The SPEAKER pro tempore (Mr. FOEY), 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), 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:

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 and, if applicable, 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 in section 301(h) 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. 313(h)))) that the Secretary determines to be a priority (consistent with sections 322(2) and 394(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 and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A).

(B) Interagency cooperation.—

(1) In general.—In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency and other collaborative undertakings with other agencies of the United States Government.

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

(3) 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 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 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.

(4) 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 controls with respect to such countermeasure.

(5) Expedited procurement authorit,

(6) 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, the Secretary may, if so authorized in the appropriation Act, limit the application of section 414 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(b)) to such purchase and instead make such purchase on other than competitive procedures as the Secretary determines necessary to meet a national security need.

(B) Limitation.—The authority provided for under subparagraph (A) shall apply only to procurements of the BioShield Program under the Project BioShield Act of 2004.

(7) Authority to limit competition.—In conducting a procurement under this paragraph, the authority provided for under subparagraph (A) shall apply only to procurements of the BioShield Program under the Project BioShield Act of 2004.

(8) Authority to modify contracts.—The authority provided for under paragraph (7) shall apply only to procurements of the BioShield Program under the Project BioShield Act of 2004.

(9) Authority to waive or modify requirements.—The authority provided for under paragraph (8) shall apply only to procurements of the BioShield Program under the Project BioShield Act of 2004.

(10) Authorization.—The authority provided for under paragraph (9) shall apply only to procurements of the BioShield Program under the Project BioShield Act of 2004.

(11) Limitation.—No provision of law and regulations referred to in such subsection, 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 paragraph (A):—

(i) Section 302(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations;

(ii) Section 302A of such Act (41 U.S.C. 252aA) and its implementing regulations;

(iii) Section 303(b) of such Act (41 U.S.C. 252b) and its implementing regulations;

(iv) Section 303(c) of such Act (41 U.S.C. 252c) and its implementing regulations;

(v) Section 303(d) of such Act (41 U.S.C. 252d) and its implementing regulations;

(vi) Section 303(e) of such Act (41 U.S.C. 252e) and its implementing regulations;

(vii) Section 303(f) of such Act (41 U.S.C. 252f) and its implementing regulations;

(viii) Section 303(g) of such Act (41 U.S.C. 252g) and its implementing regulations;

(ix) Section 303(h) of such Act (41 U.S.C. 252h) and its implementing regulations;

(x) Section 303(i) of such Act (41 U.S.C. 252i) and its implementing regulations;

(xi) Section 303(j) of such Act (41 U.S.C. 252j) and its implementing regulations;

(xii) Section 303(k) of such Act (41 U.S.C. 252k) and its implementing regulations;

(xiii) Section 303(l) of such Act (41 U.S.C. 252l) and its implementing regulations;

(xiv) Section 303(m) of such Act (41 U.S.C. 252m) and its implementing regulations;

(xv) Section 303(n) of such Act (41 U.S.C. 252n) and its implementing regulations;

(xvi) Section 303(o) of such Act (41 U.S.C. 252o) and its implementing regulations;

(xvii) Section 303(p) of such Act (41 U.S.C. 252p) and its implementing regulations;

(xviii) Section 303(q) of such Act (41 U.S.C. 252q) and its implementing regulations;

(xix) Section 303(r) of such Act (41 U.S.C. 252r) and its implementing regulations;

(xx) Section 303(s) of such Act (41 U.S.C. 252s) and its implementing regulations;

(xxi) Section 303(t) of such Act (41 U.S.C. 252t) and its implementing regulations;

(xxii) Section 303(u) of such Act (41 U.S.C. 252u) and its implementing regulations;

(xxiii) Section 303(v) of such Act (41 U.S.C. 252v) and its implementing regulations;

(xxiv) Section 303(w) of such Act (41 U.S.C. 252w) and its implementing regulations;

(xxv) Section 303(x) of such Act (41 U.S.C. 252x) and its implementing regulations;

(xxvi) Section 303(y) of such Act (41 U.S.C. 252y) and its implementing regulations;

(xxvii) Section 303(z) of such Act (41 U.S.C. 252z) and its implementing regulations;

(xxviii) Section 303(aa) of such Act (41 U.S.C. 252aa) and its implementing regulations;

(xxix) Section 303(bb) of such Act (41 U.S.C. 252ab) and its implementing regulations;

(x) Section 303(bb) of such Act (41 U.S.C. 252ab) and its implementing regulations.

