

PROJECT BIOSHIELD ACT OF 2003

—————  
JULY 8, 2003.—Ordered to be printed  
—————

Mr. COX, from the Select Committee on Homeland Security,  
submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 2122]

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

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Project BioShield Act of 2003”.

**SEC. 2. BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT AUTHORITIES.**

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319F the following section:

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

“(a) IN GENERAL.—

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

“(2) QUALIFIED COUNTERMEASURE.—For purposes of this section, the term ‘qualified countermeasure’ means a priority countermeasure (as defined in section 319F(h)) that affects national security.

“(3) INTERAGENCY COOPERATION.—

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

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

“(4) AVAILABILITY OF FACILITIES TO THE SECRETARY.—In any grant or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, and supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

“(b) EXPEDITED PROCUREMENT AUTHORITY.—

“(1) INCREASED SIMPLIFIED ACQUISITION THRESHOLD FOR BIOMEDICAL COUNTERMEASURE PROCUREMENTS.—

“(A) IN GENERAL.—For any procurement by the Secretary of property or services for use (as determined by the Secretary) in performing, administering, or supporting qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, the amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), as applicable pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), shall be deemed to be \$25,000,000 in the administration, with respect to such procurement, of—

“(i) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

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

“(B) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subparagraph (A) and the provision of law and regulations referred to in such subparagraph, each of the following provisions shall apply to procurements described in this paragraph to the same extent that such provisions would apply to such procurements in the absence of subparagraph (A):

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

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

“(iii) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the — examination of contractor records).

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

“(2) USE OF NONCOMPETITIVE PROCEDURES.—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures when—

- “(A) the procurement is as described by paragraph (1); and  
“(B) the property or services needed by the Secretary are available from only one responsible source or only from a limited number of responsible sources, and no other type of property or services will satisfy the Secretary’s needs.
- “(3) INCREASED MICROPURCHASE THRESHOLD.—  
“(A) IN GENERAL.—For a procurement described by paragraph (1), the amount specified in subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to be \$15,000 in the administration of that section with respect to such procurement.  
“(B) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for purchases that are under this paragraph and that are greater than \$2,500.  
“(C) EXCEPTION TO PREFERENCE FOR PURCHASE CARD MECHANISM.—No provision of law establishing a preference for using a Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than \$2,500.
- “(c) AUTHORITY TO EXPEDITE PEER REVIEW.—  
“(1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as applicable to a grant, contract, or cooperative agreement—  
“(A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and  
“(B) the amount of which is not greater than \$1,500,000.
- “(2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary’s determination of whether to employ expedited peer review with respect to subsequent phases of a research grant or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant or cooperative agreement.
- “(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—  
“(1) IN GENERAL.—For the purpose of performing, administering, and supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5, United States Code, but without regard to the limitations in such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.  
“(2) FEDERAL TORT CLAIMS ACT COVERAGE.—  
“(A) IN GENERAL.—A person carrying out a contract under paragraph (1), and an officer, employee, or governing board member of such person, shall be deemed to be an employee of the Department of Health and Human Services for purposes of claims under sections 1346(b) and 2672 of title 28, United States Code, for money damages for personal injury, including death, resulting from performance of functions under such contract.  
“(B) EXCLUSIVITY OF REMEDY.—The remedy provided by subparagraph (A) shall be exclusive of any other civil action or proceeding by reason of the same subject matter against the person, officer, employee, or governing board member.
- “(3) INTERNAL CONTROLS TO BE INSTITUTED.—  
“(A) IN GENERAL.—The Secretary shall institute appropriate internal controls for contracts under this subsection, including procedures for the Secretary to make a determination of whether a person, or an officer, employee, or governing board member of a person, is deemed to be an employee of the Department of Health and Human Services pursuant to paragraph (2).  
“(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or governing board member of a person, is or is not deemed to be

an employee of the Department of Health and Human Services shall be final and binding on the Secretary and the Attorney General and other parties to any civil action or proceeding.

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

“(e) STREAMLINED PERSONNEL AUTHORITY.—

“(1) IN GENERAL.—In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, without regard to such provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, not to exceed 30 such employees at any time, to positions in the National Institutes of Health to perform, administer, or support qualified countermeasure research and development activities in carrying out this section.

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

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

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

(1) in subsection (a)(1), by inserting “or the Director of the National Institute of Allergy and Infectious Diseases” after “Director of the Center”;

(2) in subsection (c)—

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

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

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

(4) in subsection (e)—

(A) in paragraph (1)—

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

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

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

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

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

(5) in subsection (f)—

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

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

(6) in subsection (i)—

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

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

(B) by adding at the end the following:

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

### SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

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

#### “SEC. 319F-2. STRATEGIC NATIONAL STOCKPILE.

“(a) STRATEGIC NATIONAL STOCKPILE.—

“(1) IN GENERAL.—The Secretary of Homeland Security (referred to in this section as the ‘Homeland Security Secretary’), in coordination with the Sec-

retary and the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

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

- “(A) consult with the working group under section 319F(a);
- “(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;
- “(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;
- “(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;
- “(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and
- “(F) ensure the adequate physical security of the stockpile.

“(b) SMALLPOX VACCINE DEVELOPMENT.—

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

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

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

“(1) IN GENERAL.—

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

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

- “(i) against a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii);
- “(ii) that is determined under paragraph (2)(B)(ii) to be a necessary countermeasure;
- “(iii) that is designed, developed, modified, or procured for the specific purpose of preventing, detecting, identifying, deterring, or mitigating actual or potential acts of chemical, biological, radiological, or nuclear catastrophe;
- “(iv)(I) that is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act, or licensed under section 351 of this Act, for use as a countermeasure to a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii); or
- “(II) for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing after the date of a determination under paragraph (5); and
- “(v) that relates to an actual or potential act of terrorism or catastrophic event or to actual or potential warfare.

“(2) DETERMINATION OF MATERIAL THREATS.—

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

- “(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and
- “(ii) determine which of such agents present a material threat against the United States population.

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

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

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

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

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

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

“(4) CALL FOR DEVELOPMENT OF COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

“(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently unavailable for procurement or available under unsuitable conditions, such Secretaries may jointly submit to the President a proposal to—

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

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

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

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

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

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

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

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

“(i) the call for the countermeasure;

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

and

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

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

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

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

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

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

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

“(6) RECOMMENDATION FOR PRESIDENT’S APPROVAL.—

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

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

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

“(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

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

“(7) PROCUREMENT.—

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

“(B) INTERAGENCY AGREEMENTS.—

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

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

“(C) PROCUREMENT.—

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

“(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agree-

ments, and for carrying out such other activities as may reasonably be required, in accordance with the provisions of this subparagraph; and

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

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

“(I) PAYMENT CONDITIONED ON SUBSTANTIAL DELIVERY.—The contract shall provide that no payment may be made until delivery has been made of a substantial portion (as determined by the Secretary) of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary’s discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform under the contract, except in special circumstances as determined by the Secretary on a contract by contract basis.

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

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

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

“(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

“(I) IN GENERAL.—The amount of any procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

“(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

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

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

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



“(bb) Subsections (a) and (b) of Section 7 of the Anti-Kick-back Act of 1986 (41 U.S.C. 57(a) and (b)).

“(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the examination of contractor records).

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

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

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

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

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

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

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

“(vii) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that the Secretary may so exclude such a source.

“(8) INTERAGENCY COOPERATION.—

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

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

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

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

“(B) administrative costs.

“(10) DEFINITIONS.—

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

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

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

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

“(d) DISCLOSURES.—No Federal agency shall disclose under section 552 of title 5, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

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

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

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

“(f) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

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

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

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

“(c) AVAILABILITY.—

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

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

“(d) RELATED AUTHORIZATIONS OF APPROPRIATIONS.—

“(1) THREAT ASSESSMENT CAPABILITIES.—For the purpose of carrying out the responsibilities of the Secretary for terror threat assessment under the security countermeasures program, there are authorized to be appropriated \$5,000,000 for fiscal year 2004, and such sums as may be necessary for each of the fiscal years 2005 and 2006, for the hiring of professional personnel within the Directorate for Information Analysis and Infrastructure Protection, who shall be analysts responsible for chemical, biological, radiological, and nuclear threat assessment (including but not limited to analysis of chemical, biological, radiological, and nuclear agents, the means by which such agents could be weaponized or used in a terrorist attack, and the capabilities, plans, and intentions of terrorists and other non-state actors who may have or acquire such agents). All such analysts shall meet the applicable standards and qualifications for the performance of intelligence activities promulgated by the Director of Central Intelligence pursuant to section 104 of the National Security Act of 1947.

“(2) INTELLIGENCE SHARING INFRASTRUCTURE.—For the purpose of carrying out the acquisition and deployment of secure facilities (including information technology and physical infrastructure, whether mobile and temporary, or permanent) sufficient to permit the Secretary to receive, not later than December 31, 2003, all classified information and products to which the Under Secretary for Information Analysis and Infrastructure Protection is entitled under subtitle

A of title II, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2006.

