

DISCUSSION DRAFT

MAY 6, 2003

9:00 p.m.

108TH CONGRESS
1ST SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

Mr. TAUZIN introduced the following bill; which was referred to the Committee
on _____

A BILL

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

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



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:

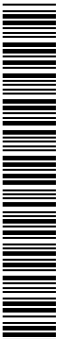
9 **“SEC. 319F-1. AUTHORITY FOR USE OF CERTAIN PROCE-**
10 **DURES REGARDING BIOMEDICAL COUNTER-**
11 **MEASURE RESEARCH AND DEVELOPMENT**
12 **ACTIVITIES.**

13 “(a) IN GENERAL.—

14 “(1) AUTHORITY.—In conducting and sup-
15 porting research and development activities regard-
16 ing biomedical countermeasures under section
17 319F(h), the Secretary may conduct and support
18 such activities in accordance with this section if the
19 activities concern qualified countermeasures.

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

25 “(3) INTERAGENCY COOPERATION.—

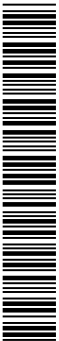


1 “(A) IN GENERAL.—In carrying out activi-
2 ties under this section, the Secretary is author-
3 ized, subject to subparagraph (B), to enter into
4 interagency agreements and other collaborative
5 undertakings with other agencies of the United
6 States Government.

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

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

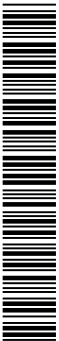
24 “(b) EXPEDITED PROCUREMENT AUTHORITY.—



1 “(1) INCREASED SIMPLIFIED ACQUISITION
2 THRESHOLD FOR BIOMEDICAL COUNTERMEASURE
3 PROCUREMENTS.—

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

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



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

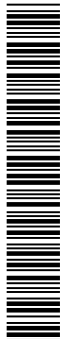
4 “(B) APPLICATION OF CERTAIN PROVI-
5 SIONS.—Notwithstanding subparagraph (A)
6 and the provision of law and regulations re-
7 ferred to in such subparagraph, each of the fol-
8 lowing provisions shall apply to procurements
9 described in this paragraph to the same extent
10 that such provisions would apply to such pro-
11 curements in the absence of subparagraph (A):

12 “(i) Chapter 37 of title 40, United
13 States Code (relating to contract work
14 hours and safety standards).

15 “(ii) Subsections (a) and (b) of Sec-
16 tion 7 of the Anti-Kickback Act of 1986
17 (41 U.S.C. 57(a) and (b)).

18 “(iii) Section 304C of the Federal
19 Property and Administrative Services Act
20 of 1949 (41 U.S.C. 254d) (relating to the
21 examination of contractor records).

22 “(C) INTERNAL CONTROLS TO BE INSTI-
23 TUTED.—The Secretary shall institute appro-
24 priate internal controls for procurements that
25 are under this paragraph, including require-



1 ments with regard to documenting the justifica-
2 tion for use of the authority in this paragraph.

3 “(2) USE OF NONCOMPETITIVE PROCEDURES.—

4 In addition to any other authority to use procedures
5 other than competitive procedures, the Secretary
6 may use such other procedures when—

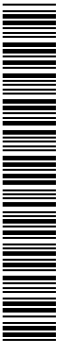
7 “(A) the procurement is as described by
8 paragraph (1); and

9 “(B) the property or services needed by
10 the Secretary are available from only one re-
11 sponsible source or only from a limited number
12 of responsible sources, and no other type of
13 property or services will satisfy the Secretary’s
14 needs.

15 “(3) INCREASED MICROPURCHASE THRESH-
16 OLD.—

17 “(A) IN GENERAL.—For a procurement
18 described by paragraph (1), the amount speci-
19 fied in subsections (c), (d), and (f) of section 32
20 of the Office of Federal Procurement Policy Act
21 (41 U.S.C. 428) shall be deemed to be \$15,000
22 in the administration of that section with re-
23 spect to such procurement.

24 “(B) INTERNAL CONTROLS TO BE INSTI-
25 TUTED.—The Secretary shall institute appro-

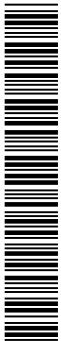


1 appropriate internal controls for purchases that are
2 under this paragraph and that are greater than
3 \$2,500.

