

108TH CONGRESS
1ST SESSION

S. 1504

To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States of America.

IN THE SENATE OF THE UNITED STATES

JULY 30 (legislative day, JULY 21), 2003

Mr. GREGG (for himself and Mr. KENNEDY) introduced the following bill;
which was read the first time

A BILL

To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States of America.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Project BioShield Act
5 of 2003”.

1 **SEC. 2. BIOMEDICAL COUNTERMEASURE RESEARCH AND**
2 **DEVELOPMENT AUTHORITIES.**

3 (a) IN GENERAL.—Part B of title IV of the Public
4 Health Service Act (42 U.S.C. 284 et seq.) is amended
5 by adding at the end the following:

6 **“SEC. 409J. BIOMEDICAL COUNTERMEASURE RESEARCH**
7 **AND DEVELOPMENT.**

8 “(a) IN GENERAL.—

9 “(1) AUTHORITY.—In carrying out research re-
10 sponsibilities under this Act, the Secretary may con-
11 duct and support research and development with re-
12 spect to biomedical countermeasures.

13 “(2) IMPLEMENTATION.—

14 “(A) IN GENERAL.—Except as provided in
15 subparagraph (C), authorities assigned by this
16 section to the Secretary shall be carried out
17 through the Director of NIH.

18 “(B) LEAD INSTITUTE.—The National In-
19 stitute of Allergy and Infectious Diseases shall
20 be the lead institute for performing, admin-
21 istering, or supporting biomedical counter-
22 measure research and development. The Direc-
23 tor of NIH may delegate to the Director of the
24 Institute authorities as are necessary to carry
25 out this function.

1 “(C) CHEMICAL, RADIOLOGICAL, AND NU-
2 CLEAR AGENTS.—To the extent that an author-
3 ity described in subparagraph (A) is exercised
4 with respect to a chemical, radiological, or nu-
5 clear agent, the Secretary may authorize the
6 Director of NIH to carry out the authority
7 through any national research institute.

8 “(D) AVAILABILITY OF FACILITIES TO THE
9 SECRETARY.—In any grant or cooperative
10 agreement entered into under the authority pro-
11 vided in this section with respect to a bio-
12 containment laboratory or other related or an-
13 cillary specialized research facility that the Sec-
14 retary determines necessary for the purpose of
15 performing, administering, and supporting bio-
16 medical countermeasures research and develop-
17 ment, the Secretary may provide that the facil-
18 ity that is the object of such grant or coopera-
19 tive agreement shall be available as needed to
20 the Secretary to respond to public health emer-
21 gencies affecting national security.

22 “(3) INTERAGENCY COOPERATION.—

23 “(A) IN GENERAL.—In carrying out activi-
24 ties under this section, the Secretary is author-
25 ized, subject to subparagraph (B), to enter into

1 interagency agreements and other collaborative
2 undertakings with other agencies of the Federal
3 Government and to use other agencies of the
4 Department of Health and Human Services.

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

9 “(b) EXPEDITED PROCUREMENT AUTHORITY.—

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

13 “(A) IN GENERAL.—For any procurement
14 by the Secretary, of property or services for use
15 (as determined by the Secretary) in performing,
16 administering, or supporting biomedical coun-
17 termeasure research or development, the
18 amount specified in section 4(11) of the Office
19 of Federal Procurement Policy Act (41 U.S.C.
20 403(11)), as applicable pursuant to section
21 302A(a) of the Federal Property and Adminis-
22 trative Services Act of 1949 (41 U.S.C.
23 252a(a)), shall be deemed to be \$25,000,000 in
24 the administration, with respect to such pro-
25 curement, of—

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

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

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

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

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

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

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

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

6 “(v) Section 303G of the Federal
7 Property and Administrative Services Act
8 of 1949 (41 U.S.C. 253g) (relating to lim-
9 iting subcontractor sales).

10 “(vi) Subsection (a) of section 304 of
11 the Federal Property and Administrative
12 Services Act of 1949 (41 U.S.C. 254(a))
13 (relating to contingent fees to middlemen),
14 other than the last sentence of such sub-
15 section.

16 “(vii) Section 6002 of the Solid Waste
17 Disposal Act (42 U.S.C. 6962).

18 “(viii) Section 1354 of title 31,
19 United States Code (relating to the limita-
20 tion on the use of appropriated funds for
21 contracts with entities not meeting vet-
22 erans’ employment reporting require-
23 ments).

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

1 appropriate internal controls for procurements made
2 under this paragraph, including requirements
3 with respect to documenting the justification
4 for use of the authority provided in this para-
5 graph.

6 “(2) USE OF NONCOMPETITIVE PROCEDURES.—

7 In addition to any other authority to use procedures
8 other than competitive procedures for procurements,
9 the Secretary may use such other noncompetitive
10 procedures when—

11 “(A) the procurement is as described by
12 paragraph (1)(A); and

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

19 “(3) INCREASED MICROPURCHASE THRESH-
20 OLD.—

21 “(A) IN GENERAL.—For a procurement
22 described by paragraph (1)(A), the amount
23 specified in subsections (c), (d), and (f) of sec-
24 tion 32 of the Office of Federal Procurement
25 Policy Act (41 U.S.C. 428) shall be deemed to

1 be \$15,000 in the administration of that section
2 with respect to such procurement.

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

8 “(C) EXCEPTION TO PREFERENCE FOR
9 PURCHASE CARD MECHANISM.—No provision of
10 law establishing a preference for using a Fed-
11 eral Government purchase card method for pur-
12 chases shall apply to procurements made under
13 this paragraph and that are greater than
14 \$2,500.

