The SPEAKER pro tempore (Mr. FOLEY). Is there objection to the request of the gentleman from Illinois? There was no objection.

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

Mr. LINCOLN DIAZ-BALART of Florida (during consideration of H.R. 4759), Committee on Rules, submitted a privileged report (Rept. No. 108-108) 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 rolcall votes. If I had been here, I would have voted in the following manner: rolcall vote No. 363, I would have voted “aye”; rolcall vote No. 364, I would have voted “aye”; rolcall vote No. 366, I would have voted “aye”; rolcall vote No. 367, I would have voted “no”; rolcall vote No. 368, I would have voted “no”; rolcall 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, biological, 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. 1. AUTHORITY FOR USE OF CERTAIN PROCEDURES REGARDING QUALIFIED COUNTERMEASURE RESEARCH AND DEVELOPMENT ACTIVITIES.

(a) In General.—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, in the case of the National Institutes of Health, as part of the program under section 446, if the activities concern qualified countermeasures.

(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, in the case 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 343(a)(2)(B) 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. 311(h))) that the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to—

(A) treat, identify, prevent harm from any biological, chemical, radiological, or nuclear agent that causes adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A);

(B) treat, identify, 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);

(C) LIMITATION.—An agreement or understanding entered into under this paragraph shall not authorize another agency to exercise the authorities provided by this section.

(E) AVAILABILITY OF FACILITIES TO THE SECRETARY.—In any agreement or cooperative agreement entered into under the authority provided in this section with respect to a biocollection laboratory or other related or 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 eligible for Federal assistance, and the Secretary may provide that the facility is to be used consistently with sections 302(2) and 304(a) of the Homeland Security Act of 2002.

(F) 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 applicable requirements.

(2) EXPEDITED PROCUREMENT AUTHORITY.—

(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 authorize another agency to exercise the authority provided in this subsection, in accordance with section 319F(f), the United States Code (relating to the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252(a))) (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(B) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subparagraph (A) and the limitation imposed by section 319F(f) of the United States Code (relating to the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252(a))) (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements), the Secretary may authorize another agency to exercise the authorities provided in this section with respect to such procurement.

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

(D) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this paragraph, the Secretary may authorize another agency to exercise the authorities provided for under subparagraph (A) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the procurement is necessary to meet a national security emergency affecting national security.

(E) PROGRAMS NOT TO BE SUBJECT TO CERTAIN REGULATIONS.—

(A) IN GENERAL.—In conducting a procurement under this section, the Secretary may authorize another agency to exercise the authorities provided in this subsection, in accordance with section 319F(f), the United States Code (relating to the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252(a))) (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(B) RELATION TO OTHER AUTHORITIES.—The authority under subparagraph (A) is in addition to any other authority to use procedures other than competitive procedures in the case of a procurement described in paragraph (1) of this subsection, the phrase ‘available from only one responsible source’ in such section 303(c)(1) shall be deemed to mean ‘available from only one responsible source or only from a limited number of responsible sources’.

(C) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—The Secretary shall authorize the use of the authority under this section in accordance with government-wide regulations implementing such section 303(c)(1) (including requirements that offers be solicited from as many potential
sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered, as such regulations apply to procurements by which an agency has authorized use procedures other than competitive procedures when the property or services needed by the agency are available from only one respon

sible source and from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

"(3) INCREASED MICROPURCHASE THRESHOLD.—

"(A) IN GENERAL.—For a procurement described in paragraph (1), the amount specified in subsections (c), (d), and (f) of section 302 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to be $15,000, provided that the limitations in such section with respect to such procurement.

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

"(C) EXCEPTION TO PREFERENCE FOR PURCHASE OF COMMERCIAL GOODS.—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 (c) of section 3533 of such title 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 of such title of such title of United States Code.

"(B) OVERSIGHT OF STAY OF CONTRACT AWARD OR PERFORMANCE COMMITTED TO AGENCY DECISION.—Notwithstanding section 1491 of title 28, United States Code, and section 3536 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 of such title of such title of United States Code.

"(C) AUTHORITY TO EXPEDITE PEER REVIEW.—

"(1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIAID, determines 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 paragraph (1) of this subsection;

"(ii) An authorization under section 3533(d)(3)(C) of such title to perform a contract for a procurement described in paragraph (1) of this subsection;

"(iii) Authority to expedite peer review procedures.

"(2) LIMITATIONS.—

"(A) IN GENERAL.—For the purpose of performing or supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, except that the Secretary shall not be required to impose any requirement with respect to peer review not otherwise required under any other law or regulation.

"(B) DETERMINATION OF EMPLOYEE STATUS—

"(i) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(ii) DETERMINATION OF EMPLOYEE STATUS—

"(A) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(B) DETERMINATION OF EMPLOYEE STATUS—

"(i) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(ii) DETERMINATION OF EMPLOYEE STATUS—

"(A) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(B) DETERMINATION OF EMPLOYEE STATUS—

"(i) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(ii) DETERMINATION OF EMPLOYEE STATUS—

"(A) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(B) DETERMINATION OF EMPLOYEE STATUS—

"(i) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(ii) DETERMINATION OF EMPLOYEE STATUS—

"(A) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(B) DETERMINATION OF EMPLOYEE STATUS—

"(i) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.

