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

There was no objection.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 4818, FOREIGN OPERATIONS, EXPORT FINANCING, AND RELATED PROGRAMS APPROPRIATIONS ACT, 2005

Mr. LINCOLN DIAZ-BALART of Florida (during consideration of H.R. 4759), from the Committee on Rules, submitted a privileged report (Rept. No. 108–604) on the resolution (H. Res. 715) providing for consideration of the bill (H.R. 4818) making appropriations for foreign operations, export financing, and related programs for the fiscal year ending September 30, 2005, and for other purposes, which was referred to the House Calendar and ordered to be printed.

PERSONAL EXPLANATION

Ms. JACKSON-LEE of Texas. Mr. Speaker, yesterday, July 13, 2004, I missed a number of rollcall votes. If I had been here, I would have voted in the following manner: rollcall vote No. 363, I would have voted ''aye''; rollcall vote No. 364, I would have voted ''aye''; rollcall vote No. 366, I would have voted ''aye''; rollcall vote No. 367, I would have voted ''no''; rollcall vote No. 368, I would have voted ''no''; rollcall vote No. 369, I would have voted ''aye''; and on final passage, I would have voted ''aye.''

PROJECT BIOSHIELD ACT OF 2004

Mr. BARTON of Texas. Mr. Speaker, pursuant to the order of the House of Tuesday, July 13, 2004, I call up the Senate bill (S. 15) to amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures, and ask for its immediate consideration.

The Clerk read the title of the bill.

The text of S. 15 is as follows:

S. 15

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Project BioShield Act of 2004''.

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 countermeasures under section 319F(h), the Secretary may conduct and support such activities in accordance with this section and, in consultation with the Director of the National Institutes of Health, as part of the program under section 446, if the activities concern qualified countermeasures.

''(2) QUALIFIED COUNTERMEASURE.—For purposes of this section, the term 'qualified countermeasure' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to—

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

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

''(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).

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

''(v) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen).

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

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

''(C) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute 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 with respect to the procurement involved.

''(D) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this paragraph, the Secretary may not use the authority provided for under subparagraph (A) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

''(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 government-wide regulations implementing such section 303(c)(1) (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), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency 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 needs of the agency.

''(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 subsection (f), section 1491 of title 28, United States Code, and section 3556 of title 31 of such Code, 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 section 1491 of title 28, United States Code, and section 3553 of title 31 of such Code, 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 any 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. Nothing in the preceding sentence may be construed to impose any requirement with respect to peer review not otherwise required under any other law or regulation.

''(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, subject to a determination by the Secretary, 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 entity involved (person, officer, employee, or governing board member) for any act or omission within the scope of the Federal Tort Claims Act.

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

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

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

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

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

''(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or governing board member of a person, is or is not deemed to be an employee of the Department of Health and Human Services shall be final and binding on the Secretary and the Attorney General and other parties to any civil action or proceeding.

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

''(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 those 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) LIMITATIONS.—The authority provided for under paragraph (1) shall be exercised in a manner that—

''(A) recruits and appoints individuals based solely on their abilities, knowledge, and skills;

''(B) does not discriminate for or against any applicant for employment on any basis described in section 2302(b)(1) of title 5, United States Code;

''(C) does not allow an official to appoint an individual who is a relative (as defined in section 3110(a)(3) of such title) of such official;

''(D) does not discriminate for or against an individual because of the exercise of any activity described in paragraph (9) or (10) of section 2302(b) of such title; and

''(E) accords a preference, among equally qualified persons, to persons who are preference eligibles (as defined in section 2108(3) of such title).

''(3) 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'';

(2) in subsection (c)—

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

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

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

(4) in subsection (e)—

(A) in paragraph (1)—

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

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

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

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

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

(5) in subsection (f)—

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

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

(6) in subsection (i)—

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

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

(B) by adding at the end the following:

''(2) NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.—For the purpose of carrying out this section with respect to the National Institute of Allergy and Infectious Diseases, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.''.

(c) 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 and 2005.''; 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 and 2005.''.

(d) 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''.

(e) 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, in coordination with the Secretary of Homeland Security (referred to in this section as the 'Homeland Security Secretary'), 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;

''(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;

''(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety; and

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

''(i)(I) –the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

''(II) the Secretary determines 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; or

''(bb) is a 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 within eight years after the date of a determination under paragraph (5); or

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

''(2) DETERMINATION OF MATERIAL THREATS.—

''(A) MATERIAL THREAT.—The Homeland Security Secretary, in consultation with the Secretary and 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 sufficient to affect national security.

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

''(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

''(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures are necessary to protect the public health.

''(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).

''(D) ASSURING ACCESS TO THREAT INFORMATION.—In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant 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 eight 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 number of, nature of, and other information concerning potential 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 AGREEMENT; COSTS.—

''(i) INTERAGENCY AGREEMENT.—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 payments made by the Secretary to a vendor for such procurement.

''(ii) OTHER COSTS.—The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1).

''(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 DELIVERY.—The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to 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 by the vendor under the contract. 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) DISCOUNTED PAYMENT.—The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

''(III) 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.

''(IV) 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.

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

''(VI) 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).

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

''(ee) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen).

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

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

''(III) INTERNAL CONTROLS TO BE ESTABLISHED.—The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

''(IV) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

''(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 government-wide regulations implementing such section 303(c)(1) (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), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency 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 needs of the agency.

''(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 2004; or

''(B) costs other than payments made by the Secretary to a vendor for a procurement of a security countermeasure under paragraph (7).

''(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 appropriate committees.

''(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 referred to in subsection (c)(10)(A).

''(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) AMENDMENTS 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—

(1) in section 502(3) (6 U.S.C. 312(3))—

(A) in subparagraph (B), by striking ''the Strategic National Stockpile,''; and

(B) in subparagraph (D), by inserting '', including requiring deployment of the Strategic National Stockpile,'' after ''resources''; and

(2) 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 'Biodefense Countermeasures' appropriations account or any other appropriation made under subsection (a).

''(c) AVAILABILITY.—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 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 180 days after the date of enactment of the Project BioShield Act of 2004, 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 2004 through 2006.''.

(c) STOCKPILE FUNCTIONS TRANSFERRED.—

(1) IN GENERAL.—Except as provided in paragraph (2), there shall be transferred to the Secretary of Health and Human Services the functions, personnel, assets, unexpended balances, and liabilities of the Strategic National Stockpile, including the functions of the Secretary of Homeland Security relating thereto.

(2) EXCEPTIONS.—

(A) FUNCTIONS.—The transfer of functions pursuant to paragraph (1) shall not include such functions as are explicitly assigned to the Secretary of Homeland Security by this Act (including the amendments made by this Act).

(B) ASSETS AND UNEXPENDED BALANCES.—The transfer of assets and unexpended balances pursuant to paragraph (1) shall not include the funds appropriated under the heading ''BIODEFENSE COUNTERMEASURES'' in the Department of Homeland Security Appropriations Act, 2004 (Public law 108–90).

(3) CONFORMING AMENDMENT.—Section 503 of the Homeland Security Act of 2002 (6 U.S.C. 313) is amended by striking paragraph (6).

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

(a) IN GENERAL.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3) is amended to read as follows:

''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 domestic emergency, or a significant potential for a domestic 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 specified 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 that affects, or has a significant potential to affect, national security, and that involves 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.

''(C) DISPOSITION OF PRODUCT.—If an authorization under this section with respect to an unapproved product ceases to be effective as a result of a termination under subparagraph (A) of this paragraph, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

''(3) ADVANCE NOTICE OF TERMINATION.—The Secretary shall provide advance notice that a declaration under this subsection 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 the product, including the return of such product (except such quantities of product as are necessary to provide for continued use consistent with subsection (f)(2)) to the manufacturer (in the case of a manufacturer that chooses to have such product returned); and

''(B) in the case of an unapproved use of an approved product, a sufficient period for the disposition of any labeling, or any information under subsection (e)(2)(B)(ii), as the case may be, that was provided with respect to the emergency use involved.

''(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register each declaration, determination, advance notice of termination, 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 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, approved or cleared under this Act, or licensed under section 351 of the Public Health Service Act, for 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 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 diagnosing, preventing, or treating such disease or condition; and

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

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

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

''(2) the Secretary's conclusions, made under subsection (c)(2)(B), that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and

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

''(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 practicable given the circumstances of the emergency, shall, for a person who carries out any activity 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 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 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 may, for a person who carries out any activity 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) Appropriate conditions with respect to the collection and analysis of information, during the period when the authorization is in effect, concerning the safety and effectiveness of the product with respect to the emergency use of such product.

''(iv) 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.

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

''(A) For a manufacturer of the product who carries out any activity for which the authorization is issued, the Secretary shall, to the extent practicable given the circumstances of the emergency, establish conditions described in clauses (i) and (ii) of paragraph (1)(A), and may establish conditions described in clauses (iii) and (iv) of such paragraph.

''(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), for a person who does not manufacture the product and who chooses to act under this clause, an authorization under this section regarding the emergency use shall, to the extent practicable given the circumstances of the emergency, authorize such person to provide appropriate information with respect to such product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). While the authorization under this section is effective, such additional information shall not be considered labeling for purposes of section 502.

''(C) The Secretary may establish with respect to the distribution and administration of the product for the unapproved use conditions no more restrictive than those established by the Secretary with respect to the distribution and administration of the product for the approved use.

''(3) GOOD MANUFACTURING PRACTICE.—With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements 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 under section 501.

''(4) ADVERTISING.—The Secretary may establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), including, as appropriate—

''(A) with respect to drugs and biological products, requirements applicable to prescription drugs pursuant to section 502(n); or

''(B) with respect to devices, requirements applicable to restricted devices pursuant to section 502(r).

''(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 to provide for continued use of an unapproved product with respect to a patient to whom it was administered during the period described by paragraph (1), to the extent found necessary by such patient's attending physician.

''(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 the criteria under subsection (c) for issuance of such authorization are no longer met or other circumstances make such revocation appropriate to protect the public health or safety.

''(h) PUBLICATION; CONFIDENTIAL INFORMATION.—

''(1) PUBLICATION.—The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, and an explanation of the reasons therefor (which may include a summary of data or information that has been submitted to the Secretary in an application under section 505(i) or section 520(g), even if such summary may indirectly reveal the existence of such application).

''(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.

''(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.—The following applies with respect to this section:

''(1) Nothing in this section impairs 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) Nothing in this section impairs the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law.

''(3) Nothing in this section (including any exercise of authority by a manufacturer under subsection (e)(2)) impairs the authority of the United States to use or manage quantities of a product that are owned or controlled by the United States (including quantities in the stockpile maintained under section 319F–2 of the Public Health Service Act).

''(k) 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 shall not be considered to constitute a clinical investigation for purposes of section 505(i), section 520(g), or any other provision of this Act or section 351 of the Public Health Service Act.

''(l) OPTION TO CARRY OUT AUTHORIZED ACTIVITIES.—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 report to 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 under the authorization. This section only has legal effect on a person who carries out an activity for which an authorization under this section is issued. This section does not modify or affect activities carried out pursuant to other provisions of this Act or section 351 of the Public Health Service Act. Nothing in this subsection may be construed as restricting the Secretary from imposing conditions on persons who carry out any activity pursuant to an authorization under this section.''.