15 “(c) AUTHORITY TO EXPEDITE PEER REVIEW.—The
16 Secretary may, as the Secretary determines necessary to
17 respond to pressing research and development needs under
18 this section, employ such expedited peer review procedures
19 (including consultation with appropriate scientific experts)
20 as the Secretary, in consultation with the Director of NIH,
21 determines to be appropriate to obtain an assessment of
22 scientific and technical merit and likely contribution to the
23 field of biomedical countermeasure research, in place of
24 the peer review and advisory council review procedures
25 that would otherwise be required under sections 301(a)(3),

1 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as
2 applicable to a grant, contract, or cooperative agree-
3 ment—

4 “(1) that is for performing, administering, or
5 supporting biomedical countermeasure research and
6 development; and

7 “(2) the amount of which is not greater than
8 \$1,500,000.

9 “(d) AGENCY FACILITIES.—In addition to any simi-
10 lar authority provided under any other provision of law,
11 in carrying out this section, the Secretary may—

12 “(1) acquire, lease, construct, improve, ren-
13 ovate, remodel, repair, operate, and maintain labora-
14 tories, other research facilities and equipment, and
15 other real or personal property as the Secretary de-
16 termines necessary for the purpose of performing,
17 administering, and supporting biomedical counter-
18 measure research and development; and

19 “(2) acquire, without regard to section 8141 of
20 title 40, United States Code, by lease or otherwise,
21 through the Administrator of General Services,
22 buildings or parts of buildings in the District of Co-
23 lumbia.

24 “(e) AUTHORITY FOR PERSONAL SERVICES CON-
25 TRACTS.—

1 “(1) IN GENERAL.—For the purpose of per-
2 forming, administering, and supporting biomedical
3 countermeasure research and development, the Sec-
4 retary may, as the Secretary determines necessary to
5 respond to pressing research and development needs
6 under this section, obtain by contract (in accordance
7 with section 3109 of title 5, United States Code, but
8 without regard to the limitations in such section on
9 the period of service and on pay) the personal serv-
10 ices of experts or consultants who have scientific or
11 other professional qualifications.

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 for any act or omission within
4 the scope of the Federal Tort Claims Act.

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

7 “(i) IN GENERAL.—Should payment
8 be made by the United States to any
9 claimant bringing a claim under this para-
10 graph, either by way of administrative de-
11 termination, settlement, or court judgment,
12 the United States shall have, notwith-
13 standing any provision of State law, the
14 right to recover for that portion of the
15 damages so awarded or paid, as well as in-
16 terest and any costs of litigation, resulting
17 from the failure of any person, officer, em-
18 ployee, or governing board member to
19 carry out any obligation or responsibility
20 assumed by such person, officer, employee,
21 or governing board member under a con-
22 tract with the United States or from any
23 grossly negligent, reckless, or illegal con-
24 duct or willful misconduct on the part of

1 such person, officer, employee, or gov-
2 erning board member.

3 “(ii) VENUE.—The United States may
4 maintain an action under this subpara-
5 graph against such person, officer, em-
6 ployee, or governing board member in the
7 district court of the United States in which
8 such person, officer, employee, or gov-
9 erning board member resides or has its
10 principal place of business.

11 “(3) INTERNAL CONTROLS TO BE INSTI-
12 TUTED.—

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

22 “(B) DETERMINATION OF EMPLOYEE STA-
23 TUS TO BE FINAL.—A determination by the
24 Secretary under subparagraph (A) that a per-
25 son, or an officer, employee, or governing board

1 member of a person, is or is not deemed to be
2 an employee of the Department of Health and
3 Human Services shall be final and binding on
4 the Secretary and the Attorney General and
5 other parties to any civil action or proceeding.

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

10 “(f) STREAMLINED PERSONNEL AUTHORITY.—

11 “(1) IN GENERAL.—In addition to any other
12 personnel authorities, the Secretary may, as the Sec-
13 retary determines necessary to respond to pressing
14 research and development needs under this section,
15 without regard to such provisions of title 5, United
16 States Code, governing appointments in the competi-
17 tive service, and without regard to the provisions of
18 chapter 51 and subchapter III of chapter 53 of such
19 title relating to classification and General Schedule
20 pay rates, appoint professional and technical employ-
21 ees, not to exceed 30 such employees at any time,
22 to positions in the National Institutes of Health to
23 perform, administer, or support biomedical counter-
24 measure research and development in carrying out
25 this section.

1 “(2) CONSISTENCY WITH CERTAIN PROVISIONS
2 OF TITLE 5.—The authority provided for under
3 paragraph (1) shall be exercised in a manner that is
4 consistent with—

5 “(A) chapter 23 of title 5, United States
6 Code (relating to merit system principles and
7 prohibited personnel practices); and

8 “(B) the provisions of title 5, United
9 States Code, relating to preference eligibles.

10 “(3) INTERNAL CONTROLS TO BE INSTI-
11 TUTED.—The Secretary shall institute appropriate
12 internal controls for appointments under this sub-
13 section.

14 “(g) DEFINITION.—As used in this section, the term
15 ‘biomedical countermeasure’ means a drug (as that term
16 is defined by section 201(g)(1) of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 321(g)(1))), biological prod-
18 uct (as that term is defined by section 351(i) of this Act
19 (42 U.S.C. 262(i))), or device (as that term is defined by
20 section 201(h) of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 321(h))) that is used—

22 “(1) to treat, identify, or prevent harm from
23 any biological, chemical, radiological, or nuclear
24 agent that may cause a public health emergency af-
25 fecting national security; or

1 “(2) to treat, identify, or prevent harm from a
2 condition that may result in adverse health con-
3 sequences or death and may be caused by admin-
4 istering a drug, biological product, or device that is
5 used as described in paragraph (1).

