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1st Session } { Part 2

PROJECT BIOSHIELD ACT OF 2003

JUNE 12, 2003.—Ordered to be printed

Mr. TOM DAVIS of Virginia, from the Committee on Government Reform, submitted the following

R E P O R T

[To accompany H.R. 2122]

[Including cost estimate of the Congressional Budget Office]

The Committee on Government Reform, to whom was referred the bill (H.R. 2122) to enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

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

"SEC. 319F–1. AUTHORITY FOR USE OF CERTAIN PROCEDURES REGARDING BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT ACTIVITIES.

"(a) IN GENERAL.—

"(1) AUTHORITY.—In conducting and supporting research and development activities regarding biomedical countermeasures under section 319F(h), the Secretary may conduct and support such activities in accordance with this section if the activities concern qualified countermeasures.

"(2) QUALIFIED COUNTERMEASURE.—For purposes of this section, the term 'qualified countermeasure' means a priority countermeasure (as defined in section 319F(h)) that affects 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 United States Government.

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

"(4) 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 qualified countermeasure 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.

"(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 qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, 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 provision of law and regulations referred to in such subparagraph, each of the following provisions shall apply to procurements described in this paragraph to the same extent that such provisions would apply to such procurements in the 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).

"(C) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for procurements that are under this paragraph, including requirements with regard to documenting the justification for use of the authority in this paragraph.

"(2) OTHER THAN FULL AND OPEN COMPETITION.—(A) In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procurement described in paragraph (1) of this subsection, the phrase 'available from only one responsible source' in such section 303(c)(1) shall be deemed to mean 'available from only one responsible source or only from a limited number of responsible sources'.

"(B) The authority under subparagraph (A) is in addition to any other authority to use procedures other than competitive procedures.

"(C) The Secretary shall implement this paragraph in accordance with applicable government-wide regulations, including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered.

"(3) INCREASED MICROPURCHASE THRESHOLD.—

"(A) IN GENERAL.—For a procurement described by paragraph (1), 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 purchases that are 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 Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than $2,500.

"(c) AUTHORITY TO EXPEDITE PEER REVIEW.—

"(1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure 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, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would 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—

"(A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and

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

"(2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary's determination of whether to employ expedited peer review with respect to subsequent phases of a research grant or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant or cooperative agreement.

"(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

"(1) IN GENERAL.—For the purpose of performing, administering, and supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure 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, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.

"(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.

"(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.

"(e) 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 qualified countermeasure 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 qualified countermeasure research and development activities in carrying out this section.

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

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

"(g) EFFECT ON RIGHT TO FILE PROTEST.—Nothing in this section shall affect the right of an interested party to file a protest with the contracting agency, to file a protest with the Comptroller General under subchapter V of chapter 35 of title 31, United States Code, or to file an action in the United States Court of Federal Claims under section 1491(b) of title 28, United States Code.".

(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";

(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"; and

(6) in subsection (i)—

(A) by striking "APPROPRIATIONS.—For the purpose of carrying out this section," and inserting the following: "APPROPRIATIONS.—

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

(B) by adding at the end the following:

"(2) NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.—For the purpose of carrying out this section with respect to the National Institute of Allergy and Infectious Diseases, there are authorized to be appropriated such sums as may be necessary for fiscal year 2003.".

SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

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

"SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE.

"(a) STRATEGIC NATIONAL STOCKPILE.—

"(1) IN GENERAL.—The Secretary of Homeland Security (referred to in this section as the 'Homeland Security Secretary'), in coordination with the Secretary and the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

"(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

"(A) consult with the working group under section 319F(a);

"(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

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

"(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

"(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

"(F) ensure the adequate physical security of the stockpile.

"(b) SMALLPOX VACCINE DEVELOPMENT.—

"(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

"(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

"(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN BIOMEDICAL COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

"(1) IN GENERAL.—

"(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund under paragraph (10).

"(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term 'security countermeasure' means a priority countermeasure (as defined in section 319F(h))—

"(i) that affects national security;

"(ii) that is determined under paragraph (2)(B)(ii) to be a necessary countermeasure; and

"(iii)(I) that is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act, or licensed under section 351 of this Act, for use as a countermeasure to a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii); or

"(II) for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing after the date of a determination under paragraph (5).

"(2) DETERMINATION OF MATERIAL THREATS.—

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

"(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

"(ii) determine which of such agents present a material threat against the United States population.

"(B) PUBLIC HEALTH IMPACT; NECESSARY COUNTERMEASURES.—The Secretary shall on an ongoing basis—

"(i) assess the potential public health consequences of use against the United States population of agents identified under subparagraph (A)(ii); and

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

"(3) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

"(4) CALL FOR SECURITY COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

"(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a security countermeasure would be appropriate, such Secretaries may jointly submit to the President a proposal to—

"(i) issue a call for the development of such security countermeasure; and

"(ii) make a commitment that, upon the first development of such security countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund under paragraph (10) be made available for the procurement of such security countermeasure.

"(B) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

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

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

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

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

"(C) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the security countermeasure involved—

"(i) the call for the countermeasure;

"(ii) specifications for the countermeasure under subparagraph (B); and

"(iii) a commitment described in subparagraph (A)(ii).

"(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

"(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund under paragraph (10) (referred to in this subsection individually as a 'procurement under this subsection').

"(B) REQUIREMENTS.—In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

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

"(ii) The feasibility of production and delivery within five years of sufficient quantities of the product.

"(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

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

"(A) RECOMMENDATION FOR PROCUREMENT.—In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (2), (3), and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of

Management and Budget, a recommendation that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

"(B) PRESIDENTIAL APPROVAL.—The special reserve fund under paragraph (10) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

"(C) NOTICE TO CONGRESS.—The Secretary and the Homeland Security Secretary shall notify the Congress of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund under paragraph (10) for procurement of such a countermeasure, including, where available, the identification of the potential supplier or suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

"(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such 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. Such a determination by the Secretary is committed to agency discretion.

"(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund under paragraph (10) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

"(7) PROCUREMENT.—

"(A) IN GENERAL.—For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

"(B) INTERAGENCY AGREEMENTS.—

"(i) FOR PROCUREMENT.—The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund under paragraph (10) shall be available for the Secretary's costs of such procurement, other than as provided in clause (ii).

"(ii) FOR ADMINISTRATIVE COSTS.—The agreement entered into between the Homeland Security Secretary and the Secretary for managing the stockpile under subsection (a) shall provide for reimbursement of the Secretary's administrative costs relating to procurements under this subsection.

"(C) PROCUREMENT.—

"(i) IN GENERAL.—The Secretary shall be responsible for—

"(I) arranging for procurement of a security 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 subparagraph; and

"(II) promulgating regulations to implement clauses (v), (vi), and (vii), and any other provisions of this subsection.

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

"(I) 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, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide

that such advance payment is required to be repaid if there is a failure to perform under the contract, except in special circumstances as determined by the Secretary on a contract by contract basis.

"(II) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding eight years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

"(III) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund under paragraph (10) shall be available for costs of shipping, handling, storage, and related costs for such product.

"(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

"(I) IN GENERAL.—If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection 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, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

"(aa) 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

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

"(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

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

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

"(cc) 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) OTHER THAN FULL AND OPEN COMPETITION.—(I) In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase 'available from only one responsible source' in such section 303(c)(1) shall be deemed to mean 'available from only one responsible source or only from a limited number of responsible sources'.

"(II) The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

"(III) The Secretary shall implement this clause in accordance with applicable government-wide regulations, including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered.

"(v) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

"(I) IN GENERAL.—If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

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

"(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

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

"(vi) 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.

"(vii) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, 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 the Secretary may so exclude such a source.

"(8) INTERAGENCY COOPERATION.—

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

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

"(9) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund under paragraph (10) shall not be used to pay—

"(A) costs for the purchase of vaccines under procurement contracts entered into before the date of the enactment of the Project BioShield Act of 2003; or

"(B) administrative costs.

"(10) SPECIAL RESERVE FUND.—For purposes of this subsection, the term 'special reserve fund' has the meaning given such term in section 510 of the Homeland Security Act of 2002.

"(d) DISCLOSURES.—No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

"(e) DEFINITION.—For purposes of subsection (a), the term 'stockpile' includes—

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

"(2) a contractual agreement between the Homeland Security Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

"(f) AUTHORIZATION OF APPROPRIATIONS.—

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

"(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.".

(b) AMENDMENT TO HOMELAND SECURITY ACT OF 2002.—Title V of the Homeland Security Act of 2002 (116 Stat. 2212; 6 U.S.C. 311 et seq.) is amended by adding at the end the following:

"SEC. 510. PROCUREMENT OF SECURITY COUNTERMEASURES FOR STRATEGIC NATIONAL STOCKPILE.

"(a) AUTHORIZATION OF APPROPRIATIONS.—For procurement of security countermeasures under section 319F–2(c) of the Public Health Service Act (referred to in this section as the 'security countermeasures program'), there is authorized to be appropriated up to $5,593,000,000 for the fiscal years 2004 through 2013. Of the amounts appropriated under the preceding sentence, not to exceed $3,418,000,000 may be obligated during the fiscal years 2004 through 2008, of which not to exceed $890,000,000 may be obligated during fiscal year 2004.