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

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

“(2) could be produced significantly less expensively by the government directly than through procurements under such section;

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

(c) CONFORMING AMENDMENT.—Section 121 of the Public Health Security and Bio-terrorism Preparedness and Response Act of 2002 (116 Stat. 611; 42 U.S.C. 300hh–12) is repealed. With respect to the program established under former section 121 of such Act, the repeal of such section under the preceding sentence applies as a modification of the program in accordance with the amendment made by subsection (a) of this section, and not as the termination of the program and the establishment of a different program.

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

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following section:

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

“(a) IN GENERAL.—

“(1) EMERGENCY USES.—Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug or device intended for use in an actual or potential emergency (referred to in this section as an ‘emergency use’).

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

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

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

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

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

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

“(B) The term ‘product’ means a drug or device.

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

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

“(b) DECLARATION OF EMERGENCY.—

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

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

“(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a

heightened risk to United States military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; or

“(C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act, affecting national security and involving a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

“(2) TERMINATION OF DECLARATION.—

“(A) IN GENERAL.—A declaration under this subsection shall terminate upon the earlier of—

“(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

“(ii) the expiration of the one-year period beginning on the date on which the declaration is made.

“(B) RENEWAL.—Notwithstanding subparagraph (A), the Secretary may renew a declaration under this subsection, and this paragraph shall apply to any such renewal.

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

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

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

“(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register each declaration, determination, and renewal under this subsection.

“(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention, to the extent feasible and appropriate given the circumstances of the emergency involved, the Secretary concludes—

“(1) that an agent specified in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

“(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

“(A) the product may be effective in detecting, diagnosing, treating, or preventing—

“(i) such disease or condition; or

“(ii) a serious or life-threatening disease or condition caused by a product authorized under this section or approved under this Act or the Public Health Service Act, for detecting, diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

“(B) the known and potential benefits of the product, when used to detect, diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

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

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

“(d) SCOPE OF AUTHORIZATION.—

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

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

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

“(C) the Secretary’s conclusions, made under subsection (c), concerning the safety and potential effectiveness of the product in detecting, diag-

nosing, preventing, or treating such diseases or conditions, including an assessment of the available scientific evidence.

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

“(e) CONDITIONS OF AUTHORIZATION.—

“(1) UNAPPROVED PRODUCT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“(A) The Secretary may, for manufacturers of the product who choose to carry out one or more activities for which the authorization is issued, estab-

lish any of the conditions described in clauses (i) through (iv) of paragraph (1)(A).

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

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

“(f) DURATION OF AUTHORIZATION.—

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

“(2) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—An authorization shall continue to be effective for continued use with respect to patients to whom it was administered during the period described by paragraph (1), to the extent found necessary by such patients’ attending physicians.

“(g) REVOCATION OF AUTHORIZATION.—

“(1) REVIEW.—The Secretary shall periodically review the circumstances and the appropriateness of an authorization under this section.

“(2) REVOCATION.—The Secretary may revoke an authorization under this section if, in the Secretary’s unreviewable discretion, the criteria under subsection (c) for issuance of such authorization are no longer met.

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

“(i) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

“(j) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to impair or otherwise affect—

“(1) the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution;

“(2) the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law; or

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

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

“(1) WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.—In the case of administration of a countermeasure to members of the armed forces, a requirement, under subsection (e)(1)(A)(ii)(III), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived by the President if the President determines, in writing, that complying with such requirement is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

“(2) PROVISION OF INFORMATION TO MEMBER OF THE ARMED FORCES.—If the Secretary makes a determination that it is not feasible for the information required by subsection (e)(1)(A)(ii) to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. Information concerning the administration of the product shall be recorded in the medical record of the member.

“(3) EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.—In the case of an authorization based on a determination by the Secretary of Defense under subsection (b)(1)(B), section 1107 of title 10, United States Code, shall not apply to use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

“(l) RELATION TO OTHER PROVISIONS.—If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization—

“(1) shall not be subject to any requirements pursuant to section 505(i) or 520(g); and

“(2) shall not be subject to any requirements otherwise applicable to clinical investigations pursuant to other provisions of this Act.

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

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

**SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS ACT.**

(a) SECRETARY OF HEALTH AND HUMAN SERVICES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) CONTENTS OF REPORTS.—The Secretary shall annually submit to the designated congressional committees (as defined in subsection (e)) a report that summarizes—

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

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

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

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

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

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

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

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

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

(b) NATIONAL ACADEMY OF SCIENCES REVIEW.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) REPORT REGARDING ADDITIONAL BARRIERS TO PROCUREMENT OF SECURITY COUNTERMEASURES.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Homeland Security and the Secretary of Health and Human Services shall report to the designated congressional committees any barriers to the procurement of security countermeasures that have not been addressed by this Act.



(e) **STATUS OF PROGRAM FOR CHEMICAL TERRORISM PREPAREDNESS.**—Not later than 180 days after the date of the enactment of this Act, the Secretary of Homeland Security shall submit to the designated congressional committees a report describing the status of the program carried out by the Secretary to enhance the preparedness of the United States to respond to terrorist attacks involving chemical agents.

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

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

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

#### **SEC. 6. OUTREACH.**

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

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

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

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

### **PURPOSE AND SUMMARY**

The purpose of the Project BioShield Act of 2003 is to provide the Secretary of Health and Human Services with greater authority and flexibility to facilitate the research and development of biomedical countermeasures; to authorize the appropriation of funding for the procurement of security countermeasures through the creation of a special reserve fund; and to authorize the emergency use of unapproved drugs, devices, and biologics and the emergency unapproved use of approved drugs, devices, and biologics.

### **BACKGROUND AND NEED FOR LEGISLATION**

During times of national, military, or public health emergency, the American people may be placed at risk of exposure to biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents. Unfortunately, there are not approved or available countermeasures to treat many diseases or conditions that may be caused by such agents. Currently, companies have little incentive to research, develop, or produce vaccines or other drugs simply for a possible one-time purchase by the Federal government for the Strategic National Stockpile. Most current private

sector research and development dollars go for drugs or devices that will have continuous commercial application. In addition, some of the current generation of drugs or devices may have special uses as countermeasures to biological agents like Ebola, but there is little incentive to perform the research or development or production activities that might tailor the drug or drug approvals for such a purpose.

Even if a product has been developed to treat such diseases or conditions, if the product has not yet been approved by the Food and Drug Administration (FDA), access to the therapy is greatly limited. Nothing in the Food and Drug Act allows the Secretary to suspend the approval requirements to ensure access to unapproved drugs and devices on a large-scale basis in times of emergency.

Under present law, if a product is not approved by the FDA, then it is unlawful to provide that product to an individual, unless the product has been authorized for distribution under an investigational new drug (IND) application (for a drug and biologic) or an investigational device exemption (IDE). When a drug or device is available under such procedures, a number of conditions apply that make the use of an IND or IDE infeasible in times of national emergency, where drugs and devices may need to be deployed at rapid rates. Even if a drug, biologic, or device is highly promising in treating a disease or condition associated with biological, chemical, radiological, or nuclear agents, and even if it is the only therapy available, current FDA law does not allow for rapid deployment of the product.

The Project Bioshield Act is designed to help resolve these problems and make our nation more secure. Like the Public Health Security and Bioterrorism Preparedness and Response Act, the Project Bioshield Act is designed to help the administration and the nation in public health emergency preparedness, but relies on the ingenuity and hard work of Americans in the private and public sector to achieve these goals.

#### HEARINGS

The Subcommittee on Emergency Preparedness and Response held a joint hearing with the Subcommittee on Health of the Committee on Energy and Commerce on "Furthering Public Health Security: Project Bioshield" on March 27, 2003. The Subcommittee received testimony from: The Honorable Tommy Thompson, Secretary, U.S. Department of Health and Human Services; Mr. Leighton Read M.D., General Partner, Alloy Ventures, on behalf of Biotechnology Industry Organization; Mr. Michael Friedman M.D., Chief Medical Officer for Biomedical Preparedness, PhRMA; Mr. James Baker Jr., Ruth Dow Doan Professor, Center for Biological Nanotechnology; and, Mr. Gary Noble M.D., Vice President of Medical and Public Affairs, Johnson & Johnson, on behalf of AdvaMed.

The Full Committee held a hearing on "Bioshield: Countering the Bioterrorist Threat" on May 15, 2003. The Committee received testimony from: Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases; Dr. L. Garry Adams, Associate Dean for Research, Biodefense & Infectious Diseases, College of Veterinary Medicine, Texas A&M University; Dr. Clarence James Peters, Director for Biodefense, Center for Biodefense and Emerging Infectious Diseases, University of Texas Medical Branch; Dr. Ronald

Crystal, Professor and Chairman, Department of Genetic Medicine, Weill Medical College of Cornell University; William A. Haseltine, Ph.D., Chairman and Chief Executive Officer, Human Genome Sciences, Inc.; Alan Pemberton, Pharmaceutical Research and Manufacturers of America; Robert J. Sutcliffe, Director, President and Chief Executive Officer, Digital Gene Technologies, Inc.; and, Frank M. Rapoport, Partner, McKenna Long & Aldridge LLP.