6 “(h) ACTIONS COMMITTED TO AGENCY DISCRE-
7 TION.—Actions by the Secretary under the authority of
8 this section are committed to agency discretion.”.

9 (b) TECHNICAL AMENDMENT.—Section 481A of the
10 Public Health Service Act (42 U.S.C. 287a–2) is amend-
11 ed—

12 (1) in subsection (a)(1), by inserting “or the
13 Director of the National Institute of Allergy and In-
14 fectious Diseases” after “Director of the Center”;

15 (2) in subsection (c)—

16 (A) in paragraph (1), by inserting “or the
17 Director of the National Institute of Allergy
18 and Infectious Diseases” after “Director of the
19 Center”; and

20 (B) in paragraph (2), in the matter pre-
21 ceding subparagraph (A), by striking “sub-
22 section (i)” and inserting “subsection (i)(1)”;

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

1 (4) in subsection (e)—

2 (A) in paragraph (1)—

3 (i) in the matter preceding subpara-
4 graph (A), by inserting “or the Director of
5 the National Institute of Allergy and Infec-
6 tious Diseases” after “Director of the Cen-
7 ter”;

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

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

14 (B) in paragraph (2), by inserting “or the
15 Director of the National Institute of Allergy
16 and Infectious Diseases” after “Director of the
17 Center”; and

18 (C) in paragraph (4), by inserting “of the
19 Center or the Director of the National Institute
20 of Allergy and Infectious Diseases” after “Di-
21 rector”; and

22 (5) in subsection (f)—

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

1 (B) in paragraph (2), by inserting “of the
2 Center or the Director of the National Institute
3 of Allergy and Infectious Diseases” after “Di-
4 rector”.

5 **SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

6 Part B of title III of the Public Health Service Act
7 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
8 tion 319A, the following:

9 **“SEC. 319A-1. BIOMEDICAL COUNTERMEASURES PROCURE-
10 MENT.**

11 “(a) DETERMINATION OF MATERIAL THREATS.—

12 “(1) RISK OF USE.—The Secretary of Home-
13 land Security, in consultation with the heads of
14 other agencies as appropriate, shall on an ongoing
15 basis—

16 “(A) assess current and emerging threats
17 of use of chemical, biological, radiological, and
18 nuclear agents; and

19 “(B) determine which of such agents
20 present a material risk of use against the
21 United States population.

22 “(2) PUBLIC HEALTH IMPACT.—The Secretary,
23 in consultation with the Secretary of Homeland Se-
24 curity, shall on an ongoing basis—

1 “(A) assess the potential public health con-
2 sequences of use against the United States pop-
3 ulation of agents identified under paragraph
4 (1)(B); and

5 “(B) determine, on the basis of such as-
6 sessment, the agents for which countermeasures
7 are necessary to protect the public health.

8 “(b) ASSESSMENT OF AVAILABILITY AND APPRO-
9 PRIATENESS OF COUNTERMEASURES.—The Secretary, in
10 consultation with the Secretary of Homeland Security,
11 shall assess on an ongoing basis the availability and appro-
12 priateness of specific countermeasures to address specific
13 threats identified under subsection (a).

14 “(c) CALL FOR NECESSARY COUNTERMEASURES;
15 COMMITMENT FOR RECOMMENDATION FOR PROCURE-
16 MENT.—

17 “(1) PROPOSAL TO THE PRESIDENT.—Based on
18 a determination of necessary countermeasures under
19 subsection (a), and the assessment of availability
20 and appropriateness of countermeasures under sub-
21 section (b), the Secretary of Homeland Security and
22 the Secretary may jointly submit to the President a
23 proposal to—

24 “(A) call for a necessary countermeasure
25 that is not available; and

1 “(B) commit to make a recommendation
2 for procurement under subsection (e) of the
3 first such specific countermeasure that meets
4 the conditions for procurement under sub-
5 section (d).

6 “(2) COUNTERMEASURE SPECIFICATIONS.—The
7 Secretary of Homeland Security and the Secretary
8 shall, to the extent practicable, include in the rec-
9 ommendation under paragraph (1)—

10 “(A) estimated quantity of purchase (in
11 the form of number of doses or number of ef-
12 fective courses of treatments regardless of dos-
13 age form);

14 “(B) necessary measures of minimum safe-
15 ty and effectiveness;

16 “(C) estimated price for each dose or effec-
17 tive course of treatment regardless of dosage
18 form; and

19 “(D) other information that may be nec-
20 essary to encourage and facilitate research, de-
21 velopment, and manufacture of the counter-
22 measure or to provide specifications for the
23 countermeasure.

24 “(3) PRESIDENTIAL APPROVAL.—If the Presi-
25 dent has approved a request under paragraph (1),

1 the Secretary of Homeland Security and the Sec-
2 retary shall make known to persons who may re-
3 spond to a call for the countermeasure—

4 “(A) the call for the countermeasure;

5 “(B) specifications for the countermeasure
6 under paragraph (2); and

7 “(C) a commitment for a recommendation
8 for procurement under subsection (e) of the
9 first such specific countermeasure that meets
10 the conditions for procurement under sub-
11 section (d) and the specifications under para-
12 graph (2).

