S. 15

One Hundred Eighth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the twentieth day of January, two thousand and four

An Act

To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures.

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

SECTION 1. SHORT TITLE.

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

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

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

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

"(a) IN GENERAL.—

"(1) AUTHORITY.—In conducting and supporting research and development activities regarding countermeasures under section 319F(h), the Secretary may conduct and support such activities in accordance with this section and, in consultation with the Director of the National Institutes of Health, as part of the program under section 446, if the activities concern qualified countermeasures.

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

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

"(B) treat, identify, or prevent harm from a condition that may result in adverse health consequences or death

and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A).

"(3) INTERAGENCY COOPERATION.—

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

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

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

"(5) TRANSFERS OF QUALIFIED COUNTERMEASURES.—Each agreement for an award of a grant, contract, or cooperative agreement under section 319F(h) for the development of a qualified countermeasure shall provide that the recipient of the award will comply with all applicable export-related controls with respect to such countermeasure.

"(b) EXPEDITED PROCUREMENT AUTHORITY.—

"(1) INCREASED SIMPLIFIED ACQUISITION THRESHOLD FOR QUALIFIED COUNTERMEASURE PROCUREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

"(2) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

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

"(B) RELATION TO OTHER AUTHORITIES.—The authority under subparagraph (A) is in addition to any other authority to use procedures other than competitive procedures.

"(C) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—The Secretary shall implement this paragraph in accordance with government-wide regulations implementing such section 303(c)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency

has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

"(3) INCREASED MICROPURCHASE THRESHOLD.—

"(A) IN GENERAL.—For a procurement described by paragraph (1), the amount specified in subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428) shall be deemed to be $15,000 in the administration of that section with respect to such procurement.

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

"(C) EXCEPTION TO PREFERENCE FOR PURCHASE CARD MECHANISM.—No provision of law establishing a preference for using a Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than $2,500.

"(4) REVIEW.—

"(A) REVIEW ALLOWED.—Notwithstanding subsection (f), section 1491 of title 28, United States Code, and section 3556 of title 31 of such Code, review of a contracting agency decision relating to a procurement described in paragraph (1) may be had only by filing a protest—

"(i) with a contracting agency; or

"(ii) with the Comptroller General under subchapter V of chapter 35 of title 31, United States Code.

"(B) OVERRIDE OF STAY OF CONTRACT AWARD OR PERFORMANCE COMMITTED TO AGENCY DISCRETION.—Notwithstanding section 1491 of title 28, United States Code, and section 3553 of title 31 of such Code, the following authorizations by the head of a procuring activity are committed to agency discretion:

"(i) An authorization under section 3553(c)(2) of title 31, United States Code, to award a contract for a procurement described in paragraph (1) of this subsection.

"(ii) An authorization under section 3553(d)(3)(C) of such title to perform a contract for a procurement described in paragraph (1) of this subsection.

"(c) AUTHORITY TO EXPEDITE PEER REVIEW.—

"(1) IN GENERAL.—The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would be required under sections 301(a)(3),

405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494, as applicable to a grant, contract, or cooperative agreement—

"(A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and

"(B) the amount of which is not greater than $1,500,000.

"(2) SUBSEQUENT PHASES OF RESEARCH.—The Secretary's determination of whether to employ expedited peer review with respect to any subsequent phases of a research grant, contract, or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant, contract, or cooperative agreement. Nothing in the preceding sentence may be construed to impose any requirement with respect to peer review not otherwise required under any other law or regulation.

"(d) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

"(1) IN GENERAL.—For the purpose of performing, administering, or supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5, United States Code, but without regard to the limitations in such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.

"(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

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

"(B) EXCLUSIVITY OF REMEDY.—The remedy provided by subparagraph (A) shall be exclusive of any other civil action or proceeding by reason of the same subject matter against the entity involved (person, officer, employee, or governing board member) for any act or omission within the scope of the Federal Tort Claims Act.

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

"(i) IN GENERAL.—Should payment be made by the United States to any claimant bringing a claim under this paragraph, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover against any entity identified in subparagraph (B) for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of

any such entity to carry out any obligation or responsibility assumed by such entity under a contract with the United States or from any grossly negligent or reckless conduct or intentional or willful misconduct on the part of such entity.

