
5 agnose conditions” and inserting “to treat, identify,  
6 or prevent conditions”.

7 (e) **RULE OF CONSTRUCTION.**—Nothing in this sec-  
8 tion has any legal effect on sections 302(2), 302(4),  
9 304(a), or 304(b) of the Homeland Security Act of 2002.

10 **SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

11 (a) **ADDITIONAL AUTHORITY REGARDING STRATEGIC**  
12 **NATIONAL STOCKPILE.**—

13 (1) **TRANSFER OF PROGRAM.**—Section 121 of  
14 the Public Health Security and Bioterrorism Pre-  
15 paredness and Response Act of 2002 (116 Stat.  
16 611; 42 U.S.C. 300hh–12) is transferred from such  
17 Act to the Public Health Service Act, is redesignated  
18 as section 319F–2, and is inserted after section  
19 319F–1 of the Public Health Service Act (as added  
20 by section 2 of this Act).

21 (2) **ADDITIONAL AUTHORITY.**—Section 319F–2  
22 of the Public Health Service Act, as added by para-  
23 graph (1), is amended to read as follows:

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

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

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

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

16                 “(A) consult with the working group under  
17                 section 319F(a);

18                 “(B) ensure that adequate procedures are  
19                 followed with respect to such stockpile for in-  
20                 ventory management and accounting, and for  
21                 the physical security of the stockpile;

22                 “(C) in consultation with Federal, State,  
23                 and local officials, take into consideration the  
24                 timing and location of special events;

1           “(D) review and revise, as appropriate, the  
2 contents of the stockpile on a regular basis to  
3 ensure that emerging threats, advanced tech-  
4 nologies, and new countermeasures are ade-  
5 quately considered;

6           “(E) devise plans for the effective and  
7 timely supply-chain management of the stock-  
8 pile, in consultation with appropriate Federal,  
9 State and local agencies, and the public and  
10 private health care infrastructure;

11           “(F) deploy the stockpile as required by  
12 the Secretary of Homeland Security to respond  
13 to an actual or potential emergency;

14           “(G) deploy the stockpile at the discretion  
15 of the Secretary to respond to an actual or po-  
16 tential public health emergency or other situa-  
17 tion in which deployment is necessary to protect  
18 the public health or safety; and

19           “(H) ensure the adequate physical security  
20 of the stockpile.

21           “(b) SMALLPOX VACCINE DEVELOPMENT.—

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

1 subsection (a) includes an amount of vaccine against  
2 smallpox as determined by such Secretary to be suf-  
3 ficient to meet the health security needs of the  
4 United States.

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

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

14 “(1) IN GENERAL.—

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

19 “(B) SECURITY COUNTERMEASURE.—For  
20 purposes of this subsection, the term ‘security  
21 countermeasure’ means a drug (as that term is  
22 defined by section 201(g)(1) of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C.  
24 321(g)(1))), biological product (as that term is  
25 defined by section 351(i) of this Act (42 U.S.C.

1           262(i)), or device (as that term is defined by  
2           section 201(h) of the Federal Food, Drug, and  
3           Cosmetic Act (21 U.S.C. 321(h))) that—

4                   “(i)(I) the Secretary determines to be  
5                   a priority (consistent with sections 302(2)  
6                   and 304(a) of the Homeland Security Act  
7                   of 2002) to treat, identify, or prevent harm  
8                   from any biological, chemical, radiological,  
9                   or nuclear agent identified as a material  
10                  threat under paragraph (2)(A)(ii), or to  
11                  treat, identify, or prevent harm from a  
12                  condition that may result in adverse health  
13                  consequences or death and may be caused  
14                  by administering a drug, biological prod-  
15                  uct, or device against such an agent;

16                  “(II) the Secretary determines under  
17                  paragraph (2)(B)(ii) to be a necessary  
18                  countermeasure; and

19                  “(III)(aa) is approved or cleared  
20                  under chapter V of the Federal Food,  
21                  Drug, and Cosmetic Act or licensed under  
22                  section 351 of this Act; or

23                  “(bb) is a countermeasure for which  
24                  the Secretary determines that sufficient  
25                  and satisfactory clinical experience or re-

1 search data (including data, if available,  
2 from pre-clinical and clinical trials) sup-  
3 port a reasonable conclusion that the coun-  
4 termeasure will qualify for approval or li-  
5 censing within eight years after the date of  
6 a determination under paragraph (5); or

7 “(ii) is authorized for emergency use  
8 under section 564 of the Federal Food,  
9 Drug, and Cosmetic Act.

10 “(2) DETERMINATION OF MATERIAL  
11 THREATS.—

12 “(A) MATERIAL THREAT.—The Homeland  
13 Security Secretary, in consultation with the  
14 Secretary and the heads of other agencies as  
15 appropriate, shall on 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 sufficient to af-  
22 fect national security.

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

1           “(i) assess the potential public health  
2           consequences for the United States popu-  
3           lation of exposure to agents identified  
4           under subparagraph (A)(ii); and

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

10          “(C) NOTICE TO CONGRESS.—The Sec-  
11          retary and the Homeland Security Secretary  
12          shall promptly notify the designated congres-  
13          sional committees (as defined in paragraph  
14          (10)) that a determination has been made pur-  
15          suant to subparagraph (A) or (B).

16          “(D) ASSURING ACCESS TO THREAT IN-  
17          FORMATION.—In making the assessment and  
18          determination required under subparagraph  
19          (A), the Homeland Security Secretary shall use  
20          all relevant information to which such Secretary  
21          is entitled under section 202 of the Homeland  
22          Security Act of 2002, including but not limited  
23          to information, regardless of its level of classi-  
24          fication, relating to current and emerging

1 threats of chemical, biological, radiological, and  
2 nuclear agents.

3 “(3) ASSESSMENT OF AVAILABILITY AND AP-  
4 PROPRIATENESS OF COUNTERMEASURES.—The Sec-  
5 retary, in consultation with the Homeland Security  
6 Secretary, shall assess on an ongoing basis the avail-  
7 ability and appropriateness of specific counter-  
8 measures to address specific threats identified under  
9 paragraph (2).

10 “(4) CALL FOR DEVELOPMENT OF COUNTER-  
11 MEASURES; COMMITMENT FOR RECOMMENDATION  
12 FOR PROCUREMENT.—

13 “(A) PROPOSAL TO THE PRESIDENT.—If,  
14 pursuant to an assessment under paragraph  
15 (3), the Homeland Security Secretary and the  
16 Secretary make a determination that a counter-  
17 measure would be appropriate but is either cur-  
18 rently unavailable for procurement as a security  
19 countermeasure or is approved, licensed, or  
20 cleared only for alternative uses, such Secre-  
21 taries may jointly submit to the President a  
22 proposal to—

23 “(i) issue a call for the development of  
24 such countermeasure; and

1           “(ii) make a commitment that, upon  
2           the first development of such counter-  
3           measure that meets the conditions for pro-  
4           curement under paragraph (5), the Secre-  
5           taries will, based in part on information  
6           obtained pursuant to such call, make a rec-  
7           ommendation under paragraph (6) that the  
8           special reserve fund under paragraph (10)  
9           be made available for the procurement of  
10          such countermeasure.

