Calendar No. 265

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

SEPTEMBER 2, 2003

Read the second time and placed on the calendar

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Project BioShield Act of 2003''.

SEC. 2. BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT AUTHORITIES.

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

"SEC. 409J. BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT.

"(a) IN GENERAL.—

"(1) AUTHORITY.—In carrying out research responsibilities under this Act, the Secretary may conduct and support research and development with respect to biomedical countermeasures.

"(2) IMPLEMENTATION.—

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

"(B) LEAD INSTITUTE.—The National Institute of Allergy and Infectious Diseases shall be the lead institute for performing, administering, or supporting biomedical countermeasure research and development. The Director of NIH may delegate to the Director of the Institute authorities as are necessary to carry out this function.

''(C) CHEMICAL, RADIOLOGICAL, AND NUCLEAR AGENTS.—To the extent that an authority described in subparagraph (A) is exercised with respect to a chemical, radiological, or nuclear agent, the Secretary may authorize the Director of NIH to carry out the authority through any national research institute.

''(D) AVAILABILITY OF FACILITIES TO THE SECRETARY.—In any grant or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, and supporting biomedical countermeasures research and development, the Secretary may provide that the facility that is the object of such grant or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

''(3) INTERAGENCY COOPERATION.—

''(A) IN GENERAL.—In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into

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

''(B) LIMITATION.—An agreement or undertaking under this paragraph may not authorize another agency to exercise the authorities provided to the Secretary by this section.

''(b) EXPEDITED PROCUREMENT AUTHORITY.—

''(1) INCREASED SIMPLIFIED ACQUISITION THRESHOLD FOR BIOMEDICAL COUNTERMEASURE PROCUREMENTS.—

''(A) IN GENERAL.—For any procurement by the Secretary, of property or services for use (as determined by the Secretary) in performing, administering, or supporting biomedical countermeasure research or development, the amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), as applicable pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

"(i) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

"(ii) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

"(B) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subparagraph (A) and the provisions of law and regulations referred to in such subparagraph, each of the following provisions and implementing regulations shall apply to procurements described in this paragraph to the same extent that such provisions and regulations would apply to such procurements in absence of subparagraph (A):

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

"(ii) Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

"(iii) Section 304C of the Federal Property and Administrative Services Act

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

''(iv) Section 3131 of title 40, United States Code (relating to bonds of contractors of public buildings or works).

''(v) Section 303G of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253g) (relating to limiting subcontractor sales).

''(vi) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen), other than the last sentence of such subsection.

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

''(viii) Section 1354 of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans' employment reporting requirements).

''(C) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appro-

priate internal controls for procurements made under this paragraph, including requirements with respect to documenting the justification for use of the authority provided in this paragraph.

''(2) USE OF NONCOMPETITIVE PROCEDURES.—In addition to any other authority to use procedures other than competitive procedures for procurements, the Secretary may use such other noncompetitive procedures when—

''(A) the procurement is as described by paragraph (1)(A); and

''(B) the property or services needed by the Secretary are available from only one responsible source or only from a limited number of responsible sources, and no other type of property or services will meet the needs of the Secretary.

''(3) INCREASED MICROPURCHASE THRESHOLD.—

''(A) IN GENERAL.—For a procurement described by paragraph (1)(A), the amount specified in subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to

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

''(B) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for procurements that are made under this paragraph and that are greater than $2,500.

''(C) EXCEPTION TO PREFERENCE FOR PURCHASE CARD MECHANISM.—No provision of law establishing a preference for using a Federal Government purchase card method for purchases shall apply to procurements made under this paragraph and that are greater than $2,500.

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

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

''(1) that is for performing, administering, or supporting biomedical countermeasure research and development; and

''(2) the amount of which is not greater than $1,500,000.