(b) REPEAL OF TERMINATION PROVISION.—Subsection (d) of section 1603 of the National Defense Authorization Act for Fiscal Year 2004 (10 U.S.C. 1107a note) is repealed.

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 number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity; 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.

(3) REPORT ON ADDITIONAL BARRIERS TO PROCUREMENT OF SECURITY COUNTERMEASURES.—Not later than one year after the date of the enactment of this Act, the Secretary, in consultation with the Secretary of Homeland Security, shall report to the designated congressional committees any potential barriers to the procurement of security countermeasures that have not been addressed by this Act.

(b) GENERAL ACCOUNTING OFFICE REVIEW.—

(1) IN GENERAL.—Four years after the date of the enactment of this Act, the Comptroller General of the United States shall initiate a study—

(A)(i) to review the Secretary of Health and Human Services' utilization of the authorities 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

(ii) to make recommendations to improve the utilization or effectiveness of such authorities in the future;

(B)(i) to review and assess the adequacy of the internal controls instituted by such Secretary with respect to such authorities, where required by this Act; and

(ii) to make recommendations to improve the effectiveness of such controls;

(C)(i) 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

(ii) to make recommendations to improve the utilization or effectiveness of such authority and to enhance protection of the public health;

(D) to identify any purchases or procurements that would not have been made or would have been significantly delayed except for the authorities described in subparagraph (A)(i); and

(E)(i) to determine whether and to what extent activities undertaken pursuant to the biomedical countermeasure research and development authorities established in this Act have enhanced the development of biomedical countermeasures affecting national security; and

(ii) to make recommendations to improve the ability of the Secretary to carry out these activities in the future.

(2) ADDITIONAL PROVISIONS REGARDING DETERMINATION ON DEVELOPMENT OF BIOMEDICAL COUNTERMEASURES AFFECTING NATIONAL SECURITY.—In the report under paragraph (1), the determination under subparagraph (E) of such paragraph shall include—

(A) the Comptroller General's assessment of the current availability of countermeasures to address threats identified by the Secretary of Homeland Security;

(B) the Comptroller General'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

(C)(i) the Comptroller General'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.

(3) REPORT.—A report providing the results of the study under paragraph (1) shall be submitted to the designated congressional committees not later than five years after the date of the enactment of this Act.

(c) REPORT REGARDING 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.

(d) 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 appropriate committees.

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 Black or African Americans, American Indians, Appalachian Americans, Alaska Natives, Asians, Native Hawaiians, other Pacific Islanders, Hispanics or Latinos, 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.

SEC. 9. AUTHORITY OF THE SECRETARY OF HEALTH AND HUMAN SERVICES DURING NATIONAL EMERGENCIES.

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

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

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

''(A) a transfer of an individual who has not been stabilized in violation of subsection

(c) of such section if the transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period; or

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

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

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

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

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

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

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

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

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

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

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

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

(5) by adding at the end the following: ''A waiver or modification provided for under paragraph (3) or (7) shall only be in effect if such actions are taken in a manner that does not discriminate among individuals on the basis of their source of payment or of their ability to pay, and shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification under such paragraph (7) shall be withdrawn after such period and the provider shall comply with the requirements under such paragraph for any patient still under the care of the provider.''.

The SPEAKER pro tempore. Pursuant to the order of the House of Tuesday, July 13, 2004, the gentleman from Texas (Mr. BARTON) and the gentleman from Ohio (Mr. BROWN) each will control 30 minutes. The gentleman from Virginia (Mr. TOM DAVIS), the gentleman from California (Mr. WAXMAN), the gentlewoman from Washington (Ms. DUNN), and the gentleman from Texas (Mr. TURNER) each will control 7½ minutes.

The Chair recognizes the gentleman from Texas (Mr. BARTON).

GENERAL LEAVE

Mr. BARTON of Texas. 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 S. 15.

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

There was no objection.

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

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

Mr. BARTON of Texas. Mr. Speaker, the Senate recently joined the House in passing one of President Bush's top legislative initiatives for this Congress, Project Bioshield. The House passed a similar bill in July 2003 by a strong bipartisan vote of 421 to 2. I want to commend our colleagues in the Senate for working with us after the House passed its legislation to provide a bill that will be acceptable to both bodies.

The bill largely reflects H.R. 2122, the bill that passed the House last year. Revisions in the Senate were made in close consultation with the House committees of jurisdiction. This is a bicameral and bipartisan product.

On the House side, I want to thank the gentleman from Louisiana (Mr. TAUZIN), my predecessor as chairman of the committee, who is on the floor this evening, for his strong leadership; and I would also like to thank the gentleman from California (Mr. COX), the gentleman from Virginia (Mr. TOM DAVIS), the gentleman from Michigan (Mr. DINGELL), the gentleman from Texas (Mr. TURNER), and the gentleman from California (Mr. WAXMAN) for their cooperation and hard work on this bill.

The bipartisan spirit reflected in this legislation is similar to the effort of the last Congress on the Public Health Security and Bioterrorism Preparedness and Response Act and also on the Homeland Security Act. We can be proud of this product, and America can be confident in our commitment to make the right investments and smart policy choices to meet the challenges and to protect our Nation's public health.

Project Bioshield will spur the research and development of new vaccines, new drugs and other countermeasures to deal with those biological, chemical, nuclear, or radiological agents that pose a material threat to our national security. This list includes anthrax, the plague, ebola and other similar viruses, many of which lack any effective treatment or antidote today.

The bill provides increased flexibility in a range of areas, from government contracting rules and peer review to personnel matters, in order to speed up government-sponsored research and development into these deadly agents.

It would also authorize a special reserve fund of money, authorized in advance, for the government's purchase of those countermeasures that ultimately are developed in response to the President's call. This latter feature is the most important because, without this clear commitment of funding in future years, private sector companies that are capable of such development will not undertake the heavy investment and risk associated with developing products that deal with agents that do not affect significant populations today and hopefully never will. Congress has already provided the advance appropriation of $5.6 billion over the next 10 years for this purpose, consistent with our authorization in the House budget resolution.

The bill before us 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 of using those products. Under current law, the only way an individual can receive an unapproved product is pursuant to a clinical investigation. In a time of national emergency, however, it may be necessary to give such investigational drugs on a large-scale basis to millions of Americans. The bill before us today says that if there is such an emergency, if no adequate alternative therapy is available, then and only then the Secretary can authorize the use of such a drug, device, or vaccine in a flexible manner.

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

I would urge my colleagues to support the bill and look forward to President Bush signing into law another of his major homeland security initiatives.

At this point in the RECORD, I will insert an exchange of letters between the gentleman from California (Mr. THOMAS) and myself on this subject.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS
Washington, DC, July 13, 2004.

The Hon. JOE BARTON,
Chairman, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC.

DEAR CHAIRMAN BARTON: I am writing concerning S. 15, the ''Project Bioshield Act of 2004,'' which is scheduled for floor consideration on Wednesday, July 14, 2004.

As you know, the Committee on Ways and Means has jurisdiction over matters concerning health issues. Specifically, Section 9 of the bill provides a waiver for application of Section 1867 of the Social Security Act, known as the Examination and Treatment for Emergency Medical Conditions and Women in Labor Act. Section 9 allows hospitals and other providers to transfer unstable patients during a declared emergency period or pursuant to a state emergency preparedness plan by waiving hospital requirements under Medicare, and thus falls within the jurisdiction of the Committee on Ways and Means.

However, in order to expedite this legislation for floor consideration, the Committee will forego action on this bill. This is being done with the understanding that it does not in any way prejudice the Committee with respect to exercising its jurisdictional prerogatives on this or similar legislation.

I would appreciate your response to this letter, confirming this understanding with respect to S. 15 and would ask that a copy of our exchange of letters on this matter be included in the Congressional Record during floor consideration.

Best regards,

BILL THOMAS,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, July 14, 2004.

Hon. BILL THOMAS,
Chairman, Committee on Ways and Means, Longworth House Office Building, Washington, DC.

DEAR CHAIRMAN THOMAS: Thank you for your letter regarding S. 15, the '' Project BioShield Act of 2004.'' As you noted, the bill contains provisions that fall within the Rule X jurisdiction of the Committee on Ways and Means.

I appreciate your willingness not to seek a referral on S. 15. I agree that your decision to forego action on the bill will not prejudice the Committee on Ways and Means with respect to its jurisdictional prerogatives on this or similar legislation.

I will include a copy of your letter and this response in the Congressional Record during consideration of S. 15 on the House floor.

Sincerely,

JOE BARTON,
Chairman.

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.

The United States, and the global community, can only benefit from the development of bioterrorism countermeasures.

By rendering biological attacks less lethal and, therefore, less attractive to would-be terrorists, new countermeasures 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 on that opportunity quickly.

That is the logic behind this legislation. It establishes an expedited process for Federal support of countermeasure research and a procurement process to encourage private sector investment.

But Project Bioshield is not a blank check. Congress has a responsibility to weigh competing priorities and set funding levels appropriately. In that context, Congress cannot rest easy once we have passed this bill.

Bioterrorism funding is certainly important, the legislation before us today is certainly important, but our investment in bioterrorism must not come at the expense of research on cancer and research on Alzheimer's and muscular dystrophy and AIDS and other significant health threats.

If investing in Bioshield means diverting from other promising medical research, TB, multiple sclerosis, all other kinds of medical research, we are not making progress. We are, in fact, making trade-offs; trade-offs that set back the clock on cures for deadly and disabling diseases; trade-offs the public did not bargain for and should not abide.

The last thing Congress or the President should do is assure the public that we are doing everything we can more than ever to find cures for major illnesses like cancer and Parkinson's when actually we are choking off funding for medical research.

During his 2000 election campaign, President Bush said, ''As President, I will fund and lead a medical moonshot to reach far beyond what seems possible today.'' Apparently it was a short trip.

According to a White House budget memo recently leaked to the press, if President Bush wins the election this fall, one of his first actions will be to propose a $587 million cut in funding for the National Institutes of Health.

Medical researchers tell us that just to sustain the pace of medical progress that NIH has fostered, the agency's budget must increase 10 percent annually, something I hope everyone here would agree with, even though the President does not. Compared to annual, double-digit increases in the NIH budget, a cut in funding is a major step backward that would undermine promising medical research.

Finding ways to prevent, to treat, and to cure disease is an enduring national priority. Interest in that should not wax and wane. That is why we do not double NIH funding, which we did bipartisanly between 1999 under President Clinton, into 2003 still supported by President Bush, but then reduced that increase and then proposed a cut in funding. Our investment must remain constant.

We have a responsibility to prepare the country for a possible bioterrorist attack, but we also have a responsibility to maintain strong support for other medical research priorities.

I urge my colleagues to support this legislation. In creating Project Bioshield, it gives America a promising weapon in the battle against terrorism.

But bioterrorism, as I have said, is just one enemy in a much broader war against disease and disability. If we fund Project Bioshield, as we should, at the expense of life-saving and life-improving NIH research, we risk winning the battle and losing the war.

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

Mr. BARTON of Texas. Mr. Speaker, I yield such time as he may consume to the gentleman from Louisiana (Mr. TAUZIN), the distinguished former chairman of the Committee on Energy and Commerce, who in a very true sense is a principal author of this piece of legislation and who has toiled tirelessly for the last several years to have it passed.