"(b) SPECIAL RESERVE FUND.—For purposes of the security countermeasures program, the term 'special reserve fund' means the appropriations account established as a result of any appropriations made under subsection (a).

"(c) AVAILABILITY.—

"(1) DURATION OF AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2), all amounts appropriated under subsection (a) are available for obligation through the end of fiscal year 2013, provided that any portion of such amount that remains unobligated for such purposes on the expiration of such term shall be returned to the United States Treasury and shall not be available for subsequent obligation for any purpose.

"(2) INITIAL AVAILABILITY FOR PARTICULAR PROCUREMENTS.—Amounts appropriated under subsection (a) become available for a procurement under the security countermeasures program only upon the approval by the President of such availability for the procurement in accordance with paragraph (6)(B) of such program.".

(c) CONFORMING AMENDMENTS.—(1) Section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (116 Stat. 611; 42 U.S.C. 300hh–12) is repealed.

(2) The item relating to section 121 in the table of contents (contained in section 1(b)) of such Act is repealed.

(3) With respect to the program established under former section 121 of such Act, the repeal of such section under paragraph (1) applies as a modification of the program in accordance with the amendment made by subsection (a) of this section, and not as the termination of the program and the establishment of a different program.

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

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 section:

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

"(a) IN GENERAL.—

"(1) EMERGENCY USES.—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 or device intended for use in an actual or potential emergency (referred to in this section as an 'emergency use').

"(2) APPROVAL STATUS OF PRODUCT.—An authorization under paragraph (1) may authorize an emergency use of a product that—

"(A) is not approved, licensed, or cleared for commercial distribution under a provision of law referred to in such paragraph (referred to in this section as an 'unapproved product'); or

"(B) is approved, licensed, or cleared under such a provision, but which use is not under such provision an approved, licensed, or cleared use of the product (referred to in this section as an 'unapproved use of an approved product').

"(3) RELATION TO OTHER USES.—An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a provision of law referred to in such paragraph.

"(4) DEFINITIONS.—For purposes of this section:

"(A) The term 'emergency use' has the meaning indicated for such term in paragraph (1).

"(B) The term 'product' means a drug or device.

"(C) The term 'unapproved product' has the meaning indicated for such term in paragraph (2)(A).

"(D) The term 'unapproved use of an approved product' has the meaning indicated for such term in paragraph (2)(B).

"(b) DECLARATION OF EMERGENCY.—

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

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

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

"(C) a determination 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 agents, or a specified disease or condition that may be attributable to such agent or agents.

"(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 one-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) ADVANCE NOTICE OF TERMINATION.—In terminating a declaration under this section, the Secretary shall provide advance notice that the declaration will be terminated. The period of advance notice shall be a period reasonably determined to provide—

"(A) in the case of an unapproved product, a sufficient period for disposition of shipments of the product, including the return of such shipments to the manufacturer (in the case of a manufacturer that chooses to have the shipments returned); and

"(B) in the case of unapproved uses of approved products, a sufficient period for the disposition of any labeling that was provided with respect to the emergency use involved.

"(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register 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 the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention, to the extent feasible and appropriate given the circumstances of the emergency involved, 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.—

"(1) IN GENERAL.—An authorization of a product under this section shall state—

"(A) each disease or condition that the product may be used to detect, diagnose, prevent, or treat within the scope of the authorization;

"(B) the Secretary's conclusions, made under subsection (c)(2)(B), that 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; and

"(C) the Secretary's conclusions, made 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.

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

"(e) CONDITIONS OF AUTHORIZATION.—

"(1) UNAPPROVED PRODUCT.—

"(A) REQUIRED CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, shall, for persons who choose to carry out one or more activities for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

"(i) Appropriate conditions designed to ensure that, to the extent feasible given the circumstances of the emergency, health care professionals administering the product are informed—

"(I) that the Secretary has authorized the emergency use of the product;

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

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

"(ii) Appropriate conditions designed to ensure that, to the extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed—

"(I) that the Secretary has authorized the emergency use of the product;

"(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

"(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

"(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

"(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

"(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, may, for persons who choose to carry out one or more activities for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

"(i) Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

"(ii) Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use.

"(iii) For persons other than manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

"(iv) With respect to the emergency use of the product, waive or limit, to the extent appropriate given the circumstances of the emergency, conditions regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including such requirements established in section 501.

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

"(A) The Secretary may, for manufacturers of the product who choose to carry out one or more activities for which the authorization is issued, establish any of the conditions described in clauses (i) through (iv) of paragraph (1)(A).

"(B)(i) If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change, such authorization may not authorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer.

"(ii) In the circumstances described in clause (i), an authorization under this section regarding the emergency use may, for persons who do not manufacture the product and who choose to act under this clause, authorize such persons to provide information on the product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). Such additional information shall not be considered labeling for purposes of section 502.

"(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, the criteria under subsection (c) for issuance of such authorization are no longer met.

"(h) PUBLICATION.—The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons therefor, under this section.

"(i) 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.

"(j) RULES OF 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;

"(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; or

"(3) the authority of the Secretary under section 319F–2 to manage the stockpile under such section.

"(k) APPLICATION TO MEMBERS OF ARMED FORCES.—

"(1) WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.—In the case of administration of a countermeasure to members of the armed forces, a requirement, under subsection (e)(1)(A)(ii)(III), 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.

"(2) PROVISION OF INFORMATION TO MEMBER OF THE ARMED FORCES.—If the Secretary makes a determination that it is not feasible for the information required by subsection (e)(1)(A)(ii) to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member 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 such administration. Information concerning the administration of the product shall be recorded in the medical record of the member.

"(3) EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.—In the case of an authorization based on a determination by the Secretary 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.

"(l) 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.

"(m) DISCRETION REGARDING USE OF AUTHORIZATION.—Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall notify the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out an activity or activities under the authorization. This section does not have any legal effect on a person who does not carry out any activity for which an authorization under this section is issued, or who carries out such an activity pursuant to other provisions of this Act or section 351 of the Public Health Service Act.

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

SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS ACT.

(a) SECRETARY OF HEALTH AND HUMAN SERVICES.—

(1) ANNUAL REPORTS ON PARTICULAR EXERCISES OF AUTHORITY.—

(A) RELEVANT AUTHORITIES.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall submit reports in accordance with subparagraph (B) regarding the exercise of authority under the following provisions of law:

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

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

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

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

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

(I) Subsection (c)(7)(C)(iii) (relating to simplified acquisition procedures).

(II) Subsection (c)(7)(C)(iv) (relating to use of noncompetitive procedures).

(III) Subsection (c)(7)(C)(v) (relating to premium provision in multiple-award contracts).

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

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

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

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

(B) CONTENTS OF REPORTS.—The Secretary shall annually submit to the Congress a report that summarizes—

(i) the particular actions that were taken under the authorities specified in subparagraph (A), including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities; and

(iii) the identification of each person or entity that received, or was considered and rejected for, grants, cooperative agreements, or contracts pursuant to the use of such authorities.

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

(A) Subsection (b)(3) (relating to increased micropurchase threshold).

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

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

With respect to subparagraph (B), the report shall include a provision specifying, for the one-year period for which the report is submitted, the number of persons who were paid amounts greater than $100,000 and the number of persons who were paid amounts between $50,000 and $100,000.

(b) NATIONAL ACADEMY OF SCIENCES REVIEW.—Not later than three years after the date of the enactment of this Act, the Secretary of Health and Human Services shall request the National Academy of Sciences to enter into an agreement for a review of the biomedical countermeasure research and development authorities established in this Act to determine whether and to what extent activities undertaken pursuant to such authorities have enhanced the development of biomedical countermeasures affecting national security, and to recommend any legislative or administrative changes necessary to improve the ability of the Secretary to carry out these activities in the future. The Secretary shall ensure that the results of the study are submitted to the Congress not later than five years after such date of enactment.

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

(1)(A) to review the Secretary of Health and Human Services' utilization of the authorities granted under this Act with respect to simplified acquisition procedures, use of noncompetitive procedures, increased micropurchase thresholds, personal services contracts, streamlined personnel authority, and the purchase of security countermeasures under the special reserve fund; and

(B) to recommend any legislative or administrative changes necessary to improve the utilization or effectiveness of such authorities in the future;

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

(B) to recommend any legislative or administrative changes necessary to improve the effectiveness of such controls; and

(3)(A) to review such Secretary's utilization of the authority granted under this Act to authorize an emergency use of a biomedical countermeasure, including the means by which the Secretary determines whether and under what conditions any such authorizations should be granted and the benefits and adverse impacts, if any, resulting from the use of such authority; and

(B) to recommend any legislative or administrative changes necessary to improve the utilization or effectiveness of such authority and to enhance protection of the public health.

The results of the study shall be submitted to the Congress not later than five years after the date of the enactment of this Act.

COMMITTEE STATEMENT AND VIEWS

PURPOSE

The purpose of H.R. 2122, the "Project Bioshield Act of 2003," is to accelerate the research, development, purchase, and availability of countermeasures to combat bioterrorist threats that could cause public health emergencies affecting national security. While recent decades have yielded rapid progress in the treatment of many serious naturally occurring diseases, there has been little improvement in the medical treatments available to combat potential bioterrioist threats. Many countermeasures for potential agents of terrorism, including smallpox, anthrax, botulinum toxin, ebola and the plague, realistically have no market other than the government and, thus, have not generated significant manufacturer interest. However, should the United States be attacked with these deadly pathogens, the need for vaccines and antitoxins would be great and immediate.

BACKGROUND AND NEED FOR LEGISLATION

The anthrax attacks that occurred in October 2001 highlighted the nation's vulnerability to bioterrorism. Letters laced with anthrax caused the deaths of five individuals and thousands more received treatment. The death toll could have been higher if there

had not been effective countermeasures to treat that particular form of anthrax. However, no such countermeasures currently exist for many of the biological threats that are considered the most dangerous by the Centers for Disease Control and Prevention. For example, botulinum toxin, plague, tularemia, and many viral hermorrhagic fevers lack licensed vaccines.[1]

The scarcity of countermeasures to combat bioterrorism can be attributed to the lack of a significant commercial market.[2] Because these diseases occur infrequently, there has been little economic incentive for pharmaceutical and biotech companies to make the significant investment required to bring new treatments to market. To promote the development of new countermeasures to combat bioterrorism, President Bush proposed Project Bioshield in his 2003 State of the Union address. H.R. 2122 is modeled after this proposal and would provide expedited procedures for bioterrorism-related procurement and research and development.

The bill has three main provisions. First, it would provide the Secretary of the Department of Health and Human Services (HHS) with streamlined authorities to promote the research and development of drugs and other products needed to protect Americans in the event of a bioterrorist attack. As a result, should the Secretary determine that there is pressing need to develop these products, the Secretary would be able to use simplified acquisition tools for research and development projects and would have expedited authorities to award research grants and to hire technical experts and consultants.

Second, the bill authorizes the procurement of biomedical countermeasures for the nation's stockpile using a special reserve fund. The bill authorizes $5.93 billion for fiscal years 2004 to 2013 for this fund. The Secretary of HHS and the Secretary of the Department of Homeland Security would be required to work together to recommend to the President the countermeasures that are needed for the stockpile. Procurements of countermeasures using the special reserve fund could only be made with the approval of the President. If the Secretary of HHS determines there is a pressing need to acquire certain products, the Secretary could use simplified acquisition procedures for the procurement of biomedical countermeasures.

Nothing in these provisions would limit the use of existing authorities of the Secretary of HHS and the Secretary of the Department of Homeland Security to enter into an agreement that provides for research and development as well as production of a countermeasure or vaccine under a single procurement, where such a single agreement (including a contract, grant, cooperative agreement, or other acquisition instrument) for research, development, and production of a countermeasure or vaccine is deemed appropriate by the proper official. This would include instances when a separate funding source is authorized and used for the research and development and that funding is different than the funding

[1] NIAID Biodefense Research Agenda for CDC Category A Agents, Responding through Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services (February 2002).

[2] Project Bioshield: Contracting for the Health and Security of the American Public: Committee on Government Reform, 108th Congress (April 4, 2003) (Statement of Dr. Mark B. McClellan, Commissioner, Food and Drug Administration and Dr. Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health).

source authorized and used for production. The Committee recognizes that such agreements providing express linkage between research, development, and production are likely to encourage entities to enter the government market for countermeasures and vaccines in accordance with the authorities provided by the "Project Bioshield Act" and urges their use where appropriate.

The Committee notes that the authorities that can be used by the Secretary of HHS in title XIV, Section 1451 of H.R. 1588 and provided to the Secretary of the Department of Homeland Security in title VIII, Section 831 of the Homeland Security Act of 2002 are applicable to research and development (including the development of a prototype) conducted under this Act.[3]

The third provision of the bill provides that in the event of a national emergence, the government would be authorized to make available new and promising treatments prior to approval by the Food and Drug Administration (FDA). The government may exercise this authority if the product is in the approval process and is urgently needed because no adequate alternatives exist. There also must be a reasonable basis to conclude that the countermeasure will be effective and that the benefits of the product outweigh the risks. Although this provision would permit the avoidance of the FDA approval process, its use should be limited to dire circumstances.

The Committee is aware of the growing problem of naturally occurring infections becoming increasingly resistant to existing antimicrobial drug products. Antimicrobial resistance is the phenomenon whereby infectious microbes mutate and become less susceptible to treatment with currently approved drugs.[4] In the hands of bioterrorists, these organisms can be used to affect national security and accordingly should be considered a material threat under Project Bioshield. For example, published documents describe how the Russians produced antibiotic-resistant anthrax.[5] However, the Committee understands that there has been limited progress in the development of countermeasures to combat the emergency of antimicrobial-resistant organisms.[6] One reason may be that the market for the few cases of multi-drug resistant bacteria is currently quite small. Success in developing appropriate countermeasures to treat emerging antibiotic resistant organisms could thwart attempts to use these organisms for bioterrorism. Inclusion of organisms with emerging antibiotic resistance within the lift of biological threats contemplated by Project Bioshield should permit acceleration of research for and government procurement of new drugs and vaccines to treat or prevent infections caused by these agents.

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[3] The Homeland Security Act of 2002, Public Law 107–296; 116 Stat. 2224.

[4] Project Bioshield: Contracting for the Health and Security of the American Public: Committee on Government Reform, 108th Congress (April 4, 2003) (Statement of Dr. John E. Edwards on behalf of the Infectious Diseases Society of America).

[5] AV Stepanov, LI Marinin, AP Pomerantsev, NA Staritsin, Development of Novel Vaccines Against Anthrax in Man, J Biotechnol, Jan. 26, 1996.

[6] Microbial Threats to Health Emergence, Detection, and Response, Committee on Emerging Microbial Threats to Health in the 21st Century, Board on Global Health, (Mark S. Smolinski et al. eds., The National Academies Press forthcoming 2003). According to this publication, in the past three decades, only two new classes of antibiotics have been developed, and resistance to one class emerged even before the drugs entered the commercial marketplace. Only four large pharmaceutical companies with antibiotic research programs remained in existence in 2002 and not one new class of antibiotics is in advanced development.

COMMITTEE HEARINGS AND TESTIMONY

The Committee on Government Reform held a hearing to consider the "Project Bioshield Act" on April 4, 2003. The committee heard testimony from the following witnesses: Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Dr. Mark McClellan. Commissioner, Food and Drug Administration; Michael Brown, Under Secretary for Emergency Preparedness and Response, Department of Homeland Security; Dr. Dale Klein, Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense Programs, Department of Defense. The Committee also heard from experts representing the pharmaceutical and biotech industries. These witnesses included Frank Rapoport, attorney at law, representing Aventis Pasteur; Dr. Michael Friedman, Chief Medical Officer for Biomedical Preparedness, Pharmaceutical Research and Manufacturers of America; Dr. Una Ryan, President, AVANT Immunotherapeutics, Inc.; Katherine Bowdish, Ph.D., President, Alexion Antibody Technologies; and Dr. John Edwards, Chief of Infectious Diseases, Harbor-UCLA Medical Center, on behalf of the Infectious Diseases Society of America.

The witnesses were supportive of the bill. They generally agreed with the need to create incentives for manufacturers to develop biomedical countermeasures through the creation of a government market. The witnesses from the pharmaceutical and biotech industries offered suggestions to amend the bill. Specifically, Mr. Rapoport suggested including language to clarify that the government is authorized to enter into single procurement contracts for research, development and production. He also suggested including additional contracting flexibility through "other transaction" authority for research and development contracts similar to the authority that is used by the Department of Defense. Witnesses also discussed the need for the bill to include liability protection for manufacturers to further encourage companies to develop countermeasures. Dr. Edwards testified about the need for the bill to cover the development of countermeasures to combat naturally occurring diseases that have become resistant to antimicrobial products.

SECTION-BY-SECTION ANALYSIS

Section 1. Short title

The short title of the bill is the "Project Bioshield Act of 2003."

Section 2. Biomedical countermeasure research and development authorities

This section would amend the Public Health Service Act to grant the Secretary of Health and Human Services (HHS) additional flexibility and authority to conduct research and development of drugs, vaccines and other products to combat biological, chemical, nuclear, and radiological agents that may affect national security.

Expedited procurement authority

This section provides the Secretary of HHS with enhanced procurement authorities to perform, administer, or support biomedical countermeasure research and development. The simplified acquisition threshold would be increased from $100,000 to $25 million for

the purchase of property or services the Secretary determines are needed to perform pressing biomedical countermeasure research and development. The simplified acquisition procedures have been in law since the mid-1990s and are designed to promote efficiency and economy in contracting and to avoid unnecessary burdens for agencies and contractors. Procurements by the Secretary of HHS of products or services under the simplified acquisition threshold would be subject to contract work hours and safety standards, anti-kickback rules, and provisions authorizing the examination of contractor records. Additionally, the Secretary would be required to institute internal controls for procurements made under this authority, including documenting the justification for use of the simplified procedures.

After making the required determination of pressing need, the Secretary of HHS would also be authorized to use other than competitive procedures for procurements of biomedical countermeasures when there are only a limited number of responsible sources and no other type of property or services will satisfy the Secretary's needs. For the purposes of using other than competitive procedures in this section, the phrase in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949, "available from only one responsible source" shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources." The other than competitive procedures authorized under this section are to be implemented in accordance with the justification and approval provisions of 41 U.S.C. 253(f) and the notice provisions of 41 U.S.C. 416. This expanded authority would be in addition to any other authority to use procedures other than competitive procedures.

This section also increases the micropurchase threshold from $2,500 to $15,000 for the procurement of property or services that are determined to be necessary for pressing countermeasure research and development. The Secretary would be required to institute internal controls for purchases greater than $2,500.

Authority to expedite peer review

The Secretary would be authorized to expedite the award process for grants, contracts, and cooperative agreements for biomedical countermeasure research and development if the Secretary deems there is a pressing need for the expedited award. This authority would be limited to awards of not more than $1.5 million and would give the Secretary greater flexibility to determine which research projects would be funded. Peer review is designed to maximize the chances that only proposals with the greatest scientific merit receive funding. The normal peer review process to consider grant proposals may take up to one year.

Authority for personal services contracts and streamlined personnel authority

This section would also give the Secretary streamlined and flexible personnel authorities for the purpose of performing, administering, and supporting qualified countermeasure research and development. Under these authorities, the Secretary could hire experts or consultants, without regard to limitations on service or pay. The Secretary could also appoint professional or technical em-

ployees to perform pressing countermeasure research and development without regard to provisions in Title 5 of the U.S. Code governing classification, pay rates, and appointments in the competitive service.

The authorities in this section would be committed to agency discretion. However, interested parties would have the authority to protest contracting decisions to the contracting agency, the General Accounting Office or the Federal Court of Claims.

Section 3. Biomedical countermeasures procurement

Procurement of certain biomedical countermeasures and availability of special reserve fund

Section 3 addresses the procurement of biomedical countermeasures for inclusion in the National stockpile. The section would require the government to follow certain procedures to determine whether to buy biomedical countermeasures from a special reserve fund created by the Act. The Secretary of the Department of Homeland Security (DHS) would be required to assess threats to the U.S. population that are posed by the use of chemical, biological, radiological, and nuclear agents. The Secretary of HHS would be required to assess the public health consequences of the use of such agents and the availability and appropriateness of countermeasures to combat the threats. After performing this analysis, both the Secretary of HHS and DHS could jointly recommend that the President procure countermeasures for the Nation's stockpile, using the special reserve fund. Nothing in the Act would restrict or alter existing authority to purchase items for the stockpile using existing discretionary appropriations for such purpose.

If the President approves the recommendation to procure a countermeasure from the special reserve fund, the Secretaries would enter into an agreement under which the Secretary of HHS would procure the countermeasure for the stockpile using the special reserve fund maintained by the Department of Homeland Security. The Secretaries would be required to notify Congress of decisions to procure a countermeasure.

Under the Act, contractors could generally not be paid until a substantial portion of the countermeasure is delivered. However, the Secretary of HHS could make an advance payment of up to 10 percent, if necessary, to ensure success of a project. Contracts for biomedical countermeasures could last for five years, but could be extended for up to eight years, if the Secretary of HHS determines that a longer period is justified because of complexities or other performance difficulties. The contract can be renewed for additional periods not to exceed five years. This section also contains a number of provisions concerning contractor storage of stockpile items, payment of premiums where there are multiple contractors, extension of closing dates for receipt of proposals, and the exclusion of sources for failure to respond to a request for information.

The Secretary of HHS would have enhanced procurement authorities for the purchase of biomedical countermeasures if the Secretary determines that there is a pressing need. The Secretary could use simplified acquisition procedures to procure any biomedical countermeasure. Contractor work hours and safety standards, anti-kickback rules, and provisions authorizing examination

of contractor records would apply to the contracts. Additionally, after a determination of pressing need, the Secretary of HHS could use other than competitive procedures if the product is available from only one responsible source or from a limited number of responsible sources and no other type of product will satisfy the Secretary's needs.

The Secretary of HHS would be authorized to use other than competitive procedures for procurements of biomedical countermeasures when there are only a limited number of responsible sources and no other type of property or services will satisfy the Secretary's needs. For the purposes of using other than competitive procedures in this section, the phrase in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949, "available from only one responsible source" shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources." The other than competitive procedures authorized under this section are to be implemented in accordance with the justification and approval provisions of 41 U.S.C. 253(f) and the notice provisions of 41 U.S.C. 416. This expanded authority would be in addition to any other authority to use procedures other than competitive procedures.

Authorization of appropriations

For procurements of biomedical countermeasures from the special reserve fund, the bill authorizes $890 million in FY 2004 and $3.4 billion and $5.6 billion over the next five and ten fiscal years respectively. All amounts appropriated under this authorization would be available for obligation through the end of FY 2013.

Section 4. Authorization for medical produces for use in emergencies

Section 4 of the Act amends the Food, Drug, and Cosmetic Act by permitting the Secretary of HHS to authorize the emergency use of drugs, devices, or biological products prior to approval, clearance or license by the FDA. The emergency use of unapproved products could only be performed during times of military, national, or public health emergencies. To exercise this authority the Secretary of HHS must conclude that:

(1) A biological, chemical, radiological or nuclear agent can cause a serious or life-threatening disease;

(2) Based on scientific evidence, the product may be effective in detecting, diagnosing, treating, or preventing the disease;

(3) The known and potential benefits of the product outweigh the known or potential risks;

(4) There is no adequate alternative to the product that is already approved and available; and

(5) Any other criteria specified by the Secretary of HHS.

A declaration of an emergency can last for a maximum of one year unless the Secretary of HHS renews it. If the Secretary authorizes the use of an unapproved product, the Secretary shall place certain conditions on such authorization (including conditions intended to provide information to both health care professionals administering the product and the recipients of the product) and may place other conditions on the authorization at the Secretary's discretion.

The Secretary of HHS may authorize a new, emergency dual use for existing FDA approved products to treat alternate diseases. Manufacturers that wish to avail themselves of such an emergency use authorization may be subjected to certain conditions.

Nothing in Section 4 requires any manufacturer, distributor, physician, pharmacist, or other person to make a product available under the emergency use authorization. However, if a person chooses to provide an emergency use product, he or she must follow conditions imposed by the Secretary of HHS. Persons failing to comply with applicable conditions under this provision will be treated as if they are providing an unapproved drug or device and could be subject to enforcement actions.

Section 5. Reports regarding authorities under this Act

The Secretary of HHS must submit an annual report to Congress detailing and summarizing the Secretary's exercise of the new authorities authorized in the previous sections of the bill. Studies by the National Academy of Sciences and the General Accounting Office concerning implementation of this Act would be required as well.

EXPLANATION OF AMENDMENTS

The provisions of the substitute are explained in this report.

COMMITTEE CONSIDERATION

H.R. 2122 was introduced by Representative W.J. (Billy) Tauzin (LA) on May 15, 2003, and was cosponsored by Rep. John Dingell (MI), Rep. Tom Davis (VA), Rep. Christopher Cox (CA), Rep. Ed Markey (MA), Rep. Mike Bilirakis (FL), Rep. Jim Davis (FL), Rep. Fred Upton (MI), Rep. Cliff Stearns (FL), Rep. John Shadegg (AZ), Rep. Darrell Issa (CA), Rep. Lincoln Diaz-Balart (FL), and Rep. Anna Eshoo (CA). The bill was referred to the Committee on Energy and Commerce, the Committee on Government Reform, and the Select Committee on Homeland Security.

On May 22, 2003, the Committee on Government Reform met in open session to consider H.R. 2122 along with seven other bills. The committee favorably approved the bill as amended by voice vote and reported it to the House of Representatives. The Energy and Commerce Committee approved H.R. 2122 by a voice vote on May 15, 2003.

At the full committee business meeting, an amendment in the nature of substitute offered by Government Reform Committee Chairman Tom Davis (VA) was approved by a voice vote. The amendment makes three changes to the bill. First, the amendment applies the "pressing need" standard used for research and development procurement in section 2, to biomedical countermeasure procurements in section 3. Second, section 2 of the bill would commit decisions about research and development projects to the HHS Secretary's discretion. The amendment would permit interested parties to protest research and development contracting decisions to the contracting agency, the Comptroller General, or the United States Court of Federal Claims. The amendment also makes technical changes in sections 2 and 3 to clarify the circumstances when the

Secretary of HHS could use other than competitive procedures for research and development and production contracts.

APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1 requires a description of the application of this bill to the legislative branch. This bill accelerates the research, development, purchase, and availability of countermeasures to combat bioterrorist threats that could cause public health emergencies affecting national security. The benefits of this bill apply equally to employees of the legislative branch.

STATEMENT OF OVERSIGHT FINDINGS AND RECOMMENDATIONS OF THE COMMITTEE

In compliance with clause 3(c)(2) of rule XIII and clause (2)(b)(1) of rule X of the Rules of the House of Representatives, the Committee's oversight findings and recommendations are reflected in the descriptive portions of this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee's performance goals and objectives are reflected in the descriptive portions of the report.

CONSTITUTIONAL AUTHORITY STATEMENT

Under clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee must include a statement citing the specific powers granted to Congress to enact the law proposed by H.R. 2122. The constitutional authority to enact this law lies within the General Welfare and Necessary and Proper clauses of Article I, Section Eight of the United States Constitution.

UNFUNDED MANDATE STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act (as amended by Section 101(a)(2) of the Unfunded Mandate Reform Act, P.L. 104–4) requires a statement whether the provisions of the reported include unfunded mandates. In compliance with this requirement the Committee has received a letter from the Congressional Budget Office included herein.

COMMITTEE ESTIMATE

Clause 3(d)(2) of rule XIII of the Rules of the House of Representatives requires an estimate and a comparison by the Committee of the costs that would be incurred in carrying out H.R. 2122. However, clause 3(d)(3)(B) of that rule provides that this requirement does not apply when the Committee has included in its report a timely submitted cost estimate of the bill prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act.

BUDGET AUTHORITY AND CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

With respect to the requirements of clause 3(c)(2) of rule XIII of the Rules of the House of Representatives and section 308(a) of the Congressional Budget Act of 1974 and with respect to requirement of clause (3)(c)(3) rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 2122 from the Director of Congressional Budget Office.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2003.

Hon. TOM DAVIS,
Chairman, Committee on Government Reform,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2122, the Project BioShield Act of 2003.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Jeanne De Sa and Sam Papenfuss.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

H.R. 2122—Project BioShield Act of 2003

Summary: H.R. 2122 would amend the Public Health Service Act (PHSA) to authorize appropriations of up to $5.6 billion for fiscal years 2004 through 2013 for procurement of certain security countermeasures (drugs, devices, and biological products to treat, identify, and prevent the public health consequences of terrorism). Of that amount, $890 million could be obligated in fiscal year 2004 and up to $3.4 billion could be obligated during fiscal years 2004 though 2008. Funding to buy these security countermeasures would be provided to the Department of Homeland Security (DHS), but the Department of Health and Human Services (HHS) would be responsible for procuring and stockpiling the countermeasures.

Assming appropriation of authorized amount and including administrative costs, CBO estimates that implementing H.R. 2122 would increase discretionary spending by $0.3 billion in 2004, $3.1 billion for fiscal years 2004 through 2008, and $5.6 billion over the 2004–2013 period. In addition, H.R. 2122 would relax certain requirements for federal agencies related to the development and approval of countermeasures. The bill would provide HHS with increased authority and flexibility to award contracts and grants for research and development of qualified countermeasures, hire technical experts, and procure items necessary for research. Those provisions might result in higher discretionary spending, but CBO does not have sufficient information to estimate their budgetary effect.

The bill also would authorize the Food and Drug Administration (FDA) to approve the use of certain security countermeasures dur-

ing emergencies designated by the Secretary of HHS. CBO estimates this provision would have no budgetary effect.

H.R. 2122 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2122 is shown in the following table. The costs of this legislation fall within budget function 550 (health). CBO assumes that H.R. 2122 would be enacted by October 1, 2003.

	By fiscal year, in million of dollars—									
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
CHANGES IN DISCRETIONARY SPENDING										
Project BioShield:										
Estimated authorization level	890	2,528	0	0	0	2,175	0	0	0	0
Estimated outlays	270	680	870	770	510	440	560	650	490	250
Administrative costs:										
Estimated authorization level	9	9	9	9	10	10	10	10	11	11
Estimated outlays	7	8	9	9	10	10	10	10	11	11

Basis of estimate

CBO assumes that this bill will be enacted during fiscal year 2003 and will take effect in October 2003.

Procurement of security countermeasures: Project BioShield

Under current law, HHS administers the Strategic National Stockpile (SNS), which contains drugs diagnostic devices, vaccines, and other biological products to combat the public health consequences of a terrorist attack or other public health emergencies. DHS currently provides the financing for those efforts, which include the procurement of a new smallpox vaccine and stockpiling of that vaccine and older versions of the vaccine. Authorization for those programs was established in the Public Health Security and Bioterrorism Preparedness Response Act of 2002 (Public Law 107–88). That act authorized appropriations of $640 million in 2002 and such sums as may be necessary for fiscal years 2003 through 2006 for the SNS and $509 million in 2002 and such sums as may be necessary for fiscal years 2003 through 2006 for the development of the smallpox vaccine. About $400 million was appropriated in 2003 for those activities.

H.R. 2122 would modify the existing authorizations for the SNS and for the development of the smallpox vaccine by codifying the provision in the PHSA instead of in Public Law 107–88. CBO estimates that this modification would have no budgetary effect.

H.R. 2112 also would authorize DHS to augment the SNS with certain additional products. That effort, called Project BioShield, would allow the federal government to enter into contracts to procure security countermeasures, which are defined in the bill as drugs, devices, biological products, vaccines, vaccine adjuvants, antivirals, or diagnostic tests used to treat, identify, or prevent harm from an agent that the Secretary determines may cause a public health emergency affecting national security. Such drugs, devices, or biological products would have to be licensed or approved by the FDA, or otherwise determined by the Secretary of HHS to have the potential to be licensed or approved by the FDA.

The federal government also could acquire products used to treat the adverse effects of drugs or biologic products used as security countermeasures.

The rate at which the funding authorized by the bill would be appropriated and spent would depend upon many factors, including the nature of advances in biotechnology, the degree of industry interest and capacity, the threat environment, and government priorities. Assuming appropriation of the authorized amounts, current and future Administrations would have the discretion to enter into multiple contracts for the manufacture of security countermeasures or to cease contracting altogether for a period of years.

To estimate spending under H.R. 2122, CBO consulted with Administration officials about activities they are planning or would consider if Project BioShield were enacted. Officials described plans to acquire and maintain stockpiles of seven security countermeasures to combat five biological agents. The Administration estimates that the cost of procuring, storing, and replacing those countermeasures would be about $5.6 billion over the 2004–2013 period if there were no constraints on funding.

Those currently planned acquisitions do not include any countermeasures for chemical, readiological, or nuclear agents, and they address only a subset of the threats for which research and development activities on countermeasures is being conducted or funded by HHS, the Department of Defense (DoD), and the private sector. Based on information provided by government officials and in consultation with outside experts, CBO has concluded that it is likely that drugs, devices, or biological products addressing some of those other threats will be developed in the coming decade and that some of those countermeasures would be stockpiled under Project Bioshield if funds were appropriated for that purpose. CBO's estimate does not assume that any specific product would be developed and procured at any specific time. It does, however, account for a range of possibilities that would be available to the government if the authorized funds are appropriated.

Authorities and Requirements Under H.R. 2122. H.R. 2122 would authorize appropriations of up to $5.6 billion for fiscal years 2004 through 2013 for the federal government to enter into contracts to procure security countermeasures. Of that amount, $890 million could be obligated in fiscal year 2004 and up to $3.4 billion could be obligated during fiscal years 2004 through 2008.

Decisions regarding what types of security countermeasures to procure would be made by the President after reviewing recommendations of the Secretaries of DHS and HHS. Subject to Presidential approval and a determination that inclusion of certain countermeasures in the stockpile is appropriate, the Secretaries of DHS and HHS would seek potential vendors to produce the countermeasures and enter into contracts to buy the countermeasures from these vendors. In making that determination, the Secretary would determine and consider several factors, including the quantity of the product necessary for the stockpile, the feasibility of obtaining sufficient quantities of the product within five years, and whether there is a significant commercial market for the product other than as a security countermeasure. Those factors would not be requirements for procurement, but considerations in deter-

mining the appropriateness for inclusion of the countermeasure in the stockpile.

The Secretary of HHS would be responsible for arranging the procurement, including negotiating the quantity, price, and production schedule in five-year contracts or cooperative agreements, though eight-year contracts would be permitted for first awards. Payment would be conditioned on the delivery of a substantial portion of promised units. However, the Secretary could provide an advance payment of not to exceed 10 percent of the contract if the Secretary determines such payment is necessary to the project's success. The Secretary could pay vendors for storage, shipping, and handling and would be permitted to use noncompetitive procedures if the product is available only from a limited number of sources. Additional countermeasures for the same threat also could be procured, if they were to provide improved safety or effectiveness or otherwise enhance public health preparedness.

The authorized funds could not be used for the purchase of vaccines under contracts entered into prior to enactment, or for administrative costs. Based on information from Administration officials, CBO expects that funding would not be available specifically for research and development, although the price for the completed products would probably cover some development costs.

The Administration's Plans To Implement Project BioShield. Based on existing science and a current assessment of potential threats to public health, the Administration has identified several agents for which countermeasures are needed to protect the public health and could be included in Project BioShield. Those agents are smallpox, anthrax, botulinum toxin, plague, and Ebola. The Administration estimates that spending for countermeasures under Project BioShield, including purchase, storage, and replacement costs, would total about $5.6 billion over the 2004–2013 period, assuming the successful development of those countermeasures and no constraints on funding. More than half of those costs would be for the improved smallpox and anthrax vaccines. A brief description follows of the security countermeasures the Administration plans to acquire and stockpile.

Smallpox. Under Project BioShield, the Administration plans to procure a next-generation version of the smallpox vaccine called modified vaccinia Ankara (MVA). This new vaccine is an attenuated version of the existing vaccine and may be used to safely vaccinate about 30 million individuals with compromised immune systems, eczema, or certain other high-risk conditions. Under the authority provided for Project BioShield, HHS plans to purchase 60 million doses of the new vaccine at about $15 per dose over a three-year period for a cost of about $900 million. The Administration expects to be able to enter into contracts and begin acquiring the vaccine in 2004. Additional costs for inventory management and replacement of expired stocks over the 2007–2013 period would likely add another $1 billion, according to Administration estimates, but could be lower if long-term refrigerated storage proves to be effective.

Anthrax. The Administration also expects to purchase about 60 million doses of a next-generation anthrax vaccine, called a recombinant protective antigen (rPA) vaccine, under Project BioShield. The rPA vaccine require fewer doses per person than the current

vaccine, and potentially could be effective for people who have already been exposed to anthrax, giving the government the ability to vaccinate about 20 million people. The Administration anticipates beginning the procurement process in the next few years and spending about $700 million on the vaccine over a three-year period. Because the rPA anthrax vaccine has an expected shelf life of five to six years, additional costs would be incurred for inventory management and replacement. The Administration estimates that costs for the rPA vaccine could total $1.4 billion over the 2004–2013 period.

Botulinum Toxin. Under current law, HHS has stockpiled some antitoxins to treat botulism, a paralytic and often fatal illness caused by a nerve toxin produced by the botulinum bacteria. However, those antitoxins are no longer manufactured, and the manufacturing process, which requires horse serum, is complicated and time intensive. After identifying a manufacturer, the Administration plans to spend about $800 million acquiring newly produced antitoxin at a cost of about $2,000 per dose as part of Project BioShield. Acquisition would be spread over a three-year period, beginning in the next few years. This antitoxin would require specialized storage and refrigeration.

In addition, the Administration has indicated that it would like to purchase both a vaccine that would protect against botulism and monoclonal antibodies to neutralize the effects of the toxin. (Monoclonal antibodies are engineered proteins that can neutralize and destroy certain pathogens and toxins.) The Administration anticipates buying vaccine and monoclonal antibodies by 2007 or 2008, at a cost of about $140 million for 750,000 doses of the vaccine and $750 million for monoclonal antibodies. The Administration estimates that spending for botulinum countermeasures, including the cost of storage and inventory management, would total $1.8 billion over the 2004–2013 period.

Plague. Plague is an infectious disease caused by a bacterium. Plague has several forms—pneumonic, bubonic, and septicemic—and can be treated by existing antibiotics. A vaccine for the plague is currently in the research and development phase, with the expectation that a product potentially could reach the advanced development phase next year. Beginning in 2005, the Administration expects to procure about 2 million doses (enough to treat people in areas surrounding any outbreak) at an estimated cost of about $40 per dose—for a total cost of about $80 million. With additional costs related to the acquisition of the vaccine, the Administration estimates spending on plague countermeasures would total about $220 million over the 2004–2013 period.

Ebola. There is no current treatment for Ebola, one of several viral hemorrhagic fevers, but the National Institutes of Health (NIH) is conducting research on a vaccine that the Administration would be interested in purchasing when it reaches an advanced development stage. Under current plans, the Administration intends to purchase enough vaccine for 3 million individuals to prevent the spread of an outbreak. Because this vaccine is still in the research and development phase, when the vaccine would become available and the potential cost per dose are unclear. The Administration assumes the vaccine will become available in 2005, and estimates the price to be about $30 per dose, for a total acquisition cost of $90

million. Combined with other costs related to the Ebola vaccine, including storage and replacement, the Administration anticipates spending would total about $260 million over the 2004–2013 period for this aspect of Project BioShield.

CBO's Estimate of the Potential Cost of Project BioShield. CBO has estimated both the cost of implementing the Administration's plan and the potential cost of acquiring other products not encompassed by that plan.

CBO's Estimate of the Administration's Plan. Without any funding constraints, CBO expects that the Administration's plans for MVA smallpox vaccine, the anthrax rPA vaccine, and the botulism antitoxins would likely take shape as described, albeit more slowly than the Administration estimates. CBO estimates that spending for vaccines and monoclonal antibodies for botulism and vaccines for plague and Ebola would likely be lower than the Administration estimates, even without funding constraints. CBO's lower estimate reflects the possibility that development of those vaccines and monoclonal antibodies might not succeed as quickly as the Administration's estimate assumes. It also reflects the possibility that Project BioShield would spend less on some of the botulism countermeasures if all three countermeasures (vaccine, antitoxins, and monoclonal antibodies) became available.

CBO estimates that about $5.2 billion would be required to procure products identified by the Administration over the 2004–2013 period.

Estimated Spending for Products Not Listed in the Administration's Plan. Under the bill, other countermeasures not in the Administration's plan could be purchased with appropriations provided through Project BioShield. Consequently, the specific security countermeasures that would be acquired under H.R. 2122 are likely to evolve over time as the result of many factors, including scientific advances, the interest and cooperation of biotech and other manufacturing companies, the emergence of new threats, and changes in this and future Administrations' assessments of which potential countermeasures should be a priority. Barriers to technological advance such as restricted laboratory space or shortage of primates for testing could slow development of countermeasures for certain agents. At the same time, rapid advances in products currently in the early-stage research and development could present the government with unforeseen countermeasure options. Acquisition of countermeasures would also be affected by whether this and future Administrations decide to procure products that require more than five years to be licensed or have a significant commercial market.

Acquisitions under the bill might include additional countermeasures for agents addressed by the Administration's plan. For instance, potential emerging treatments include the use of monoclonal antibodies. This technology has had initial application in the treatment of cancer, and possibly could be applied to anthrax, the plague, or viral hemorrhagic fevers in the coming years. Other potential countermeasures include new antiviral drugs to treat smallpox and viral hemorrhagic fevers (both biodefense research priorities for NIH) and a narrow-spectrum antibiotic for anthrax.

In addition, CBO's research indicates there are numerous other biological agents for which countermeasures ultimately could be purchased under Project BioShield. HHS has established three classes of biological agents that pose significant risks to national security and the public health. Category A agents pose the greatest risk due to their ease of transmission, mortality rates, and overall risk to the public. All of the agents included in the Administration's plan are considered Category A agents, but that initial plan does not address such Category A agents as tularemia, a bacterial infection affecting the respiratory system, and viral hemorrhagic fevers other than Ebola. Vaccines for both of those agents are biodefense research priorities of NIH. Further, the government might seek countermeasures for some Category B and C agents, including toxins such as ricin, certain bacteria such as brucellosis, and several forms of viral encephalitis.

Also, under the authority provided by the bill, the government could procure countermeasures against chemical agents (nerve, blister, blood, and pulmonary agents) and radiological and nuclear agents. The Administration currently does not plan to use the bill's authority to purchase agents that could mitigate threats from these sources, but it could do so if the perceived threat from these agents changed or if certain treatments became scientifically feasible. Countermeasures that could be acquired under Project BioShield include existing treatments for many nerve gases (including VX, Sarin, and Soman gas), Prussian Blue (a treatment for certain types of radiation poisoning), and hydroxycobalamin (a treatment for cyanide poisoning that is in an advanced stage of development).

Finally, under H.R. 2122, Project BioShield would be able to purchase devices to detect and diagnose pathogens and other agents. Costs for such devices are also not included in the Administration's estimate.

To estimate potential spending for additional countermeasures not mentioned in the Administration's plan, CBO identified several category A, B, and C biological agents and chemical and radiological agents for which countermeasures exist or are under development. The set of selected agents and countermeasures is not intended as a prediction of which countermeasures would be acquired by Project BioShield. Rather, it is intended to be representative of the countermeasures that would be eligible for acquisition if current research and development activities succeed in producing qualified countermeasures during the coming decade.

For each of the representative biological agents, CBO determined whether the countermeasure is likely to be a vaccine, an antitoxin or antiviral, or a monoclonal antibody, the dosage and method of delivery (intravenously or in pill form), and the amount necessary to treat the population that could potentially be affected. The estimate assumes that vaccines would cost $30 to $40 per dose, on average, with Project BioShield acquiring 500,000 to 2 million doses of qualified vaccines, depending on whether the agent is infectious. CBO estimates that monoclonal antibodies would cost $5,000 per treatment, and that Project Bioshield would acquire enough to treat several hundred thousand people if qualified products became available. The estimate assumes that, if other types of qualified antivirals or antitoxins became available, Project BioShield would acquire enough to treat 500,000 people, at costs ranging from

$2,000 to $5,000 per person for certain intravenously-administered forms. Other countermeasures could be less expensive on a per-person basis. For example, certain antivirals or narrow-spectrum antibiotics in pill form could cost about $100 per treatment, CBO estimates. Additionally, CBO estimates that per-person costs would average $50 for Prussian Blue, $100 for intravenous treatments for hydrogen cyanide, and $300 per treatment for countermeasures for certain radiological and nuclear agents. If Project BioShield acquired those types of countermeasures, CBO assumes that the quantity procured would be sufficient to respond to simultaneous events in several large cities.

Under optimistic assumptions about when countermeasures for the representative agents would become available, the cost of acquiring, storing, and replacing all qualified countermeasures for those agents could total $10 billion to $20 billion during the 2004–2013 period. However, CBO assumes that research and development efforts for some countermeasures will proceed slowly or be unsuccessful, and that the Administration would not acquire all products that could be designated as security countermeasures.

Assuming appropriation of the authorized amount, CBO estimates that discretionary spending to acquire and store BioShield products would total $0.3 billion in 2004 and $5.5 billion over the 2004–2013 period. Acquisition costs would comprise 70 percent to 80 percent of that amount, while inventory management and replacement costs would make up the balance.

CBO also estimates that implementing Project BioShield would add to the administrative costs of HHS and DHS, both for the contracting process and managing the stockpile. Funding for those costs would come from appropriated funds. Based on current spending for program support services for bioterrorism-related activities (including the SNS) at the Centers for Disease Control and Prevention, CBO estimates that administrative costs would be about $10 million a year. Subject to the appropriation of necessary amounts, CBO estimates that discretionary spending for such costs would increase by $7 million in 2004 and $0.1 billion over the 2004–2013 period.

Research and development into qualified countermeasures

H.R. 2122 would authorize the Secretary of HHS to expedite procurement and peer review for research related to qualified countermeasures. The bill also would allow the Secretary to secure the services of expects or consultants with relevant expertise. Implementation of these measures could increase the resources required by the agency, accelerate spending, or both. CBO does not have sufficient information to estimate the additional resources that might be required by the agency or the rate at which spending might accelerate under the bill. Such spending could come from appropriated funds.

Authorization for medical products for use in emergencies

The FDA's regulatory process allows for expedited approval of security countermeasures under current law. Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the FDA may allow certain drugs, devices, and bioligics defined as priority countermeasures to move more quickly through

the agency's regulatory process. To further expedite the development of security countermeasures, the FDA has implemented a rule that allows approval of certain drugs based on tests in animals.

H.R. 2122 would allow the Secretary of HHS to authorize the FDA to approve the use of certain drugs or devices for use during periods designated as emergencies by the Secretary of HHS, DHS, or Defense. The authorization would remain in effect for no more than one year, unless the Secretary determines otherwise based on the nature of the emergency. When the Secretary authorizes the emergency use of a product that is an unapproved use of an approved product, the bill would provide some flexibility to manufacturers in carrying out activities under the emergency use authorization.

Based on information from Administration officials, CBO expects that implementing this provision in H.R. 2122 would not increase costs to the FDA. Over the past year, the FDA has hired about 100 people to review drug applications and provide assistance to companies engaged in research and development into security countermeasures. Thus, the agency already has the infrastructure to handle the additional authority related to the proposed emergency-use authorization and would not require additional resources. Therefore, CBO estimates that this provision of H.R. 2122 would have no budgetary effect.

Previous CBO estimates: S. 15, the Project BioShield Act of 2003, as reported by the Senate Committee on Health, Education, Labor and Pensions on March 25, 2003, would amend the Public Health Service Act (PHSA) to create permanent, indefinite funding authority for the procurement of certain biomedical countermeasures. In its cost estimate dated May 7, 2003, CBO estimated that enacting S. 15 would increase direct spending by $270 million in 2004 and $8.1 billion over the 2004–2013 period.

Although both H.R. 2122 and S. 15 would authorize programs to procure countermeasures to protect the public health against terrorism, H.R. 2122 would not have an effect on direct spending; instead, the bill would authorize appropriations of up to $5.6 billion over the 2004–2013 period. Estimated spending under H.R. 2122 is less than under S. 15 because the House bill would authorize a set amount of appropriations, whereas the Senate bill would provide unlimited direct spending authority.

In several areas, H.R. 2122 would allow the Secretary more flexibility in terms of what products could be procured and how contracts would be structured. H.R. 2122 would allow the procurement of countermeasures even if they have a significant commercial application, while S. 15 would restrict the procurement authority to those without such application. While S. 15 would require the Secretary to determine that a countermeasure is likely to be approved by the FDA within five years as a condition of procurement, H.R. 2122 would require only that the Secretary consider whether a five-year limit is feasible. H.R. 2122 would provide additional flexibility in contracting by permitting the Secretary to extend first-time contracts to eight years (versus five in S. 15) and would allow the Secretary discretion to provide a 10 percent advance to companies developing new products. Those provisions would accelerate spending relative to S. 15.

On June 6, 2003, CBO transmitted a cost estimate for H.R. 2122 as ordered reported by the House Committee on Energy and Commerce on May 15, 2003. That version of H.R. 2122 is nearly identical to the version of H.R. 2122 approved by the Committee on Government Reform. CBO's estimates of the costs of the two versions of H.R. 2122 are identical.

Intergovernmental and private-sector impact: H.R. 2122 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Jeanne De Sa and Sam Papenfuss; impact on state, local, and tribal governments: Leo Lex; Impact on the private sector: Samuel Kina.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * * * *

SEC. 319F–1. AUTHORITY FOR USE OF CERTAIN PROCEDURES REGARDING BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT ACTIVITIES.

(a) IN GENERAL.—

(1) AUTHORITY.—In conducting and supporting research and development activities regarding biomedical countermeasures under section 319F(h), the Secretary may conduct and support such activities in accordance with this section if the activities concern qualified countermeasures.

(2) QUALIFIED COUNTERMEASURE.—For purposes of this section, the term "qualified countermeasure" means a priority countermeasure (as defined in section 319F(h)) that affects 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 United States Government.

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

(4) 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 qualified countermeasure 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.

(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 qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, 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 provision of law and regulations referred to in such subparagraph, each of the following provisions shall apply to procurements described in this paragraph to the same extent that such provisions would apply to such procurements in the 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).

(C) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for procurements that are under this paragraph, including requirements with regard to documenting the justification for use of the authority in this paragraph.

(2) OTHER THAN FULL AND OPEN COMPETITION.—(A) In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procurement described in paragraph (1) of this subsection, the phrase "available from only one respon-

sible source" in such section 303(c)(1) shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

(B) The authority under subparagraph (A) is in addition to any other authority to use procedures other than competitive procedures.

(C) The Secretary shall implement this paragraph in accordance with applicable government-wide regulations, including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered.

(3) INCREASED MICROPURCHASE THRESHOLD.—

(A) IN GENERAL.—For a procurement described by paragraph (1), 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 purchases that are 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 Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than $2,500.

(c) AUTHORITY TO EXPEDITE PEER REVIEW.—

(1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure 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, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would 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—

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

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

(2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary's determination of whether to employ expedited peer review with respect to subsequent phases of a research grant or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant or cooperative agreement.

(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

(1) IN GENERAL.—For the purpose of performing, administering, and supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified counter-

measure 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, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.

(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.

(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.

(e) 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 qualified countermeasure 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 qualified

countermeasure research and development activities in carrying out this section.

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

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

(g) EFFECT ON RIGHT TO FILE PROTEST.—Nothing in this section shall affect the right of an interested party to file a protest with the contracting agency, to file a protest with the Comptroller General under subchapter V of chapter 35 of title 31, United States Code, or to file an action in the United States Court of Federal Claims under section 1491(b) of title 28, United States Code.

SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE.

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), in coordination with the Secretary and the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

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

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

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

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

(F) ensure the adequate physical security of the stockpile.

(b) SMALLPOX VACCINE DEVELOPMENT.—

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

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN BIOMEDICAL COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

(1) IN GENERAL.—

(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund under paragraph (10).

(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term "security countermeasure" means a priority countermeasure (as defined in section 319F(h))—

(i) that affects national security;

(ii) that is determined under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(iii)(I) that is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act, or licensed under section 351 of this Act, for use as a countermeasure to a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii); or

(II) for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing after the date of a determination under paragraph (5).

(2) DETERMINATION OF MATERIAL THREATS.—

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

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

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

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

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

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

(3) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(4) CALL FOR SECURITY COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Sec-

retary and the Secretary make a determination that a security countermeasure would be appropriate, such Secretaries may jointly submit to the President a proposal to—

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

(ii) make a commitment that, upon the first development of such security countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund under paragraph (10) be made available for the procurement of such security countermeasure.

(B) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

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

(ii) necessary measures of minimum safety and effectiveness;

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

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

(C) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the security countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) a commitment described in subparagraph (A)(ii).

(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund under paragraph (10) (referred to in this subsection individually as a "procurement under this subsection").

(B) REQUIREMENTS.—In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

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

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

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) RECOMMENDATION FOR PRESIDENT'S APPROVAL.—

(A) RECOMMENDATION FOR PROCUREMENT.—In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (2), (3), and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

(B) PRESIDENTIAL APPROVAL.—The special reserve fund under paragraph (10) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

(C) NOTICE TO CONGRESS.—The Secretary and the Homeland Security Secretary shall notify the Congress of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund under paragraph (10) for procurement of such a countermeasure, including, where available, the identification of the potential supplier or suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such 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. Such a determination by the Secretary is committed to agency discretion.

(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund under paragraph (10) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

(7) PROCUREMENT.—

(A) IN GENERAL.—For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the

Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

(B) INTERAGENCY AGREEMENTS.—

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

(ii) FOR ADMINISTRATIVE COSTS.—The agreement entered into between the Homeland Security Secretary and the Secretary for managing the stockpile under subsection (a) shall provide for reimbursement of the Secretary's administrative costs relating to procurements under this subsection.

(C) PROCUREMENT.—

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

(I) arranging for procurement of a security 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 subparagraph; and

(II) promulgating regulations to implement clauses (v), (vi), and (vii), and any other provisions of this subsection.

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

(I) 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, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform under the contract, except in special circumstances as determined by the Secretary on a contract by contract basis.

(II) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding eight years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be

renewable for additional periods, none of which shall exceed five years.

(III) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund under paragraph (10) shall be available for costs of shipping, handling, storage, and related costs for such product.

(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

(I) IN GENERAL.—If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection 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, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

(aa) 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

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

(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

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

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

(cc) 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) OTHER THAN FULL AND OPEN COMPETITION.—(I) In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase "available from only one responsible source" in such section 303(c)(1) shall be deemed to mean "available from only

one responsible source or only from a limited number of responsible sources".