13 “(4) SUBSEQUENT SPECIFIC COUNTER-
14 MEASURES.—Procurement under subsection (f) of
15 the first such specific countermeasure, or any other
16 such countermeasure, that meets the conditions for
17 procurement under subsection (d) and the specifica-
18 tions under paragraph (2) shall not preclude the ad-
19 ditional procurement under subsection (f) of a subse-
20 quent such countermeasure that meets the condi-
21 tions of procurement under subsection (d) if such a
22 countermeasure provides improved safety or effec-
23 tiveness or for other reasons enhances preparedness
24 to respond to threats of use of a biological, chemical,
25 radiological, or nuclear agent.

1 “(d) SECRETARY’S DETERMINATION OF COUNTER-
2 MEASURES APPROPRIATE FOR PROCUREMENT UNDER
3 THIS SECTION.—

4 “(1) IN GENERAL.—The Secretary, in accord-
5 ance with this section, shall identify specific counter-
6 measures to threats identified under subsection (a)
7 that the Secretary determines, in consultation with
8 the Secretary of Homeland Security, to be appro-
9 priate for procurement with appropriations under
10 this section for inclusion in the stockpile under sec-
11 tion 121(a) of the Public Health and Bioterrorism
12 Preparedness and Response Act of 2002 (42 U.S.C.
13 300hh–12(a)).

14 “(2) REQUIREMENTS.—In order for the Sec-
15 retary to make the determination under paragraph
16 (1) with respect to a countermeasure, the following
17 requirements must be met:

18 “(A) DETERMINATION OF QUALIFIED
19 COUNTERMEASURE.—The Secretary must deter-
20 mine that the product is a qualified counter-
21 measure (as defined in subsection (h)).

22 “(B) DETERMINATION OF QUANTITIES
23 NEEDED AND FEASIBILITY OF PRODUCTION
24 AND DISTRIBUTION.—The Secretary must de-
25 termine—

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

4 “(ii) that production and delivery
5 within 5 years of sufficient quantities of
6 the product, as so determined, is reason-
7 ably expected to be feasible.

8 “(C) DETERMINATION OF NO SIGNIFICANT
9 COMMERCIAL MARKET.—The Secretary shall—

10 “(i) determine that, at the time of the
11 initial determination under this subsection,
12 there is not a significant commercial mar-
13 ket for the product other than as a bio-
14 medical countermeasure; and

15 “(ii) annually redetermine and report
16 to the President, while a determination
17 under paragraph (1) remains in effect with
18 respect to the product, whether a signifi-
19 cant commercial market exists for the
20 product other than as a biomedical coun-
21 termeasure.

22 “(e) RECOMMENDATION FOR PRESIDENT’S AP-
23 PROVAL.—

24 “(1) RECOMMENDATION FOR PROCUREMENT.—

25 In the case of a countermeasure that the Secretary

1 of Homeland Security and the Secretary have deter-
2 mined is appropriate for procurement under this sec-
3 tion for inclusion in the stockpile, in accordance with
4 the preceding provisions of this section, the Sec-
5 retary of Homeland Security and the Secretary shall
6 jointly submit to the President, in coordination with
7 the Director of the Office of Management and Budg-
8 et, a recommendation for procurement under this
9 section.

10 “(2) PRESIDENTIAL APPROVAL.—A counter-
11 measure may be procured under this section only if
12 the President has approved a recommendation under
13 paragraph (1) with respect to such countermeasure.

14 “(3) NOTICE TO CONGRESS.—The Secretary of
15 Homeland Security shall notify Congress of each de-
16 cision of the President to approve a recommendation
17 under paragraph (1).

18 “(f) PROCUREMENT.—The Secretary and the Sec-
19 retary of Homeland Security shall be responsible for the
20 following, for purposes of procurement of qualified coun-
21 termeasures for the stockpile under section 121(a) of the
22 Public Health and Bioterrorism Preparedness and Re-
23 sponse Act of 2002 (42 U.S.C. 300hh–12(a)), as approved
24 by the President under subsection (e):

1 “(1) IN GENERAL.—The Secretary shall be re-
2 sponsible for—

3 “(A) arranging for procurement of the
4 countermeasure, including negotiating terms
5 (including quantity, production schedule, and
6 price) of, and entering into, contracts and coop-
7 erative agreements, and for carrying out such
8 other activities as may reasonably be required,
9 in accordance with the provisions of this para-
10 graph; and

11 “(B) promulgating regulations to imple-
12 ment paragraphs (5), (6), and (7), and any
13 other provisions of this section.

14 “(2) CONTRACT TERMS.—A contract for pro-
15 curement under this section shall (or, as otherwise
16 specified in this paragraph, may) include the fol-
17 lowing terms:

18 “(A) PAYMENT CONDITIONED ON SUB-
19 STANTIAL DELIVERY.—The contract shall pro-
20 vide that no payment may be made until deliv-
21 ery has been made of a substantial portion (as
22 determined by the Secretary) of the total num-
23 ber of units contracted for.

24 “(B) DISCOUNTED PAYMENT FOR UNLI-
25 CENSED PRODUCT.—The contract may provide

1 for a discounted price per unit of a product
2 that is not licensed or approved as described in
3 subsection (h)(1) at the time of delivery, and
4 may provide for payment of an additional
5 amount per unit if the product becomes so li-
6 censed or approved before the expiration date of
7 the contract (including an additional amount
8 per unit of product delivered before the effective
9 date of such licensing or approval).