The Subcommittee on Emergency Preparedness and Response and The Subcommittee on Intelligence and Counterterrorism held a joint hearing on “Does the Homeland Security Act of 2002 give the Department the Tools it Needs to Determine Which Bio-Warfare Threats are Most Serious?” on June 5, 2003. The Committee received testimony from: Paul J. Redmond, Assistant Secretary, Information Analysis, Department of Homeland Security; and, Eric Tolbert, Director of the Response Division, Emergency Preparedness and Response Directorate, Department of Homeland Security.

The Full Committee held a hearing on “Bioshield: Lessons from Current Efforts to Develop Bio-Warfare Countermeasures” on June 6, 2003. The Committee received testimony from: Dr. John Ring La Montagne, Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services; and, Dr. Ali Khan, Chief Science Officer, Parasitic Diseases, National Center for Infectious Diseases, Center for Disease Control and Prevention, Department of Health and Human Services.

#### COMMITTEE CONSIDERATION

On Thursday, June 27, 2003, the Full Committee met in open markup session and ordered H.R. 2122 reported to the House, as amended, by a record vote of 29 yeas and 0 nays.

#### COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto.

H.R. 2122, to enhance research, development, procurement, and use of biomedical countermeasures to respond to public health threats affecting national security, and for other purposes; was ordered favorably reported to the House, amended, by a recorded vote of 29 yeas and 0 nays (Roll Call Vote No. 4) as follows:

**SELECT COMMITTEE ON HOMELAND SECURITY**  
**U.S. House of Representatives**  
**108<sup>th</sup> Congress**

Date: June 26, 2003Convened: 10:07 a.m.Adjourned: 1:20 p.m.Meeting on : Markup of H.R. 2122. On ordering favorably reported to the House, amended.
 Attendance       Recorded Vote      Vote Number 4      Total: Yeas 29 Nays 0

	YEA	NAY	PRESENT		YEA	NAY	PRESENT
Ms. Dunn, Washington Vice Chair	✓			Mr. Turner, Texas Ranking Member	✓		
Mr. Bill Young, Florida				Mr. Thompson, Mississippi	✓		
Mr. Don Young, Alaska				Ms. Sanchez, California	✓		
Mr. Sensenbrenner, Wisconsin				Mr. Markey, Massachusetts	✓		
Mr. Tauzin, Louisiana				Mr. Dicks, Washington	✓		
Mr. Dreier, California				Mr. Frank, Massachusetts	✓		
Mr. Hunter, California	✓			Ms. Harman, California			
Mr. Rogers, Kentucky				Mr. Cardin, Maryland			
Mr. Boehlert, New York	✓			Ms. Slaughter, New York			
Mr. Smith, Texas				Mr. DeFazio, Oregon			
Mr. Weldon, Pennsylvania				Ms. Lowey, New York	✓		
Mr. Shays, Connecticut	✓			Mr. Andrews, New Jersey	✓		
Mr. Goss, Florida				Ms. Norton, District of Columbia			
Mr. Camp, Michigan	✓			Ms. Lofgren, California	✓		
Mr. Diaz-Balart, Florida	✓			Ms. McCarthy, Missouri	✓		
Mr. Goodlatte, Virginia				Ms. Jackson-Lee, Texas	✓		
Mr. Istook, Oklahoma	✓			Mr. Pascrell, North Carolina	✓		
Mr. King, New York	✓			Ms. Christensen, U.S.V.I.	✓		
Mr. Linder, Georgia				Mr. Etheridge, North Carolina	✓		
Mr. Shadegg, Arizona	✓			Mr. Gonzalez, Texas			
Mr. Souder, Indiana	✓			Mr. Lucas, Kentucky			
Mr. Thornberry, Texas				Mr. Langevin, Rhode Island	✓		
Mr. Gibbons, Nevada	✓			Mr. Meeke, Florida	✓		
Ms. Granger, Texas							
Mr. Sessions, Texas							
Mr. Sweeney, New York	✓			Mr. Cox, California, Chairman	✓		
				<b>Total</b>	29	0	

The following amendments were offered:

An Amendment in the Nature of a Substitute offered by Mr. Cox (#1), was AGREED TO by voice vote, as amended.

An amendment offered by Mr. Hunter to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1A), Page 17, beginning on line 23, strike "Homeland Security Secretary" and insert "Homeland Security Secretary, Secretary of Defense and Secretary of State." was AGREED TO by a recorded vote of 25 yeas and 0 nays (Roll Call Vote No. 1) as follows:

**SELECT COMMITTEE ON HOMELAND SECURITY**  
**U.S. House of Representatives**  
**108<sup>th</sup> Congress**

Date: June 26, 2003Convened: 10:07 a.m.Adjourned: 1:20 p.m.Meeting on : Markup of H.R. 2122. Amendment #1A offered by Mr. Hunter.
 Attendance       Recorded Vote      Vote Number 1      Total: Yeas 25 Nays 0

	YEA	NAY	PRESENT		YEA	NAY	PRESENT
Ms. Dunn, Washington Vice Chair	✓			Mr. Turner, Texas Ranking Member	✓		
Mr. Bill Young, Florida				Mr. Thompson, Mississippi			
Mr. Don Young, Alaska				Ms. Sanchez, California	✓		
Mr. Sensenbrenner, Wisconsin				Mr. Markey, Massachusetts			
Mr. Tauzin, Louisiana	✓			Mr. Dicks, Washington			
Mr. Dreier, California				Mr. Frank, Massachusetts			
Mr. Hunter, California	✓			Ms. Harman, California			
Mr. Rogers, Kentucky				Mr. Cardin, Maryland	✓		
Mr. Boehlert, New York	✓			Ms. Slaughter, New York	✓		
Mr. Smith, Texas				Mr. DeFazio, Oregon	✓		
Mr. Weldon, Pennsylvania	✓			Ms. Lowey, New York			
Mr. Shays, Connecticut	✓			Mr. Andrews, New Jersey	✓		
Mr. Goss, Florida				Ms. Norton, District of Columbia			
Mr. Camp, Michigan	✓			Ms. Lofgren, California	✓		
Mr. Diaz-Balart, Florida	✓			Ms. McCarthy, Missouri	✓		
Mr. Goodlatte, Virginia				Ms. Jackson-Lee, Texas			
Mr. Istook, Oklahoma				Mr. Pascrell, North Carolina	✓		
Mr. King, New York	✓			Ms. Christensen, U.S.V.I.	✓		
Mr. Linder, Georgia				Mr. Etheridge, North Carolina	✓		
Mr. Shadegg, Arizona	✓			Mr. Gonzalez, Texas			
Mr. Souder, Indiana				Mr. Lucas, Kentucky	✓		
Mr. Thornberry, Texas				Mr. Langevin, Rhode Island	✓		
Mr. Gibbons, Nevada	✓			Mr. Meek, Florida			
Ms. Granger, Texas							
Mr. Sessions, Texas							
Mr. Sweeney, New York				Mr. Cox, California, Chairman	✓		
				<b>Total</b>	25	0	

An amendment offered by Mr. Hunter to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1B), Page 52, line 24, insert a new section entitled "Ensuring coordination, cooperation and the elimination of unnecessary duplication in programs designed to protect the homeland from biological, chemical, radiological, and nuclear agents" was AGREED TO by voice vote.

An amendment offered by Mr. DeFazio to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1C), to insert a new subsection entitled "Status of Program for Chemical Terrorism Preparedness" was AGREED TO by voice vote.

An amendment offered by Ms. Slaughter to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1D), to insert a new section entitled "Expatriate Corporations" was NOT AGREED TO by a recorded vote of 17 yeas and 18 nays (Roll Call Vote No. 2) as follows:

**SELECT COMMITTEE ON HOMELAND SECURITY**  
**U.S. House of Representatives**  
**108<sup>th</sup> Congress**

Date: June 26, 2003Convened: 10:07 a.m.Adjourned: 1:20 p.m.Meeting on : Markup of H.R. 2122. Amendment #1D offered by Ms. Slaughter.
 Attendance       Recorded Vote      Vote Number 2      Total: Yeas 17 Nays 18