□ 1730

Mr. TAUZIN. Mr. Speaker, I thank the gentleman for yielding me this time; and, on a very bipartisan note, let me first thank the Members of this House and of the Senate, and particularly my friend from Massachusetts, Mr. KENNEDY, for the great success we had in passing the Public Health Security Act and the Bioterrorism Preparedness and Response Act.

As my colleagues will recall, right after 9–11 it became clear to us as a Nation that we were under serious threat of attacks from agents like anthrax or perhaps even such horrible agents as botulism toxin or ebola or other similar viruses and that we were so unprepared in this country for that kind of attack that we got together, in a bipartisan fashion, and immediately passed an act to bolster the competence and the ability of the Center for Disease Control and of agents across the country to better respond to an attack of that nature.

Since the passage of those two very important actions that have better armed our country for this danger that we face perhaps even more increasingly as years go by, it has come to our attention that there were some holes even in that great act. The most important hole which this act seeks to fill is the concern we have that when it comes to some of these agents, whether they be a botulism toxin agent, ebola, or whether it is a radioactive type of attack we have to deal with in this country, that we have not done enough research and development into the antidotes, the vaccines, the treatments that victims of these attacks might find are critically necessary to save lives and prevent injury.

I do not have to tell my colleagues that this House and the Senate recently received another briefing on national security threats. The concern levels are up about an attack that might occur in this country from al Qaeda or other enemies of this country. As we fight them overseas, they are thinking about planning an attack on us here at home again. We know that. We know the attack may come in a place we do not know, in a place we are unprepared for, and it might involve radiological materials or it might involve some horrible virus or some agent the likes of which we are unprepared to deal with.

This bill seeks to make sure that the private sector does the work along with government to find the antidotes, the treatment for these kinds of agents that might be used in such an attack which might not otherwise be developed in the private sector.

What is the incentive today to develop a vaccine for ebola or for the plague when there is no real market for such a vaccine in this country? This bill and the appropriations we have already provided in the advance funds, some $5.6 billion, is designed to make sure that that research and development occurs and that those vaccines and those treatments are indeed available to our country in case the worst happens and we are subject to that kind of an attack by al Qaeda or other enemies of this country within our borders as we saw on 9–11.

Secondly, the bill tries to do something else, and that is to say we are going to change our law a little bit when it comes to the government's approval of treatment and/or it might be

a vaccine or some treatment that has not yet been approved by the Food and Drug Administration but yet has a greater ability to cure and help people than the risk involved with allowing it to be used. In other words, we are streamlining the law to make sure, if we do come under attack, if there is some vaccine, some treatment under study that has a lot of promise but has not yet been approved, that we are not forbidden to use it to help people who might be hurt or in need of that kind of treatment.

In short, this Bioshield Act, an incredibly important new step in protecting our country at a time when we are increasingly learning of the hatred and evil that exists out there that wants to inflict more damage on our country, this new act, passed again in, I hope, a very strong bipartisan way, reaching the President's desk for his signature very soon, I hope, will add this new element of protection for our country that Senator KENNEDY and I tried to provide in the first bioterrorism act for our Nation following 9–11.

This is an important step in protecting our country at a time when we are under, as you know, this increasing warning that these evil individuals are thinking about planning and trying to figure out how they might hurt us again. It is a critical two-step process in making sure that we have the protective vaccines and treatments in place when the worst might happen to our people. So I urge its adoption.

I want to congratulate all of those who have worked on completing the conference on this bill with the Senate. I want to thank the other body for its cooperation. The sooner this reaches the President's desk, the sooner all of us can feel a little better this country is becoming safer as fast as we can from the threat of these kind of agents, and I urge its final approval by this House.

The SPEAKER pro tempore (Mr. FOLEY). The gentlewoman from New York (Mrs. MALONEY) is recognized on behalf of the Committee on Government Reform.

Mrs. MALONEY. Mr. Speaker, I do claim the time on behalf of the Committee on Government Reform, and I yield myself such time as I may consume.

Mr. Speaker, we have before us today S. 15, the Project Bioshield Act. This bill is substantially the same as H.R. 2122, which passed this House on July 16 of last year by a vote of 421 to 2. This bill is, in essence, the conference report on the bill and includes some minor improvements made by the Senate. I urge Members to support this measure as well.

Given the serious threat of bioterrorism, the development of effective countermeasures to biological agents is vital to our national security. The goal of Project Bioshield is to encourage the development of these projects. 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.

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 right to review contractors' books and records.

The bill also permits the use of certain streamlined procurement procedures, but only if the Secretary of Health and Human Services determines that there is a pressing need to do so.

The Senate bill appropriately strengthens some of these provisions and also allows for recovery by the government in the event of grossly negligent or reckless conduct on the part of a contractor.

In emergency situations, we should not impede the development of necessary products. However, any exceptions from standard procurement procedures should be made only when necessary and should be subject to review. This proposal preserves that important 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. FDA must be vigilant in protecting the public against unnecessary risks from these products. In part because of these concerns, the bill requires that health care providers and patients be informed that the products have not been approved and be informed of their risks.

The bill also requires 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 HHS 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 needs for these additional conditions in each case and to impose them to the full extent necessary to protect the public from the risk of these products.

The bill before us today is an improvement over the original proposal and represents a bipartisan consensus of the House and the Senate and the White House. It deserves our support.

Mr. Speaker, I ask unanimous consent to yield the balance of my time to the gentleman from Texas (Mr. TURNER) as the ranking minority member of the Select Committee on Homeland Security and that he be allowed to control that time.

The SPEAKER pro tempore. Without objection, the Chair will recognize the gentleman from Texas (Mr. TURNER) for the time remaining to the representative from the Committee on Government Reform.

There was no objection.

Mr. BROWN of Ohio. Mr. Speaker, I also ask unanimous consent to yield the remainder of my time to the ranking member of the Select Committee on Homeland Security, the gentleman from Texas (Mr. TURNER), and that he be allowed to control that time.

The SPEAKER pro tempore. Without objection, the Chair will recognize the gentleman from Texas (Mr. TURNER) for the balance of the time allocated to the minority on the Committee on Energy and Commerce.

There was no objection.

Mr. BARTON of Texas. Mr. Speaker, could I inquire as to how much time remains that I am controlling?

The SPEAKER pro tempore. The gentleman from Texas (Mr. BARTON) has 20 minutes, and the gentleman from Texas (Mr. TURNER), for the minority, has 37 minutes.

Mr. BARTON of Texas. Mr. Speaker, I yield 2 minutes to the distinguished gentleman from Michigan (Mr. ROGERS), a member of the committee.

Mr. ROGERS of Michigan. Mr. Speaker, I thank the gentleman for yielding me this time; and I want to also thank Members on both sides of the aisle on this very, very important issue.

This legislation will greatly strengthen our Nation's capability to protect our military, first responders, and U.S. citizens from the real threat of biological, chemical, radiological, and nuclear weapons of mass destruction.

I am very pleased that this expands the definition of eligible countermeasures and would permit funding and procurement for certain FDA-licensed vaccines as well as experimental products for inclusion in the Strategic National Stockpile. I cannot say how important that is.

We find heroes and patriots both abroad and at home risking their lives in defense of freedom in this war on terror, but there are patriots and unsung heroes in my community who, under withering criticism, toiled to make their product better and get it into the hands of those who needed it most. Thanks to the employees of Bioport in Lansing, Michigan, since 1998, more than 1.1 million military and civilian personnel have been safely vaccinated with more than 4 million doses of the vaccine, including both pre- and post-exposure vaccinations of many of our own congressional colleagues and staff members after the October, 2001, anthrax attacks.

These existing products, like BioThrax vaccine, will provide our Nation with the insurance policy to strengthen its immediate bioterrorism preparedness capability in conjunction with working on new experimental vaccines.

Mr. Speaker, I would even go further and urge the Departments of Homeland Security and Health and Human Services to consider the immediate procurement of millions of additional doses of the FDA-licensed anthrax vaccines, as well as additional doses of antibiotics for the Strategic National Stockpile. These doses are essential to improving our capability and responding to another potential anthrax attack.

I want to again thank the President of the United States for making this a priority and sending a very clear and strong message that our Nation is serious about protecting the citizens and first responders from deadly terrorist threats with proven countermeasures.

The SPEAKER pro tempore. The Chair will clarify the time allotments.

The gentleman from Texas (Mr. BARTON) has 18 minutes remaining, and the gentleman from Texas (Mr. TURNER) has 37 minutes. We also have a 15-minute allocation to the majority, 7½ minutes to the gentlewoman from Washington (Ms. DUNN) on the Select Committee on Homeland Security, and 7½ minutes to the gentleman from Virginia (Mr. TOM DAVIS), chairman of the Committee on Government Reform.

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

I think we all understand that to win the war on terror we have to be much more aggressive about going after the terrorists wherever they are. Breaking up international terrorist cells is project number one for the national defense of this country.

We also know that we have to strengthen our homeland defenses and protect our vulnerabilities and protect our population from threats posed by challenges as the one addressed in this bill today, bioterrorism.

Finally, I hope we will soon learn that in order to win the war on terror we have to start addressing the policies that we need to pursue to prevent the rise of future terrorists so that someday we can stand on this floor and announce, as we did at the end of the Cold War, that we have won, that we have prevailed.

□ 1745

To win this war on terror, we must address the threat that is addressed by Project Bioshield, the threat of mass destruction through the use of bioweapons. Perhaps the most devastating weapon is a bioweapon of mass destruction. The anthrax attacks of 2001 woke this Nation up to the very real threat of bioterrorism. We know that al Qaeda intends to engage in bioterrorism, and we know that Osama bin Laden has called for the use of weapons of mass destruction against the American public. In fact, he has called it a religious duty.

In spite of this dire and clear warning, our biodefenses are no better than they were in September of 2001. No new medical treatments, vaccines, or life-saving drugs have been approved for use. There is no antitoxin for ricin poisoning, no vaccine to protect against the plague, and no treatments of any kind against the deadly ebola virus.

Mr. Speaker, we must regain the sense of urgency that we all felt in this Chamber in the aftermath of September 11, and I hope that the passage of this bill will mark a renewed sense of urgency regarding the bioterror threat. Because this bill marks but the beginning, not the end, of a long road we must travel, I hope that the passage of this legislation will renew our urgency about the threat of bioterrorism. I support the Bioshield legislation because it is a good first step to addressing the challenge.

From the beginning of this process, I and many of my colleagues on the Democratic side have been concerned that this legislation is not enough to address the threats that we face. Whether Bioshield will be a success is yet to be determined. Bioshield is, in fact, an experiment. We do not know if the incentives in this bill will drive our pharmaceutical industry to develop medicines for biodefense when we all know they can make much more money developing and putting on the market other types of products. Many experts in the field believe that the best we can hope for is that in 10 years we may have a few new countermeasures that will plug some of the holes in our biodefenses.

The longer it takes for companies to step forward to fill these gaps, the longer we will remain vulnerable. Our terrorist enemies will not wait while we experiment and our national security is at stake. We must protect our population. That is our responsibility. If the private sector does not step up to address and accept the challenge presented in this bill, then our government needs to have the authority to do the job itself directly.