4 “(C) EXCEPTION TO PREFERENCE FOR
5 PURCHASE CARD MECHANISM.—No provision of
6 law establishing a preference for using a Gov-
7 ernment purchase card method for purchases
8 shall apply to purchases that are under this
9 paragraph and that are greater than \$2,500.

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

11 “(1) IN GENERAL.—The Secretary may, as the
12 Secretary determines necessary to respond to press-
13 ing qualified countermeasure research and develop-
14 ment needs under this section, employ such exped-
15 ited peer review procedures (including consultation
16 with appropriate scientific experts) as the Secretary,
17 in consultation with the Director of NIH, deems ap-
18 propriate to obtain assessment of scientific and tech-
19 nical merit and likely contribution to the field of
20 qualified countermeasure research, in place of the
21 peer review and advisory council review procedures
22 that would be required under sections 301(a)(3),
23 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and
24 494, as applicable to a grant, contract, or coopera-
25 tive agreement—



1 “(A) that is for performing, administering,
2 or supporting qualified countermeasure research
3 and development activities; and

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

6 “(2) SUBSEQUENT PHASES OF RESEARCH.—

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

14 “(d) AUTHORITY FOR PERSONAL SERVICES CON-
15 TRACTS.—

16 “(1) IN GENERAL.—For the purpose of per-
17 forming, administering, and supporting qualified
18 countermeasure research and development activities,
19 the Secretary may, as the Secretary determines nec-
20 essary to respond to pressing qualified counter-
21 measure research and development needs under this
22 section, obtain by contract (in accordance with sec-
23 tion 3109 of title 5, United States Code, but without
24 regard to the limitations in such section on the pe-
25 riod of service and on pay) the personal services of



1 experts or consultants who have scientific or other
 2 professional qualifications, except that in no case
 3 shall the compensation provided to any such expert
 4 or consultant exceed the daily equivalent of the an-
 5 nual rate of compensation for the President.

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

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

17 “(B) EXCLUSIVITY OF REMEDY.—The
 18 remedy provided by subparagraph (A) shall be
 19 exclusive of any other civil action or proceeding
 20 by reason of the same subject matter against
 21 the person, officer, employee, or governing
 22 board member.

23 “(3) INTERNAL CONTROLS TO BE INSTI-
 24 TUTED.—



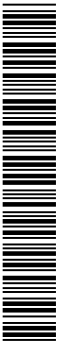
1 “(A) IN GENERAL.—The Secretary shall
2 institute appropriate internal controls for con-
3 tracts under this subsection, including proce-
4 dures for the Secretary to make a determina-
5 tion of whether a person, or an officer, em-
6 ployee, or governing board member of a person,
7 is deemed to be an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

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

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

23 “(e) STREAMLINED PERSONNEL AUTHORITY.—

24 “(1) IN GENERAL.—In addition to any other
25 personnel authorities, the Secretary may, as the Sec-

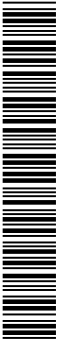


1 retary determines necessary to respond to pressing
2 qualified countermeasure research and development
3 needs under this section, without regard to such pro-
4 visions of title 5, United States Code, governing ap-
5 pointments in the competitive service, and without
6 regard to the provisions of chapter 51 and sub-
7 chapter III of chapter 53 of such title relating to
8 classification and General Schedule pay rates, ap-
9 point professional and technical employees, not to
10 exceed 30 such employees at any time, to positions
11 in the National Institutes of Health to perform, ad-
12 minister, or support qualified countermeasure re-
13 search and development activities in carrying out
14 this section.

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

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

22 (b) TECHNICAL AMENDMENT.—Section 481A of the
23 Public Health Service Act (42 U.S.C. 287a-2) is
24 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)”;

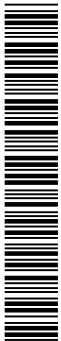
12 (3) in subsection (d), by inserting “or the Di-
13 rector of the National Institute of Allergy and Infec-
14 tious Diseases” after “Director of the Center”;

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)—

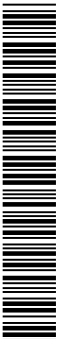
13 (A) in paragraph (1), by inserting “in the
14 case of an award by the Director of the Cen-
15 ter,” before “the applicant”; and

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 fiscal year 2003.”.