"(ii) DETERMINATION OF EMPLOYEE STATUS—

"(A) IN GENERAL.—Any individual who is a relative (as defined in section 2302(b) of such title) of the President, or a relative (as defined in section 2302(b) of such title) of a head of an agency, including an employee of such agency, is an employee of such agency.
(1) in subparagraph (B), by inserting “(or, in the case of the Institute, 75 percent)” after “40 percent”;

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

(3) in paragraph (4), by inserting “or the Center” after “Institute of Allergy and Infectious Diseases” after “Director”;

(4) in subsection (a), by striking “authorized to be appropriated” and inserting the following: “appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005. . .”;

(c) ADDITIONAL AUTHORIZATIONS OF APPROPRIATIONS.—Section 2106 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 247d) is amended—

(1) in subsection (a), by striking “authorized to be appropriated” and all that follows and inserting the following: “authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.”;

(2) in subsection (b), by striking “authorized to be appropriated” and all that follows and inserting the following: “authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.”

(d) TECHNICAL AMENDMENTS.—Section 319F of the Public Health Service Act (42 U.S.C. 247d-4) is amended—

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

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

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

SEC. 3. BIOMEDICAL COUNTERMEASURES Procurement.

(a) ADDITIONAL AUTHORITY Regarding Strategic National Stockpile.—

(1) TRANSFER OF PROGRAM.—Section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 239r) is transferred from such Act to the Public Health Service Act, in effect as section 319F-2, and is inserted after section 319F-1 of the Public Health Service Act (as added by section 2 of this Act).

(2) ADDITIONAL AUTHORITY.—Section 319F-2 of the Public Health Service Act, as added by paragraph (1), is amended to read as follows:

SEC. 319F-2. STRATEGIC NATIONAL STOCKPILE.

(1) STRATEGIC NATIONAL STOCKPILE.—

(i) The Secretary, in coordination with the Secretary of Homeland Security (referred to in this section as the ‘Home- land Security Secretary’), shall maintain a stockpile of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security for the United States by ensuring the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

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

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

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

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

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

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

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

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

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

(iii) SMALLPOX VACCINE DEVELOPMENT.—

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

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

(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, which 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 HOMEPORT 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).

(2) BONDS FOR DEVELOPMENT OF COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently unlicensed as a 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) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

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

(ii) necessary measures of minimum safety and effectiveness of the treatment of the course of treatment of any other security countermeasure for which such countermeasure is being procured, including the subsequence procurement under this subsection of any other security countermeasure for which such countermeasure has determined under subparagraph (A) is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph shall not preclude the selection of a security countermeasure under subparagraph (G) if the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusions in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund under paragraph (10) (referred to in this subsection individually as a procurement under this subsection).

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

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

(ii) the feasibility of production and delivery in the coming years of sufficient quantities of the product.

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

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

(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) PROCUREMENT.—The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating the terms (including, among other things, the price), and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(II) CONTRACT TERMS.—A contract for procurements under this subsection shall be paid for such products. The Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be paid from funds in the special reserve fund under paragraph (10) by the vendor under the contract. Nothing in this subclause may be construed as authorizing rights of vendors under provisions of law or regulations (including, for example, provisions (including, for example, provisions) that such provisions may apply to such procurements in the absence of subsection (I);
“(aa) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

“(bb) Subsections (a) and (b) of section 7 of the Army-Kickback Act of 1988 (41 U.S.C. 37(a) and (b)).

“(cc) Section 306(c) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(c)(1)) (relating to the examination of contractor records).

“(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 controls for procurements made under this subsection, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to property or services provided under this subsection.

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

“(V) PRECISION OTHER THAN FULL AND OPEN COMPETITION.—

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

“(II) RELATION TO OTHER AUTHORITIES.—The authority provided for under clause (I) is in addition to any other authority to use procedures other than competitive procedures.

“(III) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 303(c)(1) (including requirements that offers be solicited from many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations are amended from time to time.

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

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

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

“(VIII) INTERAGENCY COOPERATION.—

“(A) IN GENERAL.—In carrying out activities under this subsection, 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.

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

“(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).

“(X) 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 Homeland Security, and 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.

“(D) RELATED AUTHORIZATIONS OF APPROPRIATIONS.—

“(1) DETERMINATION.—No Federal agency shall be obligated from funds under section 522 of title 5, United States Code, for information identifying the location at which materials in the stockpile under subsection (a) are stored.

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

“(g) Section 303(c)(1) of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

“(h) Chapter 64 of title 40, United States Code (relating to bonds of contractors and subcontractors).

“(j) Section 6002 of the Solid Waste Disposal Act (42 U.S.C. 6926).
acquisition and deployment of secure facilities (including information technology and physical infrastructure, whether mobile and temporary, or permanent) sufficient to permit the Secretary to acquire, 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 transfer of assets and unexpended balances, and liabilities of the Strategic National Stockpile, including the functions of the Secretary of Homeland Security relating thereto.

(2) EXCEPTIONS.—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 referred to in 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.—Section 504 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)) is amended by adding at the end the following:

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

"(a) IN GENERAL.—Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and any other provision of law referred to in such paragraph (referred to in this section as an ‘emergency use’).

"(2) RELATION TO OTHER USES.—An emergency use authorized under paragraph (1) may be used for a disease or condition that is not an approved, licensed, or cleared product of the manufacturer referred to in such paragraph.

"(3) EFFECT.—The emergency use authorized under this section shall be the use of a product for the purpose and in the manner prescribed by, and subject to, the provisions of this section, approved or cleared under this Act, licensed under section 351 of the Public Health Service Act, for diagnosing, preventing, or treating such disease or condition caused by such an agent or such a product.

"(4) CONDITIONS OF AUTHORIZATION.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(5) RIGHT OF THE Manufacturer.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(6) NOTIFICATION.—(1) The Secretary shall promptly publish in the Federal Register each declaration, determination, advance notice of termination, and renewal under this section.

"(7) PUBLIC NOTICE.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(8) AUTHORIZATION UNDER SECTION 351.—(1) The Secretary may authorize the use of an approved product under this section, approved or cleared under this Act, or licensed under section 351 of the Public Health Service Act, for diagnosing, preventing, or treating such disease or condition caused by such an agent or such a product.