(12) Authority to use emergency funding.—The authority provided for under paragraph (7) shall apply only to procurements of the BioShield Program under the Project BioShield Act of 2004.
sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered, as such regulations apply to procurement by which an agency has authority. Use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source 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 in subsection (1), the amount specified in subsections (c), (d), and (f) of section 30 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to be $15,000, if this section and subsections (c), (d), and (f) of section 30 of such Act are amended by this paragraph and the amendments made by this Act.

"(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 FROM WBEs.—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 (3), section 3533 of title 41, United States Code, and section 3534 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 subsection (B) of chapter 31 of title 31, United States Code.

"(B) OVERRIDE OF STAY OF CONTRACT AWARD OR PERFORMANCE COMMITTED TO AGENCY DISCRETION.—Notwithstanding section 1401 of title 28, United States Code, and section 3533 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 3533(c)(2) of title 31, United States Code, to award a contract for a procurement described in subsection (1) of this section.

"(ii) An authorization under section 3533(d)(1)(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, without regard to the 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 35 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, to not 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 an 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 3101(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 2109(b)(3) of such title)."
(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 of 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 would qualify for approval or licensing within eight years after the date of a determination under paragraph (5); or

(8) for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.

(2) DETERMINATION OF MATERIAL THREAT.—

(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 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)(i); and

(ii) determine, on the basis of such assessment, whether the agents identified under subparagraph (A)(i) 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 of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

(E) ASSESSMENT OF NATIONAL SECURITY 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).

(3) MEDICAL COUNTERTREASURE PROCUREMENT, 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 final 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.

(2) Reserve fund under paragraph (10) is available under subparagraph (B); and

(3) the Secretary shall jointly submit to the section, the Homeland Security Secretary and the Secretary shall be determined by the Secretary to be 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.

(3) PROCUREMENT.

(A) IN GENERAL.—In making a determination under paragraph (1), the Homeland Security Secretary shall—

(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 of course of treatment regardless of dosage form; and

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

(4) PROCUREMENT OF SECURITY COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose shall include the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (3) 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.

(B) REQUIREMENTS.

(1) In making a determination under paragraph (1), the Homeland Security Secretary shall—

(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 of course of treatment regardless of dosage form;

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

(2) PROCUREMENT.

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

(B) INTERAGENCY AGREEMENT; COSTS.—

(I) In general.—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 necessary to carry out the provisions of this paragraph; and

(ii) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(D) 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 product that has been licensed, cleared, or approved for such product.

(ii) CONTRACT TERMS.

(3) PROCUREMENT.

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

(i) a contract for the procurement of any product shall provide that the vendor will provide specifications for the countermeasure or to provide any information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(4) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall be determined by the Secretary to be 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.

(5) PROCUREMENT.

(A) IN GENERAL.—In making a determination under paragraph (1), the Homeland Security Secretary shall—

(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 of course of treatment regardless of dosage form;

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

(6) PROCUREMENT OF SECURITY COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose shall include the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (3) 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.

(B) REQUIREMENTS.

(1) In making a determination under paragraph (1), the Homeland Security Secretary shall—

(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 of course of treatment regardless of dosage form;

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

(7) PROCUREMENT.

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

(B) INTERAGENCY AGREEMENT; COSTS.—

(I) In general.—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—

(1) 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 necessary to carry out the provisions of this paragraph; and

(ii) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(D) 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 product that has been licensed, cleared, or approved for such product.

(ii) CONTRACT TERMS.

(3) PROCUREMENT.

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

(i) a contract for the procurement of any product shall provide that the vendor will provide specifications for the countermeasure or to provide any information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(4) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall be determined by the Secretary to be 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.

(5) PROCUREMENT.

(A) IN GENERAL.—In making a determination under paragraph (1), the Homeland Security Secretary shall—

(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 of course of treatment regardless of dosage form;

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

(6) PROCUREMENT OF SECURITY COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose shall include the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (3) 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.

(B) REQUIREMENTS.

(1) In making a determination under paragraph (1), the Homeland Security Secretary shall—

(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 of course of treatment regardless of dosage form;

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

(7) PROCUREMENT.

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

(B) INTERAGENCY AGREEMENT; COSTS.—

(I) In general.—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—

(1) 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 necessary to carry out the provisions of this paragraph; and

(ii) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(D) 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 product that has been licensed, cleared, or approved for such product.