	YEA	NAY	PRESENT		YEA	NAY	PRESENT
Ms. Dunn, Washington Vice Chair		✓		Mr. Turner, Texas Ranking Member	✓		
Mr. Bill Young, Florida				Mr. Thompson, Mississippi			
Mr. Don Young, Alaska		✓		Ms. Sanchez, California			
Mr. Sensenbrenner, Wisconsin				Mr. Markey, Massachusetts	✓		
Mr. Tauzin, Louisiana		✓		Mr. Dicks, Washington			
Mr. Dreier, California				Mr. Frank, Massachusetts	✓		
Mr. Hunter, California		✓		Ms. Harman, California	✓		
Mr. Rogers, Kentucky				Mr. Cardin, Maryland			
Mr. Boehlert, New York				Ms. Slaughter, New York	✓		
Mr. Smith, Texas		✓		Mr. DeFazio, Oregon	✓		
Mr. Weldon, Pennsylvania		✓		Ms. Lowey, New York	✓		
Mr. Shays, Connecticut		✓		Mr. Andrews, New Jersey	✓		
Mr. Goss, Florida				Ms. Norton, District of Columbia			
Mr. Camp, Michigan		✓		Ms. Lofgren, California	✓		
Mr. Diaz-Balart, Florida		✓		Ms. McCarthy, Missouri	✓		
Mr. Goodlatte, Virginia				Ms. Jackson-Lee, Texas	✓		
Mr. Istook, Oklahoma		✓		Mr. Pascarell, North Carolina	✓		
Mr. King, New York		✓		Ms. Christensen, U.S.V.I.	✓		
Mr. Linder, Georgia				Mr. Etheridge, North Carolina	✓		
Mr. Shadegg, Arizona		✓		Mr. Gonzalez, Texas	✓		
Mr. Souder, Indiana		✓		Mr. Lucas, Kentucky	✓		
Mr. Thornberry, Texas				Mr. Langevin, Rhode Island	✓		
Mr. Gibbons, Nevada		✓		Mr. Meeke, Florida			
Ms. Granger, Texas		✓					
Mr. Sessions, Texas		✓					
Mr. Sweeney, New York		✓		Mr. Cox, California, Chairman		✓	
				<b>Total</b>	17	18	



An amendment offered by Mr. Markey to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1E), Page 37, line 9, add the following: "If an authorization under the preceding sentence for a product is revoked under subsection (g), or if the declaration of an emergency under subsection (b) ceases to be in effect, the product may not be introduced into interstate commerce except in accordance with section 505, 510(k), or 515, or section 351 of the Public Health Service Act, as applicable." was WITHDRAWN.

An amendment offered by Ms. Jackson-Lee to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1F), to insert a new section at the end of the bill entitled "Sec. 6. Inclusion of Certain Populations in Research, Development, and Procurement Projects." was WITHDRAWN.

An amendment offered by Mr. Tauzin to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1G), Page 28, strike line 16 and all that follows through page 29, line 19 was NOT AGREED TO by a recorded vote of 19 yeas and 19 nays (Roll Call Vote No. 3). As follows:

**SELECT COMMITTEE ON HOMELAND SECURITY**  
**U.S. House of Representatives**  
**108<sup>th</sup> Congress**

Date: June 26, 2003Convened: 10:07 a.m.Adjourned: 1:20 p.m.Meeting on : Markup of H.R. 2122. Amendment #1G offered by Mr. Tauzin.
 Attendance       Recorded Vote      Vote Number 3      Total: Yeas 19 Nays 19

	YEA	NAY	PRESENT		YEA	NAY	PRESENT
Ms. Dunn, Washington Vice Chair	✓			Mr. Turner, Texas Ranking Member		✓	
Mr. Bill Young, Florida				Mr. Thompson, Mississippi		✓	
Mr. Don Young, Alaska	✓			Ms. Sanchez, California		✓	
Mr. Sensenbrenner, Wisconsin				Mr. Markey, Massachusetts			
Mr. Tauzin, Louisiana	✓			Mr. Dicks, Washington		✓	
Mr. Dreier, California				Mr. Frank, Massachusetts		✓	
Mr. Hunter, California	✓			Ms. Harman, California		✓	
Mr. Rogers, Kentucky				Mr. Cardin, Maryland			
Mr. Boehlert, New York				Ms. Slaughter, New York			
Mr. Smith, Texas	✓			Mr. DeFazio, Oregon		✓	
Mr. Weldon, Pennsylvania	✓			Ms. Lowey, New York		✓	
Mr. Shays, Connecticut	✓			Mr. Andrews, New Jersey		✓	
Mr. Goss, Florida	✓			Ms. Norton, District of Columbia			
Mr. Camp, Michigan	✓			Ms. Lofgren, California		✓	
Mr. Diaz-Balart, Florida	✓			Ms. McCarthy, Missouri		✓	
Mr. Goodlatte, Virginia	✓			Ms. Jackson-Lee, Texas		✓	
Mr. Istook, Oklahoma	✓			Mr. Pascrell, North Carolina		✓	
Mr. King, New York	✓			Ms. Christensen, U.S.V.I.		✓	
Mr. Linder, Georgia	✓			Mr. Etheridge, North Carolina		✓	
Mr. Shadegg, Arizona				Mr. Gonzalez, Texas		✓	
Mr. Souder, Indiana	✓			Mr. Lucas, Kentucky			
Mr. Thornberry, Texas				Mr. Langevin, Rhode Island		✓	
Mr. Gibbons, Nevada	✓			Mr. Meeke, Florida		✓	
Ms. Granger, Texas	✓						
Mr. Sessions, Texas	✓						
Mr. Sweeney, New York	✓			Mr. Cox, California, Chairman		✓	
				<b>Total</b>	19	19	

An amendment offered by Mr. Andrews to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1H), on page 16, line 4 of the Cox-Turner Substitute amendment: add the following: “notwithstanding the preceding provisions of this subclause, nothing in this section shall alter the rights of the parties afforded by the Federal Acquisition Regulation or other applicable laws or regulations regarding a termination for the convenience of the government.” was WITHDRAWN.

An amendment offered by Ms. Jackson-Lee to the Amendment in the Nature of a Substitute offered by Mr. Cox (#1I), to insert at the end of the substitute the following section: “Sec. 6. Outreach.” was AGREED TO by voice vote.

#### COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has held oversight hearings and made findings that are reflected in this report.

#### STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of the Project BioShield Act of 2003 is to provide the Secretary of Health and Human Services and the Secretary of Homeland Security greater authority and flexibility to facilitate the research, development, and procurement of biomedical countermeasures.

#### NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2122, the Project Bioshield Act of 2003, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

#### CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, a cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not made available to the Committee in time for the filing of this report. The Chairman of the Committee shall cause such estimate to be printed in the *Congressional Record* upon its receipt by the Committee.

#### FEDERAL MANDATES STATEMENT

An estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act was not made available to the Committee in time for the filing of this report. The Chairman of the Committee shall cause such estimate to be printed in the *Congressional Record* upon its receipt by the Committee.

#### ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

### CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 1, which grants Congress the power to provide for the common Defense of the United States.

### APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

### SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

#### *Section 1. Short title*

Section 1 establishes the short title of the Act as the “Project BioShield Act of 2003.”

#### *Section 2. Biomedical countermeasure research and development authorities*

Section 2(a) of the Project BioShield Act of 2003 amends the Public Health Service Act to add a new section 319F–1. The section grants the Secretary of the Department of Health and Human Services (HHS) additional flexibility and authority in conducting research and development with respect to biomedical countermeasures against biological, chemical, nuclear and radiological agents that may affect national security.

New subsection 319F–1(a) provides general authority. Proposed subparagraph 319F–1(a)(4) makes the facilities of entities that enter into a grant or cooperative agreement with the Secretary of HHS under this section available as needed to such Secretary of HHS to respond to public health emergencies affecting national security.

New subsection 319F–1(b) provides expedited authority for governmental procurements used to perform, administer, or support pressing research and development activities under this section, by (1) increasing the simplified acquisition threshold from \$100,000 to \$25 million; (2) authorizing the use of procedures providing for less than full and open competition when there are only a limited number of responsible sources and no other type of services will satisfy the Secretary of HHS needs; and (3) increasing the micropurchase threshold for such procurements to \$15,000.

New subsection 319F–1(c) authorizes the Secretary of HHS to use expedited peer-review procedures in lieu of otherwise applicable peer-review procedures in the case of grants and contracts for biomedical countermeasure research and development activity, if such grants and contracts do not exceed \$1,500,000 and are necessary to respond to pressing research needs.

New subsection 319F–1(d) provides additional flexibility to the Secretary of HHS with respect to the hiring of experts and consultants when necessary to respond to pressing qualified countermeasure research and development needs. Under paragraph 319F–1(d)(2), such experts and consultants are deemed to be employees

of HHS for purposes of the Federal Torts Claims Act, which provides the exclusive remedy against such personnel for claims relating to the performance of covered duties.

New subsection 319F-1(e) provides streamlined personnel authority for the Secretary of HHS to appoint up to 30 people to positions in the National Institutes of Health without regard to ordinary classification criteria, when necessary to respond to pressing qualified countermeasure research and development needs.

New subsection 319F-1(f) provides that actions by the Secretary of HHS under the section are committed to agency discretion.

Section 2(b) of the Project BioShield Act of 2003 amends section 481A of the Public Health Service Act to add the Director of the National Institute of Allergy and Infectious Diseases to that section, and thus provide to that Director certain authorities concerning modernization and construction of research facilities. Section 2(b) further authorizes such sums as may be necessary for such purposes.

### *Section 3. Biomedical countermeasures procurement*

Section 3(a) of the Project BioShield Act of 2003 adds a new section 319F-2 to the Public Health Service Act. Several provisions of new section 319F-2 simply transfer existing provisions of law from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as amended by the Homeland Security Act of 2002. Proposed Subsection 319F-2(a) contains language from existing law establishing the Strategic National Stockpile. New section 319F-2(b) contains language from existing law concerning authorizing procurement of smallpox vaccine for the National Strategic Stockpile.