"(9) REPORT.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(10) DESIGNATION OF USE.—(1) or such a product.

"(11) AUTHORIZATION UNDER SECTION 351.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(12) RIGHT OF THE Manufacturer.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(13) NOTIFICATION.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(14) AUTHORIZATION UNDER SECTION 351.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(15) REPORT.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(16) DESIGNATION OF USE.—(1) or such a product.

"(17) RIGHT OF THE Manufacturer.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(18) NOTIFICATION.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(19) AUTHORIZATION UNDER SECTION 351.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(20) REPORT.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(21) DESIGNATION OF USE.—(1) or such a product.

"(22) RIGHT OF THE Manufacturer.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(23) NOTIFICATION.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(24) AUTHORIZATION UNDER SECTION 351.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(25) REPORT.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.

"(26) DESIGNATION OF USE.—(1) or such a product.

"(27) RIGHT OF THE Manufacturer.—(1) The Secretary shall ensure that the use of such product is consistent with subsection (f) of this section, approved or cleared under this Act.
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 bene-
fits and risks.

'(iii) Appropriate conditions for the moni-
toring and reporting of adverse events asso-
ciated with the emergency use of the prod-
uct.

'(iv) For manufacturers of the product, appro-
ropriate conditions concerning record-
keeping and reporting, including records ac-
cess to the Secretary, with respect to the emer-
gency use of the product.

'(B) AUTHORITY FOR ADDITIONAL CON-
ditions.—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 enti-
ties may administer the product with respect to
the emergency use of the product (including
limited 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 cat-
gories of such circumstances under which, the
product may be administered with respect to such use.

'(iii) Appropriate conditions with respect to
the collection and analysis of informa-
tion, during the period when the authoriza-
tion 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 manufac-
turers of the product, appropriate conditions concerns
recording and reporting, in-
cluding records access by the Secretary, with
respect to the emergency use of the product.

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

'(A) For a manufacturer of the product
who carries out any activity for which the
authorization is issued, the Secretary may,
to the extent practicable given the cir-
cumstances of the emergency, establish con-
ditions on an authorization under
subsection (b) or a revocation under
subsection (g).

'(B) For manufacturers of the product, ap-
propriate conditions concerning record-
keeping and reporting, in-
cluding records access by the Secretary, with
respect to the emergency use of such product.

'(C) The Secretary may establish with re-
spect to the distribution and administration
of the product for the unapproved use condi-
tions no more restrictive than those estab-
lished by the Secretary with respect to the
distribution and administration of the prod-
uct for the approved use.

'(3) GOOD MANUFACTURING PRACTICE.—With
respect to the emergency use of a product for
which an authorization under this section is
issued (whether an unapproved product or an
unapproved use of an approved product), the
Secretary may, to the extent practicable given the cir-
cumstances of the emergency, requirements regarding current
good manufacturing practice otherwise ap-
licable to the manufacturing, product proc-
ting, packaging, or holding of products subject to
regulation under this Act, including such re-
quirements established under section 501.

'(4) ADVERTISING.—The Secretary may es-
tablish conditions on advertisements and other promotional descriptive printed mat-
ter that relate to the emergency use of a
product for which an authorization under
this section is issued (whether an unap-
proved product or an unapproved use of an
approved product), including, as appro-
priate—

'(A) with respect to drugs and biological
products, requirements applicable to pre-
scription drugs pursuant to section 522(n) or
(B) with respect to medical devices that
are not being commercialized for emergency use
applicable to restricted devices pursuant to
section 522(q).

'(5) DURATION OF AUTHORIZATION.—

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

'(2) CONTINUED USE AFTER END OF EFFEC-
TIVE PERIOD.—Providing the termi-
nation of the declaration under subsection
(b) or a revocation under subsection (g), an
authorization shall continue to be effective to
provide for the continued use of an unap-
proved product for which an authorization under
this section is issued (whether an unap-
proved product or an unapproved use of an
approved product), including, as appro-
priate—

'(a) REVOCATION OF AUTHORIZATION.

'(1) REVIEW.—The Secretary shall periodi-
cally review the circumstances and the ap-
propriateness of an authorization under this
section.

'(2) REVOCATION.—The Secretary may
revolve 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.

'(b) PUBLICATION; CONFIDENTIAL INFOR-
MATION.

'(1) PUBLICATION.—The Secretary shall
promptly publish in the Federal Register a
notice of each authorization, and each termi-
nation or revocation of an authorization
under this section, and an explanation of the
reasons therefor (which may include a sum-
mary of data or information that has been to
submit to the Secretary in an application
under section 506(i) or section 520(g), even if
such summary may indirectly reveal the ex-
istence of such application).

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

'(c) ACTIONS COMMITTED TO AGENCY DISCU-
SSION.—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 discre-
mination.

'(d) RULES OF CONSTRUCTION.—The fol-
lowing applies to this section:

'(1) Nothing in this section impairs the au-
thority 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 au-
thority of the Secretary of Defense with re-
spect to the Department of Defense, includ-
ing the armed forces, under other provisions
of Federal law.

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

'(4) 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 in-
vestigation for purposes of section 505(b)(1),
section 520(g), or any other provision of this Act
or section 351 of the Public Health Service
Act.

'(5) OPTION TO CARRY OUT AUTHORIZED AC-
TIVITIES.—Nothing in this section provides
the Secretary any authority to require any
person to carry out any activity that be-
comes lawful pursuant to an authorization
under this section, and an authorized person
shall not be required to inform the Secretary that the person will not be carrying out such activity, except
that a manufacturer of a sole-source unap-
proved product shall report to the Secretary within a rea-
sonable 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 author-
ization under this section is issued. This sec-
tion does not modify or affect activities car-
rried out pursuant to other provisions of this
Act.