(ii) CONTRACT TERMS.
(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 Army-Kickback Act of 1988 (41 U.S.C. 57(a) and (b)).


(dd) Section 3131 of title 40, 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 subsection, and shall provide for the documentation of the justification for the use of the authority provided under this paragraph with respect to the procurements involved.

(IV) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this subsection, the Secretary may limit competition through the use of 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 provided in subsection (a) is in addition to any other authority to use procedures other than competitive procedures.

(III) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—In conducting a procurement under this subsection, the term ‘special reserve fund’ has the meaning given such term in section 412 of title 31, United States Code, as the (a) Special Reserve Fund for the Biodefense Countermeasures Program, (b) Special Reserve Fund for the BioShield Program, and (c) Special Reserve Fund for the Project BioShield Act of 2004.

(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 submitted by the Secretary under section 303 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has been given notice that the Secretary may exclude such source.

(VIII) 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 an agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(V) 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 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:

(1) in the House of Representatives: the Committee on Energy and Commerce, the Committee on Science, 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.

(11) 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.

(12) APPLICABILITY.—This subsection applies to any award of a contract or subcontract under subsection (a) and to any award of a contract or subcontract under subsection (b) (1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); and

(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).

(12) AUTHORIZATION OF APPROPRIATIONS.—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).


(1) in section 502(3) (U.S. 312)),—

(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 amounts in the special reserve fund 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 $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 section.

(d) RELATED AUTHORIZATIONS OF APPROPRIATIONS.—

(1) MAJOR 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, and for other expenses necessary for the Federal 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 other applicable qualifications for the performance of intelligence activities promulgated by the Director of Central Intelligence pursuant to section 104 of the National Security Act.

(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 of Health and Human Services Protection is entitled under such 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 (b)(5) the transfer shall be 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 include the funds appropriated under the heading “Biodefense Countermeasures” in the Department of Homeland Security Appropriations Act, 2004 (Public law 108–90).


SEC. 4. 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb–3) is amended to read as follows:—

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

“(1) In general.—

“(A) Emergency uses.—Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and subsections (b), (c), and (d) of section 351 of such Act and sections 352, 353, 354, and 355 of such Act and section 903 of the United States Code and any other provision of law referred to in such paragraph (referred to in this section as an ‘emergency use’).

“(B) Authorizations.—An authorization under paragraph (1) may authorize an emergency use of a product that—

“(I) 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

“(II) is approved, licensed, or cleared under such a provision, but which is use 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’).

“(C) Relation to other uses.—An emergency use authorized under paragraph (1) for a product in addition to any other use that is authorized for the product under a provision of law referred to in such paragraph.

“(D) Definitions.—For purposes of this section:

“(I) The term ‘emergency use’ has the meaning given such term in section 351 of the Public Health Service Act.

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

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

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

“(F) The term ‘approved product’ has the meaning indicated for such term in paragraph (2)(B).

“(G) The term ‘unapproved use of an approved product’ has the meaning indicated for such term in paragraph (2)(B).

“(H) The term ‘emergency use of an approved product’ has the meaning indicated for such term in paragraph (2)(B).

“(I) 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;

“(C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has the 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) Authorizing use.—An authorization under this subsection with respect to an unapproved product ceases to be effective as a result of a termination under paragraph (A) of this subsection, the Secretary shall notify 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 an unapproved product is 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 the approval or expiration of any information under subsection (e)(2)(B)(ii), as the case may be, that was provided with respect to the emergency use involved.

“(4) Public Notice.—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 Biomedical Advanced Research and Development Authority (to the extent feasible and appropriate given the circumstances of the emergency involved), the Secretary concludes—

“(i) that the product may be effective in diagnosing, treating, or preventing—

“(1) 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;

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

“(D) 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—

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

“(ii) that the Secretary made the determination 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

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

“(F) 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 such authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

“(B) 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; and

“(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.

“(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 Biomedical Advanced Research and Development Authority (to the extent feasible and appropriate given the circumstances of the emergency involved), the Secretary concludes—

“(i) that the product may be effective in diagnosing, treating, or preventing—

“(1) 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;

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

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

“(4) Publication.—With respect to the emergency use of an unapproved product, the Secretary shall promptly publish in the Federal Register each declaration, determination, advance notice of termination, and renewal under this subsection.