8 **SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

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

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

14 “(a) STRATEGIC NATIONAL STOCKPILE.—

15 “(1) IN GENERAL.—The Secretary of Homeland
16 Security (referred to in this section as the ‘Home-
17 land Security Secretary’), in coordination with the
18 Secretary and the Secretary of Veterans Affairs,
19 shall maintain a stockpile or stockpiles of drugs, vac-
20 cines and other biological products, medical devices,
21 and other supplies in such numbers, types, and
22 amounts as are determined by the Secretary to be
23 appropriate and practicable, taking into account
24 other available sources, to provide for the emergency
25 health security of the United States, including the



1 emergency health security of children and other vul-
2 nerable populations, in the event of a bioterrorist at-
3 tack or other public health emergency.

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

6 “(A) consult with the working group under
7 section 319F(a);

8 “(B) ensure that adequate procedures are
9 followed with respect to such stockpile for in-
10 ventory management and accounting, and for
11 the physical security of the stockpile;

12 “(C) in consultation with Federal, State,
13 and local officials, take into consideration the
14 timing and location of special events;

15 “(D) review and revise, as appropriate, the
16 contents of the stockpile on a regular basis to
17 ensure that emerging threats, advanced tech-
18 nologies, and new countermeasures are ade-
19 quately considered;

20 “(E) devise plans for the effective and
21 timely supply-chain management of the stock-
22 pile, in consultation with appropriate Federal,
23 State and local agencies, and the public and
24 private health care infrastructure; and



1 “(F) ensure the adequate physical security
2 of the stockpile.

3 “(b) SMALLPOX VACCINE DEVELOPMENT.—

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

12 “(2) RULE OF CONSTRUCTION.—Nothing in
13 this section shall be construed to limit the private
14 distribution, purchase, or sale of vaccines from
15 sources other than the stockpile described in sub-
16 section (a).

17 “(c) ADDITIONAL AUTHORITY REGARDING PRO-
18 CUREMENT OF CERTAIN BIOMEDICAL COUNTER-
19 MEASURES; AVAILABILITY OF SPECIAL RESERVE
20 FUND.—

21 “(1) IN GENERAL.—

22 “(A) USE OF FUND.—A security counter-
23 measure may, in accordance with this sub-
24 section, be procured with amounts in the special
25 reserve fund under paragraph (10).



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

5 “(i) that affects national security;

6 “(ii) that is determined under para-
7 graph (2)(B)(ii) to be a necessary counter-
8 measure; and

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

17 “(II) for which the Secretary deter-
18 mines that sufficient and satisfactory clin-
19 ical experience or research data (including
20 data, if available, from pre-clinical and
21 clinical trials) support a reasonable conclu-
22 sion that the countermeasure will qualify
23 for approval or licensing within five years
24 after the date of a determination under
25 paragraph (5).



1 “(2) DETERMINATION OF MATERIAL
2 THREATS.—

3 “(A) MATERIAL THREAT.—The Homeland
4 Security Secretary, in consultation with the
5 heads of other agencies as appropriate, shall on
6 an ongoing basis—

7 “(i) assess current and emerging
8 threats of chemical, biological, radiological,
9 and nuclear agents; and

10 “(ii) determine which of such agents
11 present a material threat against the
12 United States population.

13 “(B) PUBLIC HEALTH IMPACT; NECESSARY
14 COUNTERMEASURES.—The Secretary shall on
15 an ongoing basis—

16 “(i) assess the potential public health
17 consequences of use against the United
18 States population of agents identified
19 under subparagraph (A)(ii); and

20 “(ii) determine, on the basis of such
21 assessment, the agents for which priority
22 countermeasures are necessary to protect
23 the public health from a material threat.

24 “(3) ASSESSMENT OF AVAILABILITY AND AP-
25 PROPRIATENESS OF COUNTERMEASURES.—The Sec-



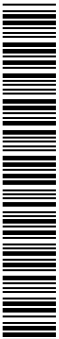
1 retary, in consultation with the Homeland Security
2 Secretary, shall assess on an ongoing basis the avail-
3 ability and appropriateness of specific counter-
4 measures to address specific threats identified under
5 paragraph (2).