(6) Nothing in this section may be construed as restricting the Secretary from
imposing conditions on persons who carry
out any activity pursuant to an authoriza-
tion under this section.

(7) REPEAL OF TERMINATION PROVISION.—
Subsection (d) of section 1853 of the National
Defense Authorization Act for Fiscal Year
2001 (10 U.S.C. 1109a note) is repealed.

SEC. 5. REPORTS REGARDING AUTHORIZATIONS

(a) SECRETARY OF HEALTH AND HUMAN
SERVICES.—

(A) ANNUAL REPORTS ON PARTICULAR EXER-
CISES 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 subpara-
graph (B) regarding the exercise of authority
under the following provisions of law:

(B) SUBMISSIONS REQUIRED TO COM-
MITTEE.—With respect to section 319F-1
of the Public Health Service Act (as added by
section 3 of this Act):

(i) Subsection (b)(1) (relating to in-
creased simplified acquisition threshold).

(ii) Subsection (b)(2) (relating to pro-
cedures other than full and open competition).

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

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

(A) Subsection (c)(7)(A)(i) (relating to
streamlined acquisition provisions in
multiple-award contracts).

(B) Subsection (c)(7)(C)(v) (relating to
major provision in multiple-award con-
tracts).
(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 authorized devices).

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

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

(IV) B(1) 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 any potential barriers to the use of such authorities, including, as applicable, the options that were considered and rejected for such a grant, cooperative agreement, or contract pursuant to the use of such authorities, the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity; and 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 2 of this Act),

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

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

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

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

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

(A)(i) to review the Secretary of Health and Human Services’ utilization of the authorities granted under this Act with respect to streamlined acquisition procedures, procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel
(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) the direction or relocation of an individual to receive medical screening in an alternate location pursuant to an appropriate State emergency preparedness plan;"

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

(3) 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 such title, relating to the requirement to distribute a notice; or

(B) section 164.522 of such title, relating to the patient’s right to request privacy restrictions; and

(C) section 164.524 of such title, relating to—

(1) the patient’s right to request confidentiality communications; and

(2) the patient’s right to request confidential communications; and

(3) by inserting at the end the following: “A waiver or modification provided for under paragraph (3) or (7) shall only be in effect if such actions are taken in a manner that does not discriminate among individuals on the basis of their source of payment or of their ability to pay, and shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification pursuant to 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.

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

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

The bill largely reflects H.R. 2122, the bill that passed the House last year. Revisions in the Senate were made in our conference with the House committee 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. Davis), the gentleman from Michigan (Mr. Dingell), the gentleman from Texas (Mr. Turner), and the gentleman from California (Mr. Waxman) for their cooperation and hard work on this bill.

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

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

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

It would also authorize a special reserve fund of money, authorized in advance, for the government’s purchase of those countermeasures that ultimately are developed in response to the President’s call. This latter feature is critical because, without this clear commitment of funding in future years, private sector companies that are capable of such development will not undertake the heavy investment and risk associated with developing products that deal with agents that do not affect significant populations today and hopefully never will.

Congress has already provided the advance appropriation of $5.6 billion over the next 10 years for this purpose, consistent with our authorization in the House budget resolution.

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

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

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

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

Dear Chairman Barton: I am writing concerning S. 15, the “Project BioShield Act of 2004,” which is scheduled for floor consideration on Wednesday, July 14, 2004.

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

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

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

Best regards,

Bill Thomas, Chairman.
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 reducing biological attacks less lethal and, therefore, less attractive to would-be terrorists, new countermeasures serve a dual purpose. They are both an antidote and a deterrent to future attacks.

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

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

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

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

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

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

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

According to a White House budget memo recently leaked to the press, if President Bush wins the election this fall, one of his first actions will be to propose a $387 million cut in funding for the National Institutes of Health.

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

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

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

I urge my colleagues to support this legislation. In creating Project Bioshield, it gives America a promising weapon that helps 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-saving and life-improving NIH research, we risk winning the battle and losing the war.

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

Mr. BARTON of Texas. Mr. Speaker, I yield such time as he may consume to the gentleman from Louisiana (Mr. TAUBIN), 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. TAUBIN. Mr. Speaker, I thank the gentleman for yielding me this time; and, on a very bipartisan note, let me first thank the Members of this House and of the Senate, and particularly my friend from Massachusetts, Mr. Kennedy, for the great success we had in passing the Public Health Security Act and the Bioterrorism Preparedness and Response Act.

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

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

I do not have to tell my colleagues that this House and the Senate recently received another briefing on national security that our concern levels are up about an attack that might occur in this country from al Qaeda or other enemies of this country. As we fight them overseas, they are thinking about planning an attack on us here at home again. We know that.

We know the attack may come in a place we do not know, in a place we are unprepared for, and it might involve radiological materials or it might involve some horrible virus or some agent the likes of which we are unprepared to deal with.

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

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

Secondly, the bill tries to do something else, and that is to say we are going to change our law a little bit when it comes to the government’s approval of treatment and/or it might be
a vaccine or some treatment that has not yet been approved by the Food and Drug Administration but yet has a greater ability to cure and help people than the risk involved with allowing it to be used. In other words, we are streamlining the law to make sure, if we do come under attack, if there is some vaccine, some treatment under study that has a lot of promise but has not yet been approved, that we are not forbidden to use it to help people who might be hurt or in need of that kind of treatment.