10 “(C) STORAGE BY VENDOR.—The contract
11 may provide that the vendor will provide stor-
12 age for stocks of a product delivered to the
13 ownership of the Government under the con-
14 tract, for such period and under such terms and
15 conditions as the Secretary may specify, and in
16 such case amounts appropriated under sub-
17 section (i) shall be available for costs of ship-
18 ping, handling, storage, and related costs for
19 such product.

20 “(D) CONTRACT DURATION.—The contract
21 shall be for a period not to exceed 5 years, re-
22 newable for additional periods none of which
23 shall exceed 5 years.

24 “(E) TERMINATION FOR NONDELIVERY.—
25 In addition to any other rights of the Secretary

1 to terminate the contract, the contract may pro-
2 vide that the Secretary may terminate the con-
3 tract for failure to deliver a reasonable number
4 (as determined by the Secretary) of units of the
5 product by 3 years after the date the contract
6 is entered into, and may further provide that
7 in such case the vendor shall not be entitled to
8 any payment under the contract.

9 “(F) PRODUCT APPROVAL.—The contract
10 shall provide that the vendor seek approval,
11 clearance, or licensing of the product from the
12 Secretary; for a timetable for the development
13 of data and other information to support such
14 approval, clearance, or licensing; and that the
15 Secretary may waive part or all of this contract
16 term on request of the vendor or on the initia-
17 tive of the Secretary.

18 “(3) AVAILABILITY OF SIMPLIFIED ACQUISI-
19 TION PROCEDURES.—

20 “(A) IN GENERAL.—The amount of any
21 procurement under this section shall be deemed
22 to be below the threshold amount specified in
23 section 4(11) of the Office of Federal Procure-
24 ment Policy Act (41 U.S.C. 403(11)), for pur-
25 poses of application to such procurement, pur-

1 suant to section 302A(a) of the Federal Prop-
2 erty and Administrative Services Act of 1949
3 (41 U.S.C. 252a(a)), of—

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

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

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

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

23 “(ii) Subsections (a) and (b) of sec-
24 tion 7 of the Anti-Kickback Act of 1986
25 (41 U.S.C. 57(a) and (b)).

1 “(iii) Section 304C of the Federal
2 Property and Administrative Services Act
3 of 1949 (41 U.S.C. 254d) (relating to the
4 examination of contractor records).

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

8 “(v) Section 303G of the Federal
9 Property and Administrative Services Act
10 of 1949 (41 U.S.C. 253g) (relating to lim-
11 iting subcontractor sales).

12 “(vi) Subsection (a) of section 304 of
13 the Federal Property and Administrative
14 Services Act of 1949 (41 U.S.C. 254(a))
15 (relating to contingent fees to middlemen),
16 other than the last sentence of such sub-
17 section.

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

20 “(viii) Section 1354 of title 31,
21 United States Code (relating to the limita-
22 tion on the use of appropriated funds for
23 contracts with entities not meeting vet-
24 erans’ employment reporting require-
25 ments).

1 “(4) USE OF NONCOMPETITIVE PROCEDURES.—

2 In addition to any other authority to use procedures
3 other than competitive procedures, the Secretary
4 may use such other procedures for a procurement
5 under this section if the product is available from
6 only one responsible source or only from a limited
7 number of responsible sources, and no other type of
8 product will satisfy such Secretary’s needs.

9 “(5) PREMIUM PROVISION IN MULTIPLE AWARD
10 CONTRACTS.—

11 “(A) IN GENERAL.—If, under this section,
12 the Secretary enters into contracts with more
13 than one person to procure a countermeasure,
14 such Secretary may, notwithstanding any other
15 provision of law, include in each of such con-
16 tracts a provision that—

17 “(i) identifies an increment of the
18 total quantity of countermeasure required,
19 whether by percentage or by numbers of
20 units; and

21 “(ii) promises to pay one or more
22 specified premiums based on the priority of
23 such persons’ production and delivery of
24 the increment identified under clause (i),

1 in accordance with the terms and condi-
2 tions of the contract.

3 “(B) DETERMINATION OF GOVERNMENT’S
4 REQUIREMENT NOT REVIEWABLE.—If the Sec-
5 retary includes in each of a set of contracts a
6 provision as described in subparagraph (A),
7 such Secretary’s determination of the total
8 quantity of countermeasure required, and any
9 amendment of such determination, is committed
10 to agency discretion.

11 “(6) EXTENSION OF CLOSING DATE FOR RE-
12 CEIPT OF PROPOSALS NOT REVIEWABLE.—A deci-
13 sion by the Secretary to extend the closing date for
14 receipt of proposals for a procurement under this
15 subsection is committed to agency discretion.

16 “(7) LIMITING COMPETITION TO SOURCES RE-
17 SPONDING TO REQUEST FOR INFORMATION.—In con-
18 ducting a procurement under this section, the Sec-
19 retary may exclude a source that has not responded
20 to a request for information under section
21 303A(a)(1)(B) of the Federal Property and Admin-
22 istrative Services Act of 1949 (41 U.S.C.
23 253a(a)(1)(B)) if such request has given notice that
24 such Secretary may so exclude such a source.

25 “(g) INTERAGENCY COOPERATION.—

1 “(1) IN GENERAL.—In carrying out activities
2 under this section, the Secretary of Homeland Secu-
3 rity and the Secretary are authorized, subject to
4 paragraph (2), to enter into interagency agreements
5 and other collaborative undertakings with other
6 agencies of the United States Government.

7 “(2) LIMITATION.—An agreement or under-
8 taking under this subsection shall not authorize an-
9 other agency to exercise the authorities provided by
10 this section to the Secretary of Homeland Security
11 or to the Secretary.