6 “(4) CALL FOR SECURITY COUNTERMEASURES;
7 COMMITMENT FOR RECOMMENDATION FOR PRO-
8 CUREMENT.—

9 “(A) PROPOSAL TO THE PRESIDENT.—If,
10 pursuant to an assessment under paragraph
11 (3), the Homeland Security Secretary and the
12 Secretary make a determination that a security
13 countermeasure would be appropriate, such Sec-
14 retaries may jointly submit to the President a
15 proposal to—

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

18 “(ii) make a commitment that, upon
19 the first development of such security
20 countermeasure that meets the conditions
21 for procurement under paragraph (5), the
22 Secretaries will, based in part on informa-
23 tion obtained pursuant to such call, make
24 a recommendation under paragraph (6)
25 that the special reserve fund under para-



1 graph (10) be made available for the pro-
2 curement of such security countermeasure.

3 “(B) COUNTERMEASURE SPECIFICA-
4 TIONS.—The Homeland Security Secretary and
5 the Secretary shall, to the extent practicable,
6 include in the proposal under subparagraph
7 (A)—

8 “(i) estimated quantity of purchase
9 (in the form of number of doses or number
10 of effective courses of treatments regard-
11 less of dosage form);

12 “(ii) necessary measures of minimum
13 safety and effectiveness;

14 “(iii) estimated price for each dose or
15 effective course of treatment regardless of
16 dosage form; and

17 “(iv) other information that may be
18 necessary to encourage and facilitate re-
19 search, development, and manufacture of
20 the countermeasure or to provide specifica-
21 tions for the countermeasure.

22 “(C) PRESIDENTIAL APPROVAL.—If the
23 President approves a proposal under subpara-
24 graph (A), the Homeland Security Secretary
25 and the Secretary shall make known to persons



1 who may respond to a call for the security
2 countermeasure involved—

3 “(i) the call for the countermeasure;

4 “(ii) specifications for the counter-
5 measure under subparagraph (B); and

6 “(iii) a commitment described in sub-
7 paragraph (A)(ii).

8 “(5) SECRETARY’S DETERMINATION OF COUN-
9 TERMEASURES APPROPRIATE FOR FUNDING FROM
10 SPECIAL RESERVE FUND.—

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

22 “(B) REQUIREMENTS.—In making a deter-
23 mination under subparagraph (A) with respect
24 to a security countermeasure, the Secretary
25 shall determine and consider the following:



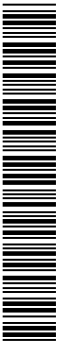
1 “(i) The quantities of the product
2 that will be needed to meet the needs of
3 the stockpile.

4 “(ii) The feasibility of production and
5 delivery within five years of sufficient
6 quantities of the product.

7 “(iii) Whether there is a lack of a sig-
8 nificant commercial market for the product
9 at the time of procurement, other than as
10 a security countermeasure.

11 “(6) RECOMMENDATION FOR PRESIDENT’S AP-
12 PROVAL.—

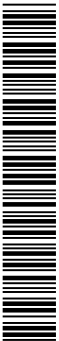
13 “(A) RECOMMENDATION FOR PROCURE-
14 MENT.—In the case of a security counter-
15 measure that the Secretary has, in accordance
16 with paragraphs (2), (3), and (5), determined
17 to be appropriate for procurement under this
18 subsection, the Homeland Security Secretary
19 and the Secretary shall jointly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



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

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

21 “(D) SUBSEQUENT SPECIFIC COUNTER-
22 MEASURES.—Procurement under this sub-
23 section of a security countermeasure for a par-
24 ticular purpose does not preclude the subse-
25 quent procurement under this subsection of any

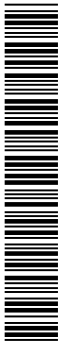


1 other security countermeasure for such purpose
2 if such countermeasure meets the conditions
3 under paragraph (5) for procurement (including
4 the specifications under paragraph (5)(B), or as
5 applicable, under paragraph (4)(B)) and if, as
6 determined by the Secretary, such counter-
7 measure provides improved safety or effective-
8 ness, or for other reasons enhances prepared-
9 ness to respond to threats of use of a biological,
10 chemical, radiological, or nuclear agent. Such a
11 determination by the Secretary is committed to
12 agency discretion.

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

21 “(7) PROCUREMENT.—

22 “(A) IN GENERAL.—For purposes of a
23 procurement under this subsection that is ap-
24 proved by the President under paragraph (6),
25 the Homeland Security Secretary and the Sec-



1 retary shall have responsibilities in accordance
2 with subparagraphs (B) and (C).