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

This is an important step in protecting our country at a time when we are under, as you know, this increasing warning that these evil individuals are thinking about planning and trying to figure out how they might hurt us again. It is a critical two-step process in making sure that we have the protective equipment 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 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 addition, the HHS secretary is authorized to institute an emergency distribution of unapproved drugs and devices, whose benefits and burdens are not fully tested, under conditions that are consistent with the definition of a public health emergency.

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

We find heroes and patriots both abroad and at home risking their lives in defense of freedom in this war on terror, but there are patriots and unsung heroes in my community who, under withering criticism, toiled to make their product better and get it into the hands of those who needed it. Thanks to the representatives of Bioport in Lansing, Michigan, since 1996, 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 homeland security preparedness capability in conjunction with working on new experimental vaccines.
Mr. Speaker, I would even go further and urge the Departments of Homeland Security and Health and Human Services to consider the immediate procurement of millions of additional doses of the FDA-licensed anthrax vaccines, as well as additional doses of antibiotics for the Strategic National Stockpile. These doses are essential to improving our capability and responding to another potential anthrax attack.

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

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

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

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

I think we all understand that to win the war on terror we have to be much more aggressive about going after the terrorist threat. They are there.

In the days ahead, as the American people rise up international terrorist cells is project number one for the national defense of this country.

We also know that we have to strengthen our homeland defenses and protect our 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.

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 intended to engage in bioterrorism, and we know that Osama bin Laden has called for the use of weapons of mass destruction against the American public. In fact, he has called it a religious duty.

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

Mr. Speaker, we must regain the sense of urgency that 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 ahead, I hope that the passage of this legislation will renew our urgency about the threat of bioterrorism. I support the Bioshield legislation because it is a good first step to addressing the challenge.

From the beginning of this process, I and many of my colleagues on the Democratic side have been concerned that this legislation is not enough to address the threats that we face. Whether Bioshield will be a success is yet to be determined. It 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 system.

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

One example of a capability that we clearly need and that Project Bioshield does not address is the ability to respond rapidly to a previously unknown or engineered pathogen. Terrorists may soon be able to genetically manipulate biological agents so they are resistant to our current stockpile of countermeasures and perhaps to those we develop in the future. That is why I, along with 35 of my Democratic colleagues, introduced 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. 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 daily.

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 first responders from deadly terrorist threats with proven countermeasures.

Committee on Government Reform.

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

Mr. Tom Davis of Virginia, distinguished whip of the Committee on Government Reform.

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.

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Mr. Tom Davis of Virginia, distinguished whip of the Committee on Government Reform.

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

I want to thank the chairman of the Committee on Energy and Commerce and the previous chairman, the gentleman from Louisiana (Mr. Tauzin), both of whom 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 use dangerous agents as their weapon. They would like to use dangerous agents like anthrax, botulinum toxin, the plague, ebola and other similar viruses, as have just been noted, even some we are not even aware of. And of course as was well explained by my colleague, the former chairman of the Committee on Energy and Commerce, the gentleman from Louisiana, in the absence of funds, in the 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 available. The American people expect that of us and both committees in both bodies have worked hard on this kind of legislation.

I want to point out that I chair the Subcommittee on Emergency Preparedness and Response of the Select Committee on Homeland Security as well as serving on the Committee on Energy and Commerce; and I chaired hearings on the House parallel to this legislation, H.R. 2122. In those hearings we discovered a fact that has been mentioned in this debate, and that is that the mere development of these countermeasures for such a biological attack will deter the attack. Think of that point. The reality is if al Qaeda knows that we are unprepared for a chemical, a biological or a radiological attack, then they are incentivized to make that kind of attack. On the other hand if they know that we have invested the money and done the research and worked 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 Bio-shield, by not only encouraging the research of these antitoxins but also encouraging their development and their stockpiling will indeed deter such attacks.

I strongly urge my colleagues to support this legislation.

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

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

Mr. ANDREWS. Mr. Speaker, I thank my friend from Texas for his leadership and hard work on this bill. I congratulate him, the gentleman from Ohio (Mr. Brown), the gentleman from Michigan (Mr. Dingell), the gentlewoman from New York (Mrs. Maloney), the gentleman from Texas (Mr. Barton), the gentleman from Louisiana (Mr. Tauzin), the gentleman from California (Mr. Cox), and all those responsible for the passage of this very important bill.

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

This is a massive and serious equivalent at the national level of whether we should prevent the traffic accident by putting up the signal ahead of time. Although this bill is not perfect, it recognizes an issue that is not much talked about today but is very much looming on the horizon as a potential catastrophe for the country. As the gentleman from Texas said very eloquently just a few minutes ago, perhaps the most ominous and destructive terrorist attack that could occur on this country would be a terrorist attack using a biological weapon. Unlike chemical weapons, unlike radiological weapons, 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 antitoxides that could cure those exposed to the attack or prevent people from being sickened or killed by the attack, that these antitoxides 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 antitoxin 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 aspects. The first is what the gentleman from Texas talks about, particularly with respect to mutant or new strains of bioweapons that would not be handled by the antitoxides developed under this bill. We need a much more rapid and focused effort to deal with those mutant or new strains.

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

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

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

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

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

Mr. BARTON of Texas. Mr. Speaker, I yield 3 minutes to the distinguished gentlewoman from Florida (Ms. Ginny Brown-Waite), a former president pro
temperate with the Florida Senator who chaired the Homeland Security Select Committee in the Florida Senate.

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

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

For this reason, America must be prepared and must do everything in its power to protect its citizens. This legislation does exactly that. Among other things, the bill gives the Secretary of HHS the authority to conduct research and development for new vaccines, antitoxins, and protective countermeasures against 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, produce, or develop countermefasures.

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 are not as prepared as we need to be to protect the American people.