One example of a capability that we clearly need and that Project Bioshield does not address is the ability to respond rapidly to a previously unknown or engineered pathogen. Terrorists may soon be able to genetically manipulate biological agents so they are resistant to our current stockpile of countermeasures and perhaps to those we develop in the future. That is why I, along with 35 of my Democratic colleagues, introduced H.R. 4258, the Rapid Cures Act. This legislation recognizes the fact that the growing power of biotechnology can render a pathogen like anthrax or smallpox immune to the vaccines and drugs we may develop through Project Bioshield. We need to develop the mechanism to go from bug to drug, that is from the identification of a pathogen to the development of a countermeasure to combat it in a matter of a few months or even weeks.

Today the average development period for a vaccine is 8 years. That is too long to address the threat that our terrorist enemies of the future may present us. Personally, I cannot think of another research goal that would bring more benefits to the security and the health of this Nation than shortening the period of drug and vaccine development. It is that kind of capability that we need legislation to bring about today.

Finally, it is incumbent on this Congress to exercise vigorous oversight in the implementation of this law and to ensure that the investment in resources which could be as much as $6 billion over 10 years produces the results that we intend. We have had biodefense failures before. The national smallpox vaccine program which was announced by the President with much fanfare at the end of 2002 has fallen far short of its goal of vaccinating 500,000 health care workers with, in fact, less than 10 percent of that number actually vaccinated today.

Forty percent of our States report that they are unable to vaccinate their populations within 10 days, that critical period, 10 days of an outbreak of smallpox. As soon as next month, we are likely to hear of the award of the first-ever Bioshield contract for 75 million doses of new anthrax vaccine. We need to be asking now before the ink dries on this multimillion-dollar contract, what is the plan? How does this vaccine fit into our biodefenses? Given the failure of our smallpox vaccine program, do we really expect our citizens to be any more receptive to the anthrax vaccine than they were to the smallpox vaccine? And if the old anthrax vaccine, as some have told us, is now safe and effective for our troops, why in fact do we need a new one?

And if as is the case and we already have a vaccine but we lack good treatments for an anthrax infection, perhaps we need to be investing in the treatment for those who may contract anthrax and need a drug to cure that dread condition. And if anthrax is not a contagious disease and we know it is not and if this vaccine will only work after three injections over 3 weeks, as I understand the proposed new anthrax vaccine requires, how will that protect us in the event of an actual anthrax attack?

So before the Secretary of Homeland Security and the Secretary of Health and Human Services decide to spend a billion dollars on a new vaccine, we in this Congress have a responsibility to get the answers to those questions.

For this Nation, Project Bioshield is an important first step, but much more work remains to be done, and we must take even stronger steps as soon as possible to protect us and to secure us in the days ahead.

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

Mr. BARTON of Texas. Mr. Speaker, I yield 3 minutes to the gentleman from Arizona (Mr. SHADEGG), the distinguished whip of the Committee on Energy and Commerce.

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

time. I rise in strong support of the Project Bioshield Act. Is the act perfect? Does it solve all problems in this area? No. But I do not think we will hear anyone take to the floor and say that this is not a bicameral, bipartisan proposal to address a serious threat to this Nation.

I want to thank the chairman of the Committee on Energy and Commerce and the previous chairman, the gentleman from Louisiana (Mr. TAUZIN), both of whom have worked very hard on this legislation, as well as the chairman of the Select Committee on Homeland Security in bringing this initiative forward and moving it as rapidly as possible through the United States Congress. I also want to thank President Bush for putting this initiative on our agenda.

Thirty years ago, perhaps 20 years ago, we had never even heard of biotechnology or genomics; but today, along with our country's unparalleled leadership in semiconductors and computing power, we are making breathtaking breakthroughs in the field of bioscience. And as my colleague from Texas just outlined, there is much more that can be done. This legislation goes at a serious vulnerability for our Nation.

As has been referred to in this debate, we are aware by the briefings we get and by the press we read that we face a threat from al Qaeda and others who would seek to use these agents against us, chemical, biological, radiological, and even nuclear, weapons. They would like to use dangerous agents like anthrax, botulinum toxin, the plague, ebola and other similar viruses, as have just been noted, even some we are not even aware of. And of course as was well explained by my colleague, the former chairman of the Committee on Energy and Commerce, the gentleman from Louisiana, in the absence of this legislation, it is very clear that there is no incentive for anyone, not the government, not the private sector, not anyone, to develop and do the research to develop the countermeasures we need for these serious threats to the American people.

This is critically important first-step legislation. It not only will encourage the research but it also encourages the development of those countermeasures and the stockpiling of them so that they are readily available. The American people expect that of us and both committees in both bodies have worked hard on this kind of legislation.

I want to point out that I chair the Subcommittee on Emergency Preparedness and Response of the Select Committee on Homeland Security as well as serving on the Committee on Energy and Commerce; and I chaired hearings on the House parallel to this legislation, H.R. 2122. In those hearings we discovered a fact that has not been mentioned in this debate, and that is that the mere development of these countermeasures for such a biological attack will deter the attack. Think of that point. The reality is if al Qaeda knows that we are unprepared for a chemical, a biological or a radiological attack, then they are incentivized to make that kind of attack. On the other hand if they know that we have invested the money and done the research and we have developed countermeasures so that a biological attack or an anthrax attack, an attack of ebola or of the plague is something we are prepared for, then they are discouraged to even make that kind of attack.

The American people expect us to do everything humanly possible to prepare for the event of an attack; but even more importantly they want us to deter any attacks. They want us to protect the American people from an attack. This legislation, Project Bioshield, by not only encouraging the research of these antitoxins but also encouraging their development and their stockpiling will indeed deter such attacks.

I strongly urge my colleagues to support this legislation.

Mr. TURNER of Texas. Mr. Speaker, I yield 5 minutes to the distinguished gentleman from New Jersey (Mr. ANDREWS), who has spent a great deal of time and energy working on this important issue.

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

Mr. ANDREWS. Mr. Speaker, I thank my friend from Texas for his leadership and hard work on this bill. I congratulate him, the gentleman from Ohio (Mr. BROWN), the gentleman from Michigan (Mr. DINGELL), the gentlewoman from New York (Mrs. MALONEY), the gentleman from Texas (Mr. BARTON), the gentleman from Louisiana (Mr. TAUZIN), the gentleman from California (Mr. COX), and all those responsible for the passage of this very important bill.

One of the most frustrating failures of local government is when there is a traffic fatality at an intersection and the residents of the community say, for years we have been warning that there was going to be a fatality at this intersection. How come you did not put a traffic light or a stop sign up before? Why did it take a fatality to get government to pay attention?

This is a massive and serious equivalent at the national level of whether we should prevent the traffic accident by putting up the signal ahead of time. Although this bill is not perfect, it recognizes an issue that is not much talked about today but is very much looming on the horizon as a potential catastrophe for the country. As the gentleman from Texas said very eloquently just a few minutes ago, perhaps the most ominous and destructive terrorist attack that could occur on this country would be a terrorist attack using a biological weapon. Unlike chemical weapons, unlike radiological weapons, even unlike nuclear weapons, the threat of a bioweapon is not localized because very often a bioweapon uses as its carrier a human being. So the spread of a bioweapon attack will not be limited to a discrete local area. It will likely be spread throughout the country and throughout the world. This makes it even more urgent that antidotes that could cure those exposed to the attack or prevent people from being sickened or killed by the attack, that these antidotes be developed as rapidly as possible.

I am particularly pleased that the committees involved worked with us to include in this bill language that will protect the interests of companies that begin the process of developing an antidote and then have their contract terminated for convenience because a better idea comes along from another vendor. It is a very important provision that will permit these investors in research to recover the funds that they put into the contract.

Let me express three concerns about the bill, and I hope that we return once this is made law to improve these areas. One is what the gentleman from Texas talks about, particularly with respect to mutant or new strains of bioweapons that would not be handled by the antidotes developed under this bill. We need a much more rapid and focused effort to deal with those mutant or new strains.

Second, I am very concerned that the liability provisions in this bill are not sufficiently protective of the companies that would step forward to address the need to create these Bioshield defenses. I am not at all convinced that the immunity is broad enough or dependable enough. Time will tell.

□ 1800

If the immunity is not broad or dependable enough, we are going to have to revisit that issue.

Finally, I am concerned, to the extent that funding under this bill is discretionary and not mandatory, the financial rewards that are necessary to induce a company to step forward and participate in this process may not be certain enough. An investor is not going to take a risk unless there is a guaranteed return. I think this bill takes a step in the right direction, but I am concerned it does not go far enough.

I wholeheartedly support this bill. I am honored to have been a part of writing and pursuing the bill. I hope that the products produced as a result of this bill are never used. That would be the real measure of success. But, God forbid, if the day comes when they need to be used, let us be prepared. Let us not look upon ourselves and say, why did we not take action in the peaceful days before the attack when we had a chance to do so?

This legislation is long overdue. I enthusiastically support it. I would ask colleagues on both the Republican and Democratic side to vote ''yes.''

Mr. BARTON of Texas. Mr. Speaker, I yield 3 minutes to the distinguished gentlewoman from Florida (Ms. GINNY BROWN-WAITE), a former president pro

tempore with the Florida Senate who chaired the Homeland Security Select Committee in the Florida Senate.

Ms. GINNY BROWN-WAITE of Florida. Mr. Speaker, I rise today in support of this legislation and certainly to congratulate both the former and current chairmen of the Committee on Energy and Commerce for their perseverance in bringing this bill to fruition today.

Since the attacks of 9–11, America has been under siege. We are fighting a war against terror and must not waver in our commitment to combating this evil. This war knows no set battleground, and the terrorists' arsenal of weapons is limitless. From using a cell phone as a bomb detonator to contemplating a crop-duster, as we found in Florida, as a vessel of pestilence, these thugs have proven both their resourcefulness and also their boldness and audacity.

For this reason, America must be prepared and must do everything in its power to protect its citizens. This legislation does exactly that. Among other things, the bill gives the Secretary of HHS the authority to conduct research and development for new vaccines that will offer protection from the possible chemical and biological agents that these arrogant fanatics conspire to exploit. Congress will provide the advance appropriation of $5.6 billion over the next 10 years to purchase these vital countermeasures.

S. 15 adds to America's security and offers us the piece of mind in knowing that if terror strikes America will be ready and we will be a whole lot safer. The tragedies of 9–11 taught us that we must do much more to protect our Nation and that the unrest around the world can have a disastrous impact on us here at home. Terrorism knows no boundaries, and neither should our efforts to prevent it.

This is a well-thought-out bill, and I encourage my colleagues on both sides of the aisle to support this proposal this evening.

Mr. TURNER of Texas. Mr. Speaker, I yield 6 minutes to the distinguished gentlewoman from Texas (Ms. JACKSON-LEE), who has worked very hard in the area of trying to improve our bioterror defenses.

(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 my friend and colleague from Texas for yielding me this time. I listened to him as he was outlining some of the positives and, of course, some of the challenges that we still have before us. We cannot thank him enough for the studious and deliberate approach that he has taken to protecting the homeland.

It is important to note as well, since there are two Texans on the floor, now three, that this is a bipartisan bill; and we thank the distinguished chairman and the number of other Members who have worked so hard on this legislation. So my remarks should not be taken out of context to the extent that I disregard the hard work and the very valuable aspects of this legislation.