New section 319F-2(c) requires the Secretary of the Department of Homeland Security (DHS) to assess threats that may be posed by chemical, biological, radiological, and nuclear agents, and requires the HHS Secretary to assess the public health consequences of such agents and the availability and appropriateness of countermeasures for the threats identified. After these steps, the Secretaries jointly may determine and recommend to the President that funding for procurement of such a countermeasure for the nation's stockpile is appropriate from the special reserve fund established by this Act.

Under section 319F-2(c)(4), the Secretaries of HHS and DHS may recommend to the President a proposal to issue a call for the development of countermeasures. Such a call includes a commitment from the Secretaries to make a recommendation for funding procurement of such a countermeasure from the special reserve fund, if government specifications for the product are achieved. The Secretaries also may secure a Presidential approval for funding prior to, or without, conducting a call.

New section 319F-2(c)(4)(B) provides that the Secretaries should include in any call for proposals for countermeasure production information that may be necessary to encourage or facilitate research and development into such countermeasures. The Committee recognizes that an important factor companies will consider in determining whether to invest scarce research and development dollars into security countermeasures is whether and to what extent they may face liability relating to the development or production of such

countermeasures. The Committee thus encourages the Secretaries to indicate in any call for proposals the potential availability of indemnification or liability protections under other laws. The Secretary of Homeland Security is further encouraged to designate such countermeasures as “qualified anti-terrorism technologies” as defined in section 862 of the Homeland Security Act.

Under section 319F–2(c)(7), if the President approves a recommendation for funding from the special reserve fund, DHS would then enter into an agreement with HHS under which HHS may procure the countermeasure for the stockpile using the DHS special reserve fund. Contracts under this paragraph are subject to certain conditions, including the condition that payment shall only be made upon “substantial delivery,” unless the Secretary of HHS determines an advance of up to 10 percent of the contract amount is necessary to ensure success of the project. This provision does not alter the rights of contracting parties under the Federal Acquisition Regulation or other applicable laws or regulations regarding a termination for the convenience of the government. The Secretary of HHS is authorized to include contract provisions limiting or forbidding non-stockpile sales of a security countermeasure. The Secretary is strongly encouraged to include such provisions when it is necessary or desirable in order to protect United States national security interests with respect to the transfer of highly specialized countermeasures or enabling intellectual property, and particularly to guard against the transfer of such countermeasures or intellectual property to specific foreign entities when the Secretary, in consultation with the Secretaries of the Departments of Homeland Security, State, and Defense, believes that the transfer would have undesirable national security implications or pose an unacceptable risk to the national security.

Section 319F–2(d) contains prohibitions on disclosure of information transferred from existing law. Section 319F–2(e) contains definitions transferred from existing law.

Section 319F–2(f) contains authorization of appropriations for the Strategic National Stockpile and smallpox vaccine development transferred from existing law with one addition. The new paragraph makes clear that such existing authorizations are in addition to amounts authorized under the special reserve fund. Nothing in the Act would restrict or alter the Secretaries’ existing authority to purchase items for the stockpile using existing discretionary appropriations for such purpose.

Section 3(b) of the Project BioShield Act of 2003 adds a new section 510 to the Homeland Security Act of 2002. This new section authorizes appropriations for the special reserve fund referenced in the new section 319F–2(c) of the Public Health Service Act. The bill authorizes \$890 million in FY 04 for such procurements, and aggregate amounts of \$3.4 billion and \$5.6 billion over the next five and ten fiscal years respectively. All amounts appropriated under this authorization would be available for obligation through the end of FY 2013.

The new section 510 of the Homeland Security Act also authorizes \$5 million in FY 04 for the hiring of professional biological, chemical, radiological, and nuclear threat analysts at DHS, and such sums as are necessary to construct secure facilities for the receipt of classified information necessary to allow the Secretary of

DHS to carry out his threat assessment responsibilities under this Act. The Committee expects that the Secretary of DHS will receive the full cooperation of other agencies in the federal government in getting up-to-date intelligence and other information, as required by the Homeland Security Act.

Subsection 510(e) allows the Secretaries of DHS and HHS to use the special reserve fund to produce security countermeasures directly, if they jointly determine, and the President approves, that procurement is not proceeding rapidly enough.

The Act defines the scope of the new authorities set forth in this section as applying to countermeasures against agents that the Secretary of DHS believes present “a material threat against the United States population” and about which the HHS and DHS Secretaries make certain additional findings. The Committee expects that both Secretaries will consider the threat of use of such agents by terrorists against the U.S. population to be a significant factor in making their respective scope determinations under these provisions. However, the Committee also recognizes and encourages the Secretaries to consider the emerging threats to public health and national security that may be caused by the spread of antibiotic resistant organisms or dangerous viruses that may spread rapidly and lack effective countermeasures today. These threats may affect national security whether by terrorists or through natural conditions. The Secretaries should consider such factors in determining whether to use these new authorities to promote research, development, and production of security countermeasures, such as broad-spectrum antibiotics, that could be useful against a range of potential threat agents.

*Section 4. Authorization for medical products for use in emergencies*

Section 4 adds a new section 564 to the Federal Food, Drug, and Cosmetic Act. New section 564(a) allows the Secretary of Health and Human Services to authorize for introduction into interstate commerce unapproved drugs, devices, and biological products or unapproved uses of approved drugs, approved/cleared devices, and biological products intended for use in an actual or potential emergency during the effective period of a declaration.

New section 564(b) allows the Secretary of HHS to declare an emergency justifying an emergency use authorization based upon a determination by the Secretary of Homeland Security that there is a national emergency or the significant potential of one, or by a determination of the Secretary of Defense that there is a military emergency, or a significant potential of one. Such emergencies must involve a heightened risk of attack with biological, chemical, radiological, or nuclear agents. Similarly, an emergency use authorization can be based upon a determination of the Secretary of HHS that there is a public health emergency affecting national security and involving biological, chemical, radiological, or nuclear agents. In making a determination about whether a public health emergency under section 319 of the Public Health Service Act affects national security, the Secretary may consider all information he deems pertinent and appropriate, and nothing in this Act requires that the Secretary consult with other executive branch officials prior to making such a determination.

Under this section, any declaration of emergency will last for one year, unless the Secretary of HHS terminates it at an earlier time. The Secretary of HHS may renew a declaration. The Secretary of HHS must publish all declarations, determinations, and renewals in the Federal Register, and the Secretary must provide reasonable advanced notice that declarations are to be terminated under this section. The Committee intends that, after a declaration is terminated, final disposition of labeling or intrastate disposition of a product may occur. Further, the Committee believes that the Commissioner of the Food and Drug Administration (Commissioner) may exercise enforcement discretion not to object to interstate shipment of an unapproved product for return to a manufacturer. A determination of what is a “reasonable” period for advanced notice of termination should consider all factors, so in some cases notice immediately preceding termination may be reasonable, while in other circumstances it may not.

Section 564(c) details the criteria for issuance of an emergency use authorization. Under this new section, the Secretary of HHS, acting through the Commissioner, may issue an authorization upon concluding (1) that a biological, chemical, radiological, or nuclear agent or agents can cause a serious or life-threatening disease or condition; (2) that the drug, device or biological product may be effective in detecting, diagnosing, treating, or preventing such disease or condition (or a serious disease or condition caused by taking a product already approved, licensed or cleared by FDA for treating or preventing such disease or condition), and the benefits of the product outweigh risks; (3) that there is no adequate, approved, and available alternative to the product; and, (4) other criteria the Secretary may by regulation specify. The Commissioner should consult with the Directors of the National Institutes of Health and the Centers for Disease Control and Prevention prior to issuing an authorization, but such consultation is limited by considerations of feasibility and appropriateness given the circumstances of the emergency.

Section 564(d) concerns the scope of an emergency use authorization. Under this section, the authorization shall state the disease or condition that the product may be used to detect, diagnose, prevent, or treat, as well as the Commissioner’s conclusions about known benefits and risks of the product and conclusions concerning safety and potential effectiveness. The Committee intends that before issuing an authorization under this section, the Commissioner will, where feasible given the nature and the extent of the emergency, notify the holder of any relevant application under this chapter or under section 351 of the Public Health Service Act. The purpose of such notification is to allow for discussion of the conditions of this authorization as required by subsection (e), as well as discussion of whether such product should be delivered pursuant to section 319F–2(c) of the Public Health Service Act.

Section 564(e) pertains to products that have never been approved, licensed, or cleared by FDA. Under this subsection, conditions shall, to the extent feasible given the circumstances of the emergency, be applied to persons who choose to carry out an activity for which the authorization is issued. Such mandatory conditions include information to providers about the emergency use of the product as well as significant known potential risks and bene-



fits, as well as appropriate conditions designed to ensure that to the maximum extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed of the emergency use of the product, risks and benefits of the product, and of the option to accept or refuse the product. Further, the Commissioner is given the authority to impose other conditions on those who carry out activities for which the authorization is issued. Such conditions imposed by the Commissioner should be designed to provide maximum flexibility to ensure that those who wish to take the product can indeed take the product, if made available by the manufacturer.