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

It is important to note as well, since there are two Texans on the floor, now three, that this is a bipartisan bill; and we thank the distinguished chairman and the number of other Members who have worked so hard on this legislation.

So my remarks should not be taken out of context to the extent that I disregard the hard work and the very valuable aspects of this legislation.

Frankly, I think, in order to make it more understandable, it is simply the method of how we do it. It is the big umbrella. It is the responsibility of this government to secure the homeland. And when the private sector has not yet reached the point when it will move deliberately and in a 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 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 actio or whether it be acts of terrorists, the question is who is in charge? All of these elements that we are facing in this instance, bioterrorism, all need to relate to an orderly focus on securing the homeland; and I believe it is extremely important that we find ourselves organizing this whole effort of the war against terrorism in a methodical way.

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

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

As recently as April 22 of this year in Tacoma, Washington, we had a bioterrorism scare. A believes powder was found in two envelopes, and 94 people had been evacuated from a mail distribution facility. Initial tests of the powder tested positive for biotoxins that cause bubonic plague or botulism.

Four people were taken to a hospital for possible decontamination, including one who suffered burning eyes and nose.

We are presently faced with the threat of a worldwide SARS outbreak. The inability of many foreign countries to adequately deal with that outbreak raises questions about our own preparedness.

What about other infectious diseases like tuberculosis? There are many ailments that our medical professionals are struggling to control, and we must do better in the area of biological warfare.

Might I also acknowledge that, as we put forward Project Bioshield that will take now some $5.6 billion, we should not forget, as our friends and colleagues on the Committee on Energy and Commerce have noted, the other preventable diseases or other contagious diseases and the other work of NIH so that we are assured that we are not repeating the mistakes of the past.

Some of us, for example, in our legislation reach out to Historically Black Colleges and Universities, those serving Black or African Americans, American Indians, Appalachian Americans, Alaskan Natives, Asians, Native Hawaiians, other Pacific Islanders, Hispanics or Latin: Americans. In order to provide resources for those institutions to be utilized in available research and development grants, contracts, cooperative agreements, and procurements under this particular legislation. If we can adequately secure the rural homeland, the urban homeland, and all segments of our population. We must secure the neighborhoods.

I support this legislation, but I also believe that we still have work undone to complete our task of assuring the American people that the homeland is securely secure.
Mr. Speaker, I rise today in support of S. 15, the “Project BioShield Act of 2004.” I support the predecessor of this bill, H.R. 2122 as it passed previously. This is important legislation because it takes America one-step closer to being prepared to deal with a biochemical threat to our national security. As we consider this legislation, Mr. Speaker, America is still not safe. We remain vulnerable. Our ports are not secure. Our critical infrastructure is not secure. Our communities are not protected from biochemical agents. S. 15, will help to make America safer.

The purpose of the Project BioShield Act of 2004 is to “enhance the research, development, procurement, and use of biomedical countermeasures to respond to public health threats of infectious disease 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, toxins, and viruses that can spread with ease 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 weapon use in the United States. Last year alone 30 million tons of cocaine was smuggled into the United States. If we can’t stop 30 million tons of cocaine from crossing our borders, how can we expect to stop a vile filled with anthrax, botulism, or small pox? A vile that could kill hundreds or possibly thousands.

To adequately protect our homeland from bioterrorist attacks we must address these and many other concerns in the Project BioShield bill. The provisions of Project BioShield provide many good start for 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 unapproved, 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 consideration 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. It is to see the retention of this provision as “Section 6, Outreach” in the bill before us today, and I wholeheartedly support its passage.

Protecting our communities is the most challenging and most important responsibility of the Federal Department of Homeland Security. The House and Senate Select Committees on Homeland Security, and all members of this Congress. An ongoing failure of all agencies responsible for homeland security is our inability to equip our local communities with the funds and supplies needed to counter a terrorist attack. As I stated on my visit 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 in Houston, TX, in April. During each of these events, America’s first responders echoed the same sentiment: They lack the funding and equipment to deal with a terrorist attack.

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

Mr. Speaker, I believe the provisions of S. 15, the Project BioShield bill, are good first steps in protecting Americans from biological attacks. However, I feel that our country is still not safe and that many protections need to be established to fully protect our communities from biochemical attacks.

SEC. 6. OUTREACH.

The Secretary of Health and Human Services shall develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of Black or African American, American Indian or Alaskan American, Latin American, Hispanic, Alaskan Native, Asian, Native Hawaiian, or 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. TUESSER) on my right, who is on the floor and has been on his feet for much of this debate. I want to thank the gentleman from Texas (Mr. BARTON), the Chairman of the Committee on Energy and Commerce; and the gentleman from Michigan (Mr. DINGELL), Ranking Democrat on that committee.

In the same way that this was a collaboration between the Committee on Energy and Commerce and the Select Committee on Homeland Security in the Congress and the Committee on Government Reform in the House of Representatives, chaired by the gentleman from Virginia (Mr. TOM DAVIS), who we 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 trying to implement. The Department of Homeland Security and the Department of Health and Human Services will partner in this first responder effort of unprecedented magnitude.

And I should say, Mr. Speaker, that this is a collaborative effort, as 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 before it becomes a pandemic. America has a mission to revise and extend his response plan. We must do more. 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 an awareness of the threat 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 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 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 Chemical Weapons to protect our Nation and our citizens from the ever-evolving threat of weapons of mass destruction.

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

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

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

Mr. WAMP. 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. And I want to tell you that story. About a year ago, when I brought "Buy America" provisions to the floor trying to insert them in this legislation, received assurances from Secretary Thompson and the gentleman from Louisiana (Chairman Tauzin) that every effort would be made to buy America where possible in all of the implementation of not just Bioshield, but all of the different treatments and antidotes that fall under Bioshield or BioShield. And 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 threat and how that was going to be procured. It is called Prussian Blue, and I was told that was still in the process of being competed.