Frankly, I think, in order to make it more understandable, it is simply the government doing what it should do. It is the big umbrella. It is the responsibility of this government to secure the homeland. And when the private sector has not yet reached the point when it can move with all due and deliberate speed and even faster, it is imperative that we, the government, move in to protect the American people.

But there lies, I believe, the core of my criticism or my critique, because I am concerned that the American people do not believe that they are more safe today than they were 4 years ago or more safe today in light of the horrific tragedy of 9–11. I think we should be very frank about questions being asked that if there was a tragedy, whether it would be by some form of nuclear reaction or activity or whether it would be bioterrorism or whether it be acts of terrorists, the question is who is in charge? All of these elements that we are now discussing, in this instance, bioterrorism, all need to relate to an orderly focus on securing the homeland; and I believe it is extremely important that we find ourselves organizing this whole effort of the war against terrorism in a methodical way.

We are very delighted that a number of us Democrats are putting forward a number of initiatives that deal step by step with securing the homeland in an orderly fashion. I believe the bioterrorism in the Project Bioshield Act of 2004 is a positive first step. It is important to note that even as recently as April we were faced with challenges dealing with the question of bioterrorism.

I am reminded of a couple of days after 9–11 when I gathered a number of our first responders from all over the county in a meeting held by my congressional district. In the midst of that meeting, just 3 days after 9–11, a number of my firefighters had to immediately leave in an emergency as some white powder was discovered at a major hospital in my community. We have not had a series of these lately, but they are occurring on a rapid basis or regularly, even though we do not see them in the news.

As recently as April 22 of this year in Tacoma, Washington, we had a bioterrorism scare. A white powder was found in two envelopes, and 94 people had been 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, Florida. 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, and we must do better in the area of biological weapons.

Might I say also that we are confronting and fighting the devastation of HIV/AIDS. We have found in this country that sometimes the infected person has used it in a criminal manner. Who is to say that it could not also be engaged in some act of bioterrorism?

So I do support the Project Bioshield Act of 2004. But, frankly, I believe that one of the things that we should get out of these legislative initiatives is to find an orderly way of putting all of these ways of protecting the homeland in a way that we know who is in charge, why they are in charge, and how they can intermesh with protecting the homeland. I will raise that question over and over again.

Might I also acknowledge that, as we put forward Project Bioshield that will take now some $5.6 billion, we should not forget, as our friends and colleagues on the Committee on Energy and Commerce have noted, the other preventable diseases or other contagious diseases and the other work of NIH so that we are assured that we are protecting the homeland in many ways. We must seek to balance the fear of the American people with the health needs of the American people. Again, we must have an orderly process of protection.

Let me make note of an amendment that I offered and added to this, because I am always concerned that protecting the homeland reaches the neighborhoods, reaches the families, the schools. In fact, I am a supporter of finding safe places in communities such as public buildings like schools and fire stations. But, Mr. Speaker, we added to this legislation that the Secretary of Health and Human Services reach out to Historically Black Colleges and Universities, those serving Black or African Americans, American Indians, Appalachian Americans, Alaska Natives, Asians, Native Hawaiians, other Pacific Islanders, Hispanics or Latinos, in order to reach out to provide resources for those institutions to be utilized in available research and development grants, contracts, cooperative agreements, and procurements under this particular legislation. If we secure the homeland, we must secure the rural homeland, the urban homeland, and all segments of our population. We must secure the neighborhoods.

So I support this legislation, but I also believe that we still have work undone to complete our task of assuring the American people that the homeland is securely secure.

Mr. Speaker, I rise today in support of S. 15, the ''Project Bioshield Act of 2004.'' I supported the predecessor of this bill, H.R. 2122 as it passed previously. This is 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. S. 15, will help to make America safer.

The purpose of the Project BioShield Act of 2004 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 and now of S. 15 are noble 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 prestamped 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 5 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 2001. As recently as April 22 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 disease 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 vile filled with anthrax, botulism, or small pox? A vile 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 Institute 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 counter measures, and empowers the government to purchase safe and effective vaccines. Finally, Project Bioshield authorizes the Food and Drug Administration to 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 the House version of this legislation, H.R. 2212 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. I am very pleased to see the retention of this provision as ''Section 6, Outreach'' in the bill before us today, and I wholeheartedly support its passage.

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. It 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 provisions of S. 15, 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.

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 Black or African Americans, American Indians, Appalachian Americans, Alaska Natives, Asians, Native Hawaiians, other Pacific Islanders, Hispanics or Latinos, or other underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under section 2 and 3 of this Act.

Mr. BARTON of Texas. Mr. Speaker, I yield such time as he may consume to the gentleman from California (Mr. COX), the distinguished chairman of the Select Committee on Homeland Security.

Mr. COX. Mr. Speaker, I thank the chairman for yielding me this time.

This has been an extraordinary collaborative effort. I want to congratulate the gentleman from Texas (Mr. TURNER), my ranking member, who is on the floor and who has been on his feet for much of this debate. I want to thank the gentleman from Texas (Mr. BARTON), the chairman of the Committee on Energy and Commerce; and the gentleman from Michigan (Mr. DINGELL), ranking Democrat on that committee.

In the same way that this was a collaboration between the Committee on Energy and Commerce and the Select Committee on Homeland Security in the Congress and the Committee on Government Reform in the House of Representatives, chaired by the gentleman from Virginia (Mr. TOM DAVIS), who will speak shortly; likewise, it was a collaborative effort in the Senate, including their Government Affairs Committee. It is a collaborative effort within the administration that we are setting up. The Department of Homeland Security and the Department of Health and Human Services will partner in this first responder effort of unprecedented magnitude.

And I should say, Mr. Speaker, that this is the largest first responder program ever enacted in American history. The purpose, of course, is to protect Americans, to protect Americans

in the event of an attack. That puts this squarely in the orbit of what we consider to be first response. But we need to make sure that our first responders have the tools that they need to arrest the spread of a biological attack and to protect Americans before it is too late. Every second, every moment really does count in the event of a terror attack, as the Senate Majority Leader Dr. FRIST has so ably pointed out in his book on this topic.

It was 18 months ago that President Bush called on Congress to enact a bill to speed the development of antidotes, vaccines, against biological warfare and against chemical weapons. We need to have drugs, vaccines, and antidotes to combat these weapons if they are used against us, as we now expect they might be.

We know, for example, that Mr. Zarqawi, when he was in Afghanistan, was working on biological and chemical weapons development. He is now attacking Americans and leading the terrorist attacks on Americans in Iraq. We know that Osama bin Laden at various times expressed interest in and may have acquired precursors of these same kinds of weapons.

We cannot take these kinds of threats lightly, and we are not. The bill that we are passing today reflects a model for future legislation because it is so collaborative. Homeland security requires us to knit together different responsibilities, different authorities, the responsibilities of different agencies of government, of law enforcement, different levels of government, Federal, State, and local, as never before.

□ 1815

That is going to happen under this bill as well.

In the first instance, it will be the responsibility of the Department of Homeland Security to assess the global threat, to tell us what are the most likely and most threatening agents that could be used against us. Then we will hand off to the Department of Health and Human Services, which will help, after the priorities are set for this research jointly with DHS, implement this program. The research priorities will be implemented based on the information that has been provided by the Department of Homeland Security.

By properly understanding the threats that confront us based on our country's best intelligence, we can allocate our resources and focus our efforts where they are most needed, on the biological, chemical and radiological agents for which the risks and potential consequences of attacks are greatest.

Another genius of this program is that it is not a government-run program. The government is putting significant resources at the ready to provide an incentive and a market to purchase any successful products that are developed as a result of our call to action, but we are unleashing the creative genius of the private sector.

Under the President's new national biodefense directive issued on April 28, 2004, all bioterrorism projects and programs will fall under a coordinated and focused strategic plan. This will help maximize these resources that we are putting to work here, and it will ensure a unified effort across all the Federal agencies.

Bioshield is an integral part of this strategic plan. It will draw upon the expertise and resources of the private sector, as almost no other government program that is part of the strategic plan, in order to produce more quickly those countermeasures necessary to make our Nation safer.

It is important to recognize the visionary leadership of the President in this regard. It is without exaggeration or embellishment that I can say that this President, President Bush, and his administration, and in particular Vice President CHENEY, have devoted more attention and more resources to the fight against bioterror than any administration in history.

Prior to 2001, our investments in research and development and other public health preparedness activities were minimal. They are now profound. The President and this Congress are allocating annually billions of dollars to this fight, and under Project Bioshield alone we will spend $5.6 billion over the next 10 years. The President is clearly leading the way.

Project Bioshield was not dreamed up here in the halls of Congress, but with big obstacles to addressing that need we have acted. So it is with both bipartisan pride, I think, and also with collaboration in mind between the executive branch and the legislative branch that we can say that we have enacted into law, we very shortly will be able to do this, next week we will be able to say this, the most significant first responder program in our Nation's history.

The Select Committee looks forward to working with President Bush, Secretary Ridge, Secretary Thompson, and the other committees in the House and Senate to make sure we leverage the resources provided by Project Bioshield to build a sustained countermeasure capacity to protect our Nation and our citizens from the ever-evolving threat of weapons of mass destruction.

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

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

Mr. BARTON of Texas. Mr. Speaker, I yield 3 minutes to the great volunteer, the gentleman from Tennessee (Mr. WAMP).

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

Mr. WAMP. Mr. Speaker, I thank the chairman for yielding me time, and I thank all of those involved for bringing this legislation to the floor in the form of a conference report.

I have to come to the floor, though, saying it is frustrating for me as a Member of the Subcommittee on Homeland Security of the Committee on Appropriations that it took a year to get the bill from the House floor back to the House floor in the form of a conference agreement, since time is very much of the essence.

Also I want to tell a story. About a year ago, when I brought ''Buy America'' provisions to the floor trying to insert them in this legislation, received assurances from Secretary Thompson and the gentleman from Louisiana (Chairman TAUZIN) that every effort would be made to buy America where possible in all of the implementation of not just Bioshield, but all of the different treatments and antidotes that fall under Bioshield or not. Then later in the fall I had an Assistant Secretary of Health and Human Services in my office, and I spoke about the treatment for a radiation event and how that was going to be procured. It is called Prussian Blue, and I was told that that was still in the process of being competed.

Little did anyone know in the room under this interagency working group that a month earlier, an exclusive contract had already been committed to procure Prussian Blue and fill up our stockpiles to a German company.

I have got to tell you, in Tennessee that does not go over very well, when there are U.S. manufacturers prepared to do this and time is of the essence. The FDA, HHS, DHS, we need to coordinate better. I am very concerned about ceding the responsibility to interagency working groups and not having an accountable person.

This is billions of dollars. It is, frankly, late. We have been appropriating the money. It cannot go forward, and time is of the essence. We are going to the conventions, and the threats are real, and we do not have the stockpiles full.

I commend the authorizers; but, darn, everybody involved needs to move quicker because we do not have the stockpiles full of these treatments, and many of them are available and on the shelf by U.S. manufacturers. I was in Tampa, Florida, a week ago Monday; and I saw those treatments, and they are not on the streets of New York or Boston or across the country, or in Athens, Greece; and U.S. manufacturers can export them.