''(d) AGENCY FACILITIES.—In addition to any similar authority provided under any other provision of law, in carrying out this section, the Secretary may—

''(1) acquire, lease, construct, improve, renovate, remodel, repair, operate, and maintain laboratories, other research facilities and equipment, and other real or personal property as the Secretary determines necessary for the purpose of performing, administering, and supporting biomedical countermeasure research and development; and

''(2) acquire, without regard to section 8141 of title 40, United States Code, by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia.

''(e) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

''(1) IN GENERAL.—For the purpose of performing, administering, and supporting biomedical countermeasure research and development, the Secretary may, as the Secretary determines necessary to respond to pressing research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5, United States Code, but without regard to the limitations in such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications.

''(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

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

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

by reason of the same subject matter against the person, officer, employee, or governing board member for any act or omission within the scope of the Federal Tort Claims Act.

''(C) RECOURSE IN CASE OF GROSS MISCONDUCT OR CONTRACT VIOLATION.—

''(i) IN GENERAL.—Should payment be made by the United States to any claimant bringing a claim under this paragraph, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any person, officer, employee, or governing board member to carry out any obligation or responsibility assumed by such person, officer, employee, or governing board member under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of

such person, officer, employee, or governing board member.

''(ii) VENUE.—The United States may maintain an action under this subparagraph against such person, officer, employee, or governing board member in the district court of the United States in which such person, officer, employee, or governing board member resides or has its principal place of business.

''(3) INTERNAL CONTROLS TO BE INSTITUTED.—

''(A) IN GENERAL.—The Secretary shall institute appropriate internal controls for contracts under this subsection, including procedures for the Secretary to make a determination of whether a person, or an officer, employee, or governing board member of a person, is deemed to be an employee of the Department of Health and Human Services pursuant to paragraph (2).

''(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or governing board

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

''(4) NUMBER OF PERSONAL SERVICES CONTRACTS LIMITED.—The number of experts and consultants whose personal services are obtained under paragraph (1) shall not exceed 30 at any time.

''(f) STREAMLINED PERSONNEL AUTHORITY.—

''(1) IN GENERAL.—In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing research and development needs under this section, without regard to such provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, not to exceed 30 such employees at any time, to positions in the National Institutes of Health to perform, administer, or support biomedical countermeasure research and development in carrying out this section.

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

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

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

''(3) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for appointments under this subsection.

''(g) DEFINITION.—As used in this section, the term 'biomedical countermeasure' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that is used—

''(1) to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

''(2) to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in paragraph (1).

''(h) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions by the Secretary under the authority of this section are committed to agency discretion.''.

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

(1) in subsection (a)(1), by inserting ''or the Director of the National Institute of Allergy and Infectious Diseases'' after ''Director of the Center'';

(2) in subsection (c)—

(A) in paragraph (1), by inserting ''or the Director of the National Institute of Allergy and Infectious Diseases'' after ''Director of the Center''; and

(B) in paragraph (2), in the matter preceding subparagraph (A), by striking ''subsection (i)'' and inserting ''subsection (i)(1)'';

(3) in subsection (d), by inserting ''or the Director of the National Institute of Allergy and Infectious Diseases'' after ''Director of the Center'';

(4) in subsection (e)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by inserting ''or the Director of the National Institute of Allergy and Infectious Diseases'' after ''Director of the Center'';

(ii) in subparagraph (A), by inserting ''(or, in the case of the Institute, 75 percent)'' after ''50 percent''; and

(iii) in subparagraph (B), by inserting ''(or, in the case of the Institute, 75 percent)'' after ''40 percent'';

(B) in paragraph (2), by inserting ''or the Director of the National Institute of Allergy and Infectious Diseases'' after ''Director of the Center''; and

(C) in paragraph (4), by inserting ''of the Center or the Director of the National Institute of Allergy and Infectious Diseases'' after ''Director''; and

(5) in subsection (f)—

(A) in paragraph (1), by inserting ''in the case of an award by the Director of the Center,'' before ''the applicant''; and

(B) in paragraph (2), by inserting ''of the Center or the Director of the National Institute of Allergy and Infectious Diseases'' after ''Director''.

SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

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

''SEC. 319A–1. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

''(a) DETERMINATION OF MATERIAL THREATS.—

''(1) RISK OF USE.—The Secretary of Homeland Security, in consultation with the heads of other agencies as appropriate, shall on an ongoing basis—

''(A) assess current and emerging threats of use of chemical, biological, radiological, and nuclear agents; and

''(B) determine which of such agents present a material risk of use against the United States population.

''(2) PUBLIC HEALTH IMPACT.—The Secretary, in consultation with the Secretary of Homeland Security, shall on an ongoing basis—

''(A) assess the potential public health consequences of use against the United States population of agents identified under paragraph (1)(B); and

''(B) determine, on the basis of such assessment, the agents for which countermeasures are necessary to protect the public health.

''(b) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—The Secretary, in consultation with the Secretary of Homeland Security, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under subsection (a).

''(c) CALL FOR NECESSARY COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

''(1) PROPOSAL TO THE PRESIDENT.—Based on a determination of necessary countermeasures under subsection (a), and the assessment of availability and appropriateness of countermeasures under subsection (b), the Secretary of Homeland Security and the Secretary may jointly submit to the President a proposal to—

''(A) call for a necessary countermeasure that is not available; and

"(B) commit to make a recommendation for procurement under subsection (e) of the first such specific countermeasure that meets the conditions for procurement under subsection (d).

"(2) COUNTERMEASURE SPECIFICATIONS.—The Secretary of Homeland Security and the Secretary shall, to the extent practicable, include in the recommendation under paragraph (1)—

"(A) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

"(B) necessary measures of minimum safety and effectiveness;

"(C) estimated price for each dose or effective course of treatment regardless of dosage form; and

"(D) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

"(3) PRESIDENTIAL APPROVAL.—If the President has approved a request under paragraph (1),

the Secretary of Homeland Security and the Secretary shall make known to persons who may respond to a call for the countermeasure—

"(A) the call for the countermeasure;

"(B) specifications for the countermeasure under paragraph (2); and

"(C) a commitment for a recommendation for procurement under subsection (e) of the first such specific countermeasure that meets the conditions for procurement under subsection (d) and the specifications under paragraph (2).

"(4) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under subsection (f) of the first such specific countermeasure, or any other such countermeasure, that meets the conditions for procurement under subsection (d) and the specifications under paragraph (2) shall not preclude the additional procurement under subsection (f) of a subsequent such countermeasure that meets the conditions of procurement under subsection (d) if such a countermeasure provides improved safety or effectiveness or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent.

''(d) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR PROCUREMENT UNDER THIS SECTION.—

''(1) IN GENERAL.—The Secretary, in accordance with this section, shall identify specific countermeasures to threats identified under subsection (a) that the Secretary determines, in consultation with the Secretary of Homeland Security, to be appropriate for procurement with appropriations under this section for inclusion in the stockpile under section 121(a) of the Public Health and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 300hh–12(a)).

''(2) REQUIREMENTS.—In order for the Secretary to make the determination under paragraph (1) with respect to a countermeasure, the following requirements must be met:

''(A) DETERMINATION OF QUALIFIED COUNTERMEASURE.—The Secretary must determine that the product is a qualified countermeasure (as defined in subsection (h)).

''(B) DETERMINATION OF QUANTITIES NEEDED AND FEASIBILITY OF PRODUCTION AND DISTRIBUTION.—The Secretary must determine—

"(i) the quantities of the product that will be needed to meet the needs of the stockpile; and

"(ii) that production and delivery within 5 years of sufficient quantities of the product, as so determined, is reasonably expected to be feasible.

"(C) DETERMINATION OF NO SIGNIFICANT COMMERCIAL MARKET.—The Secretary shall—

"(i) determine that, at the time of the initial determination under this subsection, there is not a significant commercial market for the product other than as a biomedical countermeasure; and

"(ii) annually redetermine and report to the President, while a determination under paragraph (1) remains in effect with respect to the product, whether a significant commercial market exists for the product other than as a biomedical countermeasure.

"(e) RECOMMENDATION FOR PRESIDENT'S APPROVAL.—

"(1) RECOMMENDATION FOR PROCUREMENT.—In the case of a countermeasure that the Secretary

of Homeland Security and the Secretary have determined is appropriate for procurement under this section for inclusion in the stockpile, in accordance with the preceding provisions of this section, the Secretary of Homeland Security and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation for procurement under this section.

''(2) PRESIDENTIAL APPROVAL.—A countermeasure may be procured under this section only if the President has approved a recommendation under paragraph (1) with respect to such countermeasure.

''(3) NOTICE TO CONGRESS.—The Secretary of Homeland Security shall notify Congress of each decision of the President to approve a recommendation under paragraph (1).

''(f) PROCUREMENT.—The Secretary and the Secretary of Homeland Security shall be responsible for the following, for purposes of procurement of qualified countermeasures for the stockpile under section 121(a) of the Public Health and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 300hh–12(a)), as approved by the President under subsection (e):

''(1) IN GENERAL.—The Secretary shall be responsible for—

''(A) arranging for procurement of the countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, in accordance with the provisions of this paragraph; and

''(B) promulgating regulations to implement paragraphs (5), (6), and (7), and any other provisions of this section.

''(2) CONTRACT TERMS.—A contract for procurement under this section shall (or, as otherwise specified in this paragraph, may) include the following terms:

''(A) PAYMENT CONDITIONED ON SUBSTANTIAL DELIVERY.—The contract shall provide that no payment may be made until delivery has been made of a substantial portion (as determined by the Secretary) of the total number of units contracted for.

''(B) DISCOUNTED PAYMENT FOR UNLICENSED PRODUCT.—The contract may provide

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

''(C) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts appropriated under subsection (i) shall be available for costs of shipping, handling, storage, and related costs for such product.

''(D) CONTRACT DURATION.—The contract shall be for a period not to exceed 5 years, renewable for additional periods none of which shall exceed 5 years.

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

to terminate the contract, the contract may provide that the Secretary may terminate the contract for failure to deliver a reasonable number (as determined by the Secretary) of units of the product by 3 years after the date the contract is entered into, and may further provide that in such case the vendor shall not be entitled to any payment under the contract.

''(F) PRODUCT APPROVAL.—The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

''(3) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

''(A) IN GENERAL.—The amount of any procurement under this section shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pur-

suant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

"(i) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

"(ii) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

"(B) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subparagraph (A) and the provisions of law and regulations referred to in such subparagraph, each of the following provisions and implementing regulations shall apply to procurements described in this paragraph to the same extent that such provisions and regulations would apply to such procurements in absence of subparagraph (A):

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

"(ii) Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

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

"(iv) Section 3131 of title 40, United States Code (relating to bonds of contractors of public buildings or works).

"(v) Section 303G of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253g) (relating to limiting subcontractor sales).

"(vi) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen), other than the last sentence of such subsection.

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

"(viii) Section 1354 of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans' employment reporting requirements).

''(4) USE OF NONCOMPETITIVE PROCEDURES.—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures for a procurement under this section if the product is available from only one responsible source or only from a limited number of responsible sources, and no other type of product will satisfy such Secretary's needs.

''(5) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

''(A) IN GENERAL.—If, under this section, the Secretary enters into contracts with more than one person to procure a countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

''(i) identifies an increment of the total quantity of countermeasure required, whether by percentage or by numbers of units; and

''(ii) promises to pay one or more specified premiums based on the priority of such persons' production and delivery of the increment identified under clause (i),

in accordance with the terms and conditions of the contract.

''(B) DETERMINATION OF GOVERNMENT'S REQUIREMENT NOT REVIEWABLE.—If the Secretary includes in each of a set of contracts a provision as described in subparagraph (A), such Secretary's determination of the total quantity of countermeasure required, and any amendment of such determination, is committed to agency discretion.

''(6) EXTENSION OF CLOSING DATE FOR RECEIPT OF PROPOSALS NOT REVIEWABLE.—A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

''(7) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this section, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that such Secretary may so exclude such a source.

''(g) INTERAGENCY COOPERATION.—

''(1) IN GENERAL.—In carrying out activities under this section, the Secretary of Homeland Security and the Secretary are authorized, subject to paragraph (2), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

''(2) LIMITATION.—An agreement or undertaking under this subsection shall not authorize another agency to exercise the authorities provided by this section to the Secretary of Homeland Security or to the Secretary.

''(h) DEFINITIONS.—In this section:

''(1) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' means a biomedical countermeasure—

''(A) that is approved under section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of this Act (42 U.S.C. 262) or that is approved under section 515 or cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e and 360) for use as such a countermeasure to a chemical, biological, radiological, or nuclear agent identified as a material threat under subsection (a); or

"(B) for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from preclinical and clinical trials) support a reasonable conclusion that the product will qualify for approval or licensing as such a countermeasure within 5 years after the date of a determination under subsection (d).

"(2) BIOMEDICAL COUNTERMEASURE.—The term 'biomedical countermeasure' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))), or biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))) that is used—

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

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

product that is used as described in subparagraph (A).

''(i) APPROPRIATIONS.—

''(1) IN GENERAL.— There are authorized to be appropriated not to exceed $5,593,000,000 for the period of fiscal years 2004 through 2013 for the costs incurred by the Secretary in the procurement of countermeasures under this subsection as approved by the President under subsection (e) (other than costs specified in paragraph (2)). Of the amounts appropriated under the preceding sentence, not to exceed $3,418,000,000 may be obligated during the period of fiscal years 2004 through 2008, of which not to exceed $890,000,000 may be obligated during fiscal year 2004.

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

''(A) costs for the purchase of vaccines under procurement contracts entered into before January 1, 2003;

''(B) costs under new contracts, or costs of new obligations under contracts previously entered into, for procurement of a countermeasure after the date of a determination under subsection (d)(2)(C) that there is a significant

commercial market for the countermeasure other than as a biomedical countermeasure; or

''(C) administrative costs.''.

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

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

''SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

''(a) IN GENERAL.—Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, biological product, or device intended solely for use in an actual or potential emergency.

''(b) DECLARATION OF EMERGENCY.—

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

''(A) by the Secretary of Homeland Security, that there is a domestic emergency (or a significant potential of a domestic emergency) involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent;

''(B) by the Secretary of Defense, that there is a military emergency (or a significant potential of a military emergency) involving a heightened risk to United States military forces of attack with a biological, chemical, radiological, or nuclear agent; or

''(C) by the Secretary of a public health emergency under section 319 of the Public Health Service Act, affecting national security and involving a specified biological, chemical, radiological, or nuclear agent or a specified disease or condition that may be attributable to such agent.

''(2) TERMINATION OF DECLARATION.—

''(A) IN GENERAL.—A declaration under this subsection shall terminate upon the earlier of—

''(i) a determination by the Secretary, in consultation as appropriate with the

Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

''(ii) the expiration of the 1-year period beginning on the date on which the declaration is made.

''(B) RENEWAL.—Notwithstanding subparagraph (A), the Secretary may renew a declaration under this subsection, and this paragraph shall apply to any such renewal.

''(3) NOTIFICATION.—The Secretary shall promptly publish in the Federal Register, and shall notify the appropriate committees of Congress concerning, each declaration, determination, and renewal under this subsection.

''(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—The Secretary may issue an authorization under this section with respect to a product if the Secretary concludes—

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

''(2) that, based on the totality of scientific evidence available to the Secretary, including data from

adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

"(A) the product may be effective in detecting, diagnosing, treating, or preventing—

"(i) such disease or condition; or

"(ii) a serious or life-threatening disease or condition caused by a product authorized under this section or approved under this Act or the Public Health Service Act, for detecting, diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

"(B) the known and potential benefits of the product, when used to detect, diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

"(3) that there is no adequate, approved, and available alternative to the product for detecting, diagnosing, preventing, or treating such disease or condition; and

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

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

''(1) each disease or condition and the intended use of the product within the scope of the authorization; and

''(2) the Secretary's conclusions, under subsection (c), concerning the safety and potential effectiveness of the product in detecting, diagnosing, preventing, or treating such diseases or conditions, including an assessment of the available scientific evidence.

''(e) CONDITIONS OF AUTHORIZATION.—The Secretary is authorized to impose such conditions on an authorization under this section as the Secretary determines are necessary or appropriate to protect the public health, including the following:

''(1) The Secretary shall impose, to the maximum extent feasible given the circumstances of the emergency, requirements (including requirements concerning product labeling and the provision of information) designed to ensure that health care professionals administering the product are informed—

''(A) that the Secretary has authorized the product solely for emergency use;

''(B) of the significant known and potential benefits and risks of use of the product,

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

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

''(2) The Secretary shall impose, to the maximum extent feasible given the circumstances of the emergency, requirements (including requirements concerning product labeling and the provision of information) designed to ensure that individuals to whom the product is administered are informed—

''(A) that the Secretary has authorized the product solely for emergency use;

''(B) of the significant known and potential benefits and risks of use of the product, and of the extent to which such benefits and risks are unknown; and

''(C) of any option to accept or refuse administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

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

''(4) The Secretary may impose limitations on who may administer the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered.

''(5) The Secretary may condition the authorization on the performance of studies, clinical trials, or other research needed to support marketing approval of the product.

''(6) The Secretary shall impose, to the extent feasible and appropriate given the circumstances of the emergency, requirements concerning recordkeeping and reporting, including records access by the Secretary and publication of data.

''(7) The Secretary may waive, to the extent appropriate given the circumstances of the emergency, requirements, with respect to the product, of current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act.

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

''(f) DURATION OF AUTHORIZATION.—

''(1) IN GENERAL.—Except as provided in paragraph (2), an authorization under this section shall be effective until the earlier of the termination of the declaration under subsection (b) or a revocation under subsection (g).

''(2) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—An authorization shall continue to be effective for continued use with respect to patients to whom it was administered during the period described by paragraph (1), to the extent found necessary by such patients' attending physicians.

''(g) REVOCATION OF AUTHORIZATION.—

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

''(2) REVOCATION.—The Secretary may revoke an authorization under this section if, in the Secretary's unreviewable discretion—

''(A) the conditions for such an authorization are no longer met; or

''(B) other circumstances make such revocation appropriate.

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

priate committees of Congress, a notice of each authorization, and each termination or revocation of an authorization, under this section.

''(i) RECORDKEEPING.—

''(1) IN GENERAL.—The Secretary may require persons, including a person who holds an authorization under this section, or who manufactures, distributes, prescribes, or administers a product that is the subject of such an authorization, to establish and maintain—

''(A) data that is obtained from such activity and that pertains to the effectiveness or safety of such product;

''(B) such records as are necessary to determine, or facilitate a determination, whether there may be any violation of this section or of a regulation promulgated under this section; and

''(C) such additional records as the Secretary may determine necessary.

''(2) ACCESS TO RECORDS BY SECRETARY.—

''(A) SAFETY AND EFFECTIVENESS INFORMATION.—The Secretary may require a person who holds an authorization under this section, or who manufactures, distributes, prescribes, or

administers a product that is the subject of such an authorization to provide to the Secretary all data that is obtained from such activity and that pertains to the safety or effectiveness of such product.