I have got to tell you, in Tennessee that does not go over very well, when there are U.S. manufacturers prepared to do this and time is of the essence.

The FDA, HHS, DHS, we need to coordinate better. I am very concerned about ceding the responsibility to interagency working group and not having an accountable person.

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

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

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 Chemical Weapons to protect our Nation and our citizens from the ever-evolving threat of weapons of mass destruction.

Mr. Speaker, I reserve the balance of my time.
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 yield 2 minutes remaining. I yield that time to the gentleman from Virginia (Mr. TOM DAVIS), the chairman of the Committee on Government Reform, and ask that he control the balance of the Committee on Energy and Commerce time.

The SPEAKER pro tempore (Mr. FOLEY). Is there objection to the request of the gentleman from Texas? There was no objection.

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

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

Mr. Speaker, I rise in support of S. 15, the Project BioShield Act of 2004. The bill provides the government with the necessary tools to develop and purchase vaccines and other drugs to protect Americans in the event of a bioterrorist attack. The President first announced this proposal during his 2003 State of the Union address, and it serves as the cornerstone of the administration’s strategy to prepare the Nation against the possibility of bioterrorism.

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

[From the Washington Times, July 12, 2004]

INTERCEPTING BIOTERRORISM

by Christopher Cox

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

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

Winning the war on terrorism will require our nation not only to defeat attacks with explosives and military-style weapons, but also to be prepared to overcome potential attacks with a much longer list of weapons, including sarin gas, anthrax, ricin, smallpox, plague, tularemia, botulinum toxin and viral hemorrhagic fevers (such as the Ebola virus).

Just how vulnerable are we to such attacks today? The United States now can fully meet only a handful of the 57 “top echelon” biological terror threats. That’s not an acceptable level of preparedness for the greatest power on Earth. We can launch a Tomahawk cruise missile and destroy the smokestacks of a midsized power plant a thousand miles away—once thought to be a million-to-one shot at best—yet we aren’t prepared to deal with the frightening prospect of an anthrax or sarin gas attack against our civilian population.

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

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

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

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

By guaranteeing the successful vaccines and antidotes, Project BioShield will provide incentives for private-sector scientists, physicians, and researchers to develop innovative projects. 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 develop-mental tools for use on a fast-track approval basis to save innocent lives, so long as the benefits outweigh potential risks.

President Bush asked Congress to move immediately on Project BioShield 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 vote of 409 to 1, 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 the 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 $500 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: Torrington’s fire engines can cool for any minutes. And once a bioweapon is released, every second will count.

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

In fact, we have revealed to the world that it will come to bioterrorism, Americans will be able to say: Checkmate.

Mr. Speaker, the bipartisan bill we are considering today is similar to H.R. 2122, which was passed by the House on July 22, 2003, that serves a compelling national interest.

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

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

Should the United States be attacked with these deadly pathogens, however, there will be no vaccine or treatment. 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 numbers of flexiblile, unfettered tools based on existing streamlined procedures to promote research and development and procure necessary drugs and vaccines. These tools are instrumental to the success of the BioShield program.

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

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

Aquisition 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 security 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 rigorously 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 many Members of this body feel at the time it has taken to get this measure to this floor, in a conference report form, and then send it on to the President’s desk for signature. We passed this legislation with bipartisan support, 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 spend a tremendous amount of the funds needed to research, develop or produce vaccines or other countermeasures because there is little or no market.

Despite these challenges, in my district, the Stowers Institute and the Kansas City Life Sciences Institute are both trailblazers in the field of research. The Stowers Institute’s new research facility in Kansas City incorporates the best that present technology can offer. In my community, the best and the brightest are working hard to bridge the chasm 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.

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

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

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

Partial. 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.
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 they have access to a better chance to fight off infections and the other biological assaults that may come from a bioterrorism attack.

The anthrax scare taught us that lesson. The breakdowns were fundamental ones. Project BioShield, the administration’s EDOR piece 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 misadventure, biodefense policies must be developed and adopted to ensure our safety and security. These should include reasonable steps to prevent the spread of dangerous pathogens and the technology to enhance them. Preparedness of our health infrastructure must also be enhanced and maintained. Finally, protections, including drugs and vaccines, to counter potential weaponized pathogens need to be available during a crisis.

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

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

In addition to improving antimicrobial and vaccine development capabilities, an area currently neglected by the private sector, the technical spin-offs of such an endeavor are also likely to benefit the domestic pharmaceutical and biotechnology industries more generally. Broad public health benefits will also be derived.

Extensive literature exists to show that the long timeframes (14 years) and high failure rates typical of drug development processes today are a significant cause of high R&D costs, and thus high prescription drug costs.

Mr. Speaker, today I know that we will pass this bill, but what I and other health providers, public health experts and officials and the people of this country want to know is that we will not again be caught off guard with insufficiently to fully fund the strengthening of our public health system, the training of our first responders and provide them with the tools and facilities they need to protect us in those first critical hours where lives can and must be saved.

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

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

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

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

Two words of caution: First, implementation of BioShield must be linked to the threat. Vaccines and antidotes against exotic agents may present easier, near-term opportunities for quick successes. But the Center for Disease Control and the intelligence community maintain a threat list of pathogens, and that list should focus and guide BioShield investments.

Botulinum toxin ranks right behind anthrax as a known biological threat. But testimony before the Select Committee on Homeland Security concluded development of botulinum antitoxin stocks could take up to 10 years. If Project BioShield is going to provide anything more than a symbolic barrier against biological attack, that estimate has to change.