3 “(B) INTERAGENCY AGREEMENTS.—

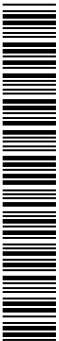
4 “(i) FOR PROCUREMENT.—The
5 Homeland Security Secretary shall enter
6 into an agreement with the Secretary for
7 procurement of a security countermeasure
8 in accordance with the provisions of this
9 paragraph. The special reserve fund under
10 paragraph (10) shall be available for the
11 Secretary’s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

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

21 “(C) PROCUREMENT.—

22 “(i) IN GENERAL.—The Secretary
23 shall be responsible for—

24 “(I) arranging for procurement
25 of a security countermeasure, includ-



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

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

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

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



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

15 “(II) 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 “(III) 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 “(iii) AVAILABILITY OF SIMPLIFIED
17 ACQUISITION PROCEDURES.—

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



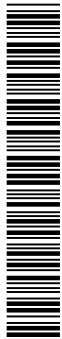
1 tion 302A(a) of the Federal Property
2 and Administrative Services Act of
3 1949 (41 U.S.C. 252a(a)), of—

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

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

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

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



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

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

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

20 “(v) PREMIUM PROVISION IN MUL-
 21 TIPLE AWARD CONTRACTS.—

22 “(I) IN GENERAL.—If, under this
 23 subsection, the Secretary enters into
 24 contracts with more than one vendor
 25 to procure a security countermeasure,



1 such Secretary may, notwithstanding
2 any other provision of law, include in
3 each of such contracts a provision
4 that—

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

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

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



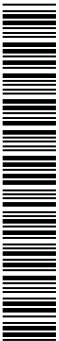
1 ment of such determination, is com-
2 mitted to agency discretion.

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

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

20 “(8) INTERAGENCY COOPERATION.—

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



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

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

8 “(9) RESTRICTIONS ON USE OF FUNDS.—
9 Amounts **【authorized/appropriated】** under para-
10 graph (10) shall not be used to pay—

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

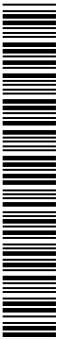
15 “(B) administrative costs.

16 “(10) SPECIAL RESERVE FUND.—

17 *[to be provided]*

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

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



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

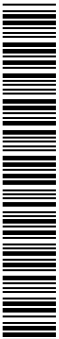
4 “(2) a contractual agreement between the
5 Homeland Security Secretary and a vendor or ven-
6 dors under which such vendor or vendors agree to
7 provide to such Secretary supplies described in sub-
8 section (a).

9 “(f) AUTHORIZATION OF APPROPRIATIONS.—

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

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

22 (b) CONFORMING AMENDMENT.—Section 121 of the
23 Public Health Security and Bioterrorism Preparedness
24 and Response Act of 2002 (116 Stat. 611; 42 U.S.C.
25 300hh–12) is repealed. With respect to the program estab-



1 lished under former section 121 of such Act, the repeal
2 of such section under the preceding sentence applies as
3 a modification of the program in accordance with the
4 amendment made by subsection (a) of this section, and
5 not as the termination of the program and the establish-
6 ment of a different program.

7 **SEC. 4. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
8 **USE IN EMERGENCIES.**

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

12 **“SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
13 **USE IN EMERGENCIES.**

14 “(a) IN GENERAL.—

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



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

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

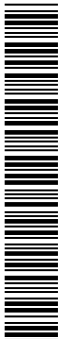
8 “(B) is approved, licensed, or cleared
9 under such a provision, but which use is not
10 under such provision an approved, licensed, or
11 cleared use of the product (referred to in this
12 section as an ‘unapproved use of an approved
13 product’).

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

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

21 “(A) The term ‘emergency use’ has the
22 meaning indicated for such term in paragraph
23 (1).

24 “(B) The term ‘product’ means a drug or
25 device.



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

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

7 “(b) DECLARATION OF EMERGENCY.—

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

11 “(A) a determination by the Secretary of
12 Homeland Security that there is a national
13 emergency, or a significant potential for a na-
14 tional emergency, involving a heightened risk of
15 attack with a specified biological, chemical, ra-
16 diological, or nuclear agent or agents;

17 “(B) a determination by the Secretary of
18 Defense that there is a military emergency, or
19 a significant potential for a military emergency,
20 involving a heightened risk to United States
21 military forces of attack with a biological,
22 chemical, radiological, or nuclear agent or
23 agents; or

24 “(C) a determination by the Secretary of a
25 public health emergency under section 319 of



1 the Public Health Service Act, affecting na-
2 tional security and involving a specified biologi-
3 cal, chemical, radiological, or nuclear agent or
4 agents, or a specified disease or condition that
5 may be attributable to such agent or agents.