12 “(h) DEFINITIONS.—In this section:

13 “(1) QUALIFIED COUNTERMEASURE.—The term
14 ‘qualified countermeasure’ means a biomedical coun-
15 termeasure—

16 “(A) that is approved under section 505(a)
17 of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 355) or licensed under section 351
19 of this Act (42 U.S.C. 262) or that is approved
20 under section 515 or cleared under section
21 510(k) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 360e and 360) for use as
23 such a countermeasure to a chemical, biological,
24 radiological, or nuclear agent identified as a
25 material threat under subsection (a); or

1 “(B) for which the Secretary determines
2 that sufficient and satisfactory clinical experi-
3 ence or research data (including data, if avail-
4 able, from preclinical and clinical trials) support
5 a reasonable conclusion that the product will
6 qualify for approval or licensing as such a coun-
7 termeasure within 5 years after the date of a
8 determination under subsection (d).

9 “(2) BIOMEDICAL COUNTERMEASURE.—The
10 term ‘biomedical countermeasure’ means a drug (as
11 that term is defined by section 201(g)(1) of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C.
13 321(g)(1))), device (as that term is defined by sec-
14 tion 201(h) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 321(h))), or biological product
16 (as that term is defined by section 351(i) of this Act
17 (42 U.S.C. 262(i))) that is used—

18 “(A) to treat, identify, or prevent harm
19 from any biological, chemical, radiological, or
20 nuclear agent that may cause a public health
21 emergency affecting national security; or

22 “(B) to treat, identify, or prevent harm
23 from a condition that may result in adverse
24 health consequences or death and may be
25 caused by administering a drug or biological

1 product that is used as described in subpara-
2 graph (A).

3 “(i) APPROPRIATIONS.—

4 “(1) IN GENERAL.— There are authorized to be
5 appropriated not to exceed \$5,593,000,000 for the
6 period of fiscal years 2004 through 2013 for the
7 costs incurred by the Secretary in the procurement
8 of countermeasures under this subsection as ap-
9 proved by the President under subsection (e) (other
10 than costs specified in paragraph (2)). Of the
11 amounts appropriated under the preceding sentence,
12 not to exceed \$3,418,000,000 may be obligated dur-
13 ing the period of fiscal years 2004 through 2008, of
14 which not to exceed \$890,000,000 may be obligated
15 during fiscal year 2004.

16 “(2) RESTRICTIONS.—Amounts appropriated
17 under this subsection shall not be available to pay—

18 “(A) costs for the purchase of vaccines
19 under procurement contracts entered into be-
20 fore January 1, 2003;

21 “(B) costs under new contracts, or costs of
22 new obligations under contracts previously en-
23 tered into, for procurement of a countermeasure
24 after the date of a determination under sub-
25 section (d)(2)(C) that there is a significant

1 commercial market for the countermeasure
2 other than as a biomedical countermeasure; or
3 “(C) administrative costs.”.

4 **SEC. 4. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
5 **USE IN EMERGENCIES.**

6 (a) IN GENERAL.—Subchapter E of Chapter V of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 360bbb, et seq.) is amended by adding at the end the fol-
9 lowing:

10 **“SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR**
11 **USE IN EMERGENCIES.**

12 “(a) IN GENERAL.—Notwithstanding sections 505,
13 510(k), and 515 of this Act and section 351 of the Public
14 Health Service Act, and subject to the provisions of this
15 section, the Secretary may authorize the introduction into
16 interstate commerce, during the effective period of a dec-
17 laration under subsection (b), of a drug, biological prod-
18 uct, or device intended solely for use in an actual or poten-
19 tial emergency.

20 “(b) DECLARATION OF EMERGENCY.—

21 “(1) IN GENERAL.—The Secretary may declare
22 an emergency justifying the authorization of a drug,
23 biological product, or device under this subsection on
24 the basis of a determination—

1 “(A) by the Secretary of Homeland Secu-
2 rity, that there is a domestic emergency (or a
3 significant potential of a domestic emergency)
4 involving a heightened risk of attack with a
5 specified biological, chemical, radiological, or
6 nuclear agent;

7 “(B) by the Secretary of Defense, that
8 there is a military emergency (or a significant
9 potential of a military emergency) involving a
10 heightened risk to United States military forces
11 of attack with a biological, chemical, radio-
12 logical, or nuclear agent; or

13 “(C) by the Secretary of a public health
14 emergency under section 319 of the Public
15 Health Service Act, affecting national security
16 and involving a specified biological, chemical,
17 radiological, or nuclear agent or a specified dis-
18 ease or condition that may be attributable to
19 such agent.

20 “(2) TERMINATION OF DECLARATION.—

21 “(A) IN GENERAL.—A declaration under
22 this subsection shall terminate upon the earlier
23 of—

24 “(i) a determination by the Secretary,
25 in consultation as appropriate with the

1 Secretary of Homeland Security or the
2 Secretary of Defense, that the cir-
3 cumstances described in paragraph (1)
4 have ceased to exist; or

5 “(ii) the expiration of the 1-year pe-
6 riod beginning on the date on which the
7 declaration is made.

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

12 “(3) NOTIFICATION.—The Secretary shall
13 promptly publish in the Federal Register, and shall
14 notify the appropriate committees of Congress con-
15 cerning, each declaration, determination, and re-
16 newal under this subsection.

