

1046, 1050, 1057, Title XI, Title XIV, sections 2825 and 2826 of the House bill, and sections 326, 801, 811, 813, 822, 831 through 833, 841, 852, 853, 1013, 1035, 1102 through 1104, and 2824 through 2826 of the Senate amendment, and modifications committed to conference: Mr. TOM DAVIS of Virginia, Mr. SHAYS, Mrs. JO ANN DAVIS of Virginia, and Messrs. PUTNAM, TURNER of Ohio, WAXMAN, VAN HOLLEN, and DAVIS of Illinois.

From the Select Committee on Homeland Security, for consideration of section 1456 of the House bill, and modifications committed to conference: Messrs. COX, SHADEGG and THOMPSON of Mississippi.

From the Committee on House Administration, for consideration of section 564 of the Senate amendment, and modifications committed to conference: Messrs. NEY, MICA, and LARSON of Connecticut.

From the Committee on International Relations, for consideration of sections 1047, 1201, 1202, 1209, Title XIII, sections 3601, 3611, 3631, 3632, 3634, 3635, and 3636 of the House bill, and sections 323, 343, 921, 1201, 1202, 1204, 1205, 1207, 1208, Title XIII and section 3141 of the Senate amendment, and modifications committed to conference: Messrs. HYDE, BEREUTER, and LANTOS.

From the Committee on the Judiciary, for consideration of sections 661 through 665 and 851 through 853 of the Senate amendment, and modifications committed to conference: Messrs. SENBRENNER, SMITH of Texas, and CONYERS.

From the Committee on Resources, for consideration of sections 311, 317 through 319, 601, and 1057 of the House bill, and sections 322, 330, and 601 of the Senate amendment, and modifications committed to conference: Messrs. POMBO, GILCHREST, REHBERG, RAHALL, and UDALL of New Mexico.

From the Committee on Science, for consideration of sections 852 and 911 of the Senate amendment, and modifications committed to conference: Messrs. BOEHLERT, SMITH of Michigan, and HALL of Texas.

From the Committee on Small Business, for consideration of section 866 of the Senate amendment, and modifications committed to conference: Mr. MANZULLO, Mrs. KELLY, and Ms. VELÁZQUEZ.

From the Committee on Transportation and Infrastructure, for consideration of sections 312, 601, 907, 1049, 1051 and 2824 of the House bill, and sections 324, 601, and 2821 of the Senate amendment, and modifications committed to conference: Messrs. YOUNG of Alaska, PETRI, and CARSON of Oklahoma.

From the Committee on Veterans' Affairs, for consideration of section 565 of the House bill, and sections 644 and 707 of the Senate amendment, and modifications committed to conference: Messrs. SMITH of New Jersey, BILIRAKIS, and FILNER.

From the Committee on Ways and Means, for consideration of section 701 of the Senate amendment, and modi-

fications committed to conference: Messrs. THOMAS, MCCRERY, and STARK.

There was no objection.

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PROJECT BIOSHIELD ACT OF 2003

Mr. TAUZIN. Mr. Speaker, pursuant to the order of the House of Tuesday, July 15, 2003, I call up 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, and ask for its immediate consideration.

The Clerk read the title of the bill.

The SPEAKER pro tempore (Mr. JENKINS). Pursuant to the order of the House of Tuesday, July 15, 2003, the bill is considered read for amendment.

The text of H.R. 2122 is as follows:

H.R. 2122

SECTION 1. SHORT TITLE.

This Act may be cited as the "Project Bio-Shield 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 inter-agency 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 counter-

measure 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)”; and

(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 ap-

propriate 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 Bioter-

rorism 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 (I) 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.

“(1) 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 Sec-

retary 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.

SECTION 1. SHORT TITLE.

This Act may be cited as the “Project Bio-Shield 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) Use of noncompetitive procedures.—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures when—

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

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

“(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.”

(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”; and

(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)”; and

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

(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”; and

(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”; and

(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) against a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii);

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

“(iii) that is designed, developed, modified, or procured for the specific purpose of preventing, detecting, identifying, deterring, or mitigating actual or potential acts of chemical, biological, radiological, or nuclear catastrophe;

“(iv)(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); and

“(v) that relates to an actual or potential act of terrorism or catastrophic event or to actual or potential warfare.

“(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.

“(C) Notice to congress.—The Secretary and the Homeland Security Secretary shall promptly notify the designated congressional committees (as defined in paragraph (10)) of any determination made pursuant to subparagraph (A) or (B). Such notice shall be in unclassified and, if necessary, classified form.

“(D) Assuring access to threat information.—In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all information to which such Secretary is entitled under section 202 of the Homeland Security Act of 2002, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

“(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 development of 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 countermeasure would be appropriate but is either currently unavailable for procurement or available under unsuitable conditions, such Secretaries may jointly submit to the President a proposal to—

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

“(ii) make a commitment that, upon the first development of such 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 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 coun-

termeasure 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 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 designated congressional committees 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.

“(IV) Non-stockpile sales of security countermeasures.—The contract may provide that the vendor will not at any time (including after performance under the contract is otherwise completed) sell or otherwise provide such countermeasure to any domestic or foreign person, or transfer to any such person any quantity of such security countermeasure, or any intellectual property relating thereto that would enable the development or production of the countermeasure, without certification by the Secretary, in consultation with the Homeland Security Secretary, the Secretary of Defense, and the Secretary of State, that such sale or transfer, or category of sales or transfers, would not adversely affect the national security; and that, for each violation of this provision of the contract, the United States is entitled to recover from the person as liquidated damages an amount equal to three times the sum of the payments made to the vendor under the contract.

“(iii) Availability of simplified acquisition procedures.—

“(I) In general.—The amount of any 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) Use of noncompetitive procedures.—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures for a procurement under this subsection if the product is available from only one responsible source or only from a limited number of responsible sources, and no other type of product will satisfy the Secretary’s needs.

“(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 re-

quired, 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) Definitions.—

“(A) 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.

“(B) Designated congressional committees.—For purposes of this section, the term ‘designated congressional committees’ means the following committees of the Congress:

“(i) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

“(ii) In the Senate: the Committee on Health, Education, Labor, and Pensions, the Committee on Appropriations, and the Committee on Government Affairs.

“(d) Disclosures.—No Federal agency shall disclose under section 552 of title 5, 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 the 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) Integrity of special reserve fund; limitation of obligational authority to fund purposes; intent of congress against reprogramming.—Subject to paragraph (2), all amounts appropriated under subsection (a) are available for obligation through the end of fiscal year 2013 and only for the specific purposes set forth in the security countermeasures program. It is the intent of the Congress that no portion of such amount that remains unobligated for such purposes shall be applied, through reprogramming or otherwise, to any other 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.

“(d) Related Authorizations of Appropriations.—

“(1) Threat assessment capabilities.—For the purpose of carrying out the responsibilities of the Secretary for terror threat assessment under the security countermeasures program, there are authorized to be appropriated \$5,000,000 for fiscal year 2004, and such sums as may be necessary for each of the fiscal years 2005 and 2006, for the hiring of professional personnel within the Directorate for Information Analysis and Infrastructure Protection, who shall be analysts responsible for chemical, biological, radiological, and nuclear threat assessment (including but not limited to analysis of chemical, biological, radiological, and nuclear agents, the means by which such agents could be weaponized or used in a terrorist attack, and the capabilities, plans, and intentions of terrorists and other non-state actors who may have or acquire such agents). All

such analysts shall meet the applicable standards and qualifications for the performance of intelligence activities promulgated by the Director of Central Intelligence pursuant to section 104 of the National Security Act of 1947.

“(2) Intelligence sharing infrastructure.—For the purpose of carrying out the acquisition and deployment of secure facilities (including information technology and physical infrastructure, whether mobile and temporary, or permanent) sufficient to permit the Secretary to receive, not later than December 31, 2003, all classified information and products to which the Under Secretary for Information Analysis and Infrastructure Protection is entitled under subtitle A of title II, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2006.

“(e) Emergency Development of Security Countermeasures.—If the Secretary of Homeland Security and the Secretary of Health and Human Services jointly determine that procurement of a security countermeasure that has been approved for procurement using the special reserve fund under subsection (a)—

“(1) is not proceeding at a sufficiently rapid pace under 319F-2 of the Public Health Service Act to protect the national security; or

“(2) could be produced significantly less expensively by the government directly than through procurements under such section; then amounts in the special reserve fund may be used by the Secretary of Health and Human Services to produce security countermeasures for placement in the stockpile under subsection (a) of section 319F-2 of such Act if the joint determination is submitted to the President and the President approves such use of the special reserve fund. Amounts made available for such use in accordance with the preceding sentence are available for obligation as of the date on which the presidential approval is made, subject to applicable law regarding the apportionment of appropriations. This subsection applies notwithstanding other provisions of this section, and notwithstanding section 319F-2 of the Public Health Service Act. This subsection may not be construed as affecting the amounts specified in subsection (a) as authorizations of appropriations or the obligation limits contained therein.”

(c) Conforming Amendment.—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. With respect to the program established under former section 121 of such Act, the repeal of such section under the preceding sentence 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 record-keeping 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 designated congressional committees (as defined in subsection (e)) 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;

(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; and

(iv) whether, with respect to each procurement that is approved by the President under section 319F-2(c)(6) of the Public Health Service Act (as added by section 3 of this Act), a contract was not entered into within one year after such approval by the President.

(2) Annual summaries regarding certain activity.—The Secretary shall annually submit to the designated congressional committees 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.—

(1) In general.—Not later than four 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 designated congressional committees not later than five years after such date of enactment.

(2) Certain contents.—The report under paragraph (1) shall include—

(A) a summary of the most recent analysis by the Department of Homeland Security and the intelligence community of the domestic threat from chemical, biological, radiological, and nuclear agents;

(B) the Academy’s assessment of the current availability of countermeasures to address such threats;

(C) the Academy’s assessment of the extent to which programs and activities under this Act will reduce any gap between the threat and the availability of countermeasures to an acceptable level of risk; and

(D)(i) the Academy’s assessment of threats to national security that are posed by technology that will enable, during the 10-year period beginning on the date of the enactment of this Act, the development of antibiotic resistant, mutated, and bioengineered strains of biological agents; and

(ii) recommendations on short-term and long-term governmental strategies for addressing such threats, including recommendations for Federal policies regarding research priorities, the development of countermeasures, and investments in technology.

(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 designated congressional committees not later than five years after the date of the enactment of this Act.

(d) Report Regarding Additional Barriers to Procurement of Security Countermeasures.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Homeland Security and the Secretary of Health and Human Services shall report to the designated congressional committees any barriers to the procurement of security countermeasures that have not been addressed by this Act.

(e) Status of Program for Chemical Terrorism Preparedness.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Homeland Security shall submit to the designated congressional committees a report describing the status of the program carried out by the Secretary to enhance the preparedness of the United States to respond to terrorist attacks involving chemical agents.

(f) Designated Congressional Committees.—For purposes of this section, the term “designated congressional committees” means the following committees of the Congress:

(1) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

(2) In the Senate: the Committee on Health, Education, Labor, and Pensions, the Committee on Appropriations, and the Committee on Government Affairs.

SEC. 6. OUTREACH.

The Secretary of Health and Human Services shall develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of Hispanics, Native Americans, Asian-Pacific Americans, or other underrepresented populations, are meaningfully aware of available research and development grants and procurements conducted under sections 2 and 3 of this Act.

SEC. 7. ENSURING COORDINATION, COOPERATION AND THE ELIMINATION OF UNNECESSARY DUPLICATION IN PROGRAMS DESIGNED TO PROTECT THE HOMELAND FROM BIOLOGICAL, CHEMICAL, RADIOLOGICAL, AND NUCLEAR AGENTS.

(a) Ensuring Coordination of Programs.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall ensure the activities of their respective Departments coordinate, complement, and do not unnecessarily duplicate programs to identify potential domestic threats from biological, chemical, radiological or nuclear agents, detect such domestic incidents, analyze such incidents, and develop necessary countermeasures. The aforementioned Secretaries shall further ensure that information and technology possessed by the Departments relevant to these activities are shared with the other Departments.

(b) Designation of Agency Coordination Officer.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall each designate an officer or employee of their respective Departments who shall coordinate, through regular meetings and communications, with the other aforementioned Departments such programs and activities carried out by their Departments.

The SPEAKER pro tempore. In lieu of the amendments recommended by the Committee on Government Reform and the Select Committee on Homeland Security printed in the bill, the amendment in the nature of a substitute designate in the previous order of the House is adopted.

The text of the amendment in the nature of a substitute 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 Bio-Shield 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 QUALIFIED 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 counter-

measure (as defined in section 319F(h) and as determined by the Secretary in accordance with such section and consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) against a chemical, biological, radiological, or nuclear agent that may cause a public health emergency affecting national security.

"(3) INTERAGENCY COOPERATION.—

"(A) IN GENERAL.—In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the 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, contract, 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, or supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant, contract, or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

"(5) TRANSFERS OF QUALIFIED COUNTERMEASURES.—Each agreement for an award of a grant, contract, or cooperative agreement under section 319F(h) for the development of a qualified countermeasure shall provide that the recipient of the award will comply with all applicable export-related controls with respect to such countermeasure.

"(b) EXPEDITED PROCUREMENT AUTHORITY.—

"(1) INCREASED SIMPLIFIED ACQUISITION THRESHOLD FOR QUALIFIED 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) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

"(A) IN GENERAL.—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) RELATION TO OTHER AUTHORITIES.—The authority under subparagraph (A) is in addition to any other authority to use procedures other than competitive procedures.

"(C) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—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.

"(4) REVIEW.—

"(A) REVIEW ALLOWED.—Notwithstanding any other provision of law, including subsection (f), review of a contracting agency decision relating to a procurement described in paragraph (1) may be had only by filing a protest—

"(i) with a contracting agency; or

"(ii) with the Comptroller General under subchapter V of chapter 35 of title 31, United States Code.

"(B) OVERRIDE OF STAY OF CONTRACT AWARD OR PERFORMANCE COMMITTED TO AGENCY DISCRETION.—Notwithstanding any other provision of law, the following authorizations by the head of a procuring activity are committed to agency discretion:

"(i) An authorization under section 3553(c)(2) of title 31, United States Code, to award a contract for a procurement described in paragraph (1) of this subsection.

"(ii) An authorization under section 3553(d)(3)(C) of such title to perform a contract for a procurement described in paragraph (1) of this subsection.

"(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, contract, 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, contract, or cooperative agreement.

“(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

“(1) IN GENERAL.—For the purpose of performing, administering, or 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 ob-

tained 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.”

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

(1) in subsection (a)(1)—

(A) by inserting “or the Director of the National Institute of Allergy and Infectious Diseases” after “Director of the Center”; and

(B) by inserting “, or in the case of the Institute, to any qualified public or private entity,” after “private entities”;

(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)”; and

(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”;

(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”;

(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 each of the fiscal years 2003 and 2004.”