Section 564(e) also applies to unapproved uses of approved products and the Commissioner may, for manufacturers who choose to carry out one or more activities pursuant to an emergency use authorization, apply certain conditions. This subsection makes clear that manufacturers do not have to avail themselves of the emergency use authorization for unapproved uses of approved products, and it makes clear that no individual may alter or obscure the labeling of already approved products. It does authorize, however, persons other than the manufacturer to provide information about the product concerning the emergency use of the product.

Under section 564(e), the Commissioner may establish conditions regarding product labeling and information conveyance concerning unapproved products. Further, the Committee intends that the Commissioner may establish conditions regarding product labeling and information conveyance on manufacturers that carry out one or more activities pursuant to an emergency use authorization with respect to the emergency use of that product that is an unapproved use of an approved product.

Subsection (f) makes clear that an emergency use authorization is effective until the declaration is terminated or revoked, but allows patients to continue using such products in certain instances. Nothing in this subsection is intended to require manufacturers or others to provide such products to patients.

Subsection (g) makes clear that the Commissioner shall periodically review the appropriateness of an authorization, and it provides the Commissioner needed flexibility to revoke an authorization if the criteria justifying the authorization are no longer met.

Subsection (h) ensures that the Commissioner shall promptly publish in the Federal Register notices of all authorizations, terminations, and revocations. Subsection (i) makes clear that all determinations under this new section are committed to agency discretion. Subsection (j) is a rule of construction noting that this new section does not impair or otherwise affect certain existing authorities.

New section 564(k) pertains to members of the Armed Forces and, among other things, it specifies that the President may waive requirements designed to ensure that such members are informed of the option to accept or refuse administration of an emergency use product, upon certain findings (which are identical to the findings found in section 1107 of Title 10). Further, the subsection requires that if certain information is not provided to members of the Armed Forces prior to an emergency use product being administered to them, then information concerning the administration of the product shall be placed in the medical record of the member.

Subsection (l) makes clear that if a product is authorized for emergency use under this new section, the investigational sections of the Act shall not apply to the products.

Subsection (m) ensures that no authority in new section 564 can require a manufacturer of a drug, device, or biological product to perform any activity that becomes lawful pursuant to the new section. That is, the Commissioner in no way is given the authority to, among other things, require a manufacturer to introduce into interstate commerce or deliver for introduction into interstate commerce any unapproved product or an approved product for an unapproved use under this section. Further, even if the Commissioner authorizes the emergency use of an already-approved, licensed or cleared product, a manufacturer can refuse to avail themselves of such emergency use authorization and continue introducing into interstate commerce its approved or cleared product under the Federal Food, Drug and Cosmetic Act, or licensed product pursuant to the Public Health Service Act. The only obligation in subsection (m) is that if the Commissioner authorizes the emergency use of a sole-source unapproved product, then the manufacturer of such product must inform the Commissioner of its intention not to carry out any activity under the authorization within a reasonable period of time. Nothing in this section shall be construed as authorizing the Commissioner to establish conditions on the distribution, administration, or labeling of any other product in any other circumstance.

Subsection (n) ensures that the present enforcement regime of the Federal Food, Drug, and Cosmetic Act will apply to individuals who carry out an activity or activities pursuant to an authorization, but fail to comply with applicable conditions. If any person carries out an activity pursuant to section 564, but violates a condition imposed by the Commissioner, then that person will be subject to Chapter III of the Act, where the “prohibited acts” are found. If a person is found to be in violation of a prohibited act found in section 301, then the Committee intends for that person to be subject to the enforcement provisions found in sections 302, 303, and 304. A violation of any condition applied to an emergency use product in no way alters or affects the emergency use status of the underlying product.

#### *Section 5. Reports*

Section 5(a) requires the Secretary of HHS to submit annual reports to Congress concerning the exercise of many of the new authorities under the Act. Section 5(b) requires a report from the National Academy of Sciences concerning whether and to what extent the research authorities granted under the Act have enhanced the development of biomedical countermeasures affecting national security. Section 5(c) requires the General Accounting Office to issue a report concerning the Secretary of HHS utilization of these new authorities. Section 5(d) requires the Secretaries of HHS and DHS to report any additional barriers to procurement of security countermeasures which have not been addressed by Bioshield. The Secretaries should include in this report information as to whether there is a shortage of adequate biocontainment facilities or other resources for carrying out necessary research and development and testing. Section 5(e) requires the Secretary of DHS to report on the status of chemical preparedness.

*Section 6. Ensuring coordination, cooperation and the elimination of unnecessary duplication in programs designed to protect the homeland from biological, chemical, radiological, and nuclear agents*

Section 6 requires the Secretaries of the HHS, DHS, and DOD to coordinate their efforts to identify and develop countermeasures to biological, chemical, radiological, and nuclear threats. These Departments are instructed to designate agency coordination officers for this purpose.

*Section 7. Outreach*

Section 7 instructs the Secretary of HHS to ensure that, to the extent practicable, Historically Black Colleges and Universities and other minority research institutions are made aware of research and development grants and procurements under Bioshield.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

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

**PUBLIC HEALTH SERVICE ACT**

\* \* \* \* \*

**TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE**

\* \* \* \* \*

**PART B—FEDERAL-STATE COOPERATION**

\* \* \* \* \*

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

(a) *IN GENERAL.*—

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

(2) *QUALIFIED COUNTERMEASURE.*—*For purposes of this section, the term “qualified countermeasure” means a priority countermeasure (as defined in section 319F(h)) that affects national security.*

(3) *INTERAGENCY COOPERATION.*—

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

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

(4) *AVAILABILITY OF FACILITIES TO THE SECRETARY.*—In any grant or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, and supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

(b) *EXPEDITED PROCUREMENT AUTHORITY.*—

(1) *INCREASED SIMPLIFIED ACQUISITION THRESHOLD FOR BIOMEDICAL COUNTERMEASURE PROCUREMENTS.*—

(A) *IN GENERAL.*—For any procurement by the Secretary of property or services for use (as determined by the Secretary) in performing, administering, or supporting qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, the amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), as applicable pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), shall be deemed to be \$25,000,000 in the administration, with respect to such procurement, of—

(i) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

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

(B) *APPLICATION OF CERTAIN PROVISIONS.*—Notwithstanding subparagraph (A) and the provision of law and regulations referred to in such subparagraph, each of the following provisions shall apply to procurements described in this paragraph to the same extent that such provisions would apply to such procurements in the absence of subparagraph (A):

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

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

(iii) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the — examination of contractor records).

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

(2) *USE OF NONCOMPETITIVE PROCEDURES.*—In addition to any other authority to use procedures other than competitive

procedures, the Secretary may use such other procedures when—

- (A) the procurement is as described by paragraph (1); and
  - (B) the property or services needed by the Secretary are available from only one responsible source or only from a limited number of responsible sources, and no other type of property or services will satisfy the Secretary's needs.
- (3) INCREASED MICROPURCHASE THRESHOLD.—
- (A) IN GENERAL.—For a procurement described by paragraph (1), the amount specified in subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to be \$15,000 in the administration of that section with respect to such procurement.
  - (B) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for purchases that are under this paragraph and that are greater than \$2,500.
  - (C) EXCEPTION TO PREFERENCE FOR PURCHASE CARD MECHANISM.—No provision of law establishing a preference for using a Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than \$2,500.
- (c) AUTHORITY TO EXPEDITE PEER REVIEW.—
- (1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as applicable to a grant, contract, or cooperative agreement—
    - (A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and
    - (B) the amount of which is not greater than \$1,500,000.
  - (2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary's determination of whether to employ expedited peer review with respect to subsequent phases of a research grant or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant or cooperative agreement.
- (d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—
- (1) IN GENERAL.—For the purpose of performing, administering, and supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5, United States Code, but without regard to the limitations in

*such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.*

**(2) FEDERAL TORT CLAIMS ACT COVERAGE.—**

*(A) IN GENERAL.—A person carrying out a contract under paragraph (1), and an officer, employee, or governing board member of such person, shall be deemed to be an employee of the Department of Health and Human Services for purposes of claims under sections 1346(b) and 2672 of title 28, United States Code, for money damages for personal injury, including death, resulting from performance of functions under such contract.*

*(B) EXCLUSIVITY OF REMEDY.—The remedy provided by subparagraph (A) shall be exclusive of any other civil action or proceeding by reason of the same subject matter against the person, officer, employee, or governing board member.*

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

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

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

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

**(e) STREAMLINED PERSONNEL AUTHORITY.—**

*(1) IN GENERAL.—In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, without regard to such provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, not to exceed 30 such employees at any time, to positions in the National Institutes of Health to perform, administer, or support qualified countermeasure research and development activities in carrying out this section.*