6 “(2) TERMINATION OF DECLARATION.—

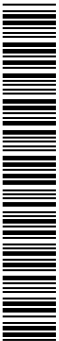
7 “(A) IN GENERAL.—A declaration under
8 this subsection shall terminate upon the earlier
9 of—

10 “(i) a determination by the Secretary,
11 in consultation as appropriate with the
12 Secretary of Homeland Security or the
13 Secretary of Defense, that the cir-
14 cumstances described in paragraph (1)
15 have ceased to exist; or

16 “(ii) the expiration of the one-year pe-
17 riod beginning on the date on which the
18 declaration is made.

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

23 “(3) ADVANCE NOTICE OF TERMINATION.—In
24 terminating a declaration under this section, the
25 Secretary shall provide advance notice that the dec-



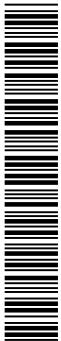
1 laration will be terminated. The period of advance
2 notice shall be a period reasonably determined to
3 provide—

4 “(A) in the case of an unapproved product,
5 a sufficient period for disposition of shipments
6 of the product, including the return of such
7 shipments to the manufacturer (in the case of
8 a manufacturer that chooses to have the ship-
9 ments returned); and

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

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

18 “(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—
19 The Secretary may issue an authorization under this sec-
20 tion with respect to the emergency use of a product only
21 if the Secretary, after consultation with the Commissioner
22 of Food and Drugs, the Director of the National Institutes
23 of Health, and the Director of the Centers for Disease
24 Control and Prevention, to the extent feasible and appro-



1 piate given the circumstances of the emergency involved,
2 concludes—

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

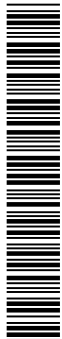
6 “(2) that, based on the totality of scientific evi-
7 dence available to the Secretary, including data from
8 adequate and well-controlled clinical trials, if avail-
9 able, it is reasonable to believe that—

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

12 “(i) such disease or condition; or

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

20 “(B) the known and potential benefits of
21 the product, when used to detect, diagnose, pre-
22 vent, or treat such disease or condition, out-
23 weigh the known and potential risks of the
24 product;



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

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

7 “(d) SCOPE OF AUTHORIZATION.—

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

10 “(A) each disease or condition that the
11 product may be used to detect, diagnose, pre-
12 vent, or treat within the scope of the authoriza-
13 tion;

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

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



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

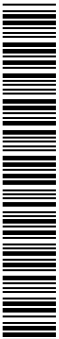
5 “(e) CONDITIONS OF AUTHORIZATION.—

6 “(1) UNAPPROVED PRODUCT.—

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

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

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



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

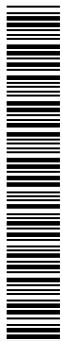
6 “(III) of the alternatives to the
7 product that are available, and of
8 their benefits and risks.

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

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

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

22 “(III) of the option to accept or
23 refuse administration of the product,
24 of the consequences, if any, of refus-
25 ing administration of the product, and



1 of the alternatives to the product that
2 are available and of their benefits and
3 risks.

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

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

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

24 “(i) Appropriate conditions on which
25 entities may distribute the product with re-



1 spect to the emergency use of the product
2 (including limitation to distribution by gov-
3 ernment entities), and on how distribution
4 is to be performed.

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

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

18 “(iv) With respect to the emergency
19 use of the product, waive or limit, to the
20 extent appropriate given the circumstances
21 of the emergency, conditions regarding
22 current good manufacturing practice other-
23 wise applicable to the manufacture, proc-
24 essing, packing, or holding of products
25 subject to regulation under this Act, in-



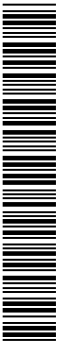
1 cluding such requirements established in
2 section 501.

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

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

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

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



1 manufacturer, subject to compliance with clause (i).