We have the best technology in the world. We do not have to lean on the French or the Germans to fill up our stockpiles for treatments in the event of more terrorism. It is not just Bioshield, it is Chemshield and Nukeshield. It is all of the major threats.

So, yes, vote for this. It is long overdue. Move it quickly to the President's desk. And then get the administration to coordinate better together.

I called Assistant Secretary Simonson today. I said, I need to talk to you. I am still waiting for the phone call. The legislation is on the floor. I am on the subcommittee. I am waiting

for the phone to ring. We need action. The American people demand no less. This is the most target-rich environment in the next 4 months that we have ever faced in the history of this country. Let us get it on.

Mr. BARTON of Texas. Mr. Speaker, I believe I have 4 minutes remaining. I yield that time to the gentleman from Virginia (Mr. TOM DAVIS), the chairman of the Committee on Government Reform, and ask that he control the balance of the Committee on Energy and Commerce time.

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

There was no objection.

The SPEAKER pro tempore. The gentleman from Virginia (Mr. TOM DAVIS) has 11½ minutes remaining, the gentlewoman from Washington (Ms. DUNN) has 7½ minutes remaining, and the gentleman from Texas (Mr. TURNER) has 17 minutes remaining.

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

Mr. Speaker, I rise in support of S. 15, the Project Bioshield Act of 2004. The 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, and it serves as the cornerstone of the administration's strategy to prepare our Nation against the possibility of bioterrorism.

A few minutes ago, we were privileged to hear from the chairman of the Select Committee on Homeland Security, the gentleman from California (Mr. COX); and I will include for the RECORD an editorial written by the gentleman from California that appeared in the Washington Times and published July 12, 2004.

[From the Washington Times, July 12, 2004]

INTERCEPTING BIOTERRORISM

(By Christopher Cox)

America is at a very dangerous crossroads. Not only al Qaeda but also terrorist groups such as Jemaah Islamiah are working on acquiring or developing new terrorism capabilities, including bioweapons. Will we be prepared?

Evidence in an Egyptian terrorism trial two years ago indicated Osama bin Laden may already have access to dangerous biological agents. Meanwhile, the risk of proliferation to terrorists continues growing, with at least eight nations running bioweapons programs, including genetic engineering of pathogens and developmental programs for new production and delivery methods.

Winning the war on terrorism will require our nation not only to defeat attacks with explosives and military-style weapons, but also to be prepared to overcome potential assaults with weaponized anthrax, ricin, smallpox, plague, tularemia, botulism toxin and viral hemmorhagic fevers (such as the Ebola virus).

Just how vulnerable are we to such attacks today? The United States now can fully meet only a handful of the 57 ''top echelon'' bioterror threats. That's not an acceptable level of preparedness for the greatest power on Earth. We can launch a Tomahawk cruise missile and thread it down the smokestack of a munitions factory from 1,000 miles away—once thought to be a million-to-one shot at best—yet we aren't prepared to deal with the frightening prospect of an anthrax or sarin gas attack against our civilian population.

It's vital that we put our best minds to work round-the-clock on new ways to prepare for a biological or chemical attack here at home. But according to a study published in the May 2004 issue of the journal Clinical Infectious Diseases, only six of 506 drugs currently in development are antibioltics—even though drug-resistant bacteria are a growing threat.

This is only because the proper incentives and funding aren't there, not because the scientific challenge is too great. Indeed, the germs that cause anthrax and plague are not nearly as difficult to analyze as a virus such as HIV. Vaccines and treatments for biological weapons such as these can be developed.

Certainly, America has made some progress in preparing for possible germ warfare on our own soil, but we're not ready to combat a major bioterror assault at this time and our enemies know it. Worse, they're looking for ways to exploit our weaknesses.

We are now on the threshold of changing that. Project Bioshield, expected to receive final legislative approval tomorrow and then be sent to the president for his signature, will shortly unleash the greatest force in world history: American ingenuity.

By guaranteeing a market for successful vaccines and antidotes, Project BioShield will provide incentives for private-sector scientists, physicians, and researchers to develop lifesaving treatments. Congress has made available $5.6 billion over 10 years to purchase and stockpile a national supply of drugs and vaccines for use if a biological weapon is set loose by terrorists on an unsuspecting American public.

BioShield will speed research and development on new drugs and antidotes at the National Institutes of Health and in our national laboratories. And it will allow, if germ warfare breaks out, distribution of developmental lifesaving drugs on a fast-track approval basis to save innocent lives, so long as the benefits outweigh potential risks.

President Bush asked Congress to move immediately on his plans for Project BioShields in the 2003 State of the Union address. The House quickly responded. Last July, the Homeland Security Committee, which I chair, worked closely with other House committees to turn the president's vision into legislation. Unfortunately, after our bipartisan bill passed the House by a wide margin, it languished in the Senate nearly a year before being rescued by Majority Leader Bill Frist, Tennessee Republican.

But now that both chambers have worked out their differences, America finally is ready to prepare in earnest for a potential terrorist attack that won't yield to bullets or bombs. Now, we'll be using the very best weapon in our defensive arsenal—our brainpower.

By approving Project BioShield, Congress is saying: ''Let the race to find lifesaving countermeasures begin.'' America's leaders have heeded the advice of experts who have estimated that without BioShield it could take 10 years, and cost up to $800 million or more, to bring a single new vaccine from development through clinical trials to market.

The war won't wait that long, of course: Terrorists could strike us at any minute. And once a bioweapon is released, every second will count.

In many ways, the war on terrorism is like a chess game. We must anticipate our enemy's moves, and mount an impenetrable defense. In their pursuit of bioweapons, the terrorists have revealed some of their game plan. Project BioShield will ensure we stay one move ahead of them.

Someday soon, when it comes to bioterrorism, Americans will be able to say: Checkmate.

Mr. Speaker, the bipartisan bill we are considering today is similar to H.R. 2122, which was passed by the House on July 16, 2003. S. 15 is a good bill that serves a compelling national interest.

Over the past few decades, we have seen rapid progress in the development of treatments for many serious, naturally occurring diseases. Pharmaceutical and biotech companies are highly capable of producing diagnostics and therapeutics when consumer demand exists. However, there has been little progress in treatments for deadly diseases like smallpox, anthrax, ebola, and plague that affect today few Americans. There is little manufacturer interest in developing treatments for these diseases since there is no significant market, other than the government.

Drug companies have little incentive for the substantial investment required to bring treatments to these deadly diseases to market. Moreover, the potential liability for an adverse reaction by a patient far outweighs any potential financial benefit in some of these cases.

Should the United States be attacked with these deadly pathogens, however, the need for vaccines, tests and treatments would be great and immediate. S. 15 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 procure necessary drugs and vaccines. These tools are instrumental to the success of the Bioshield program.

S. 15 gives the Secretary of Health and Human Services streamlined authorities to promote the research and development of drugs and other products needed to protect Americans in the event of a public health emergency affecting national security. The Secretary will be armed with flexible acquisition tools for research and development projects and would also have expedited authorities to award research grants and to hire technical experts and consultants. It would not be burdened with the existing procurement processes that could take months.

The bill authorizes the procurement of biomedical countermeasures for the Nation's stockpile, using a special reserve fund. The Secretary of Health and Human Services and the Secretary of the Department of Homeland Security would be required to work together to recommend the countermeasures that are needed for the stockpile. Acquisition of countermeasures

using the special reserve fund could only be made with the approval of the President of the United States.

This bill would permit the use of simplified acquisition procedures only when the Secretary of Health and Human Services determines that the mission of the Bioshield program would be seriously impaired without the use of such special procedures.

Finally, 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.

I especially want to thank my ranking member, the gentleman from California (Mr. WAXMAN), and his staff for working with us on this important legislation. I urge my colleagues to support it.

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

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

Mr. Speaker, first of all, let me thank all of the Members on both sides who have worked to bring us to this point in the passage of the legislation. I must say I have a great deal of agreement and sympathy for the remarks made by the gentleman from Tennessee (Mr. WAMP) a few moments ago, because the urgency of this matter certainly dictates that we move much more quickly than we have been able to move on this legislation.

The President proposed this project in his State of the Union address in 2003. The House passed the bill in July of 2003, the Senate passed the bill 2 months ago, and we are just now bringing this conference report to the floor. So there is no question that in these times of terrorist threat the stakes are very high. The risks that we face are very great, and failure to close the security gaps in the area of bioterrorism or in a host of other areas where we have serious threats is not an option for this country.

We also know that in Project Bioshield and its implementation, we face great risk; and it is my hope that the three committees who worked so well together in crafting this bill will also each in their own way vigorously exercise the oversight that is necessary to ensure that Project Bioshield is successful.

When we know that we may be hearing of a decision in the near future by Secretary Ridge and Secretary Thompson to begin to acquire a new anthrax vaccine, I think it is incumbent upon each of us in our committees, in our oversight responsibilities to ask the tough questions about whether or not we are moving in the right direction; for that first contract could be in the neighborhood of a $1 billion Federal contract.

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Failure in making that decision in the appropriate and proper way to ensure that it is successful is an essential oversight responsibility that each of us have.

So it is my hope that the good work and the good cooperation that occurred between the Committee on Commerce and the Committee on Homeland Security and the Committee on Government Reform will be carried forward as we provide the necessary oversight to ensure the success of this important piece of legislation.

Again, Mr. Speaker, this is an important bill, and I urge every Member of the House to vote aye.

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

Mr. TOM DAVIS of Virginia. Mr. Speaker, I thank the gentleman from Texas and others who have been involved in getting this legislation before us.

Let me just say I share the frustration that many Members of this body feel at the time it has taken to get this measure to this floor, in a conference report form, and then send it on to the President's desk for signature. We passed this legislation with bipartisan support a year ago, and it languished over in the other body until it was rescued by Senator FRIST.

The time is late, but the time is now. I urge my colleagues to adopt and support this legislation.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. FOLEY). The gentleman will refrain from improper references to the Senate.

Ms. MCCARTHY of Missouri. Mr. Speaker, I rise today in strong support of S. 15, legislation to protect our Nation from future biological and chemical terrorist attacks. The House passed H.R. 2122, similar legislation, last year by an overwhelming margin of 421 to 2. As a member of both the Homeland Security Committee and the Energy and Commerce Committee, I have been proud of the bipartisan work that has gone into this legislation which will add to our effort to protect the Nation from biochemical attack.

Mr. Speaker, although five people were killed in the anthrax attacks of 2001, the death toll was kept relatively low because effective medical countermeasures were available. After the outbreak, strong antibiotics were immediately prescribed to deal with the crisis. In 2002, Congress further enhanced our ability to respond by enacting the Public Health Security and Bioterrorism Preparedness Response Act (PL 107–188), which authorized funds to increase the Nation's stockpile of medicines and vaccines—particularly for smallpox—and provided aid to state and local governments and health facilities to help them prepare for possible attacks.

Unfortunately, effective vaccines or treatments do not exist for many biological threats deemed by the U.S. government to be most dangerous, including botulinum toxin, plague, and viral hemorrhagic fevers such as the Ebola virus.

The development of effective countermeasures has been hindered by the lack of a significant commercial market. Currently, companies have little financial incentive to invest the funds needed to research, develop or produce vaccines or other countermeasures because there is little or no market.