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

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

**SEC. 319F-2. STRATEGIC NATIONAL STOCKPILE.**

(a) *STRATEGIC NATIONAL STOCKPILE.*—

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

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

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

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

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

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

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

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

(b) *SMALLPOX VACCINE DEVELOPMENT.*—

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

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

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

(1) *IN GENERAL.*—

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

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

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

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

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

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

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

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

(2) *DETERMINATION OF MATERIAL THREATS.*—

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

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

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

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

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

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

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



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

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

(4) *CALL FOR DEVELOPMENT OF COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.*—

(A) *PROPOSAL TO THE PRESIDENT.*—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently unavailable for procurement or available under unsuitable conditions, such Secretaries may jointly submit to the President a proposal to—

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

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

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

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

(ii) necessary measures of minimum safety and effectiveness;

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

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

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

(i) the call for the countermeasure;

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

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

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

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

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

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

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

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

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

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

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

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

(D) *SUBSEQUENT SPECIFIC COUNTERMEASURES.*—*Procurement under this subsection of a security countermeasure for*

a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

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

(7) *PROCUREMENT.*—

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

(B) *INTERAGENCY AGREEMENTS.*—

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

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

(C) *PROCUREMENT.*—

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

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, in accordance with the provisions of this subparagraph; and

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

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

(I) *PAYMENT CONDITIONED ON SUBSTANTIAL DELIVERY.*—The contract shall provide that no pay-

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

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

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

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

(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

(I) *IN GENERAL.*—The amount of any procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

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

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

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

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

(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the examination of contractor records).

(iv) *USE OF NONCOMPETITIVE PROCEDURES.*—In addition to any other authority to use procedures other than competitive procedures, the Secretary may use such other procedures for a procurement under this subsection if the product is available from only one responsible source or only from a limited number of responsible sources, and no other type of product will satisfy the Secretary's needs.

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

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

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

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment

identified under item (aa), in accordance with the terms and conditions of the contract.

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

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

(vii) *LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.*—In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that the Secretary may so exclude such a source.

(8) *INTERAGENCY COOPERATION.*—

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

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

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

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

(B) administrative costs.

(10) *DEFINITIONS.*—

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

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

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

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

(d) *DISCLOSURES.—No Federal agency shall disclose under section 552 of title 5, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.*

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

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

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

(f) *AUTHORIZATION OF APPROPRIATIONS.—*

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

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

\* \* \* \* \*

TITLE IV—NATIONAL RESEARCH INSTITUTES

\* \* \* \* \*

PART E—OTHER AGENCIES OF NIH

\* \* \* \* \*

SEC. 481A. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

(a) *MODERNIZATION AND CONSTRUCTION OF FACILITIES.—*

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

\* \* \* \* \*

(c) *REQUIREMENTS FOR GRANTS.—*

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

*(A) \* \* \**

\* \* \* \* \*

*(2) INSTITUTIONS OF EMERGING EXCELLENCE.—From the amount appropriated under [subsection (i)] subsection (i)(1) for*

a fiscal year up to \$50,000,000, the Director of the Center shall make available 25 percent of such amount, and from the amount appropriated under such subsection for a fiscal year that is over \$50,000,000, the Director of the Center shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) \* \* \*

\* \* \* \* \*

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

(e) AMOUNT OF GRANT; PAYMENTS.—

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

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

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

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

\* \* \* \* \*

(4) WAIVER OF LIMITATIONS.—The limitations imposed under paragraph (1) may be waived at the discretion of the Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases for applicants meeting the conditions described in subsection (c).

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

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



(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so), the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

\* \* \* \* \*

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

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

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

## SECTION 510 OF THE HOMELAND SECURITY ACT OF 2002

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

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

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

(c) AVAILABILITY.—

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

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

(d) *RELATED AUTHORIZATIONS OF APPROPRIATIONS.*—

(1) *THREAT ASSESSMENT CAPABILITIES.*—For the purpose of carrying out the responsibilities of the Secretary for terror threat assessment under the security countermeasures program, there are authorized to be appropriated \$5,000,000 for fiscal year 2004, and such sums as may be necessary for each of the fiscal years 2005 and 2006, for the hiring of professional personnel within the Directorate for Information Analysis and Infrastructure Protection, who shall be analysts responsible for chemical, biological, radiological, and nuclear threat assessment (including but not limited to analysis of chemical, biological, radiological, and nuclear agents, the means by which such agents could be weaponized or used in a terrorist attack, and the capabilities, plans, and intentions of terrorists and other non-state actors who may have or acquire such agents). All such analysts shall meet the applicable standards and qualifications for the performance of intelligence activities promulgated by the Director of Central Intelligence pursuant to section 104 of the National Security Act of 1947.

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

(e) *EMERGENCY DEVELOPMENT OF SECURITY COUNTERMEASURES.*—If the Secretary of Homeland Security and the Secretary of Health and Human Services jointly determine that procurement of a security countermeasure that has been approved for procurement using the special reserve fund under subsection (a)—

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

(2) could be produced significantly less expensively by the government directly than through procurements under such section;

then amounts in the special reserve fund may be used by the Secretary of Health and Human Services to produce security countermeasures for placement in the stockpile under subsection (a) of section 319F–2 of such Act if the joint determination is submitted to the President and the President approves such use of the special reserve fund. Amounts made available for such use in accordance with the preceding sentence are available for obligation as of the date on which the presidential approval is made, subject to applicable law regarding the apportionment of appropriations. This sub-

*section applies notwithstanding other provisions of this section, and notwithstanding section 319F-2 of the Public Health Service Act. This subsection may not be construed as affecting the amounts specified in subsection (a) as authorizations of appropriations or the obligation limits contained therein.*

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**SECTION 121 OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002**

**ISEC. 121. STRATEGIC NATIONAL STOCKPILE.**

**[(a) STRATEGIC NATIONAL STOCKPILE.—**

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

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

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

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

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

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

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

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

**[(b) SMALLPOX VACCINE DEVELOPMENT.—**

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

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

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

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

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

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

[(e) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

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

(a) *IN GENERAL.*—

(1) *EMERGENCY USES.*—*Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug or device intended for use in an actual or potential emergency (referred to in this section as an “emergency use”).*

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

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

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

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

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

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

*(B) The term “product” means a drug or device.*

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

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

(b) *DECLARATION OF EMERGENCY.*—

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

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

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

(C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act, affecting national security and involving a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

(2) *TERMINATION OF DECLARATION.*—

(A) *IN GENERAL.*—A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) the expiration of the one-year period beginning on the date on which the declaration is made.

(B) *RENEWAL.*—Notwithstanding subparagraph (A), the Secretary may renew a declaration under this subsection, and this paragraph shall apply to any such renewal.

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

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

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

(4) *PUBLICATION.*—The Secretary shall promptly publish in the Federal Register each declaration, determination, and renewal under this subsection.

(c) *CRITERIA FOR ISSUANCE OF AUTHORIZATION.*—The Secretary may issue an authorization under this section with respect to the

emergency use of a product only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention, to the extent feasible and appropriate given the circumstances of the emergency involved, the Secretary concludes—

(1) that an agent specified in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

(A) the product may be effective in detecting, diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section or approved under this Act or the Public Health Service Act, for detecting, diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to detect, diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

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

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

(d) SCOPE OF AUTHORIZATION.—

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

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

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

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

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

(e) CONDITIONS OF AUTHORIZATION.—

(1) UNAPPROVED PRODUCT.—

(A) REQUIRED CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent feasible given the circumstances of the emergency, shall, for persons who choose to carry out one or more activities for which the authorization is issued, establish such

conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) DURATION OF AUTHORIZATION.—

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

(2) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—An authorization shall continue to be effective for continued use with respect to patients to whom it was administered during the period described by paragraph (1), to the extent found necessary by such patients' attending physicians.

(g) REVOCATION OF AUTHORIZATION.—

(1) REVIEW.—The Secretary shall periodically review the circumstances and the appropriateness of an authorization under this section.

(2) REVOCATION.—The Secretary may revoke an authorization under this section if, in the Secretary's unreviewable discretion, the criteria under subsection (c) for issuance of such authorization are no longer met.

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



(i) *ACTIONS COMMITTED TO AGENCY DISCRETION.*—Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

(j) *RULES OF CONSTRUCTION.*—Nothing in this section shall be construed to impair or otherwise affect—

(1) the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution;

(2) the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law; or

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

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

(1) *WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.*—In the case of administration of a countermeasure to members of the armed forces, a requirement, under subsection (e)(1)(A)(ii)(III), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived by the President if the President determines, in writing, that complying with such requirement is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

(2) *PROVISION OF INFORMATION TO MEMBER OF THE ARMED FORCES.*—If the Secretary makes a determination that it is not feasible for the information required by subsection (e)(1)(A)(ii) to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. Information concerning the administration of the product shall be recorded in the medical record of the member.