“(C) The term ‘biological product’ has the meaning given such term in section 351 of the Public Health Service Act.

“(C) The term ‘emergency use’ has the meaning indicated for such term in paragraph (1).
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 of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

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

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

"(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary 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 carry out such 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 product that are subject to 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 under this section (the "manufacturer"), the Secretary may, to the extent practicable given the circumstances of the emergency, establish appropriate conditions on an authorization under subsection (b) or a revocation under subsection (g).

"(B) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—Providing the termination of the declaration under subsection (b) or a revocation under subsection (g), an authorization shall continue to be effective for providers of 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.

"(3) REVOCATION OF AUTHORIZATION.—

"(A) In general.—Except as provided in paragraph (2), an authorization under this section shall be effective until the earlier of the expiration of the declaration under subsection (b) or a revocation under subsection (g).

"(B) 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.

"(C) 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 in support of an application under section 563(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 21, United States Code, or section 552(b)(4) of title 5 of such Code.

"(4) 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 apply 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.

"(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, section 351, 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 any 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 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 is carrying 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 this 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.

"(m) REPEAL OF TERMINATION PROVISION.—

Subsection (d) of section 510 of the National Defense Authorization Act for Fiscal Year 2001 (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 paragraph (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):

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

"(2) Subsection (b)(2) (relating to procedures other than full and open competition).

"(2) WITH RESPECT TO SEC. 319F–2 OF THE PUBLIC HEALTH SERVICE ACT (AS ADDED BY SECTION 3 OF THIS ACT):

"(1) Subsection (c)(3)(C)(i) (relating to simplification of acquisition process).

"(2) Subsection (c)(3)(C)(iv) (relating to procedures other than full and open competition).

"(3) 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 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 identifiable, the options that were considered and rejected with respect to the use of such authorities;
   (ii) the reasons underlying the decision to use such authorities, including, as applicable, 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 procurement).
   (B) Subsection (d) (relating to authority for penalties).
   (C) Subsection (e) (relating to streamlined personnel authority).

With respect to subparagraph (A), 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 to:
   (A)(i) review the Secretary of Health and Human Services’ utilization of the authorities granted under this Act with respect to new acquisition procedures, procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel processes, and other appropriate matters;
   (A)(ii) review the Secretary of Health and Human Services’ utilization of the authorities granted under this Act with respect to the purchase of security countermeasures under the special reserve fund; and
   (B)(i) to review and assess the adequacy of the information available to the Secretary with respect to such authorities, where required by this Act; and
   (ii) to make recommendations to improve the use of such authorities.

(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 on the activities of the agencies with respect to the following:
   (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

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

(3) by inserting after paragraph (5), by striking "and" and placing a comma at the end; 

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

"(7) sanctions and penalties that arise from noncompliance with the following requirements delegated under the authority of section 26(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note)—

(A) section 164.520 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) in paragraph (5), by striking the period at the end of such paragraph (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 provided for 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 7½ minutes. 

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

Mr. BARTON of Texas. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to 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.

The SPEAKER pro tempore. The gentleman from Texas (Mr. BARTON) is recognized.

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, the Project BioShield Act of 2004. 

The bill largely reflects H.R. 2122, the bill that passed the House last year. Revisions in the Senate were made in our conference with the House and its 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 DAVIES), 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.

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.

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 this bill 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 of Emergency Medical Conditions and Other Conditions Act, to provide adequate alternative therapy in the event of a declared emergency period or pursuant to a state emergency preparedness plan by waiver of 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.
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 procedure 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 worry anymore than even 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, in his first 100 days, said, ‘I will fund and lead a medical moonshot to reach far beyond what seems possible today.’ Apparent it was a short trip.

According to a White House budget memo recently leaked to the press, President Bush has no intention of increasing NIH funding. The legislation before us today contains a provision that will increase and then proposed a 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 an annual, double-digit increase in NIH budget, a cut in funding is a major step backward that would undermine promising medical research.

I urge my colleagues to support this legislation. In creating Project BioShield, it gives America a promising weapon that here and now can prevent 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-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.

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 on agents like anthrax or perhaps even such horrible agents as botulism toxin or ebola or other similar agents that we were so unprepared for. In this country the 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.

But the battle and losing the war.

As President, I will fund and lead a medical moonshot to reach far beyond what seems possible today.’ Apparent it was a short trip.
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 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. 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 protection 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.