Despite these challenges, in my district, the Stowers Institute and the Kansas City Life Sciences Institute are both trailblazers in the field of research. The Stowers Institute's new research facility in Kansas City incorporates the best that present technology can offer. In my community, the best and the brightest are working to broaden the base of knowledge in hopes of discovering cures and vaccines for today's diseases and future threats.

Today's legislation will encourage and support these efforts by providing additional funding for research and development of new countermeasures and vaccines. The bill will also provide for an expedited approval process to ensure that the fruits of our research can protect the public as soon as possible.

Mr. Speaker, all over this Nation, our first responders serve on the front lines when disasters occur and continue to be the eyes and ears of our Nation. They are a significant part of the effort to protect our homeland and guard against the invisible threat of a chemical and biological attack. Today's legislation is an important step in that process and I support it.

Mrs. CHRISTENSEN. Mr. Speaker, I want to begin by first thanking our Chairman, Mr. COX from California and Ranking member, from Texas, Mr. TURNER, for their leadership on the select committee and for this opportunity to offer my support for S. 15, Project Bioshield, and to draw attention to the critical issues of homeland security. And I also want to take the opportunity to again thank the minority leader, the gentlewoman from California, Ms. PELOSI, for the honor of serving on this important committee.

In this post 9/11 world, it has been said that bioterrorism may represent our greatest threat. Project Bioshield is important because it will help to ensure that we can spur the development of vaccines and other countermeasures that will be needed to counteract or treat an infectious, radiological or chemical attack. But it can only go so far, because we have no idea what the agent might be or how a known one might be altered. Not only is it possible that hundreds of millions of dollars could be spent to develop a medicine or vaccine and it be totally useless, but the very best of medicines, vaccines or other agents will be worthless to you, me and the people we serve without an intact public health system.

A 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.

Particular when we think about the health care disparities in minorities and in our rural areas that I have come to this floor to bring to the attention of our colleagues on many occasions did not just come about by chance. They exist because of the poor public health systems in these communities. The last 3 years of cuts to health budgets have been devastating. The lack of emphasis on minority and rural health and the even bigger cuts that the President is insisting on this year, so that those who already have the best of health care can get a tax cut and other perks, have sent States into a free fall of budget deficits, and local public health safety nets, like those in Los Angeles, and Detroit, to near collapse.

Mr. Speaker, we cannot just throw money at the problem of terrorism, as this administration has a tendency to do, without adequate planning. In this case, we must first and foremost insist that our public health system is intact and that it can ensure that people are healthy and our bodies are in a better condition to fight off infections and the other biological assaults that may come from a bioterrorism attack.

The anthrax scare taught us that lesson. The breakdowns were fundamental ones. Project Bioshield, the administration's centerpiece for public health preparedness and biological countermeasures, would not have saved the two postal workers just down the street from here who died because the public health system failed to respond. It happened here, but it could happen anywhere.

Confronting the danger posed by these advanced biological weapons is a challenge we must begin today. Thus, we must ensure that biotechnology is fundamentally ''dual-use,'' that is it can be used both for peaceful and destructive purposes. Because of its potential for misuse, balanced biodefense policies must be developed and adopted to ensure our safety and security. These should include reasonable steps to prevent the spread of dangerous pathogens and the technology to enhance them. Preparedness of our health infrastructure must also be enhanced and maintained. Finally, protections, including drugs and vaccines, to counter potential weaponized pathogens need to be available during a crisis.

It is in the area of protections for tomorrow's biological weapons threat that we are particularly weak. The primary proposal advanced to boost our protection capacities, Project Bioshield, will not address this threat because it is targeted to addressing classical agents. In addition, it relies on the current base of science and technology in drug and vaccine development, which takes an average of 14 years to develop and introduce a new medicine. As a consequence, our protective biodefenses are essentially static and unmoving in the face of a threat that is highly variable and unpredictable. The recent experience with SARS and the danger of a new flu pandemic demonstrate the dangers of a lack of effective countermeasures and a nimble ability to develop and field them.

Recently, Ranking member TURNER and I introduced H.R. 4258 The RAPID Cures Act. This bill seeks to commission the development of a strategy to achieve a dramatic reduction in the timeframe required today for the delivery of drugs and vaccines to counter pathogen threats for which we have no existing countermeasures. The achievement of reductions and the institution of a national rapid response ''Bug-to-Drug'' capability will be a significant boost to our biodefenses against the emerging and future threat of bioengineered biological weapons, as well as naturally occurring novel threats, such as SARS or pandemic flu.

In addition to improving antimicrobial and vaccine development capabilities, an area currently neglected by the private sector, the technical spin-offs of such an endeavor are also likely to benefit the domestic pharmaceutical and biotechnology industries more generally. Broad public health benefits will also be forthcoming. Extensive literature exists to show that the long timeframes (14 years) and high failure rates typical of drug development processes today are a significant cause of high R&D costs, and thus high prescription drug costs.

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 again want to take this opportunity to thank and commend Chairman COX and Ranking Member TURNER for their leadership in moving this bill through Congress.

Mr. SHAYS. Mr. Speaker, I rise today in strong support of this bipartisan legislation, the Project BioShield Act. The anthrax attacks in the fall of 2001 brought the once distant threat of biological weapons into these very buildings. It is not a question of if, but when terrorists will strike again. Project BioShield marks an important step toward preparedness to deter or defeat the next terrorist attack using deadly pathogens.

I am particularly pleased that the legislation clarified some ambiguity that I had raised during the bill's initial consideration regarding safeguards for the application of medical products during emergencies for military personnel. Initially, the legislation appeared to allow the President or Secretary of HHS to remove safeguards for military personnel that were available to the general population. This legislation addressed those concerns.

This legislation will provide $5.6 billion over 10 years to develop and procure effective countermeasures against biological, chemical and radiological weapons. To counter the grave and changing threat, the bill gives the Secretary of HHS new, flexible authorities to conduct and support research and development for new vaccines and drugs. Most importantly, Project BioShield removes barriers and provides important incentives to the private sector to spur the advance of biotechnologies. If used aggressively and wisely, the authorities in this legislation will result in significantly strengthened defenses against bioterrorism.

Two words of caution: First, implementation of BioShield must be linked to the threat. Vaccines and antidotes against exotic agents may present easier, near-term opportunities for quick successes. But the Center for Disease Control and the intelligence community maintain a threat list of pathogens, and that list should focus and guide BioShield investments. Botulinum toxin ranks right behind anthrax as a known biological threat. But testimony before the Select Committee on Homeland Security concluded development of botulinum antitoxin stocks could take up to 10 years. If Project BioShield is going to provide anything more than a symbolic barrier against biological attack, that estimate has to change.

And, the success of BioShield also depends upon broader bio-preparedness priorities. The Government Reform National Security Subcommittee, which I chair, has held several hearings on bioterrorism preparedness. We learned that massive caches of stockpiled vaccines, antibiotics and drugs will protect no one if they cannot be administered quickly and safely. Public health capacity is a critical enabler to BioShield success. Surveillance systems, diagnostic tools and trained medical personnel are prerequisites to any effective defense against natural and man-made biological outbreaks.

Terrorism thrives on uncertainty. We cannot expect to vaccinate everyone against every possible pathogen. Instead, we need a well-equipped, well-trained public health system that can rapidly respond to health emergencies.

Mr. Speaker, Project Bioshield is a much needed initiative, and I would urge all of my colleagues to support for this legislation.

Mr. DINGELL. Mr. Speaker, I rise in support of S. 15, the ''Project Bioshield Act of 2004.'' This legislation reflects bipartisan bicameral negotiations that have made minor modifications to the language of H.R. 2122 which was passed by the House on July 16, 2003. I commend the hard work and dedication of all who participated in this endeavor.

In this era of heightened threats to our national security and the increased risk of harm to Americans, Project Bioshield is an unfortunate but necessary measure. 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. The bill before us reflects further refinements and does not contain major policy changes from last year's bill.

Among the significant measures in this bill are provisions aimed at enhancing 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 Government Accountability Office (GAO) will provide reports on key economic and scientific elements of this program after it has been in effect for several years.

Finally, I am pleased to note that this bill maintains the approach of H.R. 2122 that funding be authorized, rather than a permanent, unlimited 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 support it.

Mr. WAXMAN. Mr. Speaker, we have before us today S. 15, the Project BioShield Act. This bill is substantially the same as H.R. 2122, which passed the House on July 16, of last year by a vote of 421 to 2. This bill is in essence the conference report on the bill, and includes some minor improvements made by the Senate. I urge members to support this measure as well.

Given the serious threat of bioterrorism, the development of effective countermeasures to biological agents is vital to our national security. The goal of Project BioShield is to encourage the development of these products. 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.

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 contractor's books and records. The bill also permits the use of certain streamlined procurement procedures, but only if the Secretary of Health and Human Services determines that there is a pressing need to do so.

The Senate bill appropriately strengthens some of these provisions and also allows for recovery by the government in the event of grossly negligent or reckless conduct on the part a contractor.

In emergency situations we should not impede the development of necessary products. However, any exceptions from 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. FDA must be vigilant in protecting the public against unnecessary risks from these products.

In part because of these concerns, the bill requires that health care providers and patients be informed that the products have not been approved and of their risks. The bill also requires 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 HHS 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 record keeping 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 represents a bipartisan consensus of the House, the Senate, and the White House. It deserves our support.

Mr. LANGEVIN. Mr. Speaker, I rise today in support of the Project Bioshield Act of 2004. Bioterrorism is a major threat to our national security, and I believe it is our job as members of Congress to instill confidence in the American people that a coordinated, concerted effort is being made to combat this threat. While Project Bioshield is not the only answer, it is certainly an important step towards that goal, and I hope Congress will continue to provide the funding and oversight the project needs to be effective.

This bill, much like H.R. 2212 passed by the House a year ago, authorizes the Project Bioshield initiative and will set in motion crucial efforts to develop new countermeasures to treat diseases and conditions caused by bioterror attacks and chemical, radiological and nuclear agents. Under this program, the Federal government will be able to enhance the Strategic National Stockpile, promote research and development of countermeasures, and, in an emergency, move forward with public distribution of certain drugs and treatments that may not yet have FDA approval. It is never pleasant to imagine a scenario where this kind of preparation and flexibility will be necessary, but the threat is indeed there. Project Bioshield will help lay the groundwork to respond to that threat quickly and effectively.

However, I must also mention my ongoing concern that until the Department of Homeland Security's Information Analysis and Infrastructure Protection Directorate is fully staffed and meeting expectations, the rest of DHS is at a tremendous disadvantage in determining how to allocate resources and 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 working closely with their peers at agencies like CDC and NIH to identify the most pressing dangers and develop a plan to combat them.

So, 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.

Ms. ESHOO. Mr. Speaker, I'm pleased to support the Project Bioshield Act which encourages the development of new countermeasures to deal with diseases and conditions caused by bioterrorism attacks. It authorizes $5.6 billion over 10 years for purchasing countermeasures, such as vaccines and treatments, to bioterrorist attacks. The bill also allows the government, in the event of a national emergency involving a bioterrorism or similar attack, to distribute to the public certain drugs and treatments that have not yet been approved by the Federal Drug Administration (FDA).