''(B) OTHER INFORMATION.—Every person required under this section to establish or maintain records, and every person in charge or custody of such records, shall, upon request by the Secretary, permit the Secretary at all reasonable times to have access to, to copy, and to verify such records.

''(j) CIVIL MONETARY PENALTIES.—

''(1) IN GENERAL.—A person who violates a requirement of this section or of a regulation or order promulgated pursuant to this section shall be subject to a civil money penalty of not more than $100,000 in the case of an individual, and not more than $250,000 in the case of any other person, for each violation, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

''(2) ASSESSMENT OF CIVIL PENALTIES.—Paragraphs (3), (4), and (5) of section 303(g) shall apply to a civil penalty under this subsection, and references in such paragraphs to 'paragraph (1) or (2)'

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

''(k) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

''(l) REGULATIONS.—The Secretary may promulgate regulations to implement this section.

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

''(1) the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution; or

''(2) the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law.

''(n) APPLICATION TO MEMBERS OF ARMED FORCES.—

''(1) WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.—

''(A) IN GENERAL.—In the case of the administration of a product to members of the

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

''(B) PROVISION OF INFORMATION TO MEMBER.—If the Secretary makes a determination that it is not feasible for the information required by subparagraphs (A) and (B) of subsection (e)(2) to be provided prior to the administration of the product, such information shall be provided to members of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after administration. Information concerning the administration of the product shall be recorded in the medical record of the member.

''(2) EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.—In the case of an authorization based on a determination by the Sec-

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

''(o) RELATION TO OTHER PROVISIONS.—If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization—

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

''(2) shall not be subject to any requirements otherwise applicable to clinical investigations pursuant to other provisions of this Act.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsection (e)—

(A) by striking ''504, 703'' and inserting ''504, 564, 703''; and

(B) by striking ''or 519'' and inserting ''519, or 564''; and

(2) by adding at the end the following:

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

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

''(2) Failure to comply with an information requirement under section 564(e).''.

SEC. 5. AUTHORITY OF THE SECRETARY OF HEALTH AND HUMAN SERVICES DURING NATIONAL EMERGENCIES.

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

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

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

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

''(B) the direction or relocation of an individual to receive medical screening in an alternate location pursuant to an appropriate State emergency preparedness plan;'';

(2) in paragraph (5), by striking ''and'' at the end;

(3) in paragraph (6), by striking the period and inserting ''; and'';

(4) by inserting after paragraph (6), the following:

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

''(A) section 164.510 of title 45, Code of Federal Regulations, relating to—

''(i) requirements to obtain a patient's agreement to speak with family members or friends; and

''(ii) the requirement to honor a request to opt out of the facility directory;

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

''(C) section 164.522 of such title, relating to—

''(i) the patient's right to request privacy restrictions; and

''(ii) the patient's right to request confidential communications.''; and

(5) by adding at the end the following: ''A waiver or modification provided for under paragraph (7) shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification under such paragraph (7) shall be withdrawn after such period and the provider shall comply with the requirements under such paragraph for any patient still under the care of the provider.''.

SEC. 6. GAO REPORT.

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

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

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

(3) assesses the adequacy of the internal controls established by the Secretary of Health and Human Services regarding procurements made

under the authorities provided for in the sections described in paragraph (1).

SEC. 7. FUNDING FOR PROJECT BIOSHIELD.

In the Senate, for purposes of points of order under a concurrent resolution on the budget and the Congressional Budget Act of 1974, provisions contained in any bill, resolution, amendment, motion, or conference report that change the availability of any amounts appropriated pursuant to this Act (or an amendment made by this Act) shall not be scored with respect to the level of budget authority or outlays contained in such bill, resolution, amendment, motion, or conference report.

Calendar No. 265

108TH CONGRESS
1ST SESSION

S. 1504

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.

SEPTEMBER 2, 2003

Read the second time and placed on the calendar