11          “(B)     COUNTERMEASURE     SPECIFICA-  
12          TIONS.—The Homeland Security Secretary and  
13          the Secretary shall, to the extent practicable,  
14          include in the proposal under subparagraph  
15          (A)—

16                 “(i) estimated quantity of purchase  
17                 (in the form of number of doses or number  
18                 of effective courses of treatments regard-  
19                 less of dosage form);

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

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

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

6           “(C) PRESIDENTIAL APPROVAL.—If the  
7           President approves a proposal under subpara-  
8           graph (A), the Homeland Security Secretary  
9           and the Secretary shall make known to persons  
10          who may respond to a call for the 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) the commitment described in  
16                   subparagraph (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  
25                   appropriate 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  
4 individually 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  
9 shall determine and consider the following:

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

13 “(ii) The feasibility of production and  
14 delivery within eight 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  
19 a security countermeasure.

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

22 “(A) RECOMMENDATION FOR PROCURE-  
23 MENT.—In the case of a security counter-  
24 measure that the Secretary has, in accordance  
25 with paragraphs (3) and (5), determined to be

1 appropriate for procurement under this sub-  
2 section, the Homeland Security Secretary and  
3 the Secretary shall jointly submit to the Presi-  
4 dent, in coordination with the Director of the  
5 Office of Management and Budget, a rec-  
6 ommendation that the special reserve fund  
7 under paragraph (10) be made available for the  
8 procurement of such countermeasure.

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 DESIGNATED CONGRES-  
16 SIONAL COMMITTEES.—The Secretary and the  
17 Homeland Security Secretary shall notify the  
18 designated congressional committees of each de-  
19 cision of the President to approve a rec-  
20 ommendation under subparagraph (A). Such  
21 notice shall include an explanation of the deci-  
22 sion to make available the special reserve fund  
23 under paragraph (10) for procurement of such  
24 a countermeasure, including, where available,  
25 the number of, nature of, and other information

1 concerning potential suppliers of such counter-  
2 measure, and whether other potential suppliers  
3 of the same or similar countermeasures were  
4 considered and rejected for procurement under  
5 this section and the reasons therefor.

6 “(D) SUBSEQUENT SPECIFIC COUNTER-  
7 MEASURES.—Procurement under this sub-  
8 section of a security countermeasure for a par-  
9 ticular purpose does not preclude the subse-  
10 quent procurement under this subsection of any  
11 other security countermeasure for such purpose  
12 if the Secretary has determined under para-  
13 graph (5)(A) that such countermeasure is ap-  
14 propriate for inclusion in the stockpile and if,  
15 as determined by the Secretary, such counter-  
16 measure provides improved safety or effective-  
17 ness, or for other reasons enhances prepared-  
18 ness to respond to threats of use of a biological,  
19 chemical, radiological, or nuclear agent. Such a  
20 determination by the Secretary is committed to  
21 agency discretion.

22 “(E) RULE OF CONSTRUCTION.—Rec-  
23 ommendations and approvals under this para-  
24 graph apply solely to determinations that the  
25 special reserve fund under paragraph (10) will

1 be made available for a procurement of a secu-  
2 rity countermeasure, and not to the substance  
3 of contracts for such procurement or other mat-  
4 ters relating to awards of such contracts.

5 “(7) PROCUREMENT.—

6 “(A) IN GENERAL.—For purposes of a  
7 procurement under this subsection that is ap-  
8 proved by the President under paragraph (6),  
9 the Homeland Security Secretary and the Sec-  
10 retary shall have responsibilities in accordance  
11 with subparagraphs (B) and (C).

12 “(B) INTERAGENCY AGREEMENT; COSTS.—

13 “(i) INTERAGENCY AGREEMENT.—

14 The Homeland Security Secretary shall  
15 enter into an agreement with the Secretary  
16 for procurement of a security counter-  
17 measure in accordance with the provisions  
18 of this paragraph. The special reserve fund  
19 under paragraph (10) shall be available for  
20 payments made by the Secretary to a ven-  
21 dor for such procurement.

22 “(ii) OTHER COSTS.—The actual costs  
23 to the Secretary under this section, other  
24 than the costs described in clause (i), shall

1 be paid from the appropriation provided  
2 for under subsection (f)(1).

3 “(C) PROCUREMENT.—

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

6 “(I) arranging for procurement  
7 of a security countermeasure, includ-  
8 ing negotiating terms (including quan-  
9 tity, production schedule, and price)  
10 of, and entering into, contracts and  
11 cooperative agreements, and for car-  
12 rying out such other activities as may  
13 reasonably be required, in accordance  
14 with the provisions of this subpara-  
15 graph; and

16 “(II) promulgating such regula-  
17 tions as the Secretary determines nec-  
18 essary to implement the provisions of  
19 this subsection.

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

24 “(I) PAYMENT CONDITIONED ON  
25 DELIVERY.—The contract shall pro-

1           vide that no payment may be made  
2           until delivery has been made of a por-  
3           tion, acceptable to the Secretary, of  
4           the total number of units contracted  
5           for, except that, notwithstanding any  
6           other provision of law, the contract  
7           may provide that, if the Secretary de-  
8           termines (in the Secretary's discre-  
9           tion) that an advance payment is nec-  
10          essary to ensure success of a project,  
11          the Secretary may pay an amount, not  
12          to exceed 10 percent of the contract  
13          amount, in advance of delivery. The  
14          contract shall provide that such ad-  
15          vance payment is required to be re-  
16          paid if there is a failure to perform by  
17          the vendor under the contract. Noth-  
18          ing in this subclause may be con-  
19          strued as affecting rights of vendors  
20          under provisions of law or regulation  
21          (including the Federal Acquisition  
22          Regulation) relating to termination of  
23          contracts for the convenience of the  
24          Government.

1                   “(II) DISCOUNTED PAYMENT.—

2                   The contract may provide for a dis-  
3                   counted price per unit of a product  
4                   that is not licensed, cleared, or ap-  
5                   proved as described in paragraph  
6                   (1)(B)(i)(III)(aa) at the time of deliv-  
7                   ery, and may provide for payment of  
8                   an additional amount per unit if the  
9                   product becomes so licensed, cleared,  
10                  or approved before the expiration date  
11                  of the contract (including an addi-  
12                  tional amount per unit of product de-  
13                  livered before the effective date of  
14                  such licensing, clearance, or approval).