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

4 “(f) DURATION OF AUTHORIZATION.—

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

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

16 “(g) REVOCATION OF AUTHORIZATION.—

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

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



1 “(h) PUBLICATION.—The Secretary shall promptly
2 publish in the Federal Register a notice of each authoriza-
3 tion, and each termination or revocation of an authoriza-
4 tion, and an explanation of the reasons therefor, under
5 this section.

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

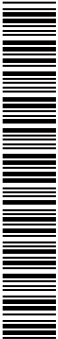
11 “(j) RULES OF CONSTRUCTION.—Nothing in this sec-
12 tion shall be construed to impair or otherwise affect—

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

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

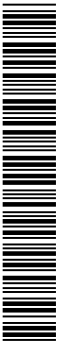
21 “(3) the authority of the Secretary under sec-
22 tion 319F-2 to manage the stockpile under such
23 section.

24 “(k) APPLICATION TO MEMBERS OF ARMED
25 FORCES.—



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

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



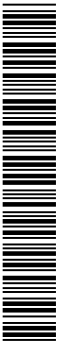
1 “(3) EFFECT ON STATUTE PERTAINING TO IN-
2 VESTIGATIONAL NEW DRUGS.—In the case of an au-
3 thorization based on a determination by the Sec-
4 retary of Defense under subsection (b)(1)(B), sec-
5 tion 1107 of title 10, United States Code, shall not
6 apply to use of a product that is the subject of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

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

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

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

18 “(m) DISCRETION REGARDING USE OF AUTHORIZA-
19 TION.—Nothing in this section provides the Secretary any
20 authority to require any person to carry out any activity
21 that becomes lawful pursuant to an authorization under
22 this section, and no person is required to inform the Sec-
23 retary that the person will not be carrying out such activ-
24 ity. This section does not have any legal effect on a person
25 who does not carry out any activity for which an author-



1 ization under this section is issued, or who carries out
2 such an activity pursuant to other provisions of this Act
3 or section 351 of the Public Health Service Act.

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

11 **SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS**
12 **ACT.**

13 (a) SECRETARY OF HEALTH AND HUMAN SERV-
14 ICES.—

15 (1) ANNUAL REPORTS ON PARTICULAR EXER-
16 CISES OF AUTHORITY.—

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

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



1 (I) Subsection (b)(1) (relating to
2 increased simplified acquisition
3 threshold).

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

6 (III) Subsection (c) (relating to
7 expedited peer review procedures).

8 (ii) With respect to section 319F-2 of
9 the Public Health Service Act (as added by
10 section 3 of this Act):

11 (I) Subsection (c)(7)(C)(iii) (re-
12 lating to simplified acquisition proce-
13 dures).

14 (II) Subsection (c)(7)(C)(iv) (re-
15 lating to use of noncompetitive proce-
16 dures).

17 (III) Subsection (c)(7)(C)(v) (re-
18 lating to premium provision in mul-
19 tiple-award contracts).

20 (iii) With respect to section 564 of the
21 Federal Food, Drug, and Cosmetic Act (as
22 added by section 4 of this Act):

23 (I) Subsection (a)(1) (relating to
24 emergency uses of certain drugs and
25 devices).



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

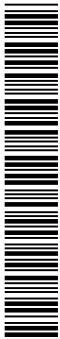
3 (III) Subsection (e) (relating to
4 conditions on authorization).

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

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

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

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



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

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

9 (B) Subsection (d) (relating to authority
10 for personal services contracts).

11 (C) Subsection (e) (relating to streamlined
12 personnel authority).

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

19 (b) NATIONAL ACADEMY OF SCIENCES REVIEW.—
20 Not later than three years after the date of the enactment
21 of this Act, the Secretary of Health and Human Services
22 shall request the National Academy of Sciences to enter
23 into an agreement for a review of the biomedical counter-
24 measure research and development authorities established
25 in this Act to determine whether and to what extent activi-

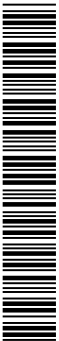


1 ties undertaken pursuant to such authorities have en-
2 hanced the development of biomedical countermeasures af-
3 fecting national security, and to recommend any legislative
4 or administrative changes necessary to improve the ability
5 of the Secretary to carry out these activities in the future.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

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

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

21 (B) to recommend any legislative or administra-
22 tive changes necessary to improve the utilization or
23 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.