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

"(3) INTERNAL CONTROLS TO BE INSTITUTED.—

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

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

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

"(e) STREAMLINED PERSONNEL AUTHORITY.—

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

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

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

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

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

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

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

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

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

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

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

(2) in subsection (c)—

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

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

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

(4) in subsection (e)—

(A) in paragraph (1)—

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

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

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

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

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

(5) in subsection (f)—

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

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

(6) in subsection (i)—

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

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

(B) by adding at the end the following:

"(2) NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.—For the purpose of carrying out this section with

respect to the National Institute of Allergy and Infectious Diseases, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.".

(c) ADDITIONAL AUTHORIZATIONS OF APPROPRIATIONS.—Section 2106 of the Public Health Service Act (42 U.S.C. 300aa–6) is amended—

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

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

(d) TECHNICAL AMENDMENTS.—Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended—

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

(2) in subsection (h)(4)(B), by striking "to diagnose conditions" and inserting "to treat, identify, or prevent conditions".

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

SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

(a) ADDITIONAL AUTHORITY REGARDING STRATEGIC NATIONAL STOCKPILE.—

(1) TRANSFER OF PROGRAM.—Section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (116 Stat. 611; 42 U.S.C. 300hh–12) is transferred from such Act to the Public Health Service Act, is redesignated as section 319F–2, and is inserted after section 319F–1 of the Public Health Service Act (as added by section 2 of this Act).

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

"SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE.

"(a) STRATEGIC NATIONAL STOCKPILE.—

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

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

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

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

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

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

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

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

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

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

"(b) SMALLPOX VACCINE DEVELOPMENT.—

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

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

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

"(1) IN GENERAL.—

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

"(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term 'security countermeasure' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that—

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

"(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

"(III)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; or

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

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

"(2) DETERMINATION OF MATERIAL THREATS.—

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

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

"(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

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

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

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

"(C) NOTICE TO CONGRESS.—The Secretary and the Homeland Security Secretary shall promptly notify the designated congressional committees (as defined in paragraph (10)) that a determination has been made pursuant to subparagraph (A) or (B).

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

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

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

"(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

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

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

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

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

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

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

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

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

"(i) the call for the countermeasure;

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

"(iii) the commitment described in subparagraph (A)(ii).

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

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

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

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

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

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

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

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

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

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

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

"(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund under paragraph (10)

will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

"(7) PROCUREMENT.—

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

"(B) INTERAGENCY AGREEMENT; COSTS.—

"(i) INTERAGENCY AGREEMENT.—The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund under paragraph (10) shall be available for payments made by the Secretary to a vendor for such procurement.

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

"(C) PROCUREMENT.—

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

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

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

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

"(I) PAYMENT CONDITIONED ON DELIVERY.—The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government.

"(II) DISCOUNTED PAYMENT.—The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

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

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

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

"(VI) NON-STOCKPILE TRANSFERS OF SECURITY COUNTERMEASURES.—The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

"(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

"(I) IN GENERAL.—If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

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

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

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

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

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

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

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

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

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

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

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

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

"(iv) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

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

"(II) RELATION TO OTHER AUTHORITIES.—The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

"(III) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 303(c)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

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

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

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

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

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

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

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

"(8) INTERAGENCY COOPERATION.—

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

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

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

"(A) costs for the purchase of vaccines under procurement contracts entered into before the date of the enactment of the Project BioShield Act of 2004; or

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

"(10) DEFINITIONS.—

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

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

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

"(ii) In the Senate: the appropriate committees.

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

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

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

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

"(f) AUTHORIZATION OF APPROPRIATIONS.—

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

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

(b) AMENDMENTS TO HOMELAND SECURITY ACT OF 2002.—Title V of the Homeland Security Act of 2002 (116 Stat. 2212; 6 U.S.C. 311 et seq.) is amended—

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

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

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

(2) by adding at the end the following:

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

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

"(b) SPECIAL RESERVE FUND.—For purposes of the security countermeasures program, the term 'special reserve fund' means the 'Biodefense Countermeasures' appropriations account or any other appropriation made under subsection (a).

