# AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. ____

**(Project BioShield Act of 2003)**

## OFFERED BY MR. TAUZIN

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 nec-

essary 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 con-

sultants 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 Infec-

tious Diseases'' after ''Director of the Center'';

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

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

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

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

(5) in subsection (f)—

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

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

(6) in subsection (i)—

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

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

(B) by adding at the end the following:

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

**SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.**

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

**''SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE.**

''(a) STRATEGIC NATIONAL STOCKPILE.—

''(1) IN GENERAL.—The Secretary of Homeland Security (referred to in this section as the 'Homeland Security Secretary'), in coordination with the Secretary and the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices,

and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

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

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

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

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

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

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

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

''(b) SMALLPOX VACCINE DEVELOPMENT.—

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

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

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

''(1) IN GENERAL.—

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

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

''(i) that affects national security;

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

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

''(II) for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and

clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing after the date of a determination under paragraph (5).

''(2) DETERMINATION OF MATERIAL THREATS.—

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

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

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

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

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

''(ii) determine, on the basis of such assessment, the agents for which priority

countermeasures are necessary to protect the public health from a material threat.

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

''(4) CALL FOR SECURITY COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

''(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a security countermeasure would be appropriate, such Secretaries may jointly submit to the President a proposal to—

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

''(ii) make a commitment that, upon the first development of such security countermeasure that meets the conditions for procurement under paragraph (5), the

Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the special reserve fund under paragraph (10) be made available for the procurement of such security countermeasure.

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

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

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

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

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

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

''(i) the call for the countermeasure;

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

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

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

''(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be 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 rec-

ommendation that the special reserve fund under paragraph (10) be made available for the procurement of such countermeasure.

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

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

''(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under this sub-

section 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 ap-

proved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

''(B) INTERAGENCY AGREEMENTS.—

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

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

''(C) PROCUREMENT.—

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

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

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

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

''(I) PAYMENT CONDITIONED ON SUBSTANTIAL DELIVERY.—The contract shall provide that no payment may be made until delivery has been made of a substantial portion (as determined by the Secretary) of the total number of units contracted for,

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

''(II) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding eight years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a pe-

riod. The contract shall be renewable for additional periods, none of which shall exceed five years.

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

''(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

''(I) IN GENERAL.—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) SPECIAL RESERVE FUND.—For purposes of this subsection, the term 'special reserve fund' has the meaning given such term in section 510 of the Homeland Security Act of 2002.

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

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

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

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

''(f) AUTHORIZATION OF APPROPRIATIONS.—

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

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

(b) AMENDMENT TO HOMELAND SECURITY ACT OF 2002.—Title V of the Homeland Security Act of 2002

(116 Stat. 2212; 6 U.S.C. 311 et seq.) is amended by adding at the end the following:

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

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

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

''(c) AVAILABILITY.—

''(1) DURATION OF AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2), all amounts appropriated under subsection (a) are available for obliga-

tion through the end of fiscal year 2013, provided that any portion of such amount that remains unobligated for such purposes on the expiration of such term shall be returned to the United States Treasury and shall not be available for subsequent obligation for any purpose.

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

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

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

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

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

''(a) IN GENERAL.—

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

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

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

''(B) is approved, licensed, or cleared under such a provision, but which use is not

under such provision an approved, licensed, or cleared use of the product (referred to in this section as an 'unapproved use of an approved product').

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

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

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

''(B) The term 'product' means a drug or device.

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

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

''(b) DECLARATION OF EMERGENCY.—

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

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

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

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

''(2) TERMINATION OF DECLARATION.—

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

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

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

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

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

''(A) in the case of an unapproved product, a sufficient period for disposition of shipments of the product, including the return of such

shipments to the manufacturer (in the case of a manufacturer that chooses to have the shipments returned); and

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

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

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

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

''(2) that, based on the totality of scientific evidence available to the Secretary, including data from

adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

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

''(i) such disease or condition; or

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

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

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

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

''(d) SCOPE OF AUTHORIZATION.—

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

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

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

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

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

''(e) CONDITIONS OF AUTHORIZATION.—

''(1) UNAPPROVED PRODUCT.—

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

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

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

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

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

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

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

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

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

''(iii) Appropriate conditions for the monitoring and reporting of adverse events

associated with the emergency use of the product.

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

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

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

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

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

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

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

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

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

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

Such additional information shall not be considered labeling for purposes of section 502.

''(f) DURATION OF AUTHORIZATION.—

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

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

''(g) REVOCATION OF AUTHORIZATION.—

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

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

''(h) PUBLICATION.—The Secretary shall promptly publish in the Federal Register a notice of each authoriza-

tion, 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 Sec-

retary 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 Congress a report that summarizes—

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

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

(iii) the identification of each person or entity that received, or was considered and rejected for, grants, cooperative agree-

ments, or contracts pursuant to the use of such authorities.

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

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

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

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

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

(b) NATIONAL ACADEMY OF SCIENCES REVIEW.—Not later than three years after the date of the enactment of this Act, the Secretary of Health and Human Services shall request the National Academy of Sciences to enter into an agreement for a review of the biomedical counter-

measure research and development authorities established in this Act to determine whether and to what extent activities undertaken pursuant to such authorities have enhanced the development of biomedical countermeasures affecting national security, and to recommend any legislative or administrative changes necessary to improve the ability of the Secretary to carry out these activities in the future. The Secretary shall ensure that the results of the study are submitted to the Congress not later than five years after such date of enactment.

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

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

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

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

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

(3)(A) to review such Secretary's utilization of the authority granted under this Act to authorize an emergency use of a biomedical countermeasure, including the means by which the 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 Congress not later than five years after the date of the enactment of this Act.