17 “(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—
18 The Secretary may issue an authorization under this sec-
19 tion with respect to a product if 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.—An authorization
25 of a product under this section shall state—

1 “(1) each disease or condition and the intended
2 use of the product within the scope of the authoriza-
3 tion; and

4 “(2) the Secretary’s conclusions, under sub-
5 section (c), concerning the safety and potential effec-
6 tiveness of the product in detecting, diagnosing, pre-
7 venting, or treating such diseases or conditions, in-
8 cluding an assessment of the available scientific evi-
9 dence.

10 “(e) CONDITIONS OF AUTHORIZATION.—The Sec-
11 retary is authorized to impose such conditions on an au-
12 thorization under this section as the Secretary determines
13 are necessary or appropriate to protect the public health,
14 including the following:

15 “(1) The Secretary shall impose, to the max-
16 imum extent feasible given the circumstances of the
17 emergency, requirements (including requirements
18 concerning product labeling and the provision of in-
19 formation) designed to ensure that health care pro-
20 fessionals administering the product are informed—

21 “(A) that the Secretary has authorized the
22 product solely for emergency use;

23 “(B) of the significant known and poten-
24 tial benefits and risks of use of the product,

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

3 “(C) of the alternatives to the product that
4 are available, and of their benefits and risks.

5 “(2) The Secretary shall impose, to the max-
6 imum extent feasible given the circumstances of the
7 emergency, requirements (including requirements
8 concerning product labeling and the provision of in-
9 formation) designed to ensure that individuals to
10 whom the product is administered are informed—

11 “(A) that the Secretary has authorized the
12 product solely for emergency use;

13 “(B) of the significant known and poten-
14 tial benefits and risks of use of the product,
15 and of the extent to which such benefits and
16 risks are unknown; and

17 “(C) of any option to accept or refuse ad-
18 ministration of the product, and of the alter-
19 natives to the product that are available and of
20 their benefits and risks.

21 “(3) The Secretary may impose limitations on
22 which entities may distribute the product (including
23 limitation to distribution by government entities),
24 and on how distribution is to be performed.

1 “(4) The Secretary may impose limitations on
2 who may administer the product, and on the cat-
3 egories of individuals to whom, and the cir-
4 cumstances under which, the product may be admin-
5 istered.

6 “(5) The Secretary may condition the author-
7 ization on the performance of studies, clinical trials,
8 or other research needed to support marketing ap-
9 proval of the product.

10 “(6) The Secretary shall impose, to the extent
11 feasible and appropriate given the circumstances of
12 the emergency, requirements concerning record-
13 keeping and reporting, including records access by
14 the Secretary and publication of data.

15 “(7) The Secretary may waive, to the extent ap-
16 propriate given the circumstances of the emergency,
17 requirements, with respect to the product, of current
18 good manufacturing practice otherwise applicable to
19 the manufacture, processing, packing, or holding of
20 products subject to regulation under this Act.

21 “(8) The Secretary shall impose, to the extent
22 feasible and appropriate given the circumstances of
23 the emergency, requirements for the monitoring and
24 reporting of adverse events associated with use of
25 the product.

1 “(f) DURATION OF AUTHORIZATION.—

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

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

13 “(g) REVOCATION OF AUTHORIZATION.—

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

17 “(2) REVOCATION.—The Secretary may revoke
18 an authorization under this section if, in the Sec-
19 retary’s unreviewable discretion—

20 “(A) the conditions for such an authoriza-
21 tion are no longer met; or

22 “(B) other circumstances make such rev-
23 ocation appropriate.

24 “(h) PUBLICATION.—The Secretary shall promptly
25 publish in the Federal Register, and provide to the appro-

1 p r i a t e c o m m i t t e e s o f C o n g r e s s , a n o t i c e o f e a c h a u t h o r i z a -
2 t i o n , a n d e a c h t e r m i n a t i o n o r r e v o c a t i o n o f a n a u t h o r i z a -
3 t i o n , u n d e r t h i s s e c t i o n .

4 “(i) RECORDKEEPING.—

5 “(1) IN GENERAL.—The Secretary may require
6 p e r s o n s , i n c l u d i n g a p e r s o n w h o h o l d s a n a u t h o r i z a -
7 t i o n u n d e r t h i s s e c t i o n , o r w h o m a n u f a c t u r e s , d i s -
8 t r i b u t e s , p r e s c r i b e s , o r a d m i n i s t e r s a p r o d u c t t h a t i s
9 t h e s u b j e c t o f s u c h a n a u t h o r i z a t i o n , t o e s t a b l i s h
10 a n d m a i n t a i n—

11 “(A) data that is obtained from such activ-
12 i t y a n d t h a t p e r t a i n s t o t h e e f f e c t i v e n e s s o r
13 s a f e t y o f s u c h p r o d u c t ;

14 “(B) such records as are necessary to de-
15 t e r m i n e , o r f a c i l i t a t e a d e t e r m i n a t i o n , w h e t h e r
16 t h e r e m a y b e a n y v i o l a t i o n o f t h i s s e c t i o n o r o f
17 a r e g u l a t i o n p r o m u l g a t e d u n d e r t h i s s e c t i o n ;
18 a n d

19 “(C) such additional records as the Sec-
20 r e t a r y m a y d e t e r m i n e n e c e s s a r y .

21 “(2) ACCESS TO RECORDS BY SECRETARY.—

22 “(A) SAFETY AND EFFECTIVENESS INFOR-
23 M A T I O N . — T h e S e c r e t a r y m a y r e q u i r e a p e r s o n
24 w h o h o l d s a n a u t h o r i z a t i o n u n d e r t h i s s e c t i o n ,
25 o r w h o m a n u f a c t u r e s , d i s t r i b u t e s , p r e s c r i b e s , o r

1 administers a product that is the subject of
2 such an authorization to provide to the Sec-
3 retary all data that is obtained from such activ-
4 ity and that pertains to the safety or effective-
5 ness of such product.

