

108TH CONGRESS
2D SESSION

S. 15

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.

108TH CONGRESS
2^D SESSION

S. 15

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.