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 must be made only when necessary and should be subject to review. This proposal preserves that important standard.

The provisions of Bioshield authorize 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 particular, because 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 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 conditions on a case-by-case basis 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 balance of the time allocated to the minority on the Committee on Energy and Commerce.

The SPEAKER pro tempore. The gentleman from Texas (Mr. TURNER) as the ranking minority member of the Select Committee on Homeland Security, the gentleman from Texas (Mr. TURNER) and represents a bipartisan consensus of the House and the Senate and the White House. It deserves our support.

Mr. TURNER of Texas. Mr. Speaker, 20 minutes, and the gentleman from Texas (Mr. TURNER), for the minority, has 27 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.

The 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 and experimental products for inclusion in the Strategic National Stockpile. I cannot say how important that is.

We find heroes and patriotism 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. Thanks to the efforts 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 our biological 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 vaccine, 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 gentleman from Washington (Ms. Dunn) on the Select Committee on Homeland Security, and 7½ minutes to the gentleman from Virginia (Mr. 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 more aggressive about going after the terrorist threats – all threats – they are that urgent. Our alliance, our partnership against Al Qaeda, against their tiny weapon of mass destruction are our most promising weapons and our most powerful weapons. Libya, Iraq, and now Afghanistan are tangible examples of this.

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.

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

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 bioweapons. We know that Al Qaeda, 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 prevailed 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 to victory, 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 going to be measured in terms of how far this Nation 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 defenses.

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, supported 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.

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 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, and if yes, are we more tolerant of a vaccine that is not 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 the most dangerous of diseases, then 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.
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 body.

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 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 like to use these dangerous agents, anthrax, botulinum, 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 discussed a fact that has been mentioned in this debate, and that is that the more 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 on the 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 want 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 gentleman 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 American policy is that there is no 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 traffic fatality at this intersection. How come you did not put up 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, 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 antitoxins that could cure those exposed to the attack or prevent people from being sickened or killed by the attack, that these antitoxins 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. The first is what Mr. Texas talks about, particularly with respect to mutant or new strains of bioweapons that would not be handled by the antitoxins 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 satisfied that the immunity is broad enough or dependable enough. Time will tell.

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

I yield 5 minutes to the distinguished gentlewoman from Florida (Ms. Ginny Brown-Waite), a former president pro
have worked so hard on this legislation and the number of other Members who have not had a series of these lately, 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 and other 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 antiterrorism measures.

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 gentleman 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 legisla-

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 need for a 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 both 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 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 manner. 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, as I said earlier, 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 false 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. Fortunately, 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.

I think we must ask 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 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.

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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.
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 bio-terrorism 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 weapons. Our critical infrastructure is not secure. Our communities are not protected from biochemical weapons.

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 the lethal bacteria is the most serious concern. As we continue our work of protecting our homelands, biological weapons pose a particularly dangerous threat. Biological weapons are 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 first death 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 agencies have reorganized the handling of the anthrax incidents. The letters were found in Fort Myers, FL. Six people were taken to a hospital for possible contamination, including one who suffered burning eyes and nose.

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

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

Positive strides have been made in the various biochemical fields. We have improved our ability to secure our borders and prevent deadly materials from entering our country. However, it is unrealistic to expect no biological weapons to enter the United States. Last year alone 30 million tons of cocaine was smuggled into the United States. If we can't stop 30 million tons of cocaine from crossing our borders, how can we expect to stop a vile filled with anthrax, botulism, or smallpox? 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 good start 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 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 unidentified, 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 the House passage 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, to the extent that 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 terrorism attack. On recent visits to 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.

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.

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 American, American Indian, Alaska Natives, American Samoa, Guam, Puerto Rico, Northern Mariana Islands, 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. THOMAS). I would like to speak shortly. It was a collaborative effort in the Senate, including their Government Affairs 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 presenting.

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.
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. I believe, as President Bush has said, that 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.

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 threats. 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 program that is part of the strategic plan. It will draw upon the expertise and resources of the private sector, as almost no other government program will. The President has created that 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 and this Congress for this effort and this program.

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.

One of the great successes of this last Congress was the Buy America provisions to the floor trying to insert them in this legislation, received assurances from Secretary Thompson and the gentleman from Louisiana (Chairman Crowley) 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 it 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 a company in Athens, Georgia; and U.S. manufacturers prepared to do this and time is of the essence.

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 these 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.