(c) ADDITIONAL AUTHORITY.—Section 319F of the Public Health Service Act (42 U.S.C. 247d-6) is amended—

(1) by redesignating subsections (i) and (j) as subsections (j) and (k), respectively; and

(2) by inserting after subsection (h) the following subsection:

“(i) PRIORITY COUNTERMEASURES FOR STRATEGIC NATIONAL STOCKPILE.—

“(1) IN GENERAL.—The Secretary, taking into consideration any recommendations of the working group under subsection (a), may initiate and sustain a program that results in the delivery of priority countermeasures for placement in the stockpile under section 319F-2.

“(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2013.”

(d) ADDITIONAL AUTHORIZATIONS OF APPROPRIATIONS.—Section 2106 of the Public Health Service Act (42 U.S.C. 300aa-6) is amended—

(1) in subsection (a), by striking “authorized to be appropriated” and all that follows and inserting the following: “authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2013.”; and

(2) in subsection (b), by striking “authorized to be appropriated” and all that follows and inserting the following: “authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2013.”

(e) TECHNICAL AMENDMENTS.—Section 319F of the Public Health Service Act (42 U.S.C. 247d-6) is amended—

(1) in subsection (a), by inserting “the Secretary of Homeland Security,” after “Management Agency,”; and

(2) in subsection (h)(4)(B), by striking “to diagnose conditions” and inserting “to treat, identify, or prevent conditions”.

(f) RULE OF CONSTRUCTION.—Nothing in this section has any legal effect on sections 302(2), 302(4), 304(a), or 304(b) of the Homeland Security Act of 2002.

SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

(a) ADDITIONAL AUTHORITY REGARDING STRATEGIC NATIONAL STOCKPILE.—

(1) TRANSFER OF PROGRAM.—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 transferred from such Act to the Public Health Service Act, is redesignated as section 319F-2, and is inserted after section 319F-1 of the Public Health Service Act (as added by section 2 of this Act).

(2) ADDITIONAL AUTHORITY.—Section 319F-2 of the Public Health Service Act, as added by paragraph (1), is amended to read as follows: “**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 bio-terrorist 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) and as determined by the Secretary in accordance with such section and consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) that—

“(i) (I) is against a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(i);

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

“(III)(aa) 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

“(bb) is a priority countermeasure 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); or

“(ii) is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act for emergency use.

“(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.

“(C) NOTICE TO CONGRESS.—The Secretary and the Homeland Security Secretary shall promptly notify the designated congressional committees (as defined in paragraph (10) that a determination has been made pursuant to subparagraph (A) or (B). Such notice shall be in unclassified or, if necessary, classified form.

“(D) ASSURING ACCESS TO THREAT INFORMATION.—In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all information to which such Secretary is entitled under section 202 of the Homeland Security Act of 2002, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

“(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 DEVELOPMENT OF 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 countermeasure would be appropriate but is either currently unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

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

“(ii) make a commitment that, upon the first development of such 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 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 countermeasure involved—

“(i) the call for the countermeasure;

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

“(iii) the 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 (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 DESIGNATED CONGRESSIONAL COMMITTEES.—The Secretary and the Homeland Security Secretary shall notify the designated congressional committees 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 such regulations as the Secretary determines necessary to implement the 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. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government.

“(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 Sec-

retary 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.

“(IV) NON-STOCKPILE TRANSFERS OF SECURITY COUNTERMEASURES.—The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

“(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) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

“(I) IN GENERAL.—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) RELATION TO OTHER AUTHORITIES.—The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

“(III) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—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) DEFINITIONS.—

“(A) 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.

“(B) DESIGNATED CONGRESSIONAL COMMITTEES.—For purposes of this section, the term ‘designated congressional committees’ means the following committees of the Congress:

“(i) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

“(ii) In the Senate: the Committee on Health, Education, Labor, and Pensions, the Committee on Appropriations, and the Committee on Government Affairs.

“(d) DISCLOSURES.—No Federal agency shall disclose under section 552 of title 5,

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 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 the 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) INTEGRITY OF SPECIAL RESERVE FUND; LIMITATION OF OBLIGATIONAL AUTHORITY TO FUND PURPOSES; INTENT OF CONGRESS AGAINST REPROGRAMMING.—Subject to paragraph (2), all amounts appropriated under subsection (a) are available for obligation through the end of fiscal year 2013 and only for the specific purposes set forth in the security countermeasures program. It is the intent of the Congress that no portion of such amount that remains unobligated for such purposes shall be applied, through reprogramming or otherwise, to any other 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.

“(d) RELATED AUTHORIZATIONS OF APPROPRIATIONS.—

“(1) THREAT ASSESSMENT CAPABILITIES.—For the purpose of carrying out the responsibilities of the Secretary for terror threat assessment under the security countermeasures program, there are authorized to be appropriated \$5,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006, for the hiring of professional personnel within the

Directorate for Information Analysis and Infrastructure Protection, who shall be analysts responsible for chemical, biological, radiological, and nuclear threat assessment (including but not limited to analysis of chemical, biological, radiological, and nuclear agents, the means by which such agents could be weaponized or used in a terrorist attack, and the capabilities, plans, and intentions of terrorists and other non-state actors who may have or acquire such agents). All such analysts shall meet the applicable standards and qualifications for the performance of intelligence activities promulgated by the Director of Central Intelligence pursuant to section 104 of the National Security Act of 1947.

“(2) INTELLIGENCE SHARING INFRASTRUCTURE.—For the purpose of carrying out the acquisition and deployment of secure facilities (including information technology and physical infrastructure, whether mobile and temporary, or permanent) sufficient to permit the Secretary to receive, not later than December 31, 2003, all classified information and products to which the Under Secretary for Information Analysis and Infrastructure Protection is entitled under subtitle A of title II, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2006.”

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, device, or biological product 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 ‘biological product’ has the meaning given such term in section 351 of the Public Health Service Act.

“(B) The term ‘emergency use’ has the meaning indicated for such term in paragraph (1).

“(C) The term ‘product’ means a drug, device, or biological product.

“(D) The term ‘unapproved product’ has the meaning indicated for such term in paragraph (2)(A).

“(E) 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 asso-

ciated 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.—Notwithstanding the termination of the declaration under subsection (b) or a revocation under subsection (g), 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 any 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 procedures other than full and open competition).

(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 procedures other than full and open competition).

(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 designated congressional committees 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;

(iii) the identification of each person or entity that received, or was considered and re-

jected for, grants, cooperative agreements, or contracts pursuant to the use of such authorities; and

(iv) whether, with respect to each procurement that is approved by the President under section 319F-2(c)(6) of the Public Health Service Act (as added by section 3 of this Act), a contract was entered into within one year after such approval by the President.

(2) ANNUAL SUMMARIES REGARDING CERTAIN ACTIVITY.—The Secretary shall annually submit to the designated congressional committees 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.—

(1) IN GENERAL.—Not later than four 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 designated congressional committees not later than five years after such date of enactment.

(2) CERTAIN CONTENTS.—The report under paragraph (1) shall include—

(A) a summary of the most recent analysis by the Department of Homeland Security and the intelligence community of the domestic threat from chemical, biological, radiological, and nuclear agents;

(B) the Academy’s assessment of the current availability of countermeasures to address such threats;

(C) the Academy’s assessment of the extent to which programs and activities under this Act will reduce any gap between the threat and the availability of countermeasures to an acceptable level of risk; and

(D)(i) the Academy’s assessment of threats to national security that are posed by technology that will enable, during the 10-year period beginning on the date of the enactment of this Act, the development of antibiotic resistant, mutated, or bioengineered strains of biological agents; and

(ii) recommendations on short-term and long-term governmental strategies for addressing such threats, including recommendations for Federal policies regarding research priorities, the development of countermeasures, and investments in technology.

(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 au-

thorities granted under this Act with respect to simplified acquisition procedures, procedures other than full and open competition, 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 designated congressional committees not later than five years after the date of the enactment of this Act.

(d) REPORT REGARDING BARRIERS TO PROCUREMENT OF SECURITY COUNTERMEASURES.—

(1) BIOCONTAINMENT FACILITIES.—Not later than 120 days after the date of the enactment of this Act, the Secretary of Homeland Security and the Secretary of Health and Human Services shall jointly report to the designated congressional committees whether there is a lack of adequate large-scale biocontainment facilities necessary for the testing of security countermeasures in accordance with Food and Drug Administration requirements.

(2) ADDITIONAL BARRIERS.—Not later than one year after the date of enactment of this Act, such Secretaries shall jointly report to the designated congressional committees any other potential barriers to the procurement of security countermeasures that have not been addressed by this Act.

(e) STATUS OF PROGRAM FOR CHEMICAL TERRORISM PREPAREDNESS.—Not later than 270 days after the date of the enactment of this Act, the Secretary of Homeland Security shall submit to the designated congressional committees a report describing the status of the program carried out by the Secretary to enhance the preparedness of the United States to respond to terrorist attacks involving chemical agents.

(f) DESIGNATED CONGRESSIONAL COMMITTEES.—For purposes of this section, the term “designated congressional committees” means the following committees of the Congress:

(1) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

(2) In the Senate: the Committee on Health, Education, Labor, and Pensions, the Committee on Appropriations, and the Committee on Government Affairs.

SEC. 6. OUTREACH.

The Secretary of Health and Human Services shall develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving

large proportions of Hispanics, Native Americans, Asian-Pacific Americans, or other underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under sections 2 and 3 of this Act.

SEC. 7. RECOMMENDATION FOR EXPORT CONTROLS ON CERTAIN BIOMEDICAL COUNTERMEASURES.

Upon the award of any grant, contract, or cooperative agreement under section 2 or 3 of this Act for the research, development, or procurement of a qualified countermeasure or a security countermeasure (as those terms are defined in this Act), the Secretary of Health and Human Services shall, in consultation with the heads of other appropriate Federal agencies, determine whether the countermeasure involved in such grant, contract, or cooperative agreement is subject to existing export-related controls and, if not, may make a recommendation to the appropriate Federal agency or agencies that such countermeasure should be included on the list of controlled items subject to such controls.

SEC. 8. ENSURING COORDINATION, COOPERATION AND THE ELIMINATION OF UNNECESSARY DUPLICATION IN PROGRAMS DESIGNED TO PROTECT THE HOMELAND FROM BIOLOGICAL, CHEMICAL, RADIOLOGICAL, AND NUCLEAR AGENTS.

(a) ENSURING COORDINATION OF PROGRAMS.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall ensure that the activities of their respective Departments coordinate, complement, and do not unnecessarily duplicate programs to identify potential domestic threats from biological, chemical, radiological or nuclear agents, detect domestic incidents involving such agents, analyze such incidents, and develop necessary countermeasures. The aforementioned Secretaries shall further ensure that information and technology possessed by the Departments relevant to these activities are shared with the other Departments.

(b) DESIGNATION OF AGENCY COORDINATION OFFICER.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall each designate an officer or employee of their respective Departments who shall coordinate, through regular meetings and communications, with the other aforementioned Departments such programs and activities carried out by their Departments.

The SPEAKER pro tempore. The gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Ohio (Mr. BROWN) each will control 30 minutes. The gentleman from Virginia (Mr. TOM DAVIS) and the gentleman from California (Mr. WAXMAN) each will control 7½ minutes. The gentleman from California (Mr. COX) and the gentleman from Texas (Mr. TURNER) each will control 7½ minutes.

The Chair recognize the gentleman from Louisiana (Mr. TAUZIN).

GENERAL LEAVE

Mr. TAUZIN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on H.R. 2122.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. TAUZIN. Mr. Speaker, I yield myself 4 minutes.

Today, Mr. Speaker, the House will address one of President Bush's top initiatives in the war against terror, Project Bioshield.

Mr. Speaker, it is absolutely critical that America's public health emergency system be prepared to respond to new and emerging threats, and we are here today to take care of that job. This bipartisan legislation is about the safety and security of American families and of our country. America is stepping up to the profound threat of terrorism and other public health emergencies, and I am proud to report that H.R. 2122 combines smart policy and provides additional resources to prepare the Nation for bioterrorism threats and for other public health emergencies.

The chairman and ranking member of both the committees of jurisdiction and the Select Committee of Homeland Security have arrived at this consensus product that is before us today. I would like to thank the gentleman from Michigan (Mr. DINGELL), the gentleman from Virginia (Mr. TOM DAVIS), the gentleman from California (Mr. WAXMAN), the gentleman from California (Mr. COX), the gentleman from Texas (Mr. TURNER) for their cooperation and hard work on this bill. This bipartisan spirit is similar to last year's effort on the Public Health Security and Bioterrorism Preparedness and Response Act that Senator KENNEDY and I had the privilege to move through the Congress last year.

Project Bioshield will spur the research and development of new vaccines, drugs, and other countermeasures to deal with these biological, chemical, nuclear or radiological agents that pose a material threat to our Nation's security. The list includes, among other dangerous agents, such things as anthrax, botulinum toxin, the plague, ebola, and other similar viruses, many of which lack any effective treatment or antidote today.

The bill before us accomplishes this goal by doing two important things. First, it provides the needed flexibility in a range of areas from government contracting rules to peer review to personnel matters in order to speed up government-sponsored research and development into these deadly agents. Second, it creates a special reserve fund of money for the government to purchase these countermeasures that may ultimately be developed in response to the President's call. Without this clear commitment of funding in future years, private sector companies that are capable of such development simply will not undertake the heavy investment and risk associated with developing products to deal with agents that do not affect significant populations today and hopefully never will.

At our urging, the House has already provided an advanced appropriations of \$5.6 billion over the next 10 years for this purpose, and this is all consistent

with our authorization in the House budget resolution.

The bill also provides new authority to the Secretary of Health and Human Services to authorize in times of emergency the use of unapproved products whose benefits in treating or preventing infection outweigh the risk. Under current law, the only way an individual can receive an unapproved product is pursuant to a clinical investigation. But in time of national emergency, when this Nation is under attack, it may be necessary to give such investigational drugs on a large scale basis to millions of Americans. H.R. 2122 provides that if there is such an emergency, and if no adequate alternative therapy is available, the Secretary can authorize the use of a drug, device, or vaccine in such a flexible manner.

While we have made improvements to the administration's initial proposal in certain areas, our bill stays close to that original proposal, granting all the additional flexibilities and authorities requested by the President and even expanding them in some cases to further encourage companies to heed our call for innovation.

Once again, I want to applaud the leadership of President Bush and the truly bipartisan work of this body across multiple committees of jurisdiction to protect our country and to promote public health security from the many new dangers that we face today.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself 3½ minutes.

Mr. Speaker, this legislation is the product of a good-faith bipartisan process. I want to thank the gentleman from Louisiana (Mr. TAUZIN), the gentleman from Florida (Mr. BILIRAKIS), as well as the ranking member, the gentleman from Michigan (Mr. DINGELL), for their work on this bill.

The United States and the global community of which we are part can only benefit from the development of bioterrorism countermeasures. Because the very existence of countermeasures renders bioterrorism less lethal and, therefore, less attractive to would-be terrorists, new countermeasures, therefore, serve a dual purpose. They are both an antidote and a deterrent to future attacks.