The Project Bioshield Act is an important part of our mission to secure and protect our homeland and hometowns. The threat of chemical, biological and radiological attacks is too great and this bill provides necessary regulatory flexibility to the Department of Homeland Security and the Department of Health and Human Services so they can speed and promote research and development of needed countermeasures.

The September 11th tragedies and subsequent anthrax attacks made the Nation aware that the public health system is ill-prepared to mange a large scale emergency. Since then, our public health system has continued to respond to high profile threats like severe acute respiratory syndromes (SARS) and West Nile Virus which illustrate how quickly infections can spread among populations and across the globe.

Over the last 3 years, our eyes have been opened to the threats we face on our own soil. We've discovered serious vulnerabilities and I'm proud of what we've done in this bill to address them. I urge the entire House to vote for this important legislation.

Mr. SENSENBRENNER. Mr. Speaker, I rise in support of S. 15, the "Project BioShield Act of 2004." This important legislation will help us to be better prepared against bioterrorism and other forms of terrorism. I just want to briefly note the jurisdictional interest of the Committee on the Judiciary in the Federal Tort Claims Act provision contained in the new § 319F–1(d)(2) which is contained in 2(a) of the bill. I support the inclusion of this provision. However, I want to note that by allowing this provision to be included in the bill, the Committee on the Judiciary does not waive its jurisdiction over the provision. With that, I urge my colleagues to support the bill.

Mr. TOM DAVIS of Virginia Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. All time having been yielded back, pursuant to the order of the House of Tuesday, July 13, 2004, the Senate bill is considered read for amendment, and the previous question is ordered.

The question is on third reading of the Senate bill.

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

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

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

Mr. TOM DAVIS of Virginia. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The vote was taken by electronic device, and there were—yeas 414, nays 2, not voting 17, as follows:

[Roll No. 376]

YEAS—414

Abercrombie
Ackerman
Aderholt
Akin
Alexander
Allen
Andrews
Baca
Bachus
Baird
Baker
Baldwin
Ballenger
Barrett (SC)
Bartlett (MD)
Barton (TX)
Bass
Beauprez
Becerra
Bell
Bereuter
Berkley
Berman
Berry
Biggert
Bilirakis
Bishop (GA)
Bishop (NY)
Bishop (UT)
Blackburn
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonner
Bono
Boozman
Boswell
Boucher
Boyd
Bradley (NH)
Brady (PA)
Brady (TX)
Brown (OH)
Brown (SC)
Brown, Corrine
Brown-Waite, Ginny
Burgess
Burns
Burr
Burton (IN)
Buyer
Calvert
Camp
Cannon
Cantor
Capito
Capps
Capuano
Cardoza
Carson (OK)
Carter
Case
Castle
Chabot
Chandler
Chocola
Clay
Clyburn
Coble
Cole
Cooper
Costello
Cox
Cramer
Crane
Crenshaw
Crowley
Cubin
Culberson
Cummings
Cunningham
Davis (AL)
Davis (CA)
Davis (FL)
Davis (IL)
Davis (TN)
Davis, Jo Ann
Davis, Tom
Deal (GA)
DeFazio
DeGette
Delahunt
DeLauro
DeLay
DeMint
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Doggett
Doolittle
Doyle
Dreier
Duncan
Dunn
Edwards
Ehlers
Emanuel
Emerson
Engel
English
Eshoo
Etheridge
Evans
Everett
Farr
Fattah
Feeney
Ferguson
Filner
Foley
Forbes
Fossella
Franks (AZ)
Frelinghuysen
Frost
Gallegly
Garrett (NJ)
Gerlach
Gibbons
Gilchrest
Gillmor
Gingrey
Gonzalez
Goode
Goodlatte
Gordon
Goss
Granger
Graves
Green (TX)

Green (WI)
Greenwood
Grijalva
Gutierrez
Gutknecht
Hall
Harman
Harris
Hart
Hastings (FL)
Hastings (WA)
Hayes
Hayworth
Hefley
Hensarling
Herger
Herseth
Hill
Hinchey
Hinojosa
Hobson
Hoekstra
Holden
Holt
Honda
Hooley (OR)
Hostettler
Hoyer
Hulshof
Hunter
Hyde
Inslee
Israel
Issa
Istook
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Jenkins
John
Johnson (CT)
Johnson (IL)
Johnson, E. B.
Johnson, Sam
Jones (NC)
Jones (OH)
Kanjorski
Kaptur
Keller
Kelly
Kennedy (MN)
Kennedy (RI)
Kildee
Kilpatrick
King (IA)
King (NY)
Kingston
Kirk
Kline
Knollenberg
Kolbe
Kucinich
LaHood
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Leach
Lee
Levin
Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
LoBiondo
Lofgren
Lowey
Lucas (KY)
Lucas (OK)
Lynch
Maloney
Manzullo
Markey
Marshall
Matheson
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCotter
McCrery
McDermott
McGovern
McHugh
McInnis
McIntyre
McKeon
McNulty
Meehan
Meek (FL)
Meeks (NY)
Menendez
Mica
Michaud
Millender-McDonald
Miller (FL)
Miller (MI)
Miller (NC)
Miller, Gary
Miller, George
Mollohan
Moore
Moran (KS)
Moran (VA)
Murphy
Murtha
Musgrave
Myrick
Nadler
Napolitano
Neal (MA)
Nethercutt
Neugebauer
Ney
Northup
Norwood
Nunes
Nussle
Oberstar
Obey
Olver
Ortiz
Osborne
Ose
Otter
Owens
Oxley
Pallone
Pascrell
Pastor
Payne
Pearce
Pelosi
Pence
Peterson (MN)
Peterson (PA)
Petri
Pickering
Pitts
Platts
Pombo
Pomeroy
Porter
Portman
Price (NC)
Pryce (OH)
Putnam
Quinn
Radanovich
Rahall
Ramstad
Regula
Rehberg
Renzi
Reyes
Reynolds
Rodriguez
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Ross
Rothman
Roybal-Allard
Royce
Ruppersberger
Rush
Ryan (OH)
Ryan (WI)
Ryun (KS)
Sabo
Sánchez, Linda T.
Sanchez, Loretta
Sanders
Sandlin
Saxton
Schakowsky
Schiff
Schrock
Scott (GA)
Scott (VA)
Sensenbrenner
Serrano
Sessions
Shadegg
Shaw
Shays
Sherman
Sherwood
Shimkus
Shuster
Simmons
Simpson
Skelton
Slaughter
Smith (MI)
Smith (NJ)
Smith (TX)
Smith (WA)
Snyder
Solis
Souder
Spratt
Stark
Stearns
Stenholm
Strickland
Stupak
Sullivan
Sweeney
Tancredo
Tanner
Tauscher
Tauzin
Taylor (MS)
Taylor (NC)
Terry
Thomas
Thompson (CA)
Thompson (MS)
Thornberry
Tiahrt
Tiberi
Tierney
Toomey
Towns
Turner (OH)
Turner (TX)
Udall (CO)
Udall (NM)
Upton
Van Hollen
Velázquez
Visclosky
Vitter
Walden (OR)
Walsh
Wamp
Waters
Watson
Watt
Waxman
Weiner
Weldon (FL)
Weldon (PA)
Weller
Wexler
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Woolsey
Wu
Wynn
Young (AK)
Young (FL)

NAYS—2

Flake
Paul

NOT VOTING—17

Cardin
Carson (IN)
Collins
Conyers
Deutsch
Dingell
Dooley (CA)
Ford
Frank (MA)
Gephardt
Hoeffel
Houghton
Isakson
Kind
Kleczka
Majette
Rangel

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. FOLEY) (during the vote). Members are advised 2 minutes remain in this vote.

□ 1900

Mr. FLAKE changed his vote from ''yea'' to ''nay.''

Mr. WAXMAN changed his vote from ''nay'' to ''yea.''

So the Senate bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

PERMISSION FOR MEMBER TO REVISE AND EXTEND REMARKS ON H. RES. 713, DEPLORING MISUSE OF THE INTERNATIONAL COURT OF JUSTICE

Mr. OBEY. Mr. Speaker, today the House will vote on a resolution condemning the International Court of Justice for rendering an advisory opinion on the legal consequences of the construction of the Israeli wall and condemning the U.N. General Assembly for requesting such an opinion. This legislation was only introduced last night and strikes me as the type of knee-jerk posturing that does more harm than good.

I oppose the bill for a number of reasons, and I ask unanimous consent that my remarks appear during the discussion of H. Res. 713, which will occur later this evening.

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

There was no objection.

REMOVAL OF NAME OF MEMBER AS COSPONSOR OF H.R. 107

Mr. MCGOVERN. Mr. Speaker, I ask unanimous consent to have my name removed as a cosponsor of H.R. 107.

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

There was no objection.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on additional motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote is objected to under clause 6 of rule XX.

Record votes on postponed questions will be taken tomorrow.

□ 1900

VIETNAM HUMAN RIGHTS ACT OF 2004

Mr. SMITH of New Jersey. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1587) to promote freedom and democracy in Vietnam, as amended.

The Clerk read as follows:

H.R. 1587

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Vietnam Human Rights Act of 2004''.

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

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
TITLE I—CONDITIONS ON INCREASED NONHUMANITARIAN ASSISTANCE TO THE GOVERNMENT OF VIETNAM
Sec. 101. Bilateral nonhumanitarian assistance.
TITLE II—ASSISTANCE TO SUPPORT HUMAN RIGHTS AND DEMOCRACY IN VIETNAM
Sec. 201. Assistance.
TITLE III—UNITED STATES PUBLIC DIPLOMACY
Sec. 301. Radio Free Asia transmissions to Vietnam.
Sec. 302. United states educational and cultural exchange programs with Vietnam.
TITLE IV—ANNUAL REPORT ON PROGRESS TOWARD FREEDOM AND DEMOCRACY IN VIETNAM
Sec. 401. Annual report.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The Socialist Republic of Vietnam is a one-party State, ruled and controlled by the Communist Party of Vietnam (CPV), which continues to deny the right of citizens to change their government. Although in recent years the National Assembly of Vietnam has played an increasingly active role as a forum for highlighting local concerns, corruption, and inefficiency, the National Assembly remains subject to CPV direction. The CPV maintains control over the selection of candidates in national and local elections.

(2) The Government of Vietnam permits no public challenge to the legitimacy of the one-party State. It prohibits independent political, labor, and social organizations, and it continues to detain and imprison persons for the peaceful expression of dissenting religious and political views, including Pham Hong Son, Tran Dung Tien, Father Nguyen Van Ly, Dr. Nguyen Dan Que, Nguyen Vu Binh, Pham Que Duong, and Pastor Nguyen Hong Quang, among others.

(3) The Government of Vietnam continues to commit serious human rights abuses. In January 2004, the Department of State reported to Congress that during the previous year the Government of Vietnam had made ''no progress'' toward releasing political and religious activists, ending official restrictions on religious activity, or respecting the rights of indigenous minorities in the Central and Northern Highlands of Vietnam.

(4)(A) The Government of Vietnam limits freedom of religion and restricts the operation of religious organizations other than those approved by the State. While officially sanctioned religious organizations are able to operate with varying degrees of autonomy, some of those organizations continue to face restrictions on selecting, training, and ordaining sufficient numbers of clergy and in conducting educational and charitable activities. The Government has previously confiscated numerous churches, temples, and other properties belonging to religious organizations, most of which have never been returned.