15                  “(III) CONTRACT DURATION.—

16                  The contract shall be for a period not  
17                  to exceed five years, except that, in  
18                  first awarding the contract, the Sec-  
19                  retary may provide for a longer dura-  
20                  tion, not exceeding eight years, if the  
21                  Secretary determines that complexities  
22                  or other difficulties in performance  
23                  under the contract justify such a pe-  
24                  riod. The contract shall be renewable

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

3 “(IV) STORAGE BY VENDOR.—

4 The contract may provide that the  
5 vendor will provide storage for stocks  
6 of a product delivered to the owner-  
7 ship of the Federal Government under  
8 the contract, for such period and  
9 under such terms and conditions as  
10 the Secretary may specify, and in  
11 such case amounts from the special  
12 reserve fund under paragraph (10)  
13 shall be available for costs of ship-  
14 ping, handling, storage, and related  
15 costs for such product.

16 “(V) PRODUCT APPROVAL.—The

17 contract shall provide that the vendor  
18 seek approval, clearance, or licensing  
19 of the product from the Secretary; for  
20 a timetable for the development of  
21 data and other information to support  
22 such approval, clearance, or licensing;  
23 and that the Secretary may waive  
24 part or all of this contract term on re-

1 quest of the vendor or on the initiative  
2 of the Secretary.

3 “(VI) NON-STOCKPILE TRANS-  
4 FERS OF SECURITY COUNTER-  
5 MEASURES.—The contract shall pro-  
6 vide that the vendor will comply with  
7 all applicable export-related controls  
8 with respect to such countermeasure.

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

11 “(I) IN GENERAL.—If the Sec-  
12 retary determines that there is a  
13 pressing need for a procurement of a  
14 specific countermeasure, the amount  
15 of the procurement under this sub-  
16 section shall be deemed to be below  
17 the threshold amount specified in sec-  
18 tion 4(11) of the Office of Federal  
19 Procurement Policy Act (41 U.S.C.  
20 403(11)), for purposes of application  
21 to such procurement, pursuant to sec-  
22 tion 302A(a) of the Federal Property  
23 and Administrative Services Act of  
24 1949 (41 U.S.C. 252a(a)), of—

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

6           “(bb) section 302A(b) of  
7 such Act (41 U.S.C. 252a(b))  
8 and its implementing regulations.

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

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

23           “(bb) Subsections (a) and  
24 (b) of section 7 of the Anti-Kick-

1 back Act of 1986 (41 U.S.C.  
2 57(a) and (b)).

3 “(cc) Section 304C of the  
4 Federal Property and Adminis-  
5 trative Services Act of 1949 (41  
6 U.S.C. 254d) (relating to the ex-  
7 amination of contractor records).

8 “(dd) Section 3131 of title  
9 40, United States Code (relating  
10 to bonds of contractors of public  
11 buildings or works).

12 “(ee) Subsection (a) of sec-  
13 tion 304 of the Federal Property  
14 and Administrative Services Act  
15 of 1949 (41 U.S.C. 254(a)) (re-  
16 lating to contingent fees to mid-  
17 dlemen).

18 “(ff) Section 6002 of the  
19 Solid Waste Disposal Act (42  
20 U.S.C. 6962).

21 “(gg) Section 1354 of title  
22 31, United States Code (relating  
23 to the limitation on the use of  
24 appropriated funds for contracts  
25 with entities not meeting vet-

1           erans employment reporting re-  
2           quirements).

3           “(III) INTERNAL CONTROLS TO  
4           BE ESTABLISHED.—The Secretary  
5           shall establish appropriate internal  
6           controls for procurements made under  
7           this clause, including requirements  
8           with respect to documentation of the  
9           justification for the use of the author-  
10          ity provided under this paragraph  
11          with respect to the procurement in-  
12          volved.

13          “(IV) AUTHORITY TO LIMIT COM-  
14          PETITION.—In conducting a procure-  
15          ment under this subparagraph, the  
16          Secretary may not use the authority  
17          provided for under subclause (I) to  
18          conduct a procurement on a basis  
19          other than full and open competition  
20          unless the Secretary determines that  
21          the mission of the BioShield Program  
22          under the Project BioShield Act of  
23          2004 would be seriously impaired  
24          without such a limitation.

1                   “(iv) PROCEDURES OTHER THAN  
2 FULL AND OPEN COMPETITION.—

3                   “(I) IN GENERAL.—In using the  
4 authority provided in section  
5 303(c)(1) of title III of the Federal  
6 Property and Administrative Services  
7 Act of 1949 (41 U.S.C. 253(c)(1)) to  
8 use procedures other than competitive  
9 procedures in the case of a procure-  
10 ment under this subsection, the  
11 phrase ‘available from only one re-  
12 sponsible source’ in such section  
13 303(c)(1) shall be deemed to mean  
14 ‘available from only one responsible  
15 source or only from a limited number  
16 of responsible sources’.

17                   “(II) RELATION TO OTHER AU-  
18 THORITIES.—The authority under  
19 subclause (I) is in addition to any  
20 other authority to use procedures  
21 other than competitive procedures.

22                   “(III) APPLICABLE GOVERN-  
23 MENT-WIDE REGULATIONS.—The Sec-  
24 retary shall implement this clause in  
25 accordance with government-wide reg-

1                   ulations implementing such section  
2                   303(c)(1) (including requirements  
3                   that offers be solicited from as many  
4                   potential sources as is practicable  
5                   under the circumstances, that re-  
6                   quired notices be published, and that  
7                   submitted offers be considered), as  
8                   such regulations apply to procure-  
9                   ments for which an agency has au-  
10                  thority to use procedures other than  
11                  competitive procedures when the prop-  
12                  erty or services needed by the agency  
13                  are available from only one respon-  
14                  sible source or only from a limited  
15                  number of responsible sources and no  
16                  other type of property or services will  
17                  satisfy the needs of the agency.

18                  “(v) PREMIUM PROVISION IN MUL-  
19                  TIPLE AWARD CONTRACTS.—

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

1 each of such contracts a provision  
2 that—

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

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

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

1           “(vi) EXTENSION OF CLOSING DATE  
2           FOR RECEIPT OF PROPOSALS NOT REVIEW-  
3           ABLE.—A decision by the Secretary to ex-  
4           tend the closing date for receipt of pro-  
5           posals for a procurement under this sub-  
6           section is committed to agency discretion.

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

18          “(8) INTERAGENCY COOPERATION.—

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

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

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

9           “(A) costs for the purchase of vaccines  
10           under procurement contracts entered into be-  
11           fore the date of the enactment of the Project  
12           BioShield Act of 2004; or

13           “(B) costs other than payments made by  
14           the Secretary to a vendor for a procurement of  
15           a security countermeasure under paragraph (7).