And, the success of BioShield also depends upon broader bio-preparedness priorities. The Government Reform National Security Subcommittee, which I chair, has held several hearings on bioterrorism preparedness. We learned that massive cashes of stockpiled vaccines, antibiotics and drugs will protect no one unless the stockpiles are acquired quickly and safely. Public health capacity is a critical enabler to BioShield success. Surveillance systems, diagnostic tools and trained medical personnel are prerequisites to any effective defense against natural and man-made biological outbreaks.

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

Mr. Speaker, Project BioShield is a much needed initiative, and I would urge all of my colleagues to support it.

Mr. DINGELL. Mr. Speaker, I rise in support of S. 15, the “Project BioShield Act of 2004.” This legislation reflects bipartisan bicameral negotiations that have made minor modifications to the language of H.R. 2122 which was passed by the House on June 17, 2003. I commend the hard work and dedication of all who participated in this endeavor.

In this era of heightened threats to our national security and the increased risk of harm to Americans, Project BioShield is an unfortunate yet necessary measure to provide strong support of this bipartisan legislation, the Project BioShield Act of 2004.

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

The bill before us reflects further refinements and does not contain major policy changes from last year’s bill.

Among the significant measures in this bill are provisions aimed at enhancing accountability for actions taken under Project BioShield. Congress will receive comprehensive information, not less than annually, on the major activities authorized by this Act. In addition, the Government Accountability Office (GAO) will provide reports on key economic and scientific elements of this program after it has been in effect for several years.

Finally, I am pleased to note that this bill maintains the approach of H.R. 2122 that funding be authorized, rather than a permanent, unlimited appropriation sought by the Administration. BioShield should not automatically be given a higher priority over other national security or public health matters.

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

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

Given the serious threat of bioterrorism, the development of effective countermeasures to biological agents is vital to our national security. The goal of Project BioShield is to encourage the development of these products. I fully
support the intent of this legislation. I also agree with its premise—that when the market cannot foster the development of critical products by itself, the government must rise to the challenge.

The bill before us today includes several significant improvements from earlier proposals. For example, it includes important provisions 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 only when necessary and should be subject to review. This proposal preserves that standard.

The provisions of BioShield authorizing the emergency distribution of unapproved drugs and devices, whose risks and benefits are not fully tested, impose an unprecedented responsibility on the government. FDA must be vigilant in protecting the public against unnecessary risks from these products.

In part because of these concerns, the bill requires that health care providers and patients be informed that the products have not been approved by the Food and Drug Administration (FDA) and that they need to be aware of the risks. The bill also requires that manufacturers monitor and report adverse reactions to the products and keep other appropriate records about the use of the products.

These conditions are essential for the safe use of unapproved products, and they should be imposed in all cases, except in truly extraordinary circumstances. In addition, the HHS Secretary is authorized to limit the distribution of the products, to limit who may administer the products, to waive good manufacturing practice requirements only when absolutely necessary, and to require record keeping by others in the chain of distribution.

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

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

Mr. LANGEVIN. Mr. Speaker, I rise today in support of the Project BioShield Act of 2004. Bioterrorism is a major threat to our national security, and I believe it is our job as members of Congress to instill confidence in the American people that a coordinated and 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 BioShield initiative and will set in motion crucial efforts to develop new countermeasures to treat diseases and conditions caused by bioterror attack 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 countermeasures that have not yet been approved by the Food and Drug Administration (FDA).

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

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

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

Mr. SENSENIBRENNER. Mr. Speaker, I rise in support of S. 15, the "Project BioShield Act of 2004." This important legislation will help us to better prepare 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 §3109f-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.
Mr. FLAKE changed his vote from "yea" to "nay."
Mr. WAXMAN changed his vote from "nay" to "yea."

So the simple bill was passed.
A motion to reconsider was announced above as recorded.

PERMISSION FOR MEMBER TO RE-VOICE AND EXTEND REMARKS ON 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 United Nations General Assembly for requesting such an opinion. This legislation was only introduced last night and strikes me as the type of legislation a House and Senate would be well advised to consider carefully before making a commitment of this magnitude.

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

The SPEAKER pro tempore. Members are advised that a motion to reconsider was laid on the table.

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

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

The SPEAKER pro tempore. The motion is agreed to.

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. Members are advised that a motion to reconsider was laid on the table.

NAYS—2

VIETNAM HUMAN RIGHTS ACT OF 2004

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

The Clerk reads as follows:

H.R. 1587

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

SECTION 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:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Radio Free Asia transmissions to Vietnam.
Sec. 4. Bilateral assistance to promote human rights and democracy in Vietnam.
Sec. 5. Annual report.

TITLE II—ASSISTANCE TO SUPPORT HUMAN RIGHTS AND DEMOCRACY IN VIETNAM

Sec. 201. Assistance.

TITLE III—UNITED STATES PUBLIC DIPLOMACY

Sec. 301. Radio Free Asia transmissions to Vietnam.
Sec. 302. United states educational and cultural exchange programs with Vietnam.

TITLE IV—ANNUAL REPORT ON PROGRESS TOWARD FREEDOM AND DEMOCRACY IN VIETNAM

Sec. 401. Annual report.

SEC. 2. FINDINGS.

Congress finds the following:

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

(2) The Government of Vietnam permits no public challenges to the legitimacy of the one-party State. It prohibits independent political, labor, and social organizations, and it continues to detain and imprison persons for the peaceful expression of 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.

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

(4)(A) The Government of Vietnam limits freedom of religion and restricts the operation of religious organizations other than those approved by the State. While officially sanctioned religious organizations are able to operate with varying degrees of autonomy, some of those organizations continue to face restrictions on selecting, training, and ordaining sufficient 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.