FDA, HHS, DHS, we need to coordinate better, and we are behind the 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.

Also, I called 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 we have 11½ 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 announced this proposal during his 2003 State of the Union address, and it was his vision to increase our preparedness 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—even though drug-resistant bacteria are a growing threat—would be ready to prepare in earnest for a potential bioterrorist attack 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 in the Senate, 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 these lifesaving medicines. Congress has already 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 development of new treatments on an expedited approval basis to save innocent lives, so long as the benefits outweigh potential risks.

President Bush asked Congress to move immediately on Project Bio-Shields 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 died 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 $600 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 are already in this country, and once a bioweapon is released, every second counts.

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 authored none of their game plan. Project BioShield will ensure we stay one move ahead of them.

In 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, man-made pathogens, such as Jemaah Islamiah are working on acquiring bioweapons that are deadly, man-made pathogens.

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, pharmaceuticals 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 tools to expedite 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.

S. 15 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 so-called 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.

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 both 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, yet 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 and institutions have difficulty investing 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 broadening the horizons 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.

Ms. CHRISTENSEN of Utah. Mr. Chairman, Ms. CHRISTENSEN of Ohio and others, 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 the attention of this critical issues of homeland security. And I also want to take the opportunity to again thank the minority leader, the gentlemanwoman from California, Ms. GIROUD, 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.

Particularly 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 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.

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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 that it can effectively 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 is 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 it can be used both for peaceful and destructive purposes. Because of its potential for military biodefense purposes, it 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 this case, we must first and foremost have a tendency to do, without adequate planning.

The bill before us reflects further refinements of Project Bioshield Act of 2004. 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 provide important incentives to the private sector to spur the advance of biotechnologies.

The basic purpose of Project Bioshield is to support research that will lead to the development and availability of the Strategic National Stockpile of “countermeasures” to combat public health emergencies that threaten national security.

Among the significant measures in this bill are provisions aimed at enhancing accountabilities, and does not contain major policy changes.

Finally, I am pleased to note that this bill maintains the approach of Project BioShield Act of 2004, Congress will receive comprehensive information, not less than annually, on the project. Bioshield. Congress will receive comprehensive information, not less than annually, on the project.
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 exceptions 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 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 fully tested, impose an unprecedented responsibility on government. FDA must be vigilant in protecting the public against unnecessary risks from these 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 toward 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 Bio-

shield 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 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 Bio-

shield 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 Home-

land Security’s Information Analysis and Infra-

structure Protection Directorate is fully staffed and matching expectations, the rest of DHS is at a tremendous disadvantage in determining how to allocate resources and focus energies. The proper implementation of Project Bio-

shield requires a reliable and comprehensive threat assessment from the Information Analy-

sis team, a team that should include bioterror experts and experts from other 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. ESCH. Mr. Speaker, I am 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 treat-

ments, to bioterrorist attacks. The bill also al-

 lows the government, in the event of a na-

tional 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. The threat of chemical, biological and radiological attacks is too great and this bill provides necessary reg-

ulatory flexibility to the Department of Home-

land 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 subse-

quent anthrax attacks caused the Nation aware that the public health system is ill-prepared to manage a large scale emergency. Since then, our public health system has continued to re-

spond 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 ad-

dress 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. The question is on the passage of the Senate bill. The question is on the passage of the Senate bill.

The vote was taken by electronic de-

vice, and there were—yeas 414, nays 2, not voting 17, as follows:

(Roll No. 376)

YEA—414

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 toward 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 Bio-

shield initiative and will set in motion crucial efforts to develop new countermeasures to
The Speaker pro tempore (Mr. Foley) (during the vote). Members are advised 2 minutes remain in this vote.

Mr. FLAKE changed his vote from "yea" to "nay." Mr. WAXMAN changed his vote from "nay" to "yea." So the previous bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was on the table.

PERMISSION FOR MEMBER TO REVERSE 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.

 opposes 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 result of the vote was announced as above recorded.

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.

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.

VIETNAMESE 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. Res. 713
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION I. 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:

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 rights of citizens to change their government.

(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 their peaceful expression of religious and political views, including Pham Hong Son, Tran Dung Tien, Father Nguyen Van Ly, Dr. Nguyen Dan Que, Nguyen Vu Binh, Pham Quoc Duc, and Pastor Nguyen Hong Quang, among others.


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.

(4A) 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 number 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.