16           “(10) DEFINITIONS.—

17           “(A) SPECIAL RESERVE FUND.—For pur-  
18           poses of this subsection, the term ‘special re-  
19           serve fund’ has the meaning given such term in  
20           section 510 of the Homeland Security Act of  
21           2002.

22           “(B) DESIGNATED CONGRESSIONAL COM-  
23           MITTEES.—For purposes of this section, the  
24           term ‘designated congressional committees’

1 means the following committees of the Con-  
2 gress:

3 “(i) In the House of Representatives:  
4 the Committee on Energy and Commerce,  
5 the Committee on Appropriations, the  
6 Committee on Government Reform, and  
7 the Select Committee on Homeland Secu-  
8 rity (or any successor to the Select Com-  
9 mittee).

10 “(ii) In the Senate: the appropriate  
11 committees.

12 “(d) DISCLOSURES.—No Federal agency shall dis-  
13 close under section 552 of title 5, United States Code, any  
14 information identifying the location at which materials in  
15 the stockpile under subsection (a) are stored.

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

18 “(1) a physical accumulation (at one or more  
19 locations) of the supplies described in subsection (a);  
20 or

21 “(2) a contractual agreement between the Sec-  
22 retary and a vendor or vendors under which such  
23 vendor or vendors agree to provide to such Secretary  
24 supplies described in subsection (a).

25 “(f) AUTHORIZATION OF APPROPRIATIONS.—

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

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

13          (b) AMENDMENTS TO HOMELAND SECURITY ACT OF  
14          2002.—Title V of the Homeland Security Act of 2002  
15          (116 Stat. 2212; 6 U.S.C. 311 et seq.) is amended—

16                 (1) in section 502(3) (6 U.S.C. 312(3))—

17                         (A) in subparagraph (B), by striking “the  
18                         Strategic National Stockpile,”; and

19                         (B) in subparagraph (D), by inserting “,  
20                         including requiring deployment of the Strategic  
21                         National Stockpile,” after “resources”; and

22                 (2) by adding 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 the  
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 ‘Biodefense Countermeasures’ ap-  
18 propriations account or any other appropriation made  
19 under subsection (a).

20 “(c) **AVAILABILITY.**—Amounts appropriated under  
21 subsection (a) become available for a procurement under  
22 the security countermeasures program only upon the ap-  
23 proval by the President of such availability for the pro-  
24 curement in accordance with paragraph (6)(B) of such  
25 program.

1       “(d) RELATED AUTHORIZATIONS OF APPROPRIA-  
2 TIONS.—

3               “(1) THREAT ASSESSMENT CAPABILITIES.—For  
4 the purpose of carrying out the responsibilities of  
5 the Secretary for terror threat assessment under the  
6 security countermeasures program, there are author-  
7 ized to be appropriated such sums as may be nec-  
8 essary for each of the fiscal years 2004 through  
9 2006, for the hiring of professional personnel within  
10 the Directorate for Information Analysis and Infra-  
11 structure Protection, who shall be analysts respon-  
12 sible for chemical, biological, radiological, and nu-  
13 clear threat assessment (including but not limited to  
14 analysis of chemical, biological, radiological, and nu-  
15 clear agents, the means by which such agents could  
16 be weaponized or used in a terrorist attack, and the  
17 capabilities, plans, and intentions of terrorists and  
18 other non-state actors who may have or acquire such  
19 agents). All such analysts shall meet the applicable  
20 standards and qualifications for the performance of  
21 intelligence activities promulgated by the Director of  
22 Central Intelligence pursuant to section 104 of the  
23 National Security Act of 1947.

24               “(2) INTELLIGENCE SHARING INFRASTRUC-  
25 TURE.—For the purpose of carrying out the acquisi-

1       tion and deployment of secure facilities (including  
2       information technology and physical infrastructure,  
3       whether mobile and temporary, or permanent) suffi-  
4       cient to permit the Secretary to receive, not later  
5       than 180 days after the date of enactment of the  
6       Project BioShield Act of 2004, all classified informa-  
7       tion and products to which the Under Secretary for  
8       Information Analysis and Infrastructure Protection  
9       is entitled under subtitle A of title II, there are au-  
10      thorized to be appropriated such sums as may be  
11      necessary for each of the fiscal years 2004 through  
12      2006.”.

13      (c) STOCKPILE FUNCTIONS TRANSFERRED.—

14           (1) IN GENERAL.—Except as provided in para-  
15      graph (2), there shall be transferred to the Secretary  
16      of Health and Human Services the functions, per-  
17      sonnel, assets, unexpended balances, and liabilities  
18      of the Strategic National Stockpile, including the  
19      functions of the Secretary of Homeland Security re-  
20      lating thereto.

21           (2) EXCEPTIONS.—

22           (A) FUNCTIONS.—The transfer of func-  
23      tions pursuant to paragraph (1) shall not in-  
24      clude such functions as are explicitly assigned  
25      to the Secretary of Homeland Security by this

1 Act (including the amendments made by this  
2 Act).

3 (B) ASSETS AND UNEXPENDED BAL-  
4 ANCES.—The transfer of assets and unexpended  
5 balances pursuant to paragraph (1) shall not  
6 include the funds appropriated under the head-  
7 ing “BIODEFENSE COUNTERMEASURES” in the  
8 Department of Homeland Security Appropria-  
9 tions Act, 2004 (Public law 108-90).

10 (3) CONFORMING AMENDMENT.—Section 503  
11 of the Homeland Security Act of 2002 (6 U.S.C.  
12 313) is amended by striking paragraph (6).

13 **SEC. 4. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**  
14 **USE IN EMERGENCIES.**

15 (a) IN GENERAL.—Section 564 of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 360bbb-3) is amended  
17 to read as follows:

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

20 “(a) IN GENERAL.—

21 “(1) EMERGENCY USES.—Notwithstanding sec-  
22 tions 505, 510(k), and 515 of this Act and section  
23 351 of the Public Health Service Act, and subject to  
24 the provisions of this section, the Secretary may au-  
25 thorize the introduction into interstate commerce,

1 during the effective period of a declaration under  
2 subsection (b), of a drug, device, or biological prod-  
3 uct intended for use in an actual or potential emer-  
4 gency (referred to in this section as an ‘emergency  
5 use’).

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

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

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

19 “(3) RELATION TO OTHER USES.—An emer-  
20 gency use authorized under paragraph (1) for a  
21 product is in addition to any other use that is au-  
22 thORIZED for the product under a provision of law re-  
23 ferred to in such paragraph.

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

1           “(A) The term ‘biological product’ has the  
2 meaning given such term in section 351 of the  
3 Public Health Service Act.

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

7           “(C) The term ‘product’ means a drug, de-  
8 vice, or biological product.