(3) *EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.*—In the case of an authorization based on a determination by the Secretary of Defense under subsection (b)(1)(B), section 1107 of title 10, United States Code, shall not apply to use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

(l) *RELATION TO OTHER PROVISIONS.*—If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization—

(1) shall not be subject to any requirements pursuant to section 505(i) or 520(g); and

(2) shall not be subject to any requirements otherwise applicable to clinical investigations pursuant to other provisions of this Act.

(m) *DISCRETION REGARDING USE OF AUTHORIZATION.*—Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such ac-

*tivity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall notify the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out an activity or activities under the authorization. This section does not have any legal effect on a person who does not carry out any activity for which an authorization under this section is issued, or who carries out such an activity pursuant to other provisions of this Act or section 351 of the Public Health Service Act.*

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



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**Memorandum**

July 1, 2003

**TO:** Honorable Louise Slaughter  
Attention: Rosaline Cohen

**FROM:** David L. Brumbaugh  
Specialist in Public Finance  
Government and Finance Division

**SUBJECT:** Homeland Security Act Provisions for "Expatriate" Corporations

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This memorandum responds to your request for a brief description of the Homeland Security Act's provisions relating to firms that reorganize their structure so that the firm's parent corporation is changed from a corporation chartered in the United States to one chartered in a foreign country. Such reorganizations are sometimes referred to as corporate "expatriations" or "inversions." The chief motivation for firms to undertake such a reorganization is to save U.S. federal taxes: unlike U.S.-chartered corporations, foreign corporations are generally not subject to U.S. tax on their foreign-source income.

The Homeland Security Act's corporate inversion provisions place restrictions on contracting by the newly created Department of Homeland Security. As originally enacted in the 107<sup>th</sup> Congress (Public Law 107-296, signed into law on November 25, 2002), section 835 of the Act generally prohibits the Department of Homeland Security from entering into any contract with a foreign firm that meets the definition of an "inverted domestic corporation" set forth by the Act. The Act generally defines an inverted domestic corporation as a foreign corporation that after the Act's date of enactment (1) acquires all the properties of a U.S.-chartered corporation or partnership; (2) is at least 80%-owned by the U.S. corporation or partnership's former stockholders or partners; and (3) has no substantial business activities in the foreign country where it is organized.

The contracting restrictions also stipulated conditions under which the Secretary of Homeland Security could waive the restrictions with respect to particular contracts. As initially enacted, the waiver conditions were the determination by the Secretary that the waiver is required (1) in the interest of homeland security; 2) to prevent the loss of any jobs in the United States; or 3) to prevent the federal government from incurring costs that would not otherwise occur.

On February 13, 2003, Congress passed H.J.Res. 2 (P.L. 108-7), an omnibus appropriations act that included a change in the Homeland Security Act's waiver of restrictions on contracting with inverted firms. The change removed the last two of the

waiver conditions listed above, leaving a determination that a contract is in the interest of homeland security as the only condition under which the Homeland Security Act's contract restrictions can be waived.

Additional Views of Representative Jim Turner  
Regarding H.R. 2122 – The Project BioShield Act  
Select Committee on Homeland Security  
July 8, 2003

The Select Committee on Homeland Security has considered legislation on one of the – if not the – compelling issue of our times, the threat to our nation from weapons of mass destruction, particularly biological weapons.

I want to congratulate Chairman Chris Cox on the work the Select Committee on Homeland Security has done on H.R. 2122, the “Project BioShield Act of 2003.” Recognizing the importance of this issue, the Chairman arranged for numerous discussions and briefings with administration officials, held four hearings, demanded a classified briefing on the threat to our nation from bioterrorism, and dedicated substantial member and staff resources in consideration of the legislation. We have gone into greater depth on this bill than any other Committee in Congress. In doing

so, we have demonstrated the value of having a single Committee that is dedicated solely to homeland security matters.

The specific legislation which we have considered – the Cox-Turner Substitute Amendment – is the product of bipartisan discussions and negotiations spanning the past month. I hope the process we have engaged in can serve as a model for the way the Select Committee can do business together in the future. All of us have the same goal – to protect America to the best of our abilities. We may have differing approaches toward that goal, but we can bring them to the table, incorporate the best ideas from both sides, and advance legislation in the national interest.

The Project BioShield legislation is designed to address the serious threats to our nation by encouraging the production of vaccines and other countermeasures for biological, chemical, radiological, and nuclear attacks. Project Bioshield proposes to accomplish this objective by guaranteeing in advance that the

government will purchase a large quantity of a vaccine or other medical countermeasure if a manufacturer produces an effective product that addresses a material national security threat. The Administration has budgeted \$5.6 billion for this project over the next ten years.

To my mind, the key question is whether Project Bioshield is a sufficiently bold response to the daunting challenge that faces this nation.

After the considerable work this Committee has done, I have concluded that Project BioShield is a worthy first step that deserves congressional approval. Yet, I remain concerned that the legislation does not do everything we can and should be doing to produce the vaccines and other medical countermeasures we so urgently need.

The Select Committee identified that the Department of Homeland Security, in its present state, is incapable of fulfilling its assigned responsibilities to identify “material threats” to our nation from biological pathogens and other agents.

We learned that the Department’s Office of Information Analysis has only one microbiologist analyzing the bioterrorism threat, and is not receiving highly classified information from other parts of the intelligence community. This is an unacceptable state of affairs. I had hoped that the Department of Homeland Security’s Office of Information Analysis would have been ready to assess threats, determine vulnerabilities, and provide guidance to the Congress as we considered the legislation.

The Cox-Turner Substitute Amendment attempts to remedy the defects in the Department’s intelligence unit by authorizing additional funds for the hiring of analysts, and demanding that the



Department has the capability to receive all levels of classified information by the end of this year.

Moreover, to ensure that the Secretary can fulfill his responsibilities under this legislation, the Cox-Turner Substitute Amendment amplifies the requirement in the Homeland Security Act that each agency of the government must make all information relating to current and emerging threats from biological, chemical, radiological, and nuclear agents available to the Department of Homeland Security.

The difficulty remains, however, that the legislation relies on the premise that if the government promises to purchase large quantities of countermeasures, then the private sector will develop them. The Select Committee, however, has heard extensive testimony that private companies may not rise to this challenge due to liability concerns, opportunity costs, or antitrust concerns. It is not clear, at this point, which economic model is correct. Thus, the

Cox-Turner Substitute Amendment contains numerous amendments to evaluate whether Project Bioshield will work.

First, the Secretary of Health and Human Services is required to report annually if the President has identified agents that are a material threat to the United States but a private company has not entered into a contract to develop countermeasures against them.

Four years from now, the National Academy of Science will conduct a full review of Project Bioshield and determine whether it has contributed to lowering our vulnerability to “an acceptable level of risk.”

And finally, the Cox-Turner Substitute Amendment provides that if the production of countermeasures is proceeding so slowly that our national security is at risk, the government may use BioShield funding to build an “in-house” capability to develop, test, and market countermeasures.

I believe that building this flexibility into the legislation is critical. For while I very much hope that the private sector will develop the medicines we need, I believe that ultimately the government will have to either supplement what the private sector does, or take on the entire job itself.

Whether we should shift our national policy in that direction is a debate that will likely be required. The Select Committee will be keeping a close eye on how Project BioShield is implemented, watching the progress of the development of countermeasures, and evaluating if our nation should be taking more aggressive action. If Project Bioshield works, our nation will be better off. But if it does not, we must be ready, willing and able to change our policy quickly, before it is too late.

A handwritten signature in black ink, appearing to read "Jim Turner", written over a horizontal line.

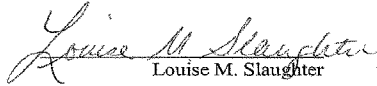
ADDITIONAL VIEWS ON HR 2122 AS REPORTED BY THE SELECT  
COMMITTEE ON HOMELAND SECURITY

During the Select Committee on Homeland Security's markup of HR 2122, Project BioShield Act of 2003, I offered an amendment that would prohibit countermeasure procurement contracts with expatriate corporations. This amendment lost on a party-line vote (17-18). Several members argued that the amendment was unnecessary and duplicative under the corporate expatriate prohibition provision in the Homeland Security Act of 2002 (P.L. 107-296). This is not the case.

Attached, please find a memorandum prepared by the Congressional Research Service, at my request, that sets forth the parameters of the limitation on access to contracts with the Department of Homeland by expatriate corporations.

The Homeland Security Act does proscribe the Department of Homeland Security from contracting with expatriate corporations. However, the Project BioShield Act does not grant the Secretary of the Department of Homeland Security the authority to contract with companies for the production of countermeasures. That responsibility is specifically given to the Secretary of Health and Human Services, who is not subject to the prohibitions contained in the Homeland Security Act. The Congressional Research Service memorandum also details how the expatriate corporation provision under the Homeland Security Act has been modified.

Expatriate corporations change their corporate structures and re-charter their parent corporations in foreign nations to avoid U.S. taxes. They should not profit from government contracts for biological countermeasures needed to protect the American people. I am submitting this information to ensure that the record reflects that my amendment was not redundant and would have properly restricted the Secretary of Health and Human Services from issuing lucrative contracts to corporate expatriates.

  
Louise M. Slaughter

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