6 “(B) OTHER INFORMATION.—Every person
7 required under this section to establish or main-
8 tain records, and every person in charge or cus-
9 tody of such records, shall, upon request by the
10 Secretary, permit the Secretary at all reason-
11 able times to have access to, to copy, and to
12 verify such records.

13 “(j) CIVIL MONETARY PENALTIES.—

14 “(1) IN GENERAL.—A person who violates a re-
15 quirement of this section or of a regulation or order
16 promulgated pursuant to this section shall be subject
17 to a civil money penalty of not more than \$100,000
18 in the case of an individual, and not more than
19 \$250,000 in the case of any other person, for each
20 violation, not to exceed \$1,000,000 for all such viola-
21 tions adjudicated in a single proceeding.

22 “(2) ASSESSMENT OF CIVIL PENALTIES.—Para-
23 graphs (3), (4), and (5) of section 303(g) shall apply
24 to a civil penalty under this subsection, and ref-
25 erences in such paragraphs to ‘paragraph (1) or (2)’

1 shall, for purposes of this subsection, be deemed to
2 refer to paragraph (1) of this subsection.

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

8 “(l) REGULATIONS.—The Secretary may promulgate
9 regulations to implement this section.

10 “(m) CONSTRUCTION.—Nothing in this section shall
11 be construed to impair or otherwise affect—

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

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

20 “(n) APPLICATION TO MEMBERS OF ARMED
21 FORCES.—

22 “(1) WAIVER OF REQUIREMENT RELATING TO
23 OPTION TO REFUSE.—

24 “(A) IN GENERAL.—In the case of the ad-
25 ministration of a product to members of the

1 armed forces, a requirement under subsection
2 (e)(2)(C) designed to ensure that individuals
3 are informed of an option to accept or refuse
4 administration of a product, may be waived by
5 the President if the President determines, in
6 writing, that complying with such requirement
7 is not feasible, is contrary to the best interests
8 of the members affected, or is not in the inter-
9 ests of national security.

10 “(B) PROVISION OF INFORMATION TO
11 MEMBER.—If the Secretary makes a determina-
12 tion that it is not feasible for the information
13 required by subparagraphs (A) and (B) of sub-
14 section (e)(2) to be provided prior to the admin-
15 istration of the product, such information shall
16 be provided to members of the armed forces (or
17 next-of-kin in the case of the death of a mem-
18 ber) to whom the product was administered as
19 soon as possible, but not later than 30 days,
20 after administration. Information concerning
21 the administration of the product shall be re-
22 corded in the medical record of the member.

23 “(2) 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 “(o) 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 (b) PROHIBITED ACTS.—Section 301 of the Federal
 16 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
 17 ed—

18 (1) in subsection (e)—

19 (A) by striking “504, 703” and inserting
 20 “504, 564, 703”; and

21 (B) by striking “or 519” and inserting
 22 “519, or 564”; and

23 (2) by adding at the end the following:

24 “(hh)(1) Promotion or use of a product that is the
 25 subject of an authorization under section 564 other than

1 as stated in the authorization, or other than during the
2 period described by section 564(g), unless such promotion
3 or use is permitted under another provision of this Act.

4 “(2) Failure to comply with an information require-
5 ment under section 564(e).”.

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

9 Section 1135(b) of the Social Security Act (42 U.S.C.
10 1320b–5(b)) is amended—

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

13 “(3) sanctions under section 1867 (relating to
14 examination and treatment for emergency medical
15 conditions and women in labor) for—

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

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

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

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

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

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

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

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

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

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

19 “(C) section 164.522 of such title, relating
20 to—

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

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

1 (5) by adding at the end the following: “A waiver
2 er or modification provided for under paragraph (7)
3 shall be limited to a 72-hour period beginning upon
4 implementation of a hospital disaster protocol. A
5 waiver or modification under such paragraph (7)
6 shall be withdrawn after such period and the pro-
7 vider shall comply with the requirements under such
8 paragraph for any patient still under the care of the
9 provider.”.

10 **SEC. 6. GAO REPORT.**

11 Not later than 4 years after the date of enactment
12 of this Act, the Comptroller General of the United States
13 shall submit to the appropriate committees of Congress
14 a report that—

15 (1) describes the activities conducted under the
16 authorities provided for in section 409J(b)(1) of the
17 Public Health Service Act (as added by section 2)
18 and section 319A–1(f)(3) and (4) of such Act (as
19 added by section 3);

20 (2) identifies any procurements that would have
21 been prohibited except for the authorities provided in
22 the sections described in paragraph (1); and

23 (3) assesses the adequacy of the internal con-
24 trols established by the Secretary of Health and
25 Human Services regarding procurements made

1 under the authorities provided for in the sections de-
2 scribed in paragraph (1).

3 **SEC. 7. FUNDING FOR PROJECT BIOSHIELD.**

4 In the Senate, for purposes of points of order under
5 a concurrent resolution on the budget and the Congres-
6 sional Budget Act of 1974, provisions contained in any
7 bill, resolution, amendment, motion, or conference report
8 that change the availability of any amounts appropriated
9 pursuant to this Act (or an amendment made by this Act)
10 shall not be scored with respect to the level of budget au-
11 thority or outlays contained in such bill, resolution,
12 amendment, motion, or conference report.

○