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

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

15       “(b) DECLARATION OF EMERGENCY.—

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

19           “(A) a determination by the Secretary of  
20 Homeland Security that there is a domestic  
21 emergency, or a significant potential for a do-  
22 mestic emergency, involving a heightened risk  
23 of attack with a specified biological, chemical,  
24 radiological, 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 specified bio-  
6           logical, chemical, radiological, or nuclear agent  
7           or 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 that affects, or  
11          has a significant potential to affect, national se-  
12          curity, and that involves a specified biological,  
13          chemical, radiological, or nuclear agent or  
14          agents, or a specified disease or condition that  
15          may be attributable to such agent or agents.

16          “(2) TERMINATION OF DECLARATION.—

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

20                         “(i) a determination by the Secretary,  
21                         in consultation as appropriate with the  
22                         Secretary of Homeland Security or the  
23                         Secretary of Defense, that the cir-  
24                         cumstances described in paragraph (1)  
25                         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                   “(C) DISPOSITION OF PRODUCT.—If an  
9                   authorization under this section with respect to  
10                  an unapproved product ceases to be effective as  
11                  a result of a termination under subparagraph  
12                  (A) of this paragraph, the Secretary shall con-  
13                  sult with the manufacturer of such product with  
14                  respect to the appropriate disposition of the  
15                  product.

16                  “(3) ADVANCE NOTICE OF TERMINATION.—The  
17                  Secretary shall provide advance notice that a dec-  
18                  laration under this subsection will be terminated.  
19                  The period of advance notice shall be a period rea-  
20                  sonably determined to provide—

21                         “(A) in the case of an unapproved product,  
22                         a sufficient period for disposition of the prod-  
23                         uct, including the return of such product (ex-  
24                         cept such quantities of product as are necessary  
25                         to provide for continued use consistent with

1 subsection (f)(2)) to the manufacturer (in the  
2 case of a manufacturer that chooses to have  
3 such product returned); and

4 “(B) in the case of an unapproved use of  
5 an approved product, a sufficient period for the  
6 disposition of any labeling, or any information  
7 under subsection (e)(2)(B)(ii), as the case may  
8 be, that was provided with respect to the emer-  
9 gency use involved.

10 “(4) PUBLICATION.—The Secretary shall  
11 promptly publish in the Federal Register each dec-  
12 laration, determination, advance notice of termi-  
13 nation, and renewal under this subsection.

14 “(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—  
15 The Secretary may issue an authorization under this sec-  
16 tion with respect to the emergency use of a product only  
17 if, after consultation with the Director of the National In-  
18 stitutes of Health and the Director of the Centers for Dis-  
19 ease Control and Prevention (to the extent feasible and  
20 appropriate given the circumstances of the emergency in-  
21 volved), the Secretary concludes—

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

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

5                   “(A) the product may be effective in diag-  
6                   nosing, treating, or preventing—

7                           “(i) such disease or condition; or

8                           “(ii) a serious or life-threatening dis-  
9                           ease or condition caused by a product au-  
10                           thorized under this section, approved or  
11                           cleared under this Act, or licensed under  
12                           section 351 of the Public Health Service  
13                           Act, for diagnosing, treating, or preventing  
14                           such a disease or condition caused by such  
15                           an agent; and

16                   “(B) the known and potential benefits of  
17                   the product, when used to diagnose, prevent, or  
18                   treat such disease or condition, outweigh the  
19                   known and potential risks of the product;

20           “(3) that there is no adequate, approved, and  
21           available alternative to the product for diagnosing,  
22           preventing, or treating such disease or condition;  
23           and

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

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

3           “(1) each disease or condition that the product  
4 may be used to diagnose, prevent, or treat within the  
5 scope of the authorization;

6           “(2) the Secretary’s conclusions, made under  
7 subsection (c)(2)(B), that the known and potential  
8 benefits of the product, when used to diagnose, pre-  
9 vent, or treat such disease or condition, outweigh the  
10 known and potential risks of the product; and

11          “(3) the Secretary’s conclusions, made under  
12 subsection (c), concerning the safety and potential  
13 effectiveness of the product in diagnosing, pre-  
14 venting, or treating such diseases or conditions, in-  
15 cluding an assessment of the available scientific evi-  
16 dence.

17       “(e) CONDITIONS OF AUTHORIZATION.—

18           “(1) UNAPPROVED PRODUCT.—

19           “(A) REQUIRED CONDITIONS.—With re-  
20 spect to the emergency use of an unapproved  
21 product, the Secretary, to the extent practicable  
22 given the circumstances of the emergency, shall,  
23 for a person who carries out any activity for  
24 which the authorization is issued, establish such  
25 conditions on an authorization under this sec-

1           tion as the Secretary finds necessary or appro-  
2           priate to protect the public health, including the  
3           following:

4                   “(i) Appropriate conditions designed  
5                   to ensure that health care professionals ad-  
6                   ministering the product are informed—

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

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

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

18                   “(ii) Appropriate conditions designed  
19                   to ensure that individuals to whom the  
20                   product is administered are informed—

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

24                           “(II) of the significant known  
25                           and potential benefits and risks of

1           such use, and of the extent to which  
2           such benefits and risks are unknown;  
3           and

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

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

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

20                   “(B) AUTHORITY FOR ADDITIONAL CONDI-  
21          TIONS.—With respect to the emergency use of  
22          an unapproved product, the Secretary may, for  
23          a person who carries out any activity for which  
24          the authorization is issued, establish such con-  
25          ditions on an authorization under this section

1 as the Secretary finds necessary or appropriate  
2 to protect the public health, including the fol-  
3 lowing:

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

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

17 “(iii) Appropriate conditions with re-  
18 spect to the collection and analysis of in-  
19 formation, during the period when the au-  
20 thorization is in effect, concerning the  
21 safety and effectiveness of the product with  
22 respect to the emergency use of such prod-  
23 uct.

24 “(iv) For persons other than manu-  
25 facturers of the product, appropriate con-

1           ditions concerning recordkeeping and re-  
2           porting, including records access by the  
3           Secretary, with respect to the emergency  
4           use of the product.

5           “(2) UNAPPROVED USE.—With respect to the  
6           emergency use of a product that is an unapproved  
7           use of an approved product:

8           “(A) For a manufacturer of the product  
9           who carries out any activity for which the au-  
10          thorization is issued, the Secretary shall, to the  
11          extent practicable given the circumstances of  
12          the emergency, establish conditions described in  
13          clauses (i) and (ii) of paragraph (1)(A), and  
14          may establish conditions described in clauses  
15          (iii) and (iv) of such paragraph.

16          “(B)(i) If the authorization under this sec-  
17          tion regarding the emergency use authorizes a  
18          change in the labeling of the product, but the  
19          manufacturer of the product chooses not to  
20          make such change, such authorization may not  
21          authorize distributors of the product or any  
22          other person to alter or obscure the labeling  
23          provided by the manufacturer.