(II) The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

(III) The Secretary shall implement this clause in accordance with applicable government-wide regulations, including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered.

(v) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

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

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

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

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

(vi) 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.

(vii) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, 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 the Secretary may so exclude such a source.

(8) INTERAGENCY COOPERATION.—

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

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

(9) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund under paragraph (10) shall not be used to pay—

(A) costs for the purchase of vaccines under procurement contracts entered into before the date of the enactment of the Project BioShield Act of 2003; or

(B) administrative costs.

(10) SPECIAL RESERVE FUND.—For purposes of this subsection, the term "special reserve fund" has the meaning given such term in section 510 of the Homeland Security Act of 2002.

(d) DISCLOSURES.—No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

(e) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

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

(2) a contractual agreement between the Homeland Security Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) AUTHORIZATION OF APPROPRIATIONS.—

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

(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART E—OTHER AGENCIES OF NIH

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SEC. 481A. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

(a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Director of NIH, acting through the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases*, may make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.

* * * * * * *

(c) REQUIREMENTS FOR GRANTS.—

(1) IN GENERAL.—The Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

(A) * * *

* * * * * * *

(2) INSTITUTIONS OF EMERGING EXCELLENCE.—From the amount appropriated under ⟦subsection (i)⟧ *subsection (i)(1)* for a fiscal year up to $50,000,000, the Director of the Center shall make available 25 percent of such amount, and from the amount appropriated under such subsection for a fiscal year that is over $50,000,000, the Director of the Center shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) * * *

* * * * * * *

(d) REQUIREMENT OF APPLICATION.—The Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(e) AMOUNT OF GRANT; PAYMENTS.—

(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases*, except that such amount shall not exceed—

(A) 50 percent *(or, in the case of the Institute, 75 percent)* of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, 40 percent *(or, in the case of the Institute, 75 percent)* of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

(2) RESERVATION OF AMOUNTS.—On the approval of any application for a grant under subsection (a), the Director of the Center *or the Director of the National Institute of Allergy and Infectious Diseases* shall reserve, from any appropriation available for such grants, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of the application or on the revision of the estimated cost of construction of the facility.

* * * * * * *

(4) WAIVER OF LIMITATIONS.—The limitations imposed under paragraph (1) may be waived at the discretion of the Director

of the Center or the Director of the National Institute of Allergy and Infectious Diseases for applicants meeting the conditions described in subsection (c).

(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

(1) *in the case of an award by the Director of the Center,* the applicant or other owner of the facility shall cease to be a public or non profit private entity; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director *of the Center or the Director of the National Institute of Allergy and Infectious Diseases* determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so),

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

* * * * * * *

(i) AUTHORIZATION OF [APPROPRIATIONS.—For the purpose of carrying out this section,] *APPROPRIATIONS.—*

(1) CENTER.—For the purpose of carrying out this section with respect to the Center, there are authorized to be appropriated $250,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(2) NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.—For the purpose of carrying out this section with respect to the National Institute of Allergy and Infectious Diseases, there are authorized to be appropriated such sums as may be necessary for fiscal year 2003.

SECTION 510 OF THE HOMELAND SECURITY ACT OF 2002

SEC. 510. PROCUREMENT OF SECURITY COUNTERMEASURES FOR STRATEGIC NATIONAL STOCKPILE.

(a) AUTHORIZATION OF APPROPRIATIONS.—For procurement of security countermeasures under section 319F–2(c) of the Public Health Service Act (referred to in this section as the "security countermeasures program"), there is authorized to be appropriated up to $5,593,000,000 for the fiscal years 2004 through 2013. Of the amounts appropriated under the preceding sentence, not to exceed $3,418,000,000 may be obligated during the fiscal years 2004 through 2008, of which not to exceed $890,000,000 may be obligated during fiscal year 2004.

(b) SPECIAL RESERVE FUND.—For purposes of the security countermeasures program, the term "special reserve fund" means the appropriations account established as a result of any appropriations made under subsection (a).

(c) AVAILABILITY.—

(1) DURATION OF AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2), all amounts appropriated under subsection (a) are available for obligation through the end of fiscal year 2013, provided that any portion of such amount that remains unobligated for such purposes on the expiration of such term shall be returned to the United States Treasury and shall not be available for subsequent obligation for any purpose.

(2) INITIAL AVAILABILITY FOR PARTICULAR PROCUREMENTS.—Amounts appropriated under subsection (a) become available for a procurement under the security countermeasures program only upon the approval by the President of such availability for the procurement in accordance with paragraph (6)(B) of such program.

PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) * * *

(b) TABLE OF CONTENTS.—The table of contents of the Act is as follows:

[SEC. 121. STRATEGIC NATIONAL STOCKPILE.

[(a) STRATEGIC NATIONAL STOCKPILE.—

[(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), in coordination with the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

[(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

[(A) consult with the working group under section 319F(a) of the Public Health Service Act;

[(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

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

[(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging

threats, advanced technologies, and new countermeasures are adequately considered;

[(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

[(F) ensure the adequate physical security of the stockpile.

[(b) SMALLPOX VACCINE DEVELOPMENT.—

[(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by the Secretary to be sufficient to meet the health security needs of the United States.

[(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

[(c) DISCLOSURES.—No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

[(d) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

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

[(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to the Secretary supplies described in subsection (a).

[(e) AUTHORIZATION OF APPROPRIATIONS.—

[(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

[(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.]

SECTION 564 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

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

(a) IN GENERAL.—

(1) EMERGENCY USES.—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 or device intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) APPROVAL STATUS OF PRODUCT.—An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under a provision of law referred to in such paragraph (referred to in this section as an "unapproved product"); or

(B) is approved, licensed, or cleared under such a provision, but which use is not under such provision an approved, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product").

(3) RELATION TO OTHER USES.—An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a provision of law referred to in such paragraph.

(4) DEFINITIONS.—For purposes of this section:

(A) The term "emergency use" has the meaning indicated for such term in paragraph (1).

(B) The term "product" means a drug or device.

(C) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).

(D) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).

(b) DECLARATION OF EMERGENCY.—

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

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

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

(C) a determination 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 agents, or a specified disease or condition that may be attributable to such agent or agents.

(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 one-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) ADVANCE NOTICE OF TERMINATION.—In terminating a declaration under this section, the Secretary shall provide advance notice that the declaration will be terminated. The period of advance notice shall be a period reasonably determined to provide—

(A) in the case of an unapproved product, a sufficient period for disposition of shipments of the product, including the return of such shipments to the manufacturer (in the case of a manufacturer that chooses to have the shipments returned); and

(B) in the case of unapproved uses of approved products, a sufficient period for the disposition of any labeling that was provided with respect to the emergency use involved.

(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register 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 the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention, to the extent feasible and appropriate given the circumstances of the emergency involved, 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.—

(1) IN GENERAL.—An authorization of a product under this section shall state—

(A) each disease or condition that the product may be used to detect, diagnose, prevent, or treat within the scope of the authorization;

(B) the Secretary's conclusions, made under subsection (c)(2)(B), that 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; and

(C) the Secretary's conclusions, made 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.

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

(e) CONDITIONS OF AUTHORIZATION.—

(1) UNAPPROVED PRODUCT.—

(A) REQUIRED CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, shall, for persons who choose to carry out one or more activities for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that, to the extent feasible given the circumstances of the emergency, health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

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

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

(ii) Appropriate conditions designed to ensure that, to the extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

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

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, may, for persons who choose to carry out one or more activities for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

(ii) Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use.

(iii) For persons other than manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(iv) With respect to the emergency use of the product, waive or limit, to the extent appropriate given the circumstances of the emergency, conditions regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including such requirements established in section 501.

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

(A) The Secretary may, for manufacturers of the product who choose to carry out one or more activities for which the authorization is issued, establish any of the conditions described in clauses (i) through (iv) of paragraph (1)(A).

(B)(i) If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change, such authorization may not authorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer.

(ii) In the circumstances described in clause (i), an authorization under this section regarding the emergency use may, for persons who do not manufacture the product and who choose to act under this clause, authorize such persons to provide information on the product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). Such additional information shall not be considered labeling for purposes of section 502.

(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, the criteria under subsection (c) for issuance of such authorization are no longer met.

(h) PUBLICATION.—The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons therefor, under this section.

(i) 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.

(j) RULES OF 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;

(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; or

(3) the authority of the Secretary under section 319F–2 to manage the stockpile under such section.

(k) APPLICATION TO MEMBERS OF ARMED FORCES.—

(1) WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.—In the case of administration of a countermeasure to members of the armed forces, a requirement, under subsection (e)(1)(A)(ii)(III), 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.

(2) PROVISION OF INFORMATION TO MEMBER OF THE ARMED FORCES.—If the Secretary makes a determination that it is not feasible for the information required by subsection (e)(1)(A)(ii) to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member 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 such administration. Information concerning the administration of

the product shall be recorded in the medical record of the member.

(3) EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.—In the case of an authorization based on a determination by the Secretary 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.

(l) 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.

(m) DISCRETION REGARDING USE OF AUTHORIZATION.—Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall notify the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out an activity or activities under the authorization. This section does not have any legal effect on a person who does not carry out any activity for which an authorization under this section is issued, or who carries out such an activity pursuant to other provisions of this Act or section 351 of the Public Health Service Act.

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

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