For the sake of national and international security, it makes sense to invest in both basic and advanced research aimed at producing new bioterrorism countermeasures. When an opportunity to produce one of these countermeasures presents itself, it makes sense to capitalize quickly on that opportunity. That is the logic behind this legislation.

The bill establishes an expedited process for Federal support of countermeasure research and a procurement process to encourage private sector investment in this research. At the same time, Mr. Speaker, the legislation is

not a blank check. Congress has a responsibility to weigh competing funding priorities and set funding levels appropriately.

In that context, it is appropriate to reiterate a concern that I raised last week while we debated the Labor, Health and Human Services appropriations bill. Bioterrorism funding is essential and important. The legislation before us is essential and important, but our investment in bioterrorism should not and must not come at the expense of research focusing on cancer and other health threats.

Let me repeat that. Our investment in bioterrorism should not and must not come at the expense of research focusing on cancer and other health threats. The appropriations bill we passed last week here funds the National Institutes of Health at a level barely sufficient to support existing research projects, much less new research. That is a direct outgrowth from the tax cut that this Congress passed recently and the tax cuts for the wealthiest, most privileged citizens this Congress passed 2 years ago. It means we have not had enough money to appropriate for basic research, for medical research for the National Institutes of Health. It means it may be difficult for us in the future to deal with bioterrorism funding as fully as we should.

This Congress has made choices by giving tax cuts to the wealthiest, most privileged citizens, and as a result has made far too many cuts in health care; and health care is clearly inadequately funded, as our committee has discussed over and over again.

Mr. Speaker, finding ways to prevent and to treat and to cure disease is an enduring national priority. Interest in it does not wane, does not wane. Our investment in it should not either. We need to make these decisions in a way that serves the public and serves the interest of more medical research. We have a responsibility to balance priorities to provide adequate resources to prepare the country for a possible bioterrorist attack while maintaining strong support for other medical research priorities.

Mr. Speaker, I hope we can work on a bipartisan basis to restore the momentum that we once had behind groundbreaking medical research while continuing to move forward in the area of bioterrorism preparedness. This legislation before us today promotes the latter goal, and I urge my colleagues to support it. I thank the gentleman from Louisiana (Mr. TAUZIN), the gentleman from Florida (Mr. BILIRAKIS), the gentleman from Michigan (Mr. DINGELL), the gentleman from Massachusetts (Mr. MARKEY), and others who worked on this legislation.

Mr. Speaker, I yield 5 minutes to the gentleman from Massachusetts (Mr. MARKEY), my good friend.

Mr. MARKEY. Mr. Speaker, I thank the gentleman from Ohio (Mr. BROWN) for yielding me time.

I rise for the purpose of entering into a colloquy with the gentleman from Louisiana (Mr. TAUZIN).

I want to commend the chairman and his staff along with the gentleman from California (Mr. COX); the ranking member, the gentleman from Michigan (Mr. DINGELL); and the gentleman from Ohio (Mr. BROWN); and the ranking member, the gentleman from Texas (Mr. TURNER) for all of their hard work and for working with me and my staff in a bipartisan fashion that ultimately led to a resolution of all of the concerns which I raised with the legislation.

I do have, however, two outstanding issues that I wish to clarify at this time. Mr. Speaker, I have concerns that relate to the emergency use section of Project Bioshield. Specifically, I want to be sure that once a declaration of an emergency is terminated or revoked, that current law applies and it will then be impermissible for anyone to move such drugs, devices or biologics in interstate commerce without going through the proper approval process. Is this the case under the legislation?

Mr. TAUZIN. Mr. Speaker, will the gentleman yield?

Mr. MARKEY. I yield to the gentleman from Louisiana.

Mr. TAUZIN. The gentleman is correct. Like you, I too want to ensure that unapproved products are available in times of emergency. And while we allow the FDA to make products available during such time of emergency, absent such emergency, current law applies. We do allow for the shipments of such therapies in limited circumstances, namely, where a physician authorizes the continued treatment of an individual who initially received the drug during an emergency. However, this is the only exception. Absent that, present law applies to these unapproved products.

Mr. MARKEY. I thank the gentleman.

Secondly, I very much appreciate the gentleman's work on crafting language to ensure that the countermeasures developed under this legislation are, where necessary, subject to the same export control laws and regulations as other chemical and biological agents and their associated countermeasures. One of the new responsibilities the Secretary of HHS is directed to assume is to review new countermeasures both in the R&D phase as well as in the procurement phase of the Bioshield Program. The Secretary is encouraged to consult with other Federal agencies who play a role in setting export control policy and to recommend whether the new countermeasure or countermeasure R&D should be added to the various lists of controlled technologies that cannot be transferred to other countries without prior permission.

Is it your understanding that the Secretary should do this as expeditiously as possible, and that each beneficiary of Bioshield funds be directed as

part of the contract or grant to abide by all applicable U.S. export laws governing the transfer of technology and R&D?

Mr. TAUZIN. The gentleman is absolutely correct. The Secretary should perform these reviews as expeditiously as possible once the R&D or procurement has started so as to prevent any exports of countermeasures or countermeasure R&D that could harm our U.S. national security.

Mr. MARKEY. I just want to thank the chairman. He has worked very hard and long on this legislation. I want to thank the gentleman's staff and Kendra Bodner from my staff for working out this language.

Mr. TAUZIN. Let me thank the gentleman from Massachusetts (Mr. MARKEY). He raised a great number of concerns as we went true this process. I want to thank the gentleman for the way in which he worked with Members on both sides of the aisle so we cannot only take care of those concerns but produce a great product for the security of our country, and he has added immeasurably to that effort.

Mr. MARKEY. Good job, Mr. Chairman, and good job to everyone who has worked on this bill on both sides of the aisle.

Mr. TAUZIN. Mr. Speaker, I yield 3 minutes to the gentleman from Ohio (Mr. LATOURETTE).

Mr. LATOURETTE. Mr. Speaker, I thank the chairman for yielding to me for the purpose of a colloquy in order to clarify the intent of two provisions.

This legislation authorizes the director of the National Institute of Allergies and Infectious Diseases to issue grants to non-Federal entities for the construction and operation of specialized research facilities. A second provision of the bill authorizes the Secretary of HHS to take control of these facilities in the event or threat of bioterror emergency.

As you know, the Public Buildings Act of 1959, which is under the exclusive jurisdiction of the Committee on Transportation and Infrastructure, governs the construction, acquisitions, repair and alteration of public buildings, including many laboratories and research facilities.

Mr. Chairman, am I correct that nothing in this legislation exempts the Secretary of HHS or the director of the institute from the requirements of the Public Buildings Act?

Mr. TAUZIN. Mr. Speaker, will the gentleman yield?

Mr. LATOURETTE. I yield to the gentleman from Louisiana.

Mr. TAUZIN. The gentleman is absolutely correct. These provisions do not preempt the Public Buildings Act to the extent that it would otherwise apply to such activities.

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Mr. LATOURETTE. Mr. Speaker, it is also my understanding that the facilities authority granted to the Secretary of HHS and the Director of the Institute of Diseases is intended only for

special use facilities, which do not meet the definition of a public building under the Public Buildings Act. Is that also correct?

Mr. TAUZIN. Mr. Speaker, if the gentleman will continue to yield, that is also correct. The Project Bioshield Act authorizes the construction of highly specialized laboratories, all of which I would expect to be biosafety level 3 or 4 laboratories unsuitable for general purpose use. Project Bioshield does not authorize the construction of "public buildings" as defined by the Public Buildings Act of 1959.

Mr. LATOURETTE. Mr. Speaker, lastly, it is my understanding that the march in authority granted the Secretary of HHS is intended to give the Secretary control of these facilities for a limited period of time only. Is that also correct?

Mr. TAUZIN. If the gentleman would continue to yield, that is also correct. The authority allows the Secretary to take control of these facilities only during, and as necessary to respond to, public health emergencies affecting national security. Under the Bioterrorism Response Act passed last year, a public health emergency can be declared by the Secretary for up to 90 days at a time; and although the Secretary may extend the designation for multiple 90-day periods, it is not the intention of this legislation to allow the Secretary to control a facility for the useful life of that facility.

Mr. LATOURETTE. Mr. Speaker, I thank the chairman for the clarification.

Mr. BROWN of Ohio. Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I yield myself such time as I may consume.

(Mr. TAUZIN asked and was given permission to revise and extend his remarks, and include extraneous material.)

Mr. TAUZIN. Mr. Speaker, I think we have a couple of other Members who need to do colloquies.

While we are waiting, I wanted to take this time, Mr. Speaker, to refer to a letter received today from the Secretary of Health and Human Services, Secretary Tommy Thompson, dated July 16, 2003; and I want to place the letter in the RECORD at this point.

THE SECRETARY OF HEALTH
AND HUMAN SERVICES,
Washington, DC, July 16, 2003.

Hon. BILLY TAUZIN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR CHAIRMAN TAUZIN: Thank you for your leadership on H.R. 2122, the Project Bioshield Act of 2003. This legislation is a critical step toward strengthening our ability to protect Americans against chemical, biological, radiological and nuclear threats.

H.R. 2122 would: (1) speed the Government's ability to turn promising scientific discoveries into necessary countermeasures by one-third or more; (2) authorize funding to purchase critical new countermeasures targeted against the most worrisome threats; and (3) allow the Food and Drug Administration to make promising treatments quickly available to Americans in emergency situations.

I would like to address two issues that have arisen as the House takes up this vital priority. First, I share Representative Wamp's interest in building domestic capacity to produce countermeasures. In implementing Project BioShield, I will do everything in my power to purchase from domestic sources. To have a secure supply, we must build capacity within the United States and my department is committed to achieving that objective. The essential purpose of Project BioShield is to ensure we have necessary and timely countermeasures. We cannot achieve this goal by relying on foreign sources. Building a robust domestic capacity to produce countermeasures is, therefore, at the very heart of Project BioShield.

Second, I agree with Representative Jackson-Lee that the Strategic National Stockpile must serve all areas of the Nation, including rural areas. The Centers for Disease Control and Prevention has positioned stockpile assets to deliver needed medical supplies anywhere in the country within 12 hours. I have a personal understanding of the challenges that rural areas face and share Representative Jackson-Lee's interest in rural America. My department is pro-actively working with state and local health departments to ensure the effective and timely delivery of stockpile assets to both rural and urban parts of our Nation.

If I can provide you or the members of the Committee with any further information or if I can otherwise be of assistance, please do not hesitate to contact me.

Sincerely,

TOMMY G. THOMPSON.

Mr. Speaker, I wanted to refer to it because the Secretary refers to several concerns raised by other Members of the House, of which I also share with him, and I think we will have a colloquy on one of those.

The first is a concern by the gentleman from Tennessee (Mr. WAMP) whose interest is in building domestic capacity to produce countermeasures; and, indeed, the Secretary indicates in his letter that it is indeed his desire to make sure those countermeasures are developed within this country. We cannot achieve the goal of securing our country if indeed we rely upon foreign sources for these measures; and, therefore, the building of robust domestic capacity to produce these countermeasures is at the very heart of the Bioshield Project.

I wanted to assure my friend, the gentleman from Tennessee (Mr. WAMP), that I share the Secretary's comments and his intentions in that regard.

Secondly, the gentlewoman from Texas (Ms. JACKSON-LEE) was concerned that strategic national stockpile must be developed in such a way as to serve rural areas of the country, not simply the urban areas of our country, because rural areas can be affected by these bioterrorism threats just as easily, obviously, as urban areas. The Secretary indicates that the Centers for Disease Control and Prevention has positioned stockpile assets anywhere in the country, delivery within 12 hours, in effect making sure that rural areas are not left out of the protection of this bill and the other bioterrorism bills that have passed the House and are part of the Centers for Disease Con-

trol stockpiles and distribution system.

So that those two concerns by our colleagues are addressed in this letter, and I wanted to share with those colleagues my agreement with the Secretary on both of those points.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself as much time as I may consume.

Mr. Speaker, I share the comments both of the chairman of the committee and Secretary Thompson in his letter that the chairman just mentioned.

I applaud the gentleman from Tennessee's (Mr. WAMP) interest in building domestic capacity; and in terms of purchasing from domestic sources, I think that is an important thing that this Congress too often forgets. When we look at our trade policy, often that tends to favor investors and tends often to hurt workers, both in this country and internationally, whether it is the Singapore-Chile agreement coming up or whether it is the fast track authority that this Congress I think wrongly gave the President fairly recently.

I also support the efforts of the gentlewoman from Texas (Ms. JACKSON-LEE) from Houston in terms of serving all the Nation, including rural areas. I think that our ability to deliver all kinds of health care, all kinds of public health care, especially in rural areas and urban areas alike, is especially important.

And I want to reiterate from my opening comments, Mr. Speaker, that while Bioshield is so very, very, very important and it gives us great opportunity to further develop our public health system, it is important that we keep in mind our long-standing, day-to-day public health system.

Bioshield can serve some synergism with the public health system as long as we keep focussed on the Centers for Disease Control, as long as we keep focused on local public health departments, because that has served the public very well, this public health system. It is too often starved, too often woefully, inadequately funded. I would hope that the synergism we can create with Bioshield and with public health will serve this country well, both in terms of deterring as an antidote and as a deterrence for bioterrorism attacks and in terms of the day-to-day issue of public health, whether it is lead-based paints, whether it is eliminating the discrepancy between rich and poor and the health care they get, whether it is providing safe drinking water and clean air and all the things that public health provide to us.

Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I yield myself such time again as I may consume.

(Mr. TAUZIN asked and was given permission to revise and extend his remarks, and include extraneous material.)

Mr. TAUZIN. Mr. Speaker, I insert at this point into the RECORD of these proceedings a statement of administration policy in strong support of this bill.

EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT AND BUDGET,

Washington, DC, July 16, 2003.

STATEMENT OF ADMINISTRATION POLICY

The Administration supports House passage of H.R. 2122, Project BioShield Act of 2003. This bill would implement a Presidential initiative to help spur the development and availability of next generation countermeasures against biological, chemical, nuclear, and radiological weapons. Specifically, H.R. 2122 would: (1) speed the Government's ability to turn promising scientific discoveries into necessary countermeasures by one-third or more; (2) authorize funding to purchase critical new countermeasures targeted against the most worrisome threats; and (3) allow the Food and Drug Administration to make promising treatments quickly available to Americans in emergency situations. Project BioShield is critical for strengthening our ability to protect Americans against biological, chemical, radiological, and nuclear terrorist threats.

The Administration notes that provisions on submission of legislative proposals, and of reports on options considered and rejected, should reflect Constitutional principles regarding Executive-originated legislative proposals and protecting Executive deliberations.

Mr. Speaker, I again center Congress' attention on the concerns that our colleague from Tennessee (Mr. WAMP) raises regarding the lack of domestic capacity to develop and produce new vaccines and countermeasures, indeed the concern he has that we might end up relying upon foreign sources for these critical supplies.

Let me first say that I share that concern about our lack of a robust domestic vaccine industry. I know that the Secretary of Health and Human Services shares that concern.