24          “(ii) In the circumstances described in  
25          clause (i), for a person who does not manufac-

1           ture the product and who chooses to act under  
2           this clause, an authorization under this section  
3           regarding the emergency use shall, to the extent  
4           practicable given the circumstances of the emer-  
5           gency, authorize such person to provide appro-  
6           priate information with respect to such product  
7           in addition to the labeling provided by the man-  
8           ufacturer, subject to compliance with clause (i).  
9           While the authorization under this section is ef-  
10          fective, such additional information shall not be  
11          considered labeling for purposes of section 502.

12                 “(C) The Secretary may establish with re-  
13                 spect to the distribution and administration of  
14                 the product for the unapproved use conditions  
15                 no more restrictive than those established by  
16                 the Secretary with respect to the distribution  
17                 and administration of the product for the ap-  
18                 proved use.

19                 “(3) GOOD MANUFACTURING PRACTICE.—With  
20                 respect to the emergency use of a product for which  
21                 an authorization under this section is issued (wheth-  
22                 er an unapproved product or an unapproved use of  
23                 an approved product), the Secretary may waive or  
24                 limit, to the extent appropriate given the cir-  
25                 cumstances of the emergency, requirements regard-

1       ing current good manufacturing practice otherwise  
2       applicable to the manufacture, processing, packing,  
3       or holding of products subject to regulation under  
4       this Act, including such requirements established  
5       under section 501.

6               “(4) ADVERTISING.—The Secretary may estab-  
7       lish conditions on advertisements and other pro-  
8       motional descriptive printed matter that relate to the  
9       emergency use of a product for which an authoriza-  
10      tion under this section is issued (whether an unap-  
11      proved product or an unapproved use of an approved  
12      product), including, as appropriate—

13               “(A) with respect to drugs and biological  
14              products, requirements applicable to prescrip-  
15              tion drugs pursuant to section 502(n); or

16               “(B) with respect to devices, requirements  
17              applicable to restricted devices pursuant to sec-  
18              tion 502(r).

19               “(f) DURATION OF AUTHORIZATION.—

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

1           “(2) CONTINUED USE AFTER END OF EFFEC-  
2           TIVE PERIOD.—Notwithstanding the termination of  
3           the declaration under subsection (b) or a revocation  
4           under subsection (g), an authorization shall continue  
5           to be effective to provide for continued use of an un-  
6           approved product with respect to a patient to whom  
7           it was administered during the period described by  
8           paragraph (1), to the extent found necessary by such  
9           patient’s attending physician.

10          “(g) REVOCATION OF AUTHORIZATION.—

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

14           “(2) REVOCATION.—The Secretary may revoke  
15           an authorization under this section if the criteria  
16           under subsection (c) for issuance of such authoriza-  
17           tion are no longer met or other circumstances make  
18           such revocation appropriate to protect the public  
19           health or safety.

20          “(h) PUBLICATION; CONFIDENTIAL INFORMATION.—

21           “(1) PUBLICATION.—The Secretary shall  
22           promptly publish in the Federal Register a notice of  
23           each authorization, and each termination or revoca-  
24           tion of an authorization under this section, and an  
25           explanation of the reasons therefor (which may in-

1       clude a summary of data or information that has  
2       been submitted to the Secretary in an application  
3       under section 505(i) or section 520(g), even if such  
4       summary may indirectly reveal the existence of such  
5       application).

6               “(2) CONFIDENTIAL INFORMATION.—Nothing  
7       in this section alters or amends section 1905 of title  
8       18, United States Code, or section 552(b)(4) of title  
9       5 of such Code.

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

15              “(j) RULES OF CONSTRUCTION.—The following ap-  
16       plies with respect to this section:

17               “(1) Nothing in this section impairs the author-  
18       ity of the President as Commander in Chief of the  
19       Armed Forces of the United States under article II,  
20       section 2 of the United States Constitution.

21               “(2) Nothing in this section impairs the author-  
22       ity of the Secretary of Defense with respect to the  
23       Department of Defense, including the armed forces,  
24       under other provisions of Federal law.

1           “(3) Nothing in this section (including any ex-  
2           ercise of authority by a manufacturer under sub-  
3           section (e)(2)) impairs the authority of the United  
4           States to use or manage quantities of a product that  
5           are owned or controlled by the United States (in-  
6           cluding quantities in the stockpile maintained under  
7           section 319F–2 of the Public Health Service Act).

8           “(k) RELATION TO OTHER PROVISIONS.—If a prod-  
9           uct is the subject of an authorization under this section,  
10          the use of such product within the scope of the authoriza-  
11          tion shall not be considered to constitute a clinical inves-  
12          tigation for purposes of section 505(i), section 520(g), or  
13          any other provision of this Act or section 351 of the Public  
14          Health Service Act.

15          “(l) OPTION TO CARRY OUT AUTHORIZED ACTIVI-  
16          TIES.—Nothing in this section provides the Secretary any  
17          authority to require any person to carry out any activity  
18          that becomes lawful pursuant to an authorization under  
19          this section, and no person is required to inform the Sec-  
20          retary that the person will not be carrying out such activ-  
21          ity, except that a manufacturer of a sole-source unap-  
22          proved product authorized for emergency use shall report  
23          to the Secretary within a reasonable period of time after  
24          the issuance by the Secretary of such authorization if such  
25          manufacturer does not intend to carry out any activity

1 under the authorization. This section only has legal effect  
 2 on a person who carries out an activity for which an au-  
 3 thorization under this section is issued. This section does  
 4 not modify or affect activities carried out pursuant to  
 5 other provisions of this Act or section 351 of the Public  
 6 Health Service Act. Nothing in this subsection may be  
 7 construed as restricting the Secretary from imposing con-  
 8 ditions on persons who carry out any activity pursuant to  
 9 an authorization under this section.”.

10 (b) REPEAL OF TERMINATION PROVISION.—Sub-  
 11 section (d) of section 1603 of the National Defense Au-  
 12 thorization Act for Fiscal Year 2004 (10 U.S.C. 1107a  
 13 note) is repealed.

14 **SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS**  
 15 **ACT.**

16 (a) SECRETARY OF HEALTH AND HUMAN SERV-  
 17 ICES.—

18 (1) ANNUAL REPORTS ON PARTICULAR EXER-  
 19 CISES OF AUTHORITY.—

20 (A) RELEVANT AUTHORITIES.—The Sec-  
 21 retary of Health and Human Services (referred  
 22 to in this subsection as the “Secretary”) shall  
 23 submit reports in accordance with subpara-  
 24 graph (B) regarding the exercise of authority  
 25 under the following provisions of law:

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

4 (I) Subsection (b)(1) (relating to  
5 increased simplified acquisition  
6 threshold).

