

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. _____**

(Project BioShield Act of 2003)

OFFERED BY MR. TAUZIN

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE.**

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

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

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

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

13 “(a) IN GENERAL.—

14 “(1) AUTHORITY.—In conducting and sup-
15 porting research and development activities regard-
16 ing biomedical countermeasures under section

1 319F(h), the Secretary may conduct and support
2 such activities in accordance with this section if the
3 activities concern qualified countermeasures.

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

9 “(3) INTERAGENCY COOPERATION.—

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

16 “(B) LIMITATION.—An agreement or un-
17 dertaking under this paragraph shall not au-
18 thorize another agency to exercise the authori-
19 ties provided by this section.

20 “(4) AVAILABILITY OF FACILITIES TO THE SEC-
21 RETARY.—In any grant or cooperative agreement
22 entered into under the authority provided in this
23 section with respect to a biocontainment laboratory
24 or other related or ancillary specialized research fa-
25 cility that the Secretary determines necessary for the

1 purpose of performing, administering, and sup-
2 porting qualified countermeasure research and devel-
3 opment, the Secretary may provide that the facility
4 that is the object of such grant or cooperative agree-
5 ment shall be available as needed to the Secretary
6 to respond to public health emergencies affecting na-
7 tional security.

8 “(b) EXPEDITED PROCUREMENT AUTHORITY.—

9 “(1) INCREASED SIMPLIFIED ACQUISITION
10 THRESHOLD FOR BIOMEDICAL COUNTERMEASURE
11 PROCUREMENTS.—

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

1 the administration, with respect to such pro-
2 curement, of—

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

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

10 “(B) APPLICATION OF CERTAIN PROVI-
11 SIONS.—Notwithstanding subparagraph (A)
12 and the provision of law and regulations re-
13 ferred to in such subparagraph, each of the fol-
14 lowing provisions shall apply to procurements
15 described in this paragraph to the same extent
16 that such provisions would apply to such pro-
17 curements in the absence of subparagraph (A):

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

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

24 “(iii) Section 304C of the Federal
25 Property and Administrative Services Act

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

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

9 “(2) USE OF NONCOMPETITIVE PROCEDURES.—
10 In addition to any other authority to use procedures
11 other than competitive procedures, the Secretary
12 may use such other procedures when—

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

15 “(B) the property or services needed by
16 the Secretary are available from only one re-
17 sponsible source or only from a limited number
18 of responsible sources, and no other type of
19 property or services will satisfy the Secretary’s
20 needs.

21 “(3) INCREASED MICROPURCHASE THRESH-
22 OLD.—

23 “(A) IN GENERAL.—For a procurement
24 described by paragraph (1), the amount speci-
25 fied in subsections (c), (d), and (f) of section 32

1 of the Office of Federal Procurement Policy Act
2 (41 U.S.C. 428) shall be deemed to be \$15,000
3 in the administration of that section with re-
4 spect to such procurement.

5 “(B) INTERNAL CONTROLS TO BE INSTI-
6 TUTED.—The Secretary shall institute appro-
7 priate internal controls for purchases that are
8 under this paragraph and that are greater than
9 \$2,500.

10 “(C) EXCEPTION TO PREFERENCE FOR
11 PURCHASE CARD MECHANISM.—No provision of
12 law establishing a preference for using a Gov-
13 ernment purchase card method for purchases
14 shall apply to purchases that are under this
15 paragraph and that are greater than \$2,500.

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

17 “(1) IN GENERAL.—The Secretary may, as the
18 Secretary determines necessary to respond to press-
19 ing qualified countermeasure research and develop-
20 ment needs under this section, employ such expe-
21 dited peer review procedures (including consultation
22 with appropriate scientific experts) as the Secretary,
23 in consultation with the Director of NIH, deems ap-
24 propriate to obtain assessment of scientific and tech-
25 nical merit and likely contribution to the field of

1 qualified countermeasure research, in place of the
2 peer review and advisory council review procedures
3 that would be required under sections 301(a)(3),
4 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and
5 494, as applicable to a grant, contract, or coopera-
6 tive agreement—

7 “(A) that is for performing, administering,
8 or supporting qualified countermeasure research
9 and development activities; and

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

12 “(2) SUBSEQUENT PHASES OF RESEARCH.—

13 The Secretary’s determination of whether to employ
14 expedited peer review with respect to subsequent
15 phases of a research grant or cooperative agreement
16 under this section shall be determined without re-
17 gard to the peer review procedures used for any
18 prior peer review of that same grant or cooperative
19 agreement.

20 “(d) AUTHORITY FOR PERSONAL SERVICES CON-
21 TRACTS.—

22 “(1) IN GENERAL.—For the purpose of per-
23 forming, administering, and supporting qualified
24 countermeasure research and development activities,
25 the Secretary may, as the Secretary determines nec-

1 essary to respond to pressing qualified counter-
2 measure research and development needs under this
3 section, obtain by contract (in accordance with sec-
4 tion 3109 of title 5, United States Code, but without
5 regard to the limitations in such section on the pe-
6 riod of service and on pay) the personal services of
7 experts or consultants who have scientific or other
8 professional qualifications, except that in no case
9 shall the compensation provided to any such expert
10 or consultant exceed the daily equivalent of the an-
11 nual rate of compensation for the President.

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

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

23 “(B) EXCLUSIVITY OF REMEDY.—The
24 remedy provided by subparagraph (A) shall be
25 exclusive of any other civil action or proceeding

1 by reason of the same subject matter against
2 the person, officer, employee, or governing
3 board member.

4 “(3) INTERNAL CONTROLS TO BE INSTI-
5 TUTED.—

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

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

24 “(4) NUMBER OF PERSONAL SERVICES CON-
25 TRACTS LIMITED.—The number of experts and con-

1 sultants whose personal services are obtained under
2 paragraph (1) shall not exceed 30 at any time.

3 “(e) STREAMLINED PERSONNEL AUTHORITY.—

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

20 “(2) INTERNAL CONTROLS TO BE INSTI-
21 TUTED.—The Secretary shall institute appropriate
22 internal controls for appointments under this sub-
23 section.

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

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

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

10 (2) in subsection (c)—

11 (A) in paragraph (1), by inserting “or the
12 Director of the National Institute of Allergy
13 and Infectious Diseases” after “Director of the
14 Center”; and

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

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

21 (4) in subsection (e)—

22 (A) in paragraph (1)—

23 (i) in the matter preceding subpara-
24 graph (A), by inserting “or the Director of
25 the National Institute of Allergy and Infec-

1 tious Diseases” after “Director of the Cen-
2 ter”;

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

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

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

13 (C) in paragraph (4), by inserting “of the
14 Center or the Director of the National Institute
15 of Allergy and Infectious Diseases” after “Di-
16 rector”;

17 (5) in subsection (f)—

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

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

25 (6) in subsection (i)—

1 (A) by striking “APPROPRIATIONS.—For
2 the purpose of carrying out this section,” and
3 inserting the following: “APPROPRIATIONS.—

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

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

7 “(2) NATIONAL INSTITUTE OF ALLERGY AND
8 INFECTIOUS DISEASES.—For the purpose of car-
9 rying out this section with respect to the National
10 Institute of Allergy and Infectious Diseases, there
11 are authorized to be appropriated such sums as may
12 be necessary for fiscal year 2003.”.

13 **SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

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

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

19 “(a) STRATEGIC NATIONAL STOCKPILE.—

20 “(1) IN GENERAL.—The Secretary of Homeland
21 Security (referred to in this section as the ‘Home-
22 land Security Secretary’), in coordination with the
23 Secretary and the Secretary of Veterans Affairs,
24 shall maintain a stockpile or stockpiles of drugs, vac-
25 cines and other biological products, medical devices,

1 and other supplies in such numbers, types, and
2 amounts as are determined by the Secretary to be
3 appropriate and practicable, taking into account
4 other available sources, to provide for the emergency
5 health security of the United States, including the
6 emergency health security of children and other vul-
7 nerable populations, in the event of a bioterrorist at-
8 tack or other public health emergency.

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

11 “(A) consult with the working group under
12 section 319F(a);

13 “(B) ensure that adequate procedures are
14 followed with respect to such stockpile for in-
15 ventory management and accounting, and for
16 the physical security of the stockpile;

17 “(C) in consultation with Federal, State,
18 and local officials, take into consideration the
19 timing and location of special events;

20 “(D) review and revise, as appropriate, the
21 contents of the stockpile on a regular basis to
22 ensure that emerging threats, advanced tech-
23 nologies, and new countermeasures are ade-
24 quately considered;

1 “(E) devise plans for the effective and
2 timely supply-chain management of the stock-
3 pile, in consultation with appropriate Federal,
4 State and local agencies, and the public and
5 private health care infrastructure; and

6 “(F) ensure the adequate physical security
7 of the stockpile.

8 “(b) SMALLPOX VACCINE DEVELOPMENT.—

9 “(1) IN GENERAL.—The Secretary shall award
10 contracts, enter into cooperative agreements, or
11 carry out such other activities as may reasonably be
12 required in order to ensure that the stockpile under
13 subsection (a) includes an amount of vaccine against
14 smallpox as determined by such Secretary to be suf-
15 ficient to meet the health security needs of the
16 United States.

17 “(2) RULE OF CONSTRUCTION.—Nothing in
18 this section shall be construed to limit the private
19 distribution, purchase, or sale of vaccines from
20 sources other than the stockpile described in sub-
21 section (a).

22 “(c) ADDITIONAL AUTHORITY REGARDING PRO-
23 CUREMENT OF CERTAIN BIOMEDICAL COUNTER-
24 MEASURES; AVAILABILITY OF SPECIAL RESERVE
25 FUND.—

1 “(1) IN GENERAL.—

2 “(A) USE OF FUND.—A security counter-
3 measure may, in accordance with this sub-
4 section, be procured with amounts in the special
5 reserve fund under paragraph (10).

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

10 “(i) that affects national security;

11 “(ii) that is determined under para-
12 graph (2)(B)(ii) to be a necessary counter-
13 measure; and

14 “(iii)(I) that is approved or cleared
15 under chapter V of the Federal Food,
16 Drug, and Cosmetic Act, or licensed under
17 section 351 of this Act, for use as a coun-
18 termeasure to a chemical, biological, radio-
19 logical, or nuclear agent identified as a
20 material threat under paragraph (2)(A)(ii);
21 or

22 “(II) for which the Secretary deter-
23 mines that sufficient and satisfactory clin-
24 ical experience or research data (including
25 data, if available, from pre-clinical and

1 clinical trials) support a reasonable conclu-
2 sion that the countermeasure will qualify
3 for approval or licensing after the date of
4 a determination under paragraph (5).

5 “(2) DETERMINATION OF MATERIAL
6 THREATS.—

7 “(A) MATERIAL THREAT.—The Homeland
8 Security Secretary, in consultation with the
9 heads of other agencies as appropriate, shall on
10 an ongoing basis—

11 “(i) assess current and emerging
12 threats of chemical, biological, radiological,
13 and nuclear agents; and

14 “(ii) determine which of such agents
15 present a material threat against the
16 United States population.

17 “(B) PUBLIC HEALTH IMPACT; NECESSARY
18 COUNTERMEASURES.—The Secretary shall on
19 an ongoing basis—

20 “(i) assess the potential public health
21 consequences of use against the United
22 States population of agents identified
23 under subparagraph (A)(ii); and

24 “(ii) determine, on the basis of such
25 assessment, the agents for which priority

1 countermeasures are necessary to protect
2 the public health from a material threat.

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 SECURITY COUNTERMEASURES;
11 COMMITMENT FOR RECOMMENDATION FOR PRO-
12 CUREMENT.—

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 security
17 countermeasure would be appropriate, such Sec-
18 retaries may jointly submit to the President a
19 proposal to—

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

22 “(ii) make a commitment that, upon
23 the first development of such security
24 countermeasure that meets the conditions
25 for procurement under paragraph (5), the

1 Secretaries will, based in part on informa-
2 tion obtained pursuant to such call, make
3 a recommendation under paragraph (6)
4 that the special reserve fund under para-
5 graph (10) be made available for the pro-
6 curement of such security countermeasure.

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

12 “(i) estimated quantity of purchase
13 (in the form of number of doses or number
14 of effective courses of treatments regard-
15 less of dosage form);

16 “(ii) necessary measures of minimum
17 safety and effectiveness;

18 “(iii) estimated price for each dose or
19 effective course of treatment regardless of
20 dosage form; and

21 “(iv) other information that may be
22 necessary to encourage and facilitate re-
23 search, development, and manufacture of
24 the countermeasure or to provide specifica-
25 tions for the countermeasure.

1 “(C) PRESIDENTIAL APPROVAL.—If the
2 President approves a proposal under subpara-
3 graph (A), the Homeland Security Secretary
4 and the Secretary shall make known to persons
5 who may respond to a call for the security
6 countermeasure involved—

7 “(i) the call for the countermeasure;

8 “(ii) specifications for the counter-
9 measure under subparagraph (B); and

10 “(iii) a commitment described in sub-
11 paragraph (A)(ii).

12 “(5) SECRETARY’S DETERMINATION OF COUN-
13 TERMEASURES APPROPRIATE FOR FUNDING FROM
14 SPECIAL RESERVE FUND.—

15 “(A) IN GENERAL.—The Secretary, in ac-
16 cordance with the provisions of this paragraph,
17 shall identify specific security countermeasures
18 that the Secretary determines, in consultation
19 with the Homeland Security Secretary, to be
20 appropriate for inclusion in the stockpile under
21 subsection (a) pursuant to procurements made
22 with amounts in the special reserve fund under
23 paragraph (10) (referred to in this subsection
24 individually as a ‘procurement under this sub-
25 section’).

1 “(B) REQUIREMENTS.—In making a deter-
2 mination under subparagraph (A) with respect
3 to a security countermeasure, the Secretary
4 shall determine and consider the following:

5 “(i) The quantities of the product
6 that will be needed to meet the needs of
7 the stockpile.

8 “(ii) The feasibility of production and
9 delivery within five years of sufficient
10 quantities of the product.

11 “(iii) Whether there is a lack of a sig-
12 nificant commercial market for the product
13 at the time of procurement, other than as
14 a security countermeasure.

15 “(6) RECOMMENDATION FOR PRESIDENT’S AP-
16 PROVAL.—

17 “(A) RECOMMENDATION FOR PROCURE-
18 MENT.—In the case of a security counter-
19 measure that the Secretary has, in accordance
20 with paragraphs (2), (3), and (5), determined
21 to be appropriate for procurement under this
22 subsection, the Homeland Security Secretary
23 and the Secretary shall jointly submit to the
24 President, in coordination with the Director of
25 the Office of Management and Budget, a rec-

1 ommendation that the special reserve fund
2 under paragraph (10) be made available for the
3 procurement of such countermeasure.

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

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

24 “(D) SUBSEQUENT SPECIFIC COUNTER-
25 MEASURES.—Procurement under this sub-

1 section of a security countermeasure for a par-
2 ticular purpose does not preclude the subse-
3 quent procurement under this subsection of any
4 other security countermeasure for such purpose
5 if the Secretary has determined under para-
6 graph (5)(A) that such countermeasure is ap-
7 propriate for inclusion in the stockpile and if,
8 as determined by the Secretary, such counter-
9 measure provides improved safety or effective-
10 ness, or for other reasons enhances prepared-
11 ness to respond to threats of use of a biological,
12 chemical, radiological, or nuclear agent. Such a
13 determination by the Secretary is committed to
14 agency discretion.

15 “(E) RULE OF CONSTRUCTION.—Rec-
16 ommendations and approvals under this para-
17 graph apply solely to determinations that the
18 special reserve fund under paragraph (10) will
19 be made available for a procurement of a secu-
20 rity countermeasure, and not to the substance
21 of contracts for such procurement or other mat-
22 ters relating to awards of such contracts.

23 “(7) PROCUREMENT.—

24 “(A) IN GENERAL.—For purposes of a
25 procurement under this subsection that is ap-

1 proved by the President under paragraph (6),
2 the Homeland Security Secretary and the Sec-
3 retary shall have responsibilities in accordance
4 with subparagraphs (B) and (C).

5 “(B) INTERAGENCY AGREEMENTS.—

6 “(i) FOR PROCUREMENT.—The
7 Homeland Security Secretary shall enter
8 into an agreement with the Secretary for
9 procurement of a security countermeasure
10 in accordance with the provisions of this
11 paragraph. The special reserve fund under
12 paragraph (10) shall be available for the
13 Secretary’s costs of such procurement,
14 other than as provided in clause (ii).

15 “(ii) FOR ADMINISTRATIVE COSTS.—
16 The agreement entered into between the
17 Homeland Security Secretary and the Sec-
18 retary for managing the stockpile under
19 subsection (a) shall provide for reimburse-
20 ment of the Secretary’s administrative
21 costs relating to procurements under this
22 subsection.

23 “(C) PROCUREMENT.—

24 “(i) IN GENERAL.—The Secretary
25 shall be responsible for—

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

11 “(II) promulgating regulations to
12 implement clauses (v), (vi), and (vii),
13 and any other provisions of this sub-
14 section.

15 “(ii) CONTRACT TERMS.—A contract
16 for procurements under this subsection
17 shall (or, as specified below, may) include
18 the following terms:

19 “(I) PAYMENT CONDITIONED ON
20 SUBSTANTIAL DELIVERY.—The con-
21 tract shall provide that no payment
22 may be made until delivery has been
23 made of a substantial portion (as de-
24 termined by the Secretary) of the
25 total number of units contracted for,

1 except that, notwithstanding any
2 other provision of law, the contract
3 may provide that, if the Secretary de-
4 termines (in the Secretary's discre-
5 tion) that an advance payment is nec-
6 essary to ensure success of a project,
7 the Secretary may pay an amount, not
8 to exceed 10 percent of the contract
9 amount, in advance of delivery. The
10 contract shall provide that such ad-
11 vance payment is required to be re-
12 paid if there is a failure to perform
13 under the contract, except in special
14 circumstances as determined by the
15 Secretary on a contract by contract
16 basis.

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

1 riod. The contract shall be renewable
2 for additional periods, none of which
3 shall exceed five years.

4 “(III) STORAGE BY VENDOR.—

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

17 “(iii) AVAILABILITY OF SIMPLIFIED
18 ACQUISITION PROCEDURES.—

19 “(I) IN GENERAL.—The amount
20 of any procurement under this sub-
21 section shall be deemed to be below
22 the threshold amount specified in sec-
23 tion 4(11) of the Office of Federal
24 Procurement Policy Act (41 U.S.C.
25 403(11)), for purposes of application

1 to such procurement, pursuant to sec-
2 tion 302A(a) of the Federal Property
3 and Administrative Services Act of
4 1949 (41 U.S.C. 252a(a)), of—

5 “(aa) section 303(g)(1)(A)
6 of the Federal Property and Ad-
7 ministrative Services Act of 1949
8 (41 U.S.C. 253(g)(1)(A)) and its
9 implementing regulations; and

10 “(bb) section 302A(b) of
11 such Act (41 U.S.C. 252a(b))
12 and its implementing regulations.

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

23 “(aa) Chapter 37 of title 40,
24 United States Code (relating to

1 contract work hours and safety
2 standards).

3 “(bb) Subsections (a) and
4 (b) of Section 7 of the Anti-Kick-
5 back Act of 1986 (41 U.S.C.
6 57(a) and (b)).

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

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

22 “(v) PREMIUM PROVISION IN MUL-
23 TIPLE AWARD CONTRACTS.—

24 “(I) IN GENERAL.—If, under this
25 subsection, the Secretary enters into

1 contracts with more than one vendor
2 to procure a security countermeasure,
3 such Secretary may, notwithstanding
4 any other provision of law, include in
5 each of such contracts a provision
6 that—

7 “(aa) identifies an increment
8 of the total quantity of security
9 countermeasure required, wheth-
10 er by percentage or by numbers
11 of units; and

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

20 “(II) DETERMINATION OF GOV-
21 ERNMENT’S REQUIREMENT NOT RE-
22 VIEWABLE.—If the Secretary includes
23 in each of a set of contracts a provi-
24 sion as described in subclause (I),
25 such Secretary’s determination of the

1 total quantity of security counter-
2 measure required, and any amend-
3 ment of such determination, is com-
4 mitted to agency discretion.

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

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

22 “(8) INTERAGENCY COOPERATION.—

23 “(A) IN GENERAL.—In carrying out activi-
24 ties under this section, the Homeland Security
25 Secretary and the Secretary are authorized,

1 subject to subparagraph (B), to enter into
2 interagency agreements and other collaborative
3 undertakings with other agencies of the United
4 States Government.

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

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

13 “(A) costs for the purchase of vaccines
14 under procurement contracts entered into be-
15 fore the date of the enactment of the Project
16 BioShield Act of 2003; or

17 “(B) administrative costs.

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

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

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

3 “(1) a physical accumulation (at one or more
4 locations) of the supplies described in subsection (a);
5 or

6 “(2) a contractual agreement between the
7 Homeland Security Secretary and a vendor or ven-
8 dors under which such vendor or vendors agree to
9 provide to such Secretary supplies described in sub-
10 section (a).

11 “(f) AUTHORIZATION OF APPROPRIATIONS.—

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

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

24 (b) AMENDMENT TO HOMELAND SECURITY ACT OF
25 2002.—Title V of the Homeland Security Act of 2002

1 (116 Stat. 2212; 6 U.S.C. 311 et seq.) is amended by add-
2 ing at the end the following:

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

6 “(a) AUTHORIZATION OF APPROPRIATIONS.—For
7 procurement of security countermeasures under section
8 319F–2(c) of the Public Health Service Act (referred to
9 in this section as the ‘security countermeasures program’),
10 there is authorized to be appropriated up to
11 \$5,593,000,000 for the fiscal years 2004 through 2013.
12 Of the amounts appropriated under the preceding sen-
13 tence, not to exceed \$3,418,000,000 may be obligated dur-
14 ing the fiscal years 2004 through 2008, of which not to
15 exceed \$890,000,000 may be obligated during fiscal year
16 2004.

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

22 “(c) AVAILABILITY.—

23 “(1) DURATION OF AVAILABILITY FOR OBLIGA-
24 TION.—Subject to paragraph (2), all amounts appro-
25 priated under subsection (a) are available for obliga-

1 tion through the end of fiscal year 2013, provided
2 that any portion of such amount that remains unob-
3 ligated for such purposes on the expiration of such
4 term shall be returned to the United States Treas-
5 ury and shall not be available for subsequent obliga-
6 tion for any purpose.

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

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

1 **SEC. 4. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
2 **USE IN EMERGENCIES.**

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

6 **“SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
7 **USE IN EMERGENCIES.**

8 “(a) IN GENERAL.—

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

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

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

25 “(B) is approved, licensed, or cleared
26 under such a provision, but which use is not

1 under such provision an approved, licensed, or
2 cleared use of the product (referred to in this
3 section as an ‘unapproved use of an approved
4 product’).

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

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

12 “(A) The term ‘emergency use’ has the
13 meaning indicated for such term in paragraph
14 (1).

15 “(B) The term ‘product’ means a drug or
16 device.

17 “(C) The term ‘unapproved product’ has
18 the meaning indicated for such term in para-
19 graph (2)(A).

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

23 “(b) DECLARATION OF EMERGENCY.—

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

4 “(A) a determination by the Secretary of
5 Homeland Security that there is a national
6 emergency, or a significant potential for a na-
7 tional emergency, involving a heightened risk of
8 attack with a specified biological, chemical, ra-
9 diological, or nuclear agent or agents;

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

17 “(C) a determination by the Secretary of a
18 public health emergency under section 319 of
19 the Public Health Service Act, affecting na-
20 tional security and involving a specified biologi-
21 cal, chemical, radiological, or nuclear agent or
22 agents, or a specified disease or condition that
23 may be attributable to such agent or agents.

24 “(2) TERMINATION OF DECLARATION.—

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

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

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

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

17 “(3) ADVANCE NOTICE OF TERMINATION.—In
18 terminating a declaration under this section, the
19 Secretary shall provide advance notice that the dec-
20 laration will be terminated. The period of advance
21 notice shall be a period reasonably determined to
22 provide—

23 “(A) in the case of an unapproved product,
24 a sufficient period for disposition of shipments
25 of the product, including the return of such

1 shipments to the manufacturer (in the case of
2 a manufacturer that chooses to have the ship-
3 ments returned); and

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

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

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

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

23 “(2) that, based on the totality of scientific evi-
24 dence available to the Secretary, including data from

1 adequate and well-controlled clinical trials, if avail-
2 able, it is reasonable to believe that—

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

5 “(i) such disease or condition; or

6 “(ii) a serious or life-threatening dis-
7 ease or condition caused by a product au-
8 thorized under this section or approved
9 under this Act or the Public Health Serv-
10 vice Act, for detecting, diagnosing, treating,
11 or preventing such a disease or condition
12 caused by such an agent; and

13 “(B) the known and potential benefits of
14 the product, when used to detect, diagnose, pre-
15 vent, or treat such disease or condition, out-
16 weigh the known and potential risks of the
17 product;

18 “(3) that there is no adequate, approved, and
19 available alternative to the product for detecting, di-
20 agnosing, preventing, or treating such disease or
21 condition; and

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

24 “(d) SCOPE OF AUTHORIZATION.—

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

3 “(A) each disease or condition that the
4 product may be used to detect, diagnose, pre-
5 vent, or treat within the scope of the authoriza-
6 tion;

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

13 “(C) the Secretary’s conclusions, made
14 under subsection (c), concerning the safety and
15 potential effectiveness of the product in detect-
16 ing, diagnosing, preventing, or treating such
17 diseases or conditions, including an assessment
18 of the available scientific evidence.

19 “(2) CONFIDENTIAL INFORMATION.—Nothing
20 in this section alters or amends section 1905 of title
21 18, United States Code, or section 552(b)(4) of title
22 5 of such Code.

23 “(e) CONDITIONS OF AUTHORIZATION.—

24 “(1) UNAPPROVED PRODUCT.—

1 “(A) REQUIRED CONDITIONS.—With re-
2 spect to the emergency use of an unapproved
3 product, the Secretary, to the extent feasible
4 given the circumstances of the emergency, shall,
5 for persons who choose to carry out one or
6 more activities for which the authorization is
7 issued, establish such conditions on an author-
8 ization under this section as the Secretary finds
9 necessary or appropriate to protect the public
10 health, including the following:

11 “(i) Appropriate conditions designed
12 to ensure that, to the extent feasible given
13 the circumstances of the emergency, health
14 care professionals administering the prod-
15 uct are informed—

16 “(I) that the Secretary has au-
17 thorized the emergency use of the
18 product;

19 “(II) of the significant known
20 and potential benefits and risks of the
21 emergency use of the product, and of
22 the extent to which such benefits and
23 risks are unknown; and

1 “(III) of the alternatives to the
2 product that are available, and of
3 their benefits and risks.

4 “(ii) Appropriate conditions designed
5 to ensure that, to the extent feasible given
6 the circumstances of the emergency, indi-
7 viduals to whom the product is adminis-
8 tered are informed—

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

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

17 “(III) of the option to accept or
18 refuse administration of the product,
19 of the consequences, if any, of refus-
20 ing administration of the product, and
21 of the alternatives to the product that
22 are available and of their benefits and
23 risks.

24 “(iii) Appropriate conditions for the
25 monitoring and reporting of adverse events

1 associated with the emergency use of the
2 product.

3 “(iv) For manufacturers of the prod-
4 uct, appropriate conditions concerning rec-
5 ordkeeping and reporting, including
6 records access by the Secretary, with re-
7 spect to the emergency use of the product.

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

19 “(i) Appropriate conditions on which
20 entities may distribute the product with re-
21 spect to the emergency use of the product
22 (including limitation to distribution by gov-
23 ernment entities), and on how distribution
24 is to be performed.

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

8 “(iii) For persons other than manu-
9 facturers of the product, appropriate con-
10 ditions concerning recordkeeping and re-
11 porting, including records access by the
12 Secretary, with respect to the emergency
13 use of the product.

14 “(iv) With respect to the emergency
15 use of the product, waive or limit, to the
16 extent appropriate given the circumstances
17 of the emergency, conditions regarding
18 current good manufacturing practice other-
19 wise applicable to the manufacture, proc-
20 essing, packing, or holding of products
21 subject to regulation under this Act, in-
22 cluding such requirements established in
23 section 501.

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

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

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

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

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

3 “(f) DURATION OF AUTHORIZATION.—

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

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

15 “(g) REVOCATION OF AUTHORIZATION.—

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

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

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

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

4 “(i) ACTIONS COMMITTED TO AGENCY DISCRE-
5 TION.—Actions under the authority of this section by the
6 Secretary, by the Secretary of Defense, or by the Sec-
7 retary of Homeland Security are committed to agency dis-
8 cretion.

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

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

15 “(2) the authority of the Secretary of Defense
16 with respect to the Department of Defense, includ-
17 ing the armed forces, under other provisions of Fed-
18 eral law; or

19 “(3) the authority of the Secretary under sec-
20 tion 319F-2 to manage the stockpile under such
21 section.

22 “(k) APPLICATION TO MEMBERS OF ARMED
23 FORCES.—

24 “(1) WAIVER OF REQUIREMENT RELATING TO
25 OPTION TO REFUSE.—In the case of administration

1 of a countermeasure to members of the armed
2 forces, a requirement, under subsection
3 (e)(1)(A)(ii)(III), designed to ensure that individuals
4 are informed of an option to accept or refuse admin-
5 istration of a product, may be waived by the Presi-
6 dent if the President determines, in writing, that
7 complying with such requirement is not feasible, is
8 contrary to the best interests of the members af-
9 fected, or is not in the interests of national security.

10 “(2) PROVISION OF INFORMATION TO MEMBER
11 OF THE ARMED FORCES.—If the Secretary makes a
12 determination that it is not feasible for the informa-
13 tion required by subsection (e)(1)(A)(ii) to be pro-
14 vided to a member of the armed forces prior to the
15 administration of the product, such information shall
16 be provided to such member of the armed forces (or
17 next-of-kin in the case of the death of a member) to
18 whom the product was administered as soon as pos-
19 sible, but not later than 30 days, after such adminis-
20 tration. Information concerning the administration
21 of the product shall be recorded in the medical
22 record of the member.

23 “(3) EFFECT ON STATUTE PERTAINING TO IN-
24 VESTIGATIONAL NEW DRUGS.—In the case of an au-
25 thorization based on a determination by the Sec-

1 retary of Defense under subsection (b)(1)(B), sec-
2 tion 1107 of title 10, United States Code, shall not
3 apply to use of a product that is the subject of such
4 authorization, within the scope of such authorization
5 and while such authorization is effective.

6 “(l) RELATION TO OTHER PROVISIONS.—If a prod-
7 uct is the subject of an authorization under this section,
8 the use of such product within the scope of the authoriza-
9 tion —

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

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

15 “(m) DISCRETION REGARDING USE OF AUTHORIZA-
16 TION.—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 notify
23 the Secretary within a reasonable period of time after the
24 issuance by the Secretary of such authorization if such
25 manufacturer does not intend to carry out an activity or

1 activities under the authorization. This section does not
2 have any legal effect on a person who does not carry out
3 any activity for which an authorization under this section
4 is issued, or who carries out such an activity pursuant to
5 other provisions of this Act or section 351 of the Public
6 Health Service Act.

7 “(n) ENFORCEMENT.—A person who carries out an
8 activity pursuant to an authorization under this section,
9 but who fails to comply with applicable conditions under
10 subsection (e), is with respect to that act of noncompliance
11 subject to the provisions of law specified in subsection (a)
12 and to the enforcement of such provisions under section
13 301.”.

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 use of noncompetitive procedures).

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

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

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

17 (II) Subsection (c)(7)(C)(iv) (re-
18 lating to use of noncompetitive proce-
19 dures).

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

23 (iii) With respect to section 564 of the
24 Federal Food, Drug, and Cosmetic Act (as
25 added by section 4 of this Act):

1 (I) Subsection (a)(1) (relating to
2 emergency uses of certain drugs and
3 devices).

4 (II) Subsection (b)(1) (relating to
5 a declaration of an emergency).

6 (III) Subsection (e) (relating to
7 conditions on authorization).

8 (B) CONTENTS OF REPORTS.—The Sec-
9 retary shall annually submit to the Congress a
10 report that summarizes—

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

18 (ii) the reasons underlying the deci-
19 sion to use such authorities, including, as
20 applicable, the options that were consid-
21 ered and rejected with respect to the use of
22 such authorities; and

23 (iii) the identification of each person
24 or entity that received, or was considered
25 and rejected for, grants, cooperative agree-

1 ments, or contracts pursuant to the use of
2 such authorities.

3 (2) ANNUAL SUMMARIES REGARDING CERTAIN
4 ACTIVITY.—The Secretary shall annually submit to
5 the Congress a report that summarizes the activity
6 undertaken pursuant to the following authorities
7 under section 319F–1 of the Public Health Service
8 Act (as added by section 2 of this Act):

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

11 (B) Subsection (d) (relating to authority
12 for personal services contracts).

13 (C) Subsection (e) (relating to streamlined
14 personnel authority).

15 With respect to subparagraph (B), the report shall
16 include a provision specifying, for the one-year pe-
17 riod for which the report is submitted, the number
18 of persons who were paid amounts greater than
19 \$100,000 and the number of persons who were paid
20 amounts between \$50,000 and \$100,000.

21 (b) NATIONAL ACADEMY OF SCIENCES REVIEW.—
22 Not later than three years after the date of the enactment
23 of this Act, the Secretary of Health and Human Services
24 shall request the National Academy of Sciences to enter
25 into an agreement for a review of the biomedical counter-

1 measure research and development authorities established
2 in this Act to determine whether and to what extent activi-
3 ties undertaken pursuant to such authorities have en-
4 hanced the development of biomedical countermeasures af-
5 fecting national security, and to recommend any legislative
6 or administrative changes necessary to improve the ability
7 of the Secretary to carry out these activities in the future.
8 The Secretary shall ensure that the results of the study
9 are submitted to the Congress not later than five years
10 after such date of enactment.

11 (c) GENERAL ACCOUNTING OFFICE REVIEW.—Four
12 years after the date of the enactment of this Act, the
13 Comptroller General of the United States shall initiate a
14 study—

15 (1)(A) to review the Secretary of Health and
16 Human Services' utilization of the authorities grant-
17 ed under this Act with respect to simplified acquisi-
18 tion procedures, use of noncompetitive procedures,
19 increased micropurchase thresholds, personal serv-
20 ices contracts, streamlined personnel authority, and
21 the purchase of security countermeasures under the
22 special reserve fund; and

23 (B) to recommend any legislative or administra-
24 tive changes necessary to improve the utilization or
25 effectiveness of such authorities in the future;

1 (2)(A) to review the internal controls instituted
2 by such Secretary with respect to such authorities,
3 where required by this Act; and

4 (B) to recommend any legislative or administra-
5 tive changes necessary to improve the effectiveness
6 of such controls; and

7 (3)(A) to review such Secretary's utilization of
8 the authority granted under this Act to authorize an
9 emergency use of a biomedical countermeasure, in-
10 cluding the means by which the Secretary deter-
11 mines whether and under what conditions any such
12 authorizations should be granted and the benefits
13 and adverse impacts, if any, resulting from the use
14 of such authority; and

15 (B) to recommend any legislative or administra-
16 tive changes necessary to improve the utilization or
17 effectiveness of such authority and to enhance pro-
18 tection of the public health.

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