I also know that one of the primary purposes behind Project Bioshield is to help the Nation address this important problem by giving incentives to all companies, but especially our domestic pharmaceutical companies, to invest in this capacity, in this vaccine antidote producing capacity so that we have domestic supplies and domestic countermeasures available without relying upon foreign sources to protect this country in case of a domestic attack.

I just read from the Secretary's letter his commitment to do exactly that, to use this Act to make sure that we incentivize the capacity of our country to produce those vaccines and those countermeasures, those antidotes, whatever may be required, in case of the unbelievable attack upon our country with some of these awful agents, and I am confident the Secretary will implement the Act with that goal in mind.

We obviously on the Committee on Energy and Commerce will aggressively oversight the implementation of this Act so that we are satisfied that we are, in fact, encouraging domestic corporations to compete for these contracts.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I have no other speakers, and I am willing to yield back if the gentleman from Louisiana (Mr. TAUZIN) is.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Georgia (Mr. NORWOOD), a distinguished member of our committee.

Mr. NORWOOD. Mr. Speaker, I rise out of breath simply to urge my colleagues to vote for this. This is an enormous undertaking. The Secretary has done a great job for us. I think all Americans I know are as concerned about bioterrorism as any part of terrorism out there.

I thank the chairman for bringing this bill, and hopefully everybody here will help him and help the Secretary move this thing forward.

Mr. BROWN of Ohio. Mr. Speaker, I yield 3 minutes to the gentleman from California (Mr. WAXMAN).

Mr. WAXMAN. Mr. Speaker, I thank the gentleman for yielding time to me.

I have had the opportunity to review this legislation from the prospect of two committees, as a member of the Committee on Energy and Commerce, which looks at the health impact of the threat of bioterrorism, as well as the Committee on Government Reform; and given the serious threat of bioterrorism, the development of effective countermeasures is vital to our national security.

Project Bioshield represents the administration's proposal to encourage the development of these products, and I fully support the intent of this legislation. I also agree with its premise that when the market cannot foster the development of critical products by itself, the government must rise to the challenge.

This bill is the product of collaboration between the majority and minority of three separate committees. Although the final bill may not be perfect, I believe the end product is one that all Members should support.

The bill before us today includes several significant improvements from earlier proposals. For example, it includes important protections against waste and abuse that are standard for government contracts, such as preserving the government's rights to review contractors' books and records.

The bill also permits the use of certain streamlined procurement procedures but only if the Secretary determines that there is a pressing need to do so. In emergency situations, we should not impede the development of necessary products. However, any exception from the standard procurement procedures should be made only when necessary and should be subject to review. This proposal preserves that standard.

The provisions of Bioshield authorizing the emergency distribution of unapproved drugs and devices, whose risks and benefits are not fully tested,

impose an unprecedented responsibility on the government. The FDA must be vigilant in protecting the public against unnecessary risks from these products.

In part because of these concerns, the bill has been modified to require that health care providers and patients be informed that the products have not been approved and of their risks. The bill also has been modified to require that manufacturers monitor and report adverse reactions to the products and keep other appropriate records about the use of the products.

These conditions are essential for the safe use of unapproved products, and they should be imposed in all cases, except in truly extraordinary circumstances.

In addition, the Secretary is authorized to limit the distribution of the products, to limit who may administer the products, to waive good manufacturing practice requirements only when absolutely necessary, and to require recordkeeping by others in the chain of distribution.

We expect the Secretary to consider the need for these additional conditions in each case and to impose them to the full extent necessary to protect the public from the risks of these products.

The bill before us today is an improvement over the original proposal, and it deserves our support.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Florida (Mr. BILIRAKIS), the distinguished chairman of the Subcommittee on Health of the Committee on Energy and Commerce, who celebrates his birthday today.

Mr. BILIRAKIS. Mr. Speaker, I appreciate the gentleman, my good friend, the chairman for recognizing me, and I speak in support of the Project Bioshield Act of 2003.

Mr. Speaker, in 2001, we really learned about the real threat of terrorism and the importance of being adequately prepared for an attack. The possibility that our enemies might attack us with biological, chemical or radiological weapons still remains, unfortunately, a significant threat.

During the last Congress, the Committee on Energy and Commerce worked together in a bipartisan fashion to produce the Public Health Security and Bioterrorism Response Act which became law in June of 2002. I was proud to have been a small part of this important effort. However, while our legislation has helped get critical resources out to the States and moved us closer to the reality of a more comprehensive strategic national stockpile, more still needs to be done.

I am pleased to have worked with my colleagues and the Bush administration to develop legislation that would help make the vision of Project Bioshield a reality. As we have heard, this initiative is designed to speed the development and availability of medical countermeasures that will help us respond to any future terrorist attacks.

The bill will also provide the Federal Government with tools to help encourage our research-driven pharmaceutical, biotechnology and medical technology to develop new countermeasures where none exists today.

It remains our responsibility to do what we can to ensure that the United States is ready for whatever biological, chemical or radiological threat we might face.

□ 1430

It is for that reason that I join the others in urging my colleagues to join us in supporting the Project BioShield Act of 2003.

Mr. WAXMAN. Mr. Speaker, I control the time on behalf of the Democrats on the Committee on Government Reform, and I ask unanimous consent to yield the time that we have to the gentleman from Ohio (Mr. BROWN) to control that time.

The SPEAKER pro tempore (Mr. GILCHREST). Is there objection to the request of the gentleman from California?

There was no objection.

The SPEAKER pro tempore. The gentleman from Ohio (Mr. BROWN) will be recognized for an additional 7½ minutes.

Mr. BROWN of Ohio. Mr. Speaker, could you tell us how much time I have, the Committee on Energy and Commerce and the Committee on Government Reform, and how much time the gentleman from Louisiana (Mr. TAUZIN) has?

The SPEAKER pro tempore. The gentleman from Ohio (Mr. BROWN) has 24½ minutes remaining, and the gentleman from Louisiana (Mr. TAUZIN) has 16½ minutes remaining.

Mr. TAUZIN. Mr. Speaker, I yield 3 minutes to the gentleman from Connecticut (Mr. SHAYS).

Mr. SHAYS. Mr. Speaker, I rise to engage the chairman of the Committee on Energy and Commerce, the gentleman from Louisiana (Mr. TAUZIN), in a colloquy.

Mr. Speaker, I am concerned that certain provisions of section 4 of the bill will unfairly treat the men and women of our armed services. Specifically, the bill would create a new section 564 of the Federal Food, Drug and Cosmetic Act that would allow the application of medical products to the general population in emergencies, but only with appropriate safeguards. New subsection (k) of the act, however, seems to allow the President to waive or the Secretary of HHS to modify the application of these safeguards for military personnel. Can the chairman enlighten me as to his intent in this provision?

Mr. TAUZIN. Mr. Speaker, will the gentleman yield?

Mr. SHAYS. I yield to the gentleman from Louisiana.

Mr. TAUZIN. Mr. Speaker, I will be happy to speak to that.

New subsection (k) permits the President to waive, in writing, only the con-

sent portion of the conditions of authorization set forth in section 564(e) with respect to armed services personnel, and only to the extent that complying with the requirement is not feasible, is contrary to the best interests of the personnel, or is not in the interest of national security.

It is not my intent that the President may ever waive pursuant to subsection (k) the other conditions. They are that the individual to whom the product is to be administered is informed, one, that the Secretary has authorized the emergency use of a product, and, two, about the significant known and potential benefits and risks of the use of the product. The committee intends, absent extraordinary circumstances, that such information be provided to individuals prior to receiving the unapproved product.

After the gentleman raised these issues with us, we took a closer look at the language, and I acknowledge that there is a crossreference in new section 564(k)(2) that could be confusing. I want to continue to work with the gentleman and the gentleman from New York (Mr. TOWNS), who I know cares deeply about this issue, along with you and many of us, to make sure that the final version of this bill from the conference that we will have with the Senate, I am sure, provides that our military are informed of the drugs that are given before these drugs are administered.

Let me also assure the gentleman from Connecticut that we understand the importance of the protections for military personnel receiving unapproved countermeasures contained in current law, title X, section 1107; and we intend the waiver authority in this bill to be used only in the very extraordinary circumstances that we describe in the bill.

Mr. SHAYS. Mr. Speaker, reclaiming my time, I thank the gentleman for his explanation, and I look forward to working with him to make sure that we clear this matter up in conference with the Senate.

Mr. TAUZIN. Mr. Speaker, if the gentleman will continue to yield, I thank my friend and give him that assurance.

Mr. BROWN of Ohio. Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I yield 2 minutes to the gentleman from Nevada (Mr. GIBBONS).

Mr. GIBBONS. Mr. Speaker, I want to thank my friend, the chairman, for yielding me this time. I rise in support of Project BioShield. It is a very important step for the Department of Homeland Security.

Project BioShield aims to rapidly transfer technology into products that can be used to protect individuals against biological and chemical agents used as weapons of terrorism or mass destruction. The emphasis is on rapid introduction of new countermeasures into actual use, as many technologies currently under development need to be transitioned through regulatory commercial or regulatory cycles.

The Homeland Security Act gave the Department of Homeland Security responsibility for integrating intelligence information and assessing terrorist threats and vulnerabilities. This information makes full use of the Department's capabilities. Identifying the most urgent threats and setting research priorities will be vital to meeting the bioterror threat.

Obtaining the best intelligence and performing accurate threat assessment is absolutely critical. By properly understanding the threats that confront us, we can allocate our resources and focus our efforts where they are most needed, on agents for which the risk and potential consequence of attack are greatest.

BioShield tasks the Secretary of the Department of Homeland Security with using the best information available to identify the greatest threats to the national security. Incorporated into the bill are several provisions that will strengthen the Secretary's threat assessment capabilities.

This legislation, Mr. Speaker, provides the Secretary of the Department of Homeland Security the authority and resources needed to quickly hire the necessary bioterror analysts and rapidly build a bioterror intelligence infrastructure.

I urge all my colleagues to support H.R. 2122, the Project BioShield Act of 2003.

Mr. BROWN of Ohio. Mr. Speaker, I rise again in support of this bill, and I ask unanimous consent that I be allowed to yield my remaining 24½ minutes to the gentleman from New Jersey (Mr. ANDREWS) with permission that he be allowed to yield said time.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Ohio?

There was no objection.

The SPEAKER pro tempore. The gentleman from New Jersey (Mr. ANDREWS) is recognized for the remaining time.

Mr. ANDREWS. Mr. Speaker, I yield myself such time as I may consume; and I thank my friend, the gentleman from Ohio (Mr. BROWN), for yielding me this time. I assure my colleagues I will not personally take all 24 minutes; I will reserve the right to yield to other Members, and the gentleman from Texas (Mr. TURNER) should be here forthrightly and he will be yielding.

Mr. Speaker, I want to thank the gentleman from Louisiana (Mr. TAUZIN) and the leadership of the gentleman from Michigan (Mr. DINGELL) on our side of the aisle, the other committees of jurisdiction, the gentleman from California (Mr. COX), and the gentleman from Texas (Mr. TURNER) for bringing this very important legislation to the floor.

Mr. Speaker, I think that history will reflect that this is our generation's version of the Manhattan Project. These are uncharted scientific waters. It is a world that we have not yet become accustomed to navigating.

It is the world of massive biological attack against the United States of America. I have supreme confidence that we will be able to meet and deter such an attack, but only if we are able to engage the machinery of the best minds in our universities and our companies, in our government, and throughout society.

I believe that is exactly what this legislation does. It brings to the forefront the abilities of our researchers, of our scientists, of our entrepreneurs, of our public officials to systematically identify the biological risks that our country faces, to methodically analyze the best opportunities for addressing those biological risks, and to use a process that will effectively meet those risks.

I commend the authors for properly balancing the mechanisms of money, market, and exclusivity. It is very important there be adequate resources for the companies who we are asking to engage in this so that they will in fact engage in it. It is important that we create a market, because it is our fervent wish that there will never be a market for these products. We hope they are never needed. But in the absence of that market, it is important the law contain a specific guarantee to move forward.

Finally, with respect to exclusivity and insulation from antitrust considerations, it is very important that those who are willing to risk their capital and their energy to come up with these agents are afforded the protection of the law.

Mr. TAUZIN. Mr. Speaker, will the gentleman yield?

Mr. ANDREWS. I yield to the gentleman from Louisiana.

Mr. TAUZIN. Mr. Speaker, I thank the gentleman and will be happy to enter into a discussion with him.

Let me first thank him for the excellent statement he has made. I think the gentleman is correct. I think it is as important to our country as perhaps the Manhattan Project was. I remember when Speaker O'Neill used to remind this House that partisanship ended at the water's edge. He meant to tell us that when it came to protecting our country, we were not Democrats or Republicans, we were Americans. And where the water's edge used to be the boundary of the threats against our country, because of 9-11, we now understand the water's edge is no longer the boundary. Within our country we now face these potential threats.

So I thank the gentleman. And, indeed, the bill is designed to do exactly that, to balance those important elements of the equation and to make sure we incentivize the private marketplace, but also provide the public monies, \$5.6 billion over 10 years, to make sure we have the available money in a trust fund, through our budget resolution, appropriated through our process, to make sure we can acquire those countermeasures, stockpile them, distribute them around the country, as

the Secretary is prepared to do, to make sure that those countermeasures are available.

It also balances the need to build in our own country the capability of building those vaccines and countermeasures that otherwise would never be built. Because who would, in the private sector, want to build a vaccine for the plague today, without this particular legislation? So I thank the gentleman.

Mr. ANDREWS. Mr. Speaker, reclaiming my time, I agree with the chairman. I think he is correct that bipartisanship cannot simply begin at the water's edge in a world where the battlefield is here. And there is a virtual battlefield that we are all, unfortunately, living in.

I would like to make two other points before I stop. The first is that I very much appreciate the inclusion into this bill, with the help of the gentleman from California (Mr. COX), language that I suggested with respect to making it clear that when there is a termination for reason of convenience by the government, that all of the normal cost recovery rights that would accrue to the vendor in fact accrue under this bill. I very much appreciate that inclusion.

Mr. TAUZIN. Mr. Speaker, will the gentleman yield?

Mr. ANDREWS. I yield to the gentleman from Louisiana.

Mr. TAUZIN. Mr. Speaker, I want to thank the gentleman for that language. The neat thing about the way this bill has been processed is that all through the process Democrats and Republicans have assisted in building it into a much better bill. And the language the gentleman has added to the bill is an extraordinary addition to the bill, and I thank him for it.

Mr. ANDREWS. Reclaiming my time once again, Mr. Speaker, I appreciate the chairman's cooperation in that regard.

Second, I would like to say it is very important that the chairman has very skillfully, along with the ranking member, assured that there will be continuing oversight by the Congress of the activities under this bill. We had to strike the proper balance here between a guaranteed funding stream so that the companies involved in this would know that their investment would in fact be recovered, but at the same time not yielding the important oversight function that this Congress should exercise. And I commend the chairman and the ranking member and all the authors for making that the case.

Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I would ask how much time is available on both sides at this point.