7 (II) Subsection (b)(2) (relating to  
8 procedures other than full and open  
9 competition).

10 (III) Subsection (c) (relating to  
11 expedited peer review procedures).

12 (ii) With respect to section 319F–2 of  
13 the Public Health Service Act (as added by  
14 section 3 of this Act):

15 (I) Subsection (c)(7)(C)(iii) (re-  
16 lating to simplified acquisition proce-  
17 dures).

18 (II) Subsection (c)(7)(C)(iv) (re-  
19 lating to procedures other than full  
20 and open competition).

21 (III) Subsection (c)(7)(C)(v) (re-  
22 lating to premium provision in mul-  
23 tiple-award contracts).

1 (iii) With respect to section 564 of the  
2 Federal Food, Drug, and Cosmetic Act (as  
3 added by section 4 of this Act):

4 (I) Subsection (a)(1) (relating to  
5 emergency uses of certain drugs and  
6 devices).

7 (II) Subsection (b)(1) (relating to  
8 a declaration of an emergency).

9 (III) Subsection (e) (relating to  
10 conditions on authorization).

11 (B) CONTENTS OF REPORTS.—The Sec-  
12 retary shall annually submit to the designated  
13 congressional committees a report that  
14 summarizes—

15 (i) the particular actions that were  
16 taken under the authorities specified in  
17 subparagraph (A), including, as applicable,  
18 the identification of the threat agent,  
19 emergency, or the biomedical counter-  
20 measure with respect to which the author-  
21 ity was used;

22 (ii) the reasons underlying the deci-  
23 sion to use such authorities, including, as  
24 applicable, the options that were consid-

1           ered and rejected with respect to the use of  
2           such authorities;

3           (iii) the number of, nature of, and  
4           other information concerning the persons  
5           and entities that received a grant, coopera-  
6           tive agreement, or contract pursuant to the  
7           use of such authorities, and the persons  
8           and entities that were considered and re-  
9           jected for such a grant, cooperative agree-  
10          ment, or contract, except that the report  
11          need not disclose the identity of any such  
12          person or entity; and

13          (iv) whether, with respect to each pro-  
14          curement that is approved by the President  
15          under section 319F-2(c)(6) of the Public  
16          Health Service Act (as added by section 3  
17          of this Act), a contract was entered into  
18          within one year after such approval by the  
19          President.

20           (2) ANNUAL SUMMARIES REGARDING CERTAIN  
21          ACTIVITY.—The Secretary shall annually submit to  
22          the designated congressional committees a report  
23          that summarizes the activity undertaken pursuant to  
24          the following authorities under section 319F-1 of

1 the Public Health Service Act (as added by section  
2 of this Act):

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

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

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

9 With respect to subparagraph (B), the report shall  
10 include a provision specifying, for the one-year pe-  
11 riod for which the report is submitted, the number  
12 of persons who were paid amounts greater than  
13 \$100,000 and the number of persons who were paid  
14 amounts between \$50,000 and \$100,000.

15 (3) REPORT ON ADDITIONAL BARRIERS TO PRO-  
16 CUREMENT OF SECURITY COUNTERMEASURES.—Not  
17 later than one year after the date of the enactment  
18 of this Act, the Secretary, in consultation with the  
19 Secretary of Homeland Security, shall report to the  
20 designated congressional committees any potential  
21 barriers to the procurement of security counter-  
22 measures that have not been addressed by this Act.

23 (b) GENERAL ACCOUNTING OFFICE REVIEW.—

1           (1) IN GENERAL.—Four years after the date of  
2 the enactment of this Act, the Comptroller General  
3 of the United States shall initiate a study—

4                   (A)(i) to review the Secretary of Health  
5 and Human Services' utilization of the authori-  
6 ties granted under this Act with respect to sim-  
7 plified acquisition procedures, procedures other  
8 than full and open competition, increased  
9 micropurchase thresholds, personal services con-  
10 tracts, streamlined personnel authority, and the  
11 purchase of security countermeasures under the  
12 special reserve fund; and

13                   (ii) to make recommendations to improve  
14 the utilization or effectiveness of such authori-  
15 ties in the future;

16                   (B)(i) to review and assess the adequacy of  
17 the internal controls instituted by such Sec-  
18 retary with respect to such authorities, where  
19 required by this Act; and

20                   (ii) to make recommendations to improve  
21 the effectiveness of such controls;

22                   (C)(i) to review such Secretary's utilization  
23 of the authority granted under this Act to au-  
24 thorize an emergency use of a biomedical coun-  
25 termeasure, including the means by which the

1 Secretary determines whether and under what  
2 conditions any such authorizations should be  
3 granted and the benefits and adverse impacts,  
4 if any, resulting from the use of such authority;  
5 and

6 (ii) to make recommendations to improve  
7 the utilization or effectiveness of such authority  
8 and to enhance protection of the public health;

9 (D) to identify any purchases or procure-  
10 ments that would not have been made or would  
11 have been significantly delayed except for the  
12 authorities described in subparagraph (A)(i);  
13 and

14 (E)(i) to determine whether and to what  
15 extent activities undertaken pursuant to the  
16 biomedical countermeasure research and devel-  
17 opment authorities established in this Act have  
18 enhanced the development of biomedical coun-  
19 termeasures affecting national security; and

20 (ii) to make recommendations to improve  
21 the ability of the Secretary to carry out these  
22 activities in the future.

23 (2) ADDITIONAL PROVISIONS REGARDING DE-  
24 TERMINATION ON DEVELOPMENT OF BIOMEDICAL  
25 COUNTERMEASURES AFFECTING NATIONAL SECUR-

1 RITY.—In the report under paragraph (1), the deter-  
2 mination under subparagraph (E) of such paragraph  
3 shall include—

4 (A) the Comptroller General’s assessment  
5 of the current availability of countermeasures to  
6 address threats identified by the Secretary of  
7 Homeland Security;

8 (B) the Comptroller General’s assessment  
9 of the extent to which programs and activities  
10 under this Act will reduce any gap between the  
11 threat and the availability of countermeasures  
12 to an acceptable level of risk; and

13 (C)(i) the Comptroller General’s assess-  
14 ment of threats to national security that are  
15 posed by technology that will enable, during the  
16 10-year period beginning on the date of the en-  
17 actment of this Act, the development of anti-  
18 biotic resistant, mutated, or bioengineered  
19 strains of biological agents; and

20 (ii) recommendations on short-term and  
21 long-term governmental strategies for address-  
22 ing such threats, including recommendations for  
23 Federal policies regarding research priorities,  
24 the development of countermeasures, and in-  
25 vestments in technology.

1           (3) REPORT.—A report providing the results of  
2           the study under paragraph (1) shall be submitted to  
3           the designated congressional committees not later  
4           than five years after the date of the enactment of  
5           this Act.