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

"(d) RELATED AUTHORIZATIONS OF APPROPRIATIONS.—

"(1) THREAT ASSESSMENT CAPABILITIES.—For the purpose of carrying out the responsibilities of the Secretary for terror threat assessment under the security countermeasures program, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2006, for the hiring of professional personnel within the Directorate for Information Analysis and Infrastructure Protection, who shall be analysts responsible for chemical, biological, radiological, and nuclear threat assessment (including but not limited to analysis of chemical, biological, radiological, and nuclear

agents, the means by which such agents could be weaponized or used in a terrorist attack, and the capabilities, plans, and intentions of terrorists and other non-state actors who may have or acquire such agents). All such analysts shall meet the applicable standards and qualifications for the performance of intelligence activities promulgated by the Director of Central Intelligence pursuant to section 104 of the National Security Act of 1947.

"(2) INTELLIGENCE SHARING INFRASTRUCTURE.—For the purpose of carrying out the acquisition and deployment of secure facilities (including information technology and physical infrastructure, whether mobile and temporary, or permanent) sufficient to permit the Secretary to receive, not later than 180 days after the date of enactment of the Project BioShield Act of 2004, all classified information and products to which the Under Secretary for Information Analysis and Infrastructure Protection is entitled under subtitle A of title II, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2006.".

(c) STOCKPILE FUNCTIONS TRANSFERRED.—

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

(2) EXCEPTIONS.—

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

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

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

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

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

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

"(a) IN GENERAL.—

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

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

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

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

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

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

"(A) The term 'biological product' has the meaning given such term in section 351 of the Public Health Service Act.

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

"(C) The term 'product' means a drug, device, or biological product.

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

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

"(b) DECLARATION OF EMERGENCY.—

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

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

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

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

"(2) TERMINATION OF DECLARATION.—

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

"(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland

Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

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

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

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

"(3) ADVANCE NOTICE OF TERMINATION.—The Secretary shall provide advance notice that a declaration under this subsection will be terminated. The period of advance notice shall be a period reasonably determined to provide—

"(A) in the case of an unapproved product, a sufficient period for disposition of the product, including the return of such product (except such quantities of product as are necessary to provide for continued use consistent with subsection (f)(2)) to the manufacturer (in the case of a manufacturer that chooses to have such product returned); and

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

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

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

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

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

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

"(i) such disease or condition; or

"(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this Act, or licensed under section 351 of the Public Health Service Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

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

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

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

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

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

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

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

"(e) CONDITIONS OF AUTHORIZATION.—

"(1) UNAPPROVED PRODUCT.—

"(A) REQUIRED CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the circumstances of the emergency, shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

"(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

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

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

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

"(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

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

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

"(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of

the alternatives to the product that are available and of their benefits and risks.

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

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

"(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

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

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

"(iii) Appropriate conditions with respect to the collection and analysis of information, during the period when the authorization is in effect, concerning the safety and effectiveness of the product with respect to the emergency use of such product.

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

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

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

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

"(ii) In the circumstances described in clause (i), for a person who does not manufacture the product and who chooses to act under this clause, an authorization under this section regarding the emergency use shall, to the

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

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

"(3) GOOD MANUFACTURING PRACTICE.—With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including such requirements established under section 501.

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

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

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

"(f) DURATION OF AUTHORIZATION.—

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

"(2) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—Notwithstanding the termination of the declaration under subsection (b) or a revocation under subsection (g), an authorization shall continue to be effective to provide for continued use of an unapproved product with respect to a patient to whom it was administered during the period described by paragraph (1), to the extent found necessary by such patient's attending physician.

"(g) REVOCATION OF AUTHORIZATION.—

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

"(2) REVOCATION.—The Secretary may revoke an authorization under this section if the criteria under subsection (c) for issuance of such authorization are no longer met or other circumstances make such revocation appropriate to protect the public health or safety.

"(h) PUBLICATION; CONFIDENTIAL INFORMATION.—

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

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

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

"(j) RULES OF CONSTRUCTION.—The following applies with respect to this section:

"(1) Nothing in this section impairs the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution.

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

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

"(k) RELATION TO OTHER PROVISIONS.—If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of section 505(i), section 520(g), or any other provision of this Act or section 351 of the Public Health Service Act.

"(l) OPTION TO CARRY OUT AUTHORIZED ACTIVITIES.—Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall report to the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out any activity under the authorization. This section only has legal effect on a person who carries out an activity for which an authorization under this section is issued. This section does not modify or affect activities carried out pursuant to other provisions of this Act or section 351 of the Public Health Service Act. Nothing in this subsection may be construed as restricting the Secretary from imposing conditions on persons who carry out any activity pursuant to an authorization under this section.".

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