The SPEAKER pro tempore. The gentleman from Louisiana (Mr. TAUZIN) has 11½ minutes remaining, and the gentleman from New Jersey (Mr. ANDREWS) has 19½ minutes remaining.

Mr. TAUZIN. Mr. Speaker, I commended the gentleman from Virginia (Mr. TOM DAVIS) and the gentleman from California (Mr. COX) previously, along with the ranking members for their extraordinary work we did together; and I now ask unanimous consent to yield the balance of my time to the gentleman from Virginia (Mr. TOM DAVIS) so that Chairman Davis can control the balance of that time.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. TOM DAVIS of Virginia. Mr. Speaker, as I understand it, I would have the time yielded to the Committee on Government Reform in addition to the time yielded to me by the Committee on Energy and Commerce?

The SPEAKER pro tempore. The gentleman is correct.

Mr. TOM DAVIS of Virginia. Mr. Speaker, I yield 3 minutes to the gentleman from New York (Mr. BOEHLERT).

(Mr. BOEHLERT asked and was given permission to revise and extend his remarks.)

Mr. BOEHLERT. Mr. Speaker, we live in a different world than we did 2 years ago, a world where the threat of attack from biological and chemical agents remains high. Here on Capitol Hill we know this all too well. We were all victims of a vicious attack using anthrax and poisoning our own postal system. The attack shut down half of an entire branch of our government and lives were lost. A very real threat became a sad reality.

Project BioShield will take the necessary steps to provide greater protection for Americans from those malicious attacks, to research, develop, manufacture and stockpile effective drugs and vaccines. In order to make this plan a reality, the Department of Health and Human Services and the National Institutes of Health must have a strong infrastructure of laboratories and facilities designed for research on the most dangerous of pathogens.

The research stage of this process is the most important part of developing a broad and effective basis for this project. In my own district, there is an effort underway to build a national biocontainment laboratory to be administered by the National Institute of Allergy and Infectious Diseases. This state-of-the-art facility would take on the daunting task of testing these dangerous agents that could threaten our communities, and they have got the charge to come up with the vaccines and drugs necessary to effectively deal with them. I am fully supportive of this plan and hope this critical facility will soon call upstate New York home.

Development of these vital medical countermeasures to biological and chemical agents can take years. With the building of new facilities to do the research and expedite the development of vaccines, more diseases may one day

be eradicated or at least treatable to avoid mass casualty from any type of attack.

I am pleased that Project BioShield may offer assistance to enterprising companies like Viral Therapeutics of Ithaca, New York, that are currently producing needed vaccines and is interested in answering the call to expand research and development as well as production.

□ 1445

Mr. Speaker, I am proud of my service on the Select Committee on Homeland Security and our determined effort to give the American people what they desire and deserve, a comprehensive and balanced effort to protect them from the evils of biological and chemical weapons. This legislation is designed to do exactly that. I commend all those involved with the formulation of this bipartisan product for the American good.

Mr. ANDREWS. Mr. Speaker, I yield 4 minutes to the gentleman from Rhode Island (Mr. LANGEVIN), who has had experience in State government with homeland security, who has had experience here on the Committee on Armed Services and now on the Select Committee on Homeland Security.

Mr. LANGEVIN. Mr. Speaker, I thank the gentleman for yielding me this time on this incredibly important issue.

Mr. Speaker, I rise today in strong support of the Project BioShield Act. Bioterrorism is a national threat to our national security, and I believe it is our job as the Members of the United States Congress to instill confidence in the American people that a coordinated, concerted effort is being made to combat this threat.

We have some incredibly talented people in this country in the public and in the private sector, and this joint partnership will ensure that we are moving ahead to effectively protect the American people from the potential of a bioterrorism attack.

While Project BioShield is not the only answer, it is certainly an important step toward that goal, and I hope Congress will continue to provide the funding and the oversight that the project needs to be effective.

However, I must mention my ongoing concern with the operation of Department of Homeland Security's information analysis and infrastructure protection directorate. This is truly a life-and-death issue. If this unit is not running effectively, then the rest of DHS is at a tremendous disadvantage in determining how to allocate resources and where to focus energies.

The proper implementation of Project BioShield requires a reliable and comprehensive threat assessment from the information analysis team, a team that should include bioterror experts, while working closely with their peers at CDC and NIH to identify the most pressing dangers.

Mr. ANDREWS. Mr. Speaker, will the gentleman yield?

Mr. LANGEVIN. I yield to the gentleman from New Jersey.

Mr. ANDREWS. Mr. Speaker, I very much appreciate the point the gentleman is making. The BioShield Project is built on a foundation of accurate assessment of the threats that we face. For example, if there is an assessment that we face a significant threat from botulism, the full resources of this bill are applied to finding an antidote to botulism.

The gentleman's point is very well taken. If the threat assessment is flawed, then we run the risk of either spending money on a threat that is not very viable, or failing to spend energy and money on a threat that is viable that we have failed to detect.

So we can employ the very best resources of our scientists, our engineers, our researchers, our entrepreneurs, but have them working on the wrong problem if there is not an adequate intelligence-gathering capability and then an adequate response to that intelligence-gathering capability shared with the Department of Homeland Security. I think the gentleman's point is very well taken.

Mr. LANGEVIN. Mr. Speaker, I thank the gentleman from New Jersey (Mr. ANDREWS) for interjecting that point, and I wholeheartedly concur.

The proper implementation of Project BioShield requires a reliable and comprehensive threat assessment from the information analysis team, a team that should include bioterror experts working closely with their peers at agencies like CDC and NIH to identify the most pressing dangers and develop a plan to combat them.

Mr. Speaker, I urge my colleagues to support this legislation and hope that DHS will do its part to make Project BioShield as effective as possible.

Mr. TOM DAVIS of Virginia. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 2122, the Project BioShield Act. This bill provides the government with the necessary tools to develop and purchase vaccines and other drugs to protect Americans in the event of a bioterrorist attack.

The President first announced this proposal during his 2003 State of the Union address. It is the cornerstone of the administration's strategy to prepare our Nation against the possibility of a bioterrorist attack. The bill we are considering today was introduced by the gentleman from Louisiana (Mr. TAUZIN), chairman of the Committee on Energy and Commerce, and was referred to the committee, as well as the Committee on Government Reform which I chair, and the Select Committee on Homeland Security. It is a good bill which serves a compelling national interest.

As we tragically learned during the fall of 2001, our Nation is vulnerable to biological terrorism. Letters laced with anthrax caused the deaths of five individuals and thousands more had to

be treated. The death toll could have been higher if there had not been an effective countermeasure to treat that form of anthrax. Unfortunately, there has been little progress in treatment for other deadly diseases, like smallpox, Ebola and plague, which effect few, if any, Americans.

The reality is that there is little manufacturer interest in developing necessary treatments for these diseases because there is no significant commercial market existing outside of government. The absence of financial incentives has provided drug companies with little reason to make the substantial investment that would be required to develop treatments for these deadly diseases.

Should the United States be attacked with any of these deadly pathogens, the needs for vaccines, tests and treatments would be great, and it would be immediate. H.R. 2122 is designed to ensure that our country is prepared. The bill provides the Secretary of Health and Human Services with a number of flexible acquisition tools based on existing streamlined procedures to promote research and development and procurement of necessary drugs and vaccines. These tools are instrumental to the success of the BioShield program.

For example, the bill increases the simplified acquisition threshold for research and development projects from the current level of \$100,000 to \$25 million. This increase will help the Secretary promote sophisticated research and development projects by streamlining the acquisition process. The bill also authorizes the procurement of biomedical countermeasures, again using tailored, flexible acquisition tools for inclusion in the Nation's stockpile using a special reserve fund.

The Secretary would also have expedited authorities to award research grants and hire technical experts and consultants. During national emergencies, the bill would permit the government to make available new and promising treatments prior to approval by the Food and Drug Administration. The Committee on Government Reform, which I chair, held a hearing to examine the BioShield proposal on April 4, 2003. Witnesses from the government, academia, and pharmaceutical and biotech companies were supportive of the bill. They all recognize the need to create incentives for manufacturers to develop biomedical countermeasures.

Our committee favorably reported the bill on May 22. Working in a bipartisan fashion with the gentleman from California (Mr. WAXMAN), we unanimously adopted some amendments to ensure greater accountability in the acquisition process and to clarify the circumstances when biocountermeasures can be processed.

Specifically, the amendments we approved permit the use of simplified acquisition procedures only when the Secretary of Health and Human Services determines there is a pressing need

for the procurement of specific countermeasures. The bill commits decisions about research and development projects to the discretion of the Secretary of Health and Human Services. However, we approved an amendment which preserves a limited right for companies to appeal to the General Accounting Office contracting decisions made by the Secretary, but appeals could not be used to stall the research and development procurement process.

We also made some technical changes that seek to clarify the circumstances when the Secretary could use other than fully competitive procedures for research and development and production contracts.

Mr. ANDREWS. Mr. Speaker, will the gentleman yield?

Mr. TOM DAVIS of Virginia. I yield to the gentleman from New Jersey.

Mr. ANDREWS. Mr. Speaker, I would like to thank the chairman for working with the gentleman from California (Mr. COX) and the gentleman from Texas (Mr. TURNER) on the issue of termination for convenience. We think it is a very important clarification that if there is a termination by the government for reasons of convenience, the companies involved in the project can recover their costs under the normal rules for that. I know that the gentleman's committee was involved in making that possible, and I wanted to thank him for his cooperation.

Mr. TOM DAVIS of Virginia. Mr. Speaker, the gentleman is correct, and it makes them more likely to be involved in this process.

We think that all of these amendments, and I thank the gentleman from California (Mr. WAXMAN) for working with us as well, have been agreed to by the majority and the minority on the various committees; and they are part of the bill that we are considering today.

Since our markup, we have continued to work on this bill in a bipartisan fashion. This issue is really too important to play party politics with. We have worked out language to ensure that the rights of contractors with respect to payment are protected in the event they are terminated for convenience. This is a good bill and deserves our support.

Mr. Speaker, I reserve the balance of my time.

Mr. ANDREWS. Mr. Speaker, I ask unanimous consent to yield the balance of my time to the gentleman from Texas (Mr. TURNER) and that he may further allocate that time.

The SPEAKER pro tempore (Mr. GILCREST). Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. TURNER of Texas. Mr. Speaker, I yield myself such time as I may consume.

To win the war on terror, we must do everything we can to protect the American people from the threat posed by terrorists using weapons of mass de-

struction. We know that our forces in Afghanistan uncovered plans by al Qaeda to engage in bioterrorism. We know from recent arrests in Europe that terrorist groups have the means and the will to carry out such attacks. It is without question that bioterrorism is a clear and present danger to the American people, perhaps one of our greatest threats.

In response to this threat, the administration is proposing this legislation, commonly known as Project BioShield. This bill is a first step toward ensuring that we protect Americans from the horror of bioterrorism. The purpose of the BioShield legislation is to provide incentives to private companies to produce the medicines, the vaccines, the antidotes we need to counter a biological attack.

Quite frankly, this concept is an experiment, a grand experiment, but no less an experiment. We do not know if the incentives will drive our pharmaceutical industry to invest the resources needed to truly prepare our country for the full range of possible biological attacks. If we do, we will have been successful and our country will be better off. If they do not, our country will remain dangerously vulnerable.

I support Project BioShield because I believe this is an experiment worth conducting; but from the beginning of this process, I have been working to build mechanisms into the legislation that would monitor whether the legislation is truly making our Nation safer.

For example, the Select Committee on Homeland Security added a requirement that the Secretary of Health and Human Services report annually if the President has identified biological agents that are threats to the United States, but no private company has contracted to produce a countermeasure. Thus, if there is a bioterrorist threat to the American people and private industry will not rise to the challenge of searching for a cure, we have the right to know about it.

These concerns were shared by the gentleman from California (Mr. COX), chairman of the Select Committee on Homeland Security. They were also shared by the gentleman from Louisiana (Chairman TAUZIN) of the Committee on Energy and Commerce and the ranking member, the gentleman from Michigan (Mr. DINGELL).

If BioShield does not work as we hope it will, we will need plan B. Thus, I am very pleased that the legislation contains clear authority that allows the government to operate an emergency program to develop and produce vaccines. In my view, this is so very important because protecting our population is our first responsibility. If the private sector is not producing the medicines we need and we find ourselves under the threat of biological attack, then the government needs to have the authority to do the job directly.

The language that has been inserted in the legislation gives the President, the Secretary of Health and Human Services, the Secretary of Homeland Security the necessary authority to take action in the event that this experiment with the private sector fails to produce the results we all hope it will produce.

□ 1500

My final concern, Mr. Speaker, is that Project BioShield, despite its creative name, is really a fairly modest proposal. If we are lucky at the end of 10 years, we will have some vaccines to address a few of the possible pathogens that terrorists could use during a bioterror attack. But the potential problems are much more expansive. Terrorists may soon be able to genetically manipulate biological agents so they are resistant to our current stockpile of antibodies and perhaps to the vaccines we develop.

This possibility presents a daunting threat to our Nation. That is why I would like to see a much more robust proposal than the one before us today, an approach that moves us faster and stronger toward creating a comprehensive defense to the full range of threats we face from bioterrorism. Based on the information that we all know about, we clearly need a Manhattan Project to prepare this country to deal with the vast array and the diverse types of biological threats that we may face in the years ahead.

Time and time again when faced with such a great challenge, the government has played a central role in organizing a massive response. When war threatened to consume the world, we put an end to it through the success of the original Manhattan Project. When we raced the Russians to the stars, the Apollo Project put a man on the Moon. It will take these kinds of bold actions, this kind of bold leadership and deep resolve to prevail in the war on terror.

Mr. Speaker, I wholeheartedly support this current legislation, but I also believe that our Nation must take even stronger steps much sooner in order to protect us and to secure us in the days ahead.

Mr. Speaker, I reserve the balance of my time.

Mr. TOM DAVIS of Virginia. Mr. Speaker, I yield 4 minutes to the gentleman from Connecticut (Mr. SHAYS), the distinguished vice chairman of the Committee on Government Reform.

Mr. SHAYS. Mr. Speaker, I appreciate my chairman yielding me this time.

Throughout committee consideration of H.R. 2122, I expressed some skepticism about both the short- and long-term impact of the proposed approach on our ability to develop, procure and use new medical countermeasures against chemical, biological or radiological weapons. Thanks to the work of the Committee on Energy and Commerce, the Committee on Government Reform and the Select Committee on

Homeland Security, the bill before us today represents a substantial improvement over the original proposal. This bill would create agile, proactive capabilities in meeting the threat of unconventional weapons, capabilities we do not have today.

Part of the value of Project BioShield would be purely deterrent. Just having the ability to develop and stockpile vaccines and antidotes decreases the likelihood, or the lethality, of a biological attack.

However, as I indicated in my earlier colloquy with Chairman TAUZIN, any authority to actually use experimental drugs or medical devices in emergency situations has to be defined and wielded with nothing less than surgical precision. Prior informed consent in connection with the administration of experimental therapy is a basic human right, a right no one should be asked to surrender except under the most extraordinary of circumstances. For example, if a patient is unconscious and cannot give consent or be informed before onset of a life-threatening disease or event, medical ethics allow use of an experimental therapy.

Mere military inconvenience can never justify waiving consent or failing to inform service members about medical countermeasures. No loosely defined concept of feasibility should allow the Secretary of HHS to waive or delay the requirement to provide essential information on medical risks and benefits prior to administration of a drug or vaccine, as could happen under the language in this bill Chairman TAUZIN has agreed to revisit. If the medicine can get to the front, there should always be room in the transport for the leaflet describing its dosage, interactions and contraindications.

In the 1991 Persian Gulf War, soldiers, sailors, aircrews and Marines were ordered to take experimental drugs and vaccines. Despite Pentagon promises to provide critical medical information and keep accurate medical records, very little information was provided and very few records survived the trip home. That cannot happen again. In the course of 14 hearings on the subsequent health problems of Gulf War veterans, the Government Reform subcommittee I chair reached this stark conclusion: "Unless providing medical information to service members is mandatory, it's just too easy for the military, in the heat of battle, to decide it's just not feasible."

In the war against terrorism, we are all on the front lines. The citizen-soldiers of our all-voluntary Armed Forces fight and die to protect our rights and freedoms. They should not be asked to surrender those fundamental rights under different, less rigorous, circumstances than those they left behind.

Again, I appreciate the very good work of Chairman TAUZIN, Chairman DAVIS and Chairman COX and their respective ranking members; and I look forward to a conference agreement that

relies on the protections of current law and requires prior notification of service members whenever an unapproved drug or device has to be used.

Mr. TURNER of Texas. Mr. Speaker, I yield 4 minutes to the distinguished gentlewoman from the Virgin Islands (Mrs. CHRISTENSEN).

Mrs. CHRISTENSEN. Mr. Speaker, I rise today as a member of the Select Committee on Homeland Security and also of the Subcommittee on Emergency Preparedness and Response in qualified support of the Project BioShield Act of 2003, the purpose of which is to increase the development of countermeasures to bioterrorism and facilitate their approval for use in mass production so that they would be readily available when needed.

While research and development of such products is extremely important, I remain very concerned that a commensurate amount of time and effort has not been devoted to furthering our public health security, a broader, more basic and more immediate issue.

Through the four or five hearings on Project BioShield, I joined several other of my colleagues in calling attention to the inadequacies and deficiencies that exist throughout the public health system in this country, especially in rural and minority communities.

With the focus on cost containment rather than care, our lack of focus on prevention and our failure to insure everyone's equal access to quality health care, added to the system's continued deterioration because of repeated funding cuts and misguided departmental policies, our Nation's public health infrastructure today is in worse shape than ever.

Project BioShield, though, is important because it will help to make sure that we have the vaccines and other countermeasures as quickly as possible in the case of a bioterrorism attack. But all of those fancy medicines and other agents will be worthless to you and me and to the people we serve without an intact public health system.

The recent bipartisan commission's report, "First Responders Underfunded and Unprepared," documents the dire need of our public health and other responders in stark and frightening terms. I am still waiting for a formal hearing on their findings, and we should not be afraid to have the report aired. We should really be more afraid not to pay attention to its findings and its recommendations.

Mr. Speaker, I am happy that the gentlewoman from Texas (Ms. JACKSON-LEE) and I were able to amend the bill in committee to ensure that the historically black colleges and universities and other minority-serving institutions of higher learning will be provided with special outreach to ensure their participation in this program to the fullest extent possible. This is an extremely important provision, and I thank our chair and ranking member

and Chairman TAUZIN for working with us to include it in the bill.

Mr. Speaker, today I know that we will pass this bill, but what I and other health providers, public health experts and officials and the people of this country want to know is that we will always move just as determinedly and expeditiously to fully fund the strengthening of our public health system, the training of our first responders and provide them with the tools and facilities they need to protect us in those first critical hours where lives can and must be saved.

I want to take this opportunity to thank and commend Chairman COX and Ranking Member TURNER for their guiding what is often not an easy committee to guide and for their shepherding of this bill through that committee.

I ask the support of my colleagues for Project BioShield, but I also ask that when this is passed that we move on from here to soon pass "Project Public Health."

Mr. TOM DAVIS of Virginia. Mr. Speaker, I yield the balance of my time to the gentleman from California (Mr. COX).

Mr. COX. Mr. Speaker, I want to thank the chairman not only for yielding time but for the exceptional work that the Committee on Government Reform has done both on the majority and minority sides to bring us to this point; likewise, the Committee on Energy and Commerce, of which I am a member, and Chairman TAUZIN and Chairman DINGELL for their extraordinary leadership and commitment to bringing this bill to the floor; and my ranking member on the Select Committee on Homeland Security, which I chair, the gentleman from Texas (Mr. TURNER), who is with me on the floor now.

This has been a bipartisan effort for one simple reason. The terrorists do not discriminate between Democrats and Republicans. They certainly are not going to protect us because we are on one or another side of this debate. We are all in their sights. The committees of jurisdiction working closely together have managed to create a process in bringing this bill to the floor that has been focused on producing the best possible policy and thus the best possible security for our country. It is not focused on Capitol Hill turf battles. This type of cooperation serves as a model for our efforts to make America more secure against terrorist attack.

In the fall of 2001, we caught a glimpse of the terrible potential of a bioterror attack when anthrax attacks were loosed on the Nation's capital. A broader attack on the American population, on our armed services involving one of the many biologic agents for which we have no antidote could be devastating. The potential toll in lives would far exceed what happened on September 11, 2001. We must, of course, do all we can to prevent such attacks, but ultimately we must be prepared.

Because no scheme of prevention, no matter how expert and reliable our intelligence collection and analysis, is going to be perfect. We must be prepared.

This legislation, the BioShield Project launched in this bill, will provide the resources and authorities we need to develop the next generation of biological countermeasures. It will help to ensure that we avoid the kind of catastrophe we are contemplating here on the floor today in the future.

The ability of the Secretary of Homeland Security to identify from around the world the most serious potential biological threats to our population is key to making Project BioShield effective, and it is key to the vital task that we have of meeting this threat. To do that, Secretary Ridge will have to get the very best intelligence available. By learning everything we can about the biological weapon threats that confront us, we can allocate our resources and focus our efforts where they will be most effective. By identifying the bioterror agents for which the risks and potential consequences of attacks are greatest, we can use these substantial new first responder resources most wisely.

That brings us, therefore, to the creation of Project BioShield in fulfillment of President Bush's charge to this Congress in his State of the Union message. Both President Bush and Vice President CHENEY have made this a priority, and we are responding in this Congress.

The BioShield Project is by far the most expansive, broadest, largest first responder program initiated in the history of our country. It is budgeted for \$5.6 billion, but we have made it very plain that, through the appropriations process and through the budget process, we will put the resources behind this program that are needed to develop the antidotes and, if a presidential decision on a recommendation of both the Secretary of Health and Human Services and the Secretary of Homeland Security is made, if the President decides to stockpile enough antidotes, vaccines to immunize the entire American population in the event of a catastrophe.

The Secretary of Homeland Security as part of this process is charged with identifying the most significant biological, chemical and nuclear agents that threaten the American population. Because our ability to collect, analyze and put to use timely and accurate intelligence information is at the very heart of doing this job, certainly in preventing a biological attack but also of being prepared to respond to it, in this legislation we have given the Secretary of Homeland Security the information analysis tools that he needs.

□ 1515

This bill is very important to the Select Committee on Homeland Security. We worked hard to get it right. We

have held extensive hearings and nearly 3 months of work in three of our subcommittees and twice in the full committee. We conducted a series of oversight hearings which examined the new Department's ability to carry out its threat assessment function; and as a result, we have incorporated into the bill several provisions designed to strengthen the Secretary's threat assessment capabilities. We have given the Secretary the authority and the resources he needs to quickly hire the necessary bioterror analysts and to rapidly build a bioterror intelligence infrastructure. The Select Committee on Homeland Security added these provisions to this bill.

This legislation greatly increases our ability to conduct bioterror research against the most urgent threats identified by the Department of Homeland Security. But most importantly, rather than trying to create a parallel government bioterror industry, or I should say bioterror response industry, BioShield will draw on the expertise and resources of the private sector.

Our American industries lead the world in these categories. And our health care innovation, our free markets, our strong patent protections have led American industry to spend more on research and development on new products and treatments than all of Europe and Japan combined. To make the progress that is necessary in these noncommercial areas that are so essential to national security, it is essential we tap into this strength in the private sector. To accomplish this, the legislation establishes a reserve fund that will be available to stockpile security countermeasures that are produced against government requirements, even though these countermeasures do not presently exist.

We want to stimulate the invention, the productivity, the research that is necessary to find these antidotes, these vaccines to bioweapons that exist but for which countermeasures do not presently exist. The gentleman from Louisiana (Chairman TAUZIN) and I worked with the gentleman from Kentucky (Chairman ROGERS) of the new Appropriations Homeland Security Subcommittee to provide this funding in a 10-year advance appropriation. This money will remain available for a full decade, creating, in essence, a homeland security market for the development of critical security countermeasures for which no commercial market exists. The knowledge that funding will be available for a full decade and not be subject to the annual appropriations process will encourage the biotech industry to devote resources to develop and produce the next generation of treatments for bioterror agents.

So once again I want to thank the Members on both sides who have worked so hard on this legislation for their spirit of cooperation, of bipartisan cooperation; and I strongly urge my colleagues to support this very important legislation.

Mr. Speaker, I reserve the balance of my time.

I inquire how much time I have remaining.

The SPEAKER pro tempore (Mr. GILCREST). The gentleman from California (Mr. COX) has 6 minutes remaining.

Mr. COX. Mr. Speaker, is that 6 minutes the time that was earlier yielded to me by the gentleman from Virginia (Mr. TOM DAVIS)?

The SPEAKER pro tempore. The gentleman from Virginia (Mr. TOM DAVIS) yielded 7 minutes, with a total of 14½ minutes.

Mr. COX. So the time that we are speaking of, Mr. Speaker, comprises also the time allotted for purposes of debate to the Select Committee on Homeland Security?

The SPEAKER pro tempore. That is correct.

Mr. TURNER of Texas. Mr. Speaker, I yield 6 minutes to the gentleman from New Jersey (Mr. PASCRELL), one of the most vigorous advocates for equipping and training first responders to protect America.

Mr. PASCRELL. Mr. Speaker, the tragic events of September 11, and the anthrax attacks shortly thereafter, reinforced the possibility of a widespread bioterrorist strike on America; and that is very real. There was a report submitted to us by Warren Rudman, who was the chairman of the Independent Task Force on Emergency Responders dealing with this subject very recently, and in that report it says the following: public health labs in most States still lack basic equipment and expertise to adequately respond to a chemical or a biological attack, and 75 percent of State laboratories report being overwhelmed by too many testing requests.

In fact, Mr. Speaker, we were told of this threat well before 9-11. In January of 2001, a report submitted by the National Intelligence Council stated that the number of players, that is, state players and nonstate players, bioterrorism sponsored by state governments, bioterrorism sponsored by nonstate terrorist organizations throughout the world possessing or seeking to acquire a biological weapon, that group is growing despite the fact that biological weapons are banned by international treaty.

We were warned of this in January, 2001. While Congress has made progress over the last 18 months on expanding our vaccine stockpile, an enormous amount of work still remains. The Project BioShield Act of 2003 is so important because it encourages the development for new countermeasures against a bioterror attack in a comprehensive manner. This committee, the Select Committee on Homeland Security, was given a rude awakening upon hearing the testimony of Mr. Paul Redmond, the assistant secretary for information analysis at the Department of Homeland Security. We learned that Mr. Redmond's office had

only one person working under him on the bioterror threat and that Mr. Redmond had limited access to the intelligence himself. Imagine, we are asking two people to protect 290 million Americans about a possible biological threat they do not know about.

The Cox-Turner amendment, approved by our committee, correctly concentrates on increasing not only access to intelligence but an increase in the staff of those folks who collect intelligence. Specifically, it requires that the Secretary of the Department of Health and Human Services be provided all intelligence information from all other agencies relating to the threats regardless of classification and regardless of whether the Secretary has requested the information.

This bill is not just about creating a significant stockpile of vaccines and medical devices. It is about making sure that our first responders do have the tools to effectively operate their attack. Mr. Speaker, they will be the first ones there, be it a firefighter, be it a cop, be it someone working in emergency services. They will be the first one there; and if they do not know what they are doing, if we do not train them, if we do not provide the training, we are doing a disservice to them and we are certainly putting them in harm's way. A nurse or a doctor will be able to immediately provide a vaccine and prevent the spread. A fireman will have a mask to breathe purified air while a building with biological agents burns.

This bill will make those and other lifesaving tools available so we can begin to protect ourselves, protect our children and our grandchildren from the threats of today and the unfathomable biological threat of tomorrow. This is just the beginning, Mr. Speaker. There is a great deal that we still do not know. When one reads the report of the National Intelligence Council on biological warfare, one understands what scale we are talking about and what a delayed onset is and what a delayed response will lead to. Most biological agents cause symptoms that have a delayed onset ranging from a few hours to many days. This is serious business. The fact that an attack has taken place can be masked, and the identification of the perpetrators would be extremely difficult to find out. I am confident, Mr. Speaker, that H.R. 2122 will help, will help protect every American against the unimaginable.

The importance of Project BioShield cannot be overstated, and I congratulate the leadership of both parties for bringing it to the floor today.

Mr. COX. Mr. Speaker, I yield 3 minutes to the distinguished gentlewoman from the State of Washington (Ms. DUNN), the vice chairman of the full Select Committee on Homeland Security.

Ms. DUNN. Mr. Speaker, I rise today in support of the Project BioShield Act of 2003. As the Members have heard

today, Mr. Speaker, from the debate we have had on the floor, this is truly bipartisan legislation. It is also a major step towards giving Americans necessary protections to address the biological and the chemical threats that exist today. H.R. 2122 will provide for private companies the incentives they need to develop vaccines for biological agents. It also will increase our national pharmaceutical stockpile, and it will provide DHS, the Department of Homeland Security, better intelligence capabilities so that they can protect against biological and chemical attacks.

Earlier this year, President Bush announced his intentions to develop a vaccination program that would protect against an attack involving biological and chemical weapons. For months, three committees, including my committee, the Select Committee on Homeland Security, have held numerous hearings to consider the best ways to protect our constituents. I believe it is time to pass this legislation. Mr. Speaker, this bill will provide \$5.6 billion over a 10-year period to develop vaccines to protect against some of the most dangerous biological agents that this country and this world has ever known. These funds are necessary to create an incentive for private companies to do research and development on drugs that might not normally be in demand in the marketplace. I believe this investment is worthwhile, considering the possible effects of a large-scale biological attack.

In addition to authorizing funds for this program, the BioShield program also addresses the sharing of intelligence. In order to develop an effective vaccination program, the Department of Homeland Security must have the intelligence capabilities to predict what the real threats are thought to be. By understanding the threats, DHS can focus its resources on those areas of highest vulnerability to the people who live in this country.

This legislation will authorize specific funds to be used by DHS for terror threat assessment. In addition, it will require other intelligence agencies such as the CIA to share timely information and threat analyses with the Department of Homeland Security.

One of the lessons we learned from the anthrax attacks during the fall of 2001 is the importance of responding to a biological attack quickly in order to minimize the damage it causes. While it is indeed tragic that during those attacks five people died, we all have to appreciate that. It could have been far worse if the vaccine had not immediately been available. H.R. 2122 will help us be prepared to respond quickly to agents such as ebola, plague and smallpox. I ask that we answer the President's call to develop the BioShield Project and that people support and that we pass H.R. 2122.

Mr. TURNER of Texas. Mr. Speaker, I yield 5 minutes to the gentlewoman from Texas (Ms. JACKSON-LEE), one of

the foremost leaders in trying to prepare her city and this country to protect us against the threat of bioterrorism.

(Ms. JACKSON-LEE of Texas asked and was given permission to revise and extend her remarks.)

Ms. JACKSON-LEE of Texas. Mr. Speaker, I thank the distinguished gentleman from Texas for yielding me this time.

This is an important statement, if you will, an actuality of the work that the Select Committee on Homeland Security has done along with collaborative efforts of our respective committees of jurisdiction.

□ 1530

Let me again thank the gentleman from Texas (Mr. TURNER) for his work and the chairman for his work and realize that, as we begin this debate or as we engage in this debate, we need to do much more.

I rise to support this legislation because it takes America one step closer to being prepared in dealing with a biochemical terrorist attack. But as we consider this legislation, Mr. Speaker, I think it is important to note that, while America is on the trail, on the pathway, on the journey toward being safe, we are still not safe. We remain vulnerable. Our ports are not secure, our critical infrastructures are not secure, our communities are not protected from biochemical agents, but H.R. 2122 will help to make America safer.

The purpose of this Act is to enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security and for other purposes. What it begins to do, Mr. Speaker, is to focus our attention narrowly on the question of what do we do if we are subjected to a bioterrorist attack. What kind of chemicals, if you will, will thwart the attack? What kind of research needs to be done in advance of the diabolical thoughts of anyone who would want to perpetrate a terrorist act with some chemical yet unknown?

We already have had the experience of the fear and the intimidation of anthrax. We have already had the terrible situation of people who had nothing better to do or wanted to intimidate or scare or frighten, use anything from salt to sugar to powder to suggest that they were utilizing anthrax. We know what can be done through a bioterrorist attack or the suggestion that there would be an attack by some sort of chemical.

Biological weapons pose a particularly dangerous threat. Biological weapons are highly portable and difficult to detect. So this concept of BioShield is more than overdue. Its time has come. Bioterrorism attacks not only pose a danger to human lives, they also have the ability to cripple the operation of our society and severely harm our economy.

After 9/11, when we were allowed to fly home from Washington, I held one of the first town hall meetings with over 400 people on September 14, 2001, on a Sunday, in fact, to be able to bring some sort of order to people's thoughts, the fear that was going on, the actual intimidation as far away as Houston. There were all kinds of suggestions that Houston was next in line, that Houston was about to be attacked.

But, shortly thereafter, I also held a meeting with my first responders. As we were having a meeting, my hazardous materials team had to run out to a hospital about 50 miles down from where our meeting was being held because a woman drove to the hospital saying that she had anthrax; someone had put anthrax in her apartment or in her home. And without the understanding of what anthrax represents and the hospital officials not yet experienced, took whatever she had through the hospital, up the stairs, or wherever, up the elevator and, by its very exposure, caused the hazardous materials team to have to run out and shut down the hospital. A crippling effect, maybe just one hospital, but it shows the magnitude of what can happen if we are dealing with bioterrorism.

We all recall the primary and secondary impact of the anthrax attacks in 2001. The attacks involved a series of letters mailed in pre-stamped envelopes to places like Florida and New York and to the offices of Senator TOM DASCHLE and PATRICK LEAHY. Those kinds of incidences prove that it is vital that we focus on the research aspect. I am gratified that my colleagues saw the importance of spreading the knowledge, the research, the input, the collaboration throughout our Nation.

Therefore, we have included language to make sure that we include historically black, Hispanic-serving, Native American, and Pacific Islander institutions, that they are able to be exposed, if you will, to the various opportunities to engage in high-level research so that, as they are able to relate to different cultures and different communities, they, too, can be a part of securing the homeland.

It is important as well, as I noted in an amendment that I was going to propose, that the stockpiles of chemicals that will thwart bioterrorist attacks that are in this country should be strategically placed, that they can reach any urban center and any rural area, any hamlet, any town, any village. I am glad to note by a letter that has been submitted into the RECORD dated July 16, 2003, that the Secretary of Health and Human Services recognizes that my letter had merit and that he will continue to monitor and be astutely aware of whether or not the stockpiles we have are sufficient, whether they are within the sufficient depth, and whether they will be able to protect all of America.

Let me conclude, Mr. Speaker, by simply saying that I rise to support this legislation with the knowledge

that we will be inclusive and that the idea is not only to secure the places we know and that are renowned but to secure the places where people live and to make sure that the home front and the home neighborhoods are secure in our country.

I ask my colleagues to support this legislation.

Mr. Speaker, I rise today in support of H.R. 2122, the "Project Bioshield Act of 2003." I support this important legislation because it takes America one-step closer to being prepared to deal with a biochemical terrorist attack. As we consider this legislation, Mr. Speaker, America is still not safe. We remain vulnerable. Our ports are not secure. Our critical infrastructure is not secure. Our communities are not protected from biochemical agents. H.R. 2122, will help to make America safer.

The purpose of the Project BioShield Act of 2003 is to "enhance the research, development, procurement and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes." The stated purpose of H.R. 2122 is a noble one given the danger posed by biochemical weapons.

The threat of bioterrorism is substantial, and protecting America from biochemical agents and terrorist attacks must be one of our chief concerns as we continue our work of protecting our homelands. Biological weapons pose a particularly dangerous threat. Biological weapons are highly portable and difficult to detect.

Bioterrorism attacks not only pose a danger to human lives, they also have the ability to cripple the operation of our society and severely harm our economy. We all recall the primary and secondary impact of the anthrax attacks in 2001. The attacks involved a series of letters mailed in pre-stamped envelopes to media outlets in Florida and New York and to the offices of Senators THOMAS DASCHLE and PATRICK J. LEAHY (D-VT). The anthrax attacks killed five Americans and left 13 others severely ill. The five people who died from inhalation anthrax included two postal workers at the Brentwood postal facility in Washington, a Florida photojournalist, a New York hospital worker and a 94-year-old woman in Connecticut. Thousands more were exposed to the lethal bacteria. The letters passed through various post offices and postal distribution centers along the East Coast leaving a trail of contamination. Buildings from the Brentwood mail facility, to the Congressional office buildings, to NBC headquarters had to cease operations.

The threat of bioterrorism did not end in September of 2001. As recently as April 22nd of this year in Tacoma, WA, we had a bioterrorism scare. A white powder was found in two envelopes, and 94 people had to be evacuated from a mail distribution facility. Initial tests of the powder tested positive for biotoxins that cause bubonic plague or botulism. Four people at the facility had to be decontaminated. The same day, a suspicious powder was found in a Federal Express cargo area at Southwest Florida International Airport, in Fort Myers, FL. Six people were taken to a hospital for possible decontamination, including one who suffered burning eyes and nose.

We are presently faced with the threat of a worldwide SARS outbreak. The inability of

many foreign countries to adequately deal with that outbreak raises questions about our own preparedness. What about other infectious diseases like tuberculosis? There are many ailments that our medical professionals are struggling to control. We must do better in the area of biological weapons.

The ease with which biological weapons can be manufactured is also a danger. The equipment and ingredients needed to manufacture many biological agents can be purchased over the Internet. Additionally, as our failure to apprehend those responsible for the 2001 anthrax attacks illustrates, biological terrorists can operate with more secrecy than traditional terrorists.

Positive strides have been made in the various biochemical fields. We have improved our ability to secure our borders and prevent deadly materials from entering our country. However, it is unrealistic to expect no biological weapons to enter the United States. Last year alone 30 million tons of cocaine was smuggled into the United States. If we can't stop 30 million tons of cocaine from crossing our borders, how can we expect to stop a vial filled with anthrax, botulism, or smallpox? A vial that could kill hundreds or possibly thousands.

To adequately protect our homeland from bioterrorist attacks we must address these and many other concerns in the Project Bioshield bill. The provisions of Project Bioshield provide a good start to protecting Americans from a bioterrorist attack but work remains. Presently Project Bioshield's provisions grant the National Institutes of Health new powers, through grants and contract awards, to speed effective research and development efforts on bioterrorism countermeasures. Project Bioshield also creates a long-term funding mechanism for the development of medical countermeasures, and empowers the government to purchase safe and effective vaccines. Finally, Project Bioshield authorizes the Food and Drug Administration use promising, yet uncertified, biological treatments in the case of emergencies.

The research, development, and procurement provisions of the Project Bioshield bill are instrumental to the development of countermeasures for protecting our communities. The development of effective vaccines will mean the difference between life and death. There needs to be research and development participation from diverse institutions nationwide, so that the expertise of as many biological and chemical industry leaders can be utilized. During markup of this legislation in the Select Committee on Homeland Security, I negotiated the inclusion of language to ensure that Historically Black Colleges and Universities, and institutions serving large populations of Native Americans, Hispanic Americans, and Asian Pacific Americans are meaningfully aware of research and development grants. Provisions such as this not only include diverse scientists in the research and development process, they facilitate dispersal of information to all communities.

Protecting our communities is the most challenging and most important responsibility of the federal Department of Homeland Security, the House and Senate Select Committees on Homeland Security, and all Members of this Congress. An ongoing failure of all agencies responsible for homeland security is our inability to equip our local communities with the

funds and supplies needed to counter a terrorist attack now. During recent on-site reviews in Colorado and California, I spoke with first responders and individuals responsible for securing our ports. I also organized a briefing with testimony on the issue of homeland security in Houston, TX, in April. During each of these events, America's first responders echoed the same sentiment: they lack the funding and equipment to deal with a terrorist attack.

The Project Bioshield bill is an opportunity to correct this continuing failure. If is insufficient to simply research and develop bioterrorism countermeasures. We must also get those countermeasures into the hands of the health professionals and other first responders responsible for administering vaccines to the victims of bioterror attacks. We must not delay. First responders need these supplies immediately.

Mr. Speaker, I believe the provision of H.R. 2122, the Project Bioshield bill, are good first steps in protecting Americans from biological attacks. However, I feel that our country is still not safe and that many protections need to be established to fully protect our communities from biochemical attacks.

Mr. COX. Mr. Speaker, I yield 2 minutes to the gentleman from Arizona (Mr. SHADEGG), the chairman of the Subcommittee on Emergency Preparedness and Response.

Mr. SHADEGG. Mr. Speaker, I thank the gentleman for yielding me this time.

As a member of both the Select Committee on Homeland Security and the Committee on Energy Commerce, I rise in strong support of H.R. 2122, the Project BioShield Act.

Mr. Speaker, today, the House takes an important step toward preparing our Nation for the threat of bioterrorism. Clearly, we are living in a transformational era. Thirty years ago, none of us knew what biotechnology or genomics were, but, today, combined with our country's unparalleled leadership in semiconductors and computing power, we are on the verge of breathtaking breakthroughs in the field of bioscience.

Congress has played an important role not only by doubling the funding for the National Institutes of Health, but also by committing \$6 billion in fiscal year 2003 to develop strategies and countermeasures to protect the American public from bioterror attacks.

Even though we are in a better position in terms of preparedness than we were just a few months ago prior to the anthrax attacks here on Capitol Hill, we have much more to do. Project BioShield is a critically important step in that process. In many ways, it will serve as our Nation's primary response to bioterror.

Mr. Speaker, the Subcommittee on Emergency Preparedness and Response of the Select Committee on Homeland Security, which I chair, held several hearings on this issue; and, during that process, we learned that having measures to counter bioterror threats will actually serve as a deterrent to those threats, as would-be terrorists see that

America can be protected against bioagents which al Qaeda or other terrorists would use against us.

By providing a steady stream of funding for countermeasures, increased research capability at NIH, and expedited distribution during emergencies, project BioShield is a forward-thinking solution to bioterrorism.

Mr. Speaker, our subcommittee worked hard on this legislation. I believe it takes an important step in the right direction. I commend the full committee chairman and the other committees for their work on it, and I urge my colleagues to support the Project BioShield Act and to support H.R. 2122.

Mr. COX. Mr. Speaker, I yield 1 minute to the gentleman from Florida (Mr. LINCOLN DIAZ-BALART), the chairman of the Select Committee on Homeland Security Subcommittee on Rules.

Mr. LINCOLN DIAZ-BALART of Florida. Mr. Speaker, I thank the gentleman for yielding me this time.

For years the National Institutes of Health have served as our Pentagon in the war against disease. I think Americans, as well as people around the world, have benefited. Now, we must call upon, and we do so in this important piece of legislation, for the NIH to utilize its expertise and innovation, the expertise and innovation of all of its scientists to guard this Nation against the horrors that a serious biological attack would mean.

We have already seen, Mr. Speaker, a biological attack on this country. We know the great damage that it can cause. So what this legislation is doing is taking another important step, taking another important step by this Congress to protect the Nation from the great damage that a biological attack would cause.

I thank the gentleman from California (Chairman Cox) and the entire committee for its hard work in bringing forth this important piece of legislation today.

Mr. TURNER of Texas. Mr. Speaker, may I inquire of the time remaining on both sides?

The SPEAKER pro tempore (Mr. GILCHREST). The gentleman from Texas (Mr. TURNER) has 3 minutes remaining. The time of the gentleman from California (Mr. COX) has expired.

Mr. TURNER of Texas. Mr. Speaker, I yield myself 1½ minutes.

Mr. Speaker, let me first commend the gentleman from California (Chairman COX), along with the gentleman from Michigan (Mr. DINGELL), the ranking member, and the gentleman from Louisiana (Chairman TAUZIN), the gentleman from Virginia (Chairman DAVIS), and the gentleman from California (Mr. WAXMAN) for their excellent work on putting together this legislation in a bipartisan way. I know we all appreciate the work that Secretary Thompson and Secretary Ridge did on behalf of the President on this very important initiative.

I hope that we are successful with this legislation, and I hope that the de-

sired result can be accomplished. But I also want to end with a caution that the ability of our enemies in the years ahead to develop, alter, and modify biological pathogens will be at a level unknown to us today. I urge all of us to commit ourselves to the task of developing the agility and the responsiveness that we need to address those threats that we inevitably will face in the future.

The Washington Post today spoke in an editorial entitled "New Bugs" that it is important for us to shorten the time frame from the identification of a dangerous pathogen to the development of a drug or antidote. The shortening of this time span will require a tremendous commitment on the part of the American people and our government, and I hope this step that we take today will be but a first step in ensuring that we can adequately meet the biological threat that this Nation will face in the future.

Mr. Speaker, I yield the balance of my time to the distinguished gentleman from California (Mr. COX), the chairman of the Select Committee on Homeland Security.

Mr. COX. Mr. Speaker, I thank the gentleman from Texas for yielding me the remaining time.

I want to take a moment to say not only how productive it was to work with the gentleman from Texas but what a pleasure it has been, because both sides of the aisle, the Republicans and the Democrats, have worked together, as we should, after September 11 to put our Nation's security first.

I hope that our Nation never sees the kind of bioterror attack that we have been discussing on the floor here today. It is our job to be prepared against that eventuality. The legislative steps that we are taking today, the resources that we are providing, the intelligence infrastructure that we are building, the stockpile of vaccines and antidotes that we may requisition under Project BioShield are all intended to protect against mass casualties that would result in the event of a terrorist attack that we hope to prevent and we hope never to see in this country.

After September 11, I daresay every Member of this body determined that we will win this war against these terrorists. They are not superhuman. They are individuals. They do not have infinite capabilities. They have finite resources. We can find them, we can defeat them, and we shall. And we will be prepared. That is the purpose of this legislation today. I strongly urge a vote in support.

Mrs. LOWEY. Mr. Speaker, I support Project BioShield.

Over the last few months, I have been having meetings with local officials, first responders, hospitals, and school superintendents, to talk about how we can better prepare for the unimaginable, improve emergency planning, implement 21st century communication systems, and foster better cooperation among local, state, and federal public health and safety officials.

But all of these efforts won't amount to much if we do not have the right tools to counteract biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents. And that's the crux of this legislation.

With that said, I continue to have some concerns about whether this bill will be enough of an engine to spur research within the pharmaceutical industry and if our public health system is prepared and ready to assume the new products developed by BioShield.

During the drafting process of this bill, a number of expert witnesses stated that Project BioShield might not be tempting enough bait to entice the pharmaceutical industry to bite. These fears are legitimate. And that is why I am pleased that the bill includes a provision allowing the federal government to assume this work in-hours if private industry does not or cannot produce countermeasures fast enough.

On the other hand, if BioShield is successful, which I know we all hope it will be, and new countermeasures are developed, the success of these products depend on our public health systems' ability to distribute and deliver these serums to the general public in a timely, safe, and orderly fashion. In the case of smallpox, the cost of vaccinating—roughly \$200 per vaccination because of screening, testing, post vaccination surveillance, and treatment of adverse reactions—has been a significant impediment to the program. Thus, the key to effective countermeasures depends on a lot of factors and costs other than buying countermeasures and putting them in the Strategic National Stockpile.

As I have discussed with my colleagues and Administration officials during both Homeland Security Committee and Labor HHS Appropriations Subcommittee hearings, the bioterrorism grants provided through the Centers for Disease Control and Prevention and Health Resources Services Administration have not been adequate, particularly in the context of the current economy and failing state budgets. Basic health care programs are starved for cash for their core public health missions while also trying to take on greater responsibilities in the terrorism preparedness arena.

So today, I want to go on record with my colleagues that we must be prepared to better invest in our public health network if we truly want a sound and secure homeland.

Despite these criticisms, the BioShield proposal is a well-intended one, and a vitally important component in the fight against terrorism. The reality is: the more countermeasures we have, the less capable terrorists will be. And one way or another Project BioShield is going to make that happen.

Mr. KENNEDY of Rhode Island. Mr. Speaker, I rise in support of the BioShield legislation, and commend the committees for their diligence in meeting the challenge of bioterrorism.

While this bill is an important step in ensuring our nation's preparedness for bioterrorism, I am concerned that it does not fully meet our needs. This act does well in raising our defenses against the "bio," but does nothing to defend against the "terror."

Mr. Speaker, the point of all terrorism, including bioterrorism, is not primarily to inflict physical damage, but to undermine our social, political, and economic vibrancy. Whether terrorists succeed depends not only on our ability

to prevent or mitigate the physical impact of their acts, but whether we can prevent or mitigate the paralysis, panic, and demoralization they seek to create.

Tom Kean, Rudolph Giuliani, the National Academy of Sciences, first responders, and others have talked about the need to build resilience in our communities. Our preparedness efforts must include plans to ensure that officials' communications calm instead of panic. We need to make sure that the public, first responders, teachers, and others have the proper information delivered in an appropriate way about threats, safety measures, and emergency plans. If we do not specifically address the social and behavioral impacts of terrorism and the threat of terrorism, the measure we debate today and our other preparations will not be as effective as they could be.

I support this bill as component of our defense against biological terrorism, and hope that we can take the important next step as well.

Mr. DINGELL. Mr. Speaker, I rise in support of the Project Bioshield Act of 2003. This legislation reflects bipartisan negotiations that have significantly improved the language submitted to us by the Administration. That is a credit to the Committee on Energy and Commerce and to other committees and colleagues. I commend the good work of all who participated in this endeavor.

Project Bioshield is unfortunately a necessary measure in view of the increased risk of harm to Americans in this era of heightened threats to our national security. There are no effective therapies for many of the "select agents" that have been identified as potential instrumentalities of terrorism. The basic purpose of Project Bioshield is to support research that will lead to the development and availability in the Strategic National Stockpile of "countermeasures" to combat public health emergencies that threaten our national security.

The bill has three basic features: enhanced countermeasure research; procurement of countermeasures; and emergency regulatory authority for approval and use of drugs, biologics, and devices that are qualified countermeasures. The Committees' work clarified, modified, and otherwise improved on the Administration's proposal in each of these areas.

Significantly, the bill before us contains an additional section that enhances accountability for actions taken pursuant to Project Bioshield. Congress will receive comprehensive information, not less than annually, on the major activities authorized by this act. In addition, the General Accounting Office and the National Academy of Sciences will provide reports on key economic and scientific elements of this program after it has been in effect for several years.

Finally, I commend Chairman TAUZIN of the Committee on Energy and Commerce and my other colleagues for deciding to proceed with an authorization for funding, rather than with the mandatory appropriation sought by the Administration. Bioshield should not automatically be given a higher priority over other national security or public health matters.

This is a good bill, and is a worthy continuation of our important, and bipartisan work on bioterrorism preparedness. I urge all of my colleagues to vote for this bill.

Mr. NUSSLE. Mr. Speaker, I rise today to speak on H.R. 2122, the Project BioShield Act

of 2003. This Act would amend the Public Health Service Act to authorize appropriations to procure security countermeasures to treat, identify, and prevent the public health consequences of bio-terrorism.

Project BioShield has been described by President Bush as "a key part of our all-out effort to prepare for the threat of bio-terror." So I am pleased that the Project BioShield Act of 2003 will be voted on today in this House.

The framework for this bill was initially established in the FY 04 Budget Resolution that was adopted in April. The budget resolution set aside \$5.593 billion over ten years to establish a program to accelerate the research, development and acquisition of biomedical threat countermeasures. Recognizing the importance of this legislation, it took the somewhat usual step of establishing firewalls around these funds to ensure they are not used for any other purpose.

I am very pleased that the bill we are considering today is consistent with the budget resolution. It would authorize appropriations of \$5.6 billion for fiscal years 2004 through 2013. As some of my colleagues may be aware, the House already passed appropriations for this bill as part of the Appropriations bill for Energy and Water. Accordingly, as provided by the budget resolution, I adjusted the 302(a) allocation to the Appropriations Committee to accommodate the appropriations for this important bill.

I would also like to comment on the funding mechanism for BioShield. At the time the budget resolution was adopted, it was unclear whether this program would be funded through annual appropriations or with a permanent indefinite appropriation. Both the Budget and Appropriations Committees expressed a preference for subjecting the program to periodic review of the annual appropriation process. The Administration preferred a new entitlement that would be automatically funded without further legislative action.

I believe the funding mechanism in this bill strikes the right balance. It would fund Project BioShield through what is effectively a multi-year appropriation that would give the Administration flexibility in the amount that is obligated in each year. It subjects the program to periodic Congressional review through the appropriations process but provides the pharmaceutical companies that develop the countermeasures the assurance of future funding.

In conclusion, speaking for myself, and my colleagues, H.R. 2122 reflects our strongest support for those necessary efforts to protect our people and our way of life.

Mr. VAN HOLLEN. Mr. Speaker, I rise today as the Representative of the Congressional District that is the intended home of a key component of the Project Bioshield Act, a \$186 million bio-defense laboratory that is planned to be built on the northeast corner of the National Institutes of Health campus in Bethesda, Maryland. While I support the Bioshield initiative, I have serious concerns about the proposed location of the bio-defense laboratory.

Many of my constituents have expressed to me their concerns about the potential safety risks that the location of this laboratory poses to our community, and the possibility that it could become a target for terrorist attacks. Given that our government determined—even before this new laboratory was proposed—that a perimeter fence is required to safeguard the

buildings and employees at the National Institutes of Health. I believe a number of questions must be answered before we proceed further with the plan to locate the laboratory on the NIH campus.

I have written to the Director of the National Institutes of Health and asked him to address the following issues:

(1) The property of locating this laboratory in an urban setting like Bethesda, as opposed to at Fort Detrick, where a bio-safety level 3 laboratory is already under construction;

(2) if located on the Bethesda campus, whether it can be located centrally on the campus, either in a new building or by renovating an existing building and relocating the offices and laboratories of that building to a building in the location chosen for Building 33; and

(3) the precautions that will be taken to ensure that, in the event of a terrorist attack or human error, that any potential risk to our community presented by the presence of this laboratory on the Bethesda campus is minimized or eliminated.

Mr. Speaker, I know that all of my colleagues in this House are united in our common effort to combat terrorism. But we owe it to our constituents to approach this endeavor carefully. I urge my colleagues and the Administration to consider all options so that we do right by all Americans.

Mr. COX. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. Pursuant to the order of the House of Tuesday, July 15, 2003, the previous question is ordered on the bill, as amended.

The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, was read the third time.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the yeas appeared to have it.

Mr. COX. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this question will be postponed.

□ 1545

PROVIDING FOR CONSIDERATION OF H.R. 2691, DEPARTMENT OF INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 2004

Mr. HASTINGS of Washington. Mr. Speaker, by direction of the Committee on Rules, I call up House Resolution 319 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

H. RES. 319

Resolved, That at any time after the adoption of this resolution the Speaker may, pursuant to clause 2(b) of rule XVIII, declare the House resolved into the Committee of the Whole House on the state of the Union for consideration of the bill (H.R. 2691) making appropriations for the Department of the Interior and related agencies for the fiscal year

ending September 30, 2004, and for other purposes. The first reading of the bill shall be dispensed with. All points of order against consideration of the bill are waived. General debate shall be confined to the bill and shall not exceed one hour equally divided and controlled by the chairman and ranking minority member of the Committee on Appropriations. After general debate the bill shall be considered for amendment under the five-minute rule. Points of order against provisions in the bill for failure to comply with clause 2 of rule XXI are waived except as follows: page 84, line 21, through page 89; page 90, line 4 through line 9. During consideration of the bill for amendment, the Chairman of the Committee of the Whole may accord priority in recognition on the basis of whether the Member offering an amendment has caused it to be printed in the portion of the Congressional Record designated for that purpose in clause 8 of rule XVIII. Amendments so printed shall be considered as read. During consideration of the bill, points of order against amendments for failure to comply with clause 2(e) of rule XXI are waived. At the conclusion of consideration of the bill for amendment the Committee shall rise and report the bill to the House with such amendments as may have been adopted. The previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions.

The SPEAKER pro tempore (Mr. GILCHREST). The gentleman from Washington (Mr. HASTINGS) is recognized for 1 hour.

Mr. HASTINGS of Washington. Mr. Speaker, for the purpose of debate only, I yield the customary 30 minutes to the gentlewoman from New York (Ms. SLAUGHTER), pending which I yield myself such time as I may consume. During consideration of this resolution, all time yielded is for the purpose of debate only.

(Mr. HASTINGS of Washington asked and was given permission to revise and extend his remarks.)

Mr. HASTINGS of Washington. Mr. Speaker, House Resolution 319 is an open rule providing for the consideration of H.R. 2691, the Department of Interior and Related Agencies Appropriations Act of 2004. The rule provides for 1 hour of general debate equally divided and controlled by the chairman and ranking minority member of the Committee on Appropriations. The rule waives all points of order against consideration; and under the rules of House, the bill shall be read for amendment by paragraph.

The rule waives points of order against provisions in the bill for failure to comply with clause 2 of rule XXI, prohibiting unauthorized appropriations or legislative provisions in an appropriations bill, except as specified in the resolution.

The rule further waives points of order against amendments for failure to comply with clause 2(e) of rule XXI, prohibiting designated emergencies in reported appropriations bills.

Finally, the rule authorizes the Chair to accord priority in recognition to Members who have preprinted their amendments in the CONGRESSIONAL RECORD and provides one motion to recommit with or without instructions.

Mr. Speaker, H.R. 2691 provides funding for the Department of Interior as well as various agencies and programs and Departments of Agriculture, Energy, Health and Human Services. H.R. 2691 appropriates \$19.6 billion in new budget authority, which is \$186 million less than last year's enacted level and \$110 million more than the President's request. Almost half of the bill's funding finances the Interior Department's programs to manage and study the Nation's animal, plant and mineral resources and support programs benefiting Native Americans.

Among the bill's many provisions are several of special interest to residents of central Washington and my district, including \$2.5 billion for Wildland Fire Fighting and the National Fire Plan. This funding will increase firefighting readiness, hazardous fuels reduction, and forest health restoration activities.

As a Member whose district includes significant Federal land holdings, I am particularly pleased that payment in lieu of taxes, or PILT, is funded at \$225 million, which is \$5 million above the current enacted level and \$25 million above the administration's request.

In the area of fisheries management, the committee is to be commended for providing \$113 million for fisheries, an increase of nearly \$10 million over the administration's request, which includes an increase of \$3 million for the Washington State Hatchery Improvement Project.

It should also be noted that the bill includes \$4.6 million for the Partners of Fish and Wildlife Program, of which \$1.4 million goes to the Washington Regional Fisheries Enhancement programs.

Finally, Mr. Speaker, I commend the gentleman from North Carolina (Mr. TAYLOR) for his efforts to focus attention to the critically important task of maintaining our national parks.

The bill includes \$682 million to attack the enormous backlog of badly needed maintenance at our national park facilities.

Mr. Speaker, this bill is a bill which carefully balances a number of important objectives, including natural resources protections and providing access for the public to our Nation's many significant parks and refuges. It makes real progress in management of forests, fisheries. And rangeland; and it does so in a cost-effective way in these challenging budgetary times.

Accordingly, Mr. Speaker, I urge my colleagues to support the rule and the underlying bill.

Mr. Speaker, I reserve the balance of my time.

Ms. SLAUGHTER. Mr. Speaker, I yield myself such time as I may consume, and I thank the gentleman from Washington for yielding me the customary 30 minutes.

(Ms. SLAUGHTER asked and was given permission to revise and extend her remarks.)

Ms. SLAUGHTER. Mr. Speaker, former President Theodore Roosevelt,