6           (c) REPORT REGARDING BIOCONTAINMENT FACILI-  
7           TIES.—Not later than 120 days after the date of the en-  
8           actment of this Act, the Secretary of Homeland Security  
9           and the Secretary of Health and Human Services shall  
10          jointly report to the designated congressional committees  
11          whether there is a lack of adequate large-scale biocontain-  
12          ment facilities necessary for the testing of security coun-  
13          termeasures in accordance with Food and Drug Adminis-  
14          tration requirements.

15          (d) DESIGNATED CONGRESSIONAL COMMITTEES.—  
16          For purposes of this section, the term “designated con-  
17          gressional committees” means the following committees of  
18          the Congress:

19                 (1) In the House of Representatives: the Com-  
20                 mittee on Energy and Commerce, the Committee on  
21                 Appropriations, the Committee on Government Re-  
22                 form, and the Select Committee on Homeland Secu-  
23                 rity (or any successor to the Select Committee).

24                 (2) In the Senate: the appropriate committees.

1 **SEC. 6. OUTREACH.**

2       The Secretary of Health and Human Services shall  
3 develop outreach measures to ensure to the extent prac-  
4 ticable that diverse institutions, including Historically  
5 Black Colleges and Universities and those serving large  
6 proportions of Black or African Americans, American In-  
7 dians, Appalachian Americans, Alaska Natives, Asians,  
8 Native Hawaiians, other Pacific Islanders, Hispanics or  
9 Latinos, or other underrepresented populations, are mean-  
10 ingfully aware of available research and development  
11 grants, contracts, cooperative agreements, and procure-  
12 ments conducted under sections 2 and 3 of this Act.

13 **SEC. 7. RECOMMENDATION FOR EXPORT CONTROLS ON**  
14 **CERTAIN BIOMEDICAL COUNTERMEASURES.**

15       Upon the award of any grant, contract, or cooperative  
16 agreement under section 2 or 3 of this Act for the re-  
17 search, development, or procurement of a qualified coun-  
18 termeasure or a security countermeasure (as those terms  
19 are defined in this Act), the Secretary of Health and  
20 Human Services shall, in consultation with the heads of  
21 other appropriate Federal agencies, determine whether the  
22 countermeasure involved in such grant, contract, or coop-  
23 erative agreement is subject to existing export-related con-  
24 trols and, if not, may make a recommendation to the ap-  
25 propriate Federal agency or agencies that such counter-

1 measure should be included on the list of controlled items  
2 subject to such controls.

3 **SEC. 8. ENSURING COORDINATION, COOPERATION AND**  
4 **THE ELIMINATION OF UNNECESSARY DUPLI-**  
5 **CATION IN PROGRAMS DESIGNED TO PRO-**  
6 **TECT THE HOMELAND FROM BIOLOGICAL,**  
7 **CHEMICAL, RADIOLOGICAL, AND NUCLEAR**  
8 **AGENTS.**

9 (a) ENSURING COORDINATION OF PROGRAMS.—The  
10 Secretary of Health and Human Services, the Secretary  
11 of Homeland Security, and the Secretary of Defense shall  
12 ensure that the activities of their respective Departments  
13 coordinate, complement, and do not unnecessarily dupli-  
14 cate programs to identify potential domestic threats from  
15 biological, chemical, radiological or nuclear agents, detect  
16 domestic incidents involving such agents, analyze such in-  
17 cidents, and develop necessary countermeasures. The  
18 aforementioned Secretaries shall further ensure that infor-  
19 mation and technology possessed by the Departments rel-  
20 evant to these activities are shared with the other Depart-  
21 ments.

22 (b) DESIGNATION OF AGENCY COORDINATION OFFI-  
23 CER.—The Secretary of Health and Human Services, the  
24 Secretary of Homeland Security, and the Secretary of De-  
25 fense shall each designate an officer or employee of their

1 respective Departments who shall coordinate, through reg-  
2 ular meetings and communications, with the other afore-  
3 mentioned Departments such programs and activities car-  
4 ried out by their Departments.

5 **SEC. 9. AUTHORITY OF THE SECRETARY OF HEALTH AND**  
6 **HUMAN SERVICES DURING NATIONAL EMER-**  
7 **GENCIES.**

8 Section 1135(b) of the Social Security Act (42 U.S.C.  
9 1320b-5(b)) is amended—

10 (1) by striking paragraph (3) and inserting the  
11 following:

12 “(3) actions under section 1867 (relating to ex-  
13 amination and treatment for emergency medical con-  
14 ditions and women in labor) for—

15 “(A) a transfer of an individual who has  
16 not been stabilized in violation of subsection (c)  
17 of such section if the transfer is necessitated by  
18 the circumstances of the declared emergency in  
19 the emergency area during the emergency pe-  
20 riod; or

21 “(B) the direction or relocation of an indi-  
22 vidual to receive medical screening in an alter-  
23 nate location pursuant to an appropriate State  
24 emergency preparedness plan;”;

1           (2) in paragraph (5), by striking “and” at the  
2           end;

3           (3) in paragraph (6), by striking the period and  
4           inserting “; and”;

5           (4) by inserting after paragraph (6), the fol-  
6           lowing:

7           “(7) sanctions and penalties that arise from  
8           noncompliance with the following requirements (as  
9           promulgated under the authority of section 264(e) of  
10          the Health Insurance Portability and Accountability  
11          Act of 1996 (42 U.S.C. 1320d-2 note)—

12                   “(A) section 164.510 of title 45, Code of  
13          Federal Regulations, relating to—

14                           “(i) requirements to obtain a patient’s  
15                           agreement to speak with family members  
16                           or friends; and

17                           “(ii) the requirement to honor a re-  
18                           quest to opt out of the facility directory;

19                           “(B) section 164.520 of such title, relating  
20          to the requirement to distribute a notice; or

21                           “(C) section 164.522 of such title, relating  
22          to—

23                           “(i) the patient’s right to request pri-  
24          vacy restrictions; and

1                   “(ii) the patient’s right to request  
2                   confidential communications.”; and

3                   (5) by adding at the end the following: “A waiv-  
4                   er or modification provided for under paragraph (3)  
5                   or (7) shall only be in effect if such actions are  
6                   taken in a manner that does not discriminate among  
7                   individuals on the basis of their source of payment  
8                   or of their ability to pay, and shall be limited to a  
9                   72-hour period beginning upon implementation of a  
10                  hospital disaster protocol. A waiver or modification  
11                  under such paragraph (7) shall be withdrawn after  
12                  such period and the provider shall comply with the  
13                  requirements under such paragraph for any patient  
14                  still under the care of the provider.”.

Passed the Senate May 19, 2004.

Attest:

*Secretary.*

108<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 15

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## AN ACT

To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures.