Calendar No. 53

108TH CONGRESS
1ST SESSION

S. 15

To amend the Public Health Service Act to provide for the payment of compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures, to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States, and to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program.

IN THE SENATE OF THE UNITED STATES

MARCH 11, 2003

Mr. GREGG (for himself, Mr. FRIST, Mr. ALEXANDER, Mr. WARNER, Mr. ENZI, Mr. SESSIONS, Mr. ROBERTS, Mr. GRAHAM of South Carolina, Mr. BOND, Mr. INHOFE, and Mr. STEVENS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

MARCH 25, 2003

Reported by Mr. GREGG, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Public Health Service Act to provide for the payment of compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures, to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against

the United States, and to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Biodefense Improvement and Treatment for America Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—PROTECTION FOR SMALLPOX EMERGENCY PERSONNEL

SEC. 101. SHORT TITLE.

This title may be cited as the ''Smallpox Emergency Personnel Protection Act of 2003''.

SEC. 102. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Part A of title H of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by inserting after section 224 the following:

''SEC. 224A. PROTECTION FOR SMALLPOX EMERGENCY PERSONNEL.

''(a) DEFINITIONS.—In this section:

‘‘(1) COVERED COUNTERMEASURE.—The term ‘covered countermeasure’ means a covered countermeasure as specified in article III of the Declaration.

‘‘(2) COVERED INDIVIDUAL.—The term ‘covered individual’ means an individual—

‘‘(A) who is—

‘‘(i) a health care worker, a law enforcement officer, a firefighter, a security-related worker, an emergency medical worker, or a public safety worker who is identified in a State, local, or Department of Health and Human Services plan that is approved by the Secretary; or

‘‘(ii) an individual with respect to whom the Secretary determines and declares that it is advisable to administer the vaccine (not including any individual to whom the Secretary determines only that such vaccine should be made available); and

‘‘(B) to whom a vaccine is administered during the period in which the Declaration is effective (including the portion of such period

before the date of enactment of this section) and ending on the later of—

"(i) the expiration of the 120-day period that begins on the effective date of the initial interim final regulations to implement this section;

"(ii) the expiration of the 120-day period that begins on the date on which an individual becomes an individual within a category specified in subparagraph (A); or

"(iii) the date on which the Secretary publicly announces that an active case of smallpox has been identified either within or outside the United States.

"(3) COVERED INJURY.—The term 'covered injury' includes—

"(A) an injury, disability, illness, condition, or death determined, pursuant to the procedures established under subsection (b), to have been sustained as the direct result of administration to an individual of a covered countermeasure during the effective period of the Declaration (other than a minor injury such as minor scarring or minor local reaction); and

"(B) an injury, disability, illness, condition, or death determined, pursuant to the procedures established under subsection (b), to have been sustained as the direct result of accidental vaccinia inoculation through contact with an individual who is (or who was accidentally inoculated by) an individual in a category specified in Article IV of the Declaration to whom vaccinia vaccine has been administered during the effective period of the Declaration.

"(4) DECLARATION.—The term 'Declaration' means the Declaration Regarding Administration of Smallpox Countermeasures issued by the Secretary of Health and Human Services on January 24, 2003, and published in the Federal Register on January 28, 2003, including any subsequent amendment.

"(5) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who is (as determined in accordance with section 3)—

"(A) a covered individual who sustains a covered injury as the direct result of administration of a covered countermeasure; or

"(B) any individual who contracts vaccinia during the effective period of the Declaration or within 30 days after the end of such period—

"(i) to whom vaccinia vaccine was not administered;

"(ii) who has resided with, or has been in close contact with, a covered individual; and

"(iii) who sustains a covered injury as the direct result of contracting vaccinia.

"(6) SECRETARY.—Except as provided otherwise, the term 'Secretary' means the Secretary of Health and Human Services.

"(b) DETERMINATION OF ELIGIBILITY.—

"(1) IN GENERAL.—The Secretary, in consultation with the Attorney General and the Secretary of Labor, shall establish administrative procedures for determining, as applicable with respect to an individual—

"(A) whether the individual is an eligible individual;

"(B) whether the individual has sustained a covered injury or injuries for which medical benefits and employment income-loss compensation may be available under subsections (d) and

(c), and the amount of such benefits or compensation; and

"(C) whether the covered injury or injuries of the individual constitute a compensable disability, or caused the individual's death, for purposes of benefits under subsection (f).

"(2) COVERED INDIVIDUALS.—The Secretary may accept a certification, by a Federal, State, or local government entity or private health care entity participating in the administration of covered countermeasures under the Declaration, that an individual is an individual in a category specified in article IV of the Declaration to whom such a countermeasure has been administered by the applicable deadline specified in subsection (a)(2)(B), as establishing that the individual is a covered individual.

"(3) DETERMINATION OF CAUSATION.—

"(A) INJURIES SPECIFIED IN INJURY TABLE.—In any case where an injury or other adverse effect specified in the injury table established under subsection (c) as a known effect of a covered countermeasure manifests in an individual within the time period specified in such table, such injury or other effect shall be

rebuttably presumed to have resulted from administration of such covered countermeasure.

"(B) OTHER DETERMINATIONS.—In making determinations other than those described in subparagraph (A) as to the causation or severity of an injury, the Secretary shall take into consideration all relevant medical and scientific evidence presented for consideration, and may obtain and consider the views of qualified medical experts.

"(4) DEADLINE FOR FILING CLAIM.—The Secretary shall not consider any claim for a benefit under this subsection with respect to an individual that is filed later than 1 year after—

"(A) the date a covered countermeasure was administered to the individual; or

"(B) in the case of a claim based on contact vaccination (as described in subsection (a)(5)(B)), the date of the first symptom or manifestation of onset of an adverse effect of such vaccination.

"(5) REVIEW OF DETERMINATION.—

"(A) SECRETARY'S REVIEW AUTHORITY.—The Secretary may review a determination under this subsection at any time on the Sec-

retary's own motion or on application, and may affirm, vacate, or modify such determination.

''(B) SECRETARY'S ACTION NOT JUDICIALLY REVIEWABLE.—The determinations of the Secretary under this subsection shall not be subject to review by another official of the United States or by a court by mandamus or otherwise.

''(c) COUNTERMEASURE INJURY TABLE.—

''(1) SMALLPOX COUNTERMEASURE INJURY TABLE.—The Secretary shall establish by interim final regulation a table identifying—

''(A) adverse effects (including injuries, disabilities, illnesses, conditions, and deaths) that shall be presumed to result from the administration of (or exposure to) a covered countermeasure; and

''(B) the time periods in which the first symptom, or manifestation of onset of each such adverse effect, must manifest in order for such presumption to apply.

''(2) AMENDMENTS.—The Secretary may amend by regulation the table established under paragraph (1). Such amendments shall apply retroactively to claims filed or pending at the time of the

promulgation of final amending regulations and to claims filed after such promulgation.

''(d) MEDICAL BENEFITS.—

''(1) IN GENERAL.—Subject to paragraph (2), an eligible individual shall be entitled to payment by the Secretary for medical items and services as reasonable and necessary to treat a covered injury. The Secretary may consider the provisions of chapter 81 of title 5, United States Code, (and the implementing regulations with respect to such chapter) in determining the amount of such payment and the circumstances under which such payments are reasonable and necessary.

''(2) LIMITATIONS.—

''(A) BENEFITS SECONDARY TO OTHER COVERAGE.—The obligation of the Secretary to pay for any services or benefits under paragraph (1) shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer) under any other provision of law or contractual agreement, to pay for or provide such services or benefits.

''(B) NO BENEFITS FOR MEDICARE-ELIGIBLE INDIVIDUAL.—No benefits shall be avail-

able to an individual under this subsection with respect to any period in which the individual is eligible for benefits under title XVIII of the Social Security section (42 U.S.C. 1395 et seq.).

''(c) COMPENSATION FOR LOST EMPLOYMENT INCOME.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), an eligible individual shall be entitled to payment of compensation by the Secretary for loss of employment income incurred as a result of a covered injury, at the rate specified in paragraph (2).

''(2) AMOUNT OF COMPENSATION.—

''(A) IN GENERAL.—Compensation under this subsection shall be at the rate of 66⅔ percent of monthly pay. The Secretary may consider the provisions of sections 8114 and 8115 of title 5, United States Code (and any implementing regulations) in determining the amount of such payment and the circumstances under which such payments are reasonable and necessary.

''(B) TREATMENT OF SELF-EMPLOYMENT INCOME.—For purposes of this subsection—

''(i) the term 'employment income' includes income from self-employment; and

“(ii) for purposes of computation of pay and determination of wage-earning capacity under subparagraph (A), self-employment income shall be treated as wages.

“(3) LIMITATIONS.—

“(A) BENEFITS SECONDARY TO OTHER COVERAGE.—The obligation of the Secretary to pay compensation under paragraph (1) shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income.

“(B) NO BENEFITS FOR DEATH OR PERMANENT AND TOTAL DISABILITY.—No payment shall be made under this subsection in compensation for loss of employment income due to the death or permanent and total disability of an eligible individual.

“(C) LIMIT ON TOTAL BENEFITS.—Total benefits paid to an individual under this subsection shall not exceed $50,000.

“(D) WAITING PERIOD.—An eligible individual is not entitled to compensation under

this subsection for the first 5 work days of disability.

''(f) PAYMENT FOR DEATH AND PERMANENT, TOTAL DISABILITY.—

''(1) BENEFIT FOR PERMANENT AND TOTAL DISABILITY.—Subject to the succeeding provisions of this subsection, an eligible individual who is determined, in accordance with the procedures established under subsection (b), to have a covered injury or injuries meeting the definition of disability in section 216(i) of the Social Security Act (42 U.S.C. 416(i)) shall be entitled to have payment made by the Secretary of an amount determined under paragraph (3), in the same manner as disability benefits are paid pursuant to the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) with respect to an eligible public safety officer.

''(2) DEATH BENEFIT.—Subject to the succeeding provisions of this subsection, in the case of an eligible individual whose death is determined, in accordance with the procedures established under subsection (b), to have directly resulted from a covered injury or injuries a death benefit in the amount

determined under paragraph (3) shall be payable by the Secretary to the survivor or survivors in the same manner as death benefits are paid pursuant to the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) with respect to an eligible deceased public safety officer.

"(3) BENEFIT AMOUNT.—The amount of the disability or death benefit under paragraph (1) or (2) in a fiscal year shall, subject to paragraph (5)(B), equal the amount of the comparable benefit calculated under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) in such fiscal year, without regard to any reduction attributable to a limitation on appropriations.

"(4) BENEFIT IN ADDITION TO MEDICAL BENEFITS.—A benefit under this subsection shall be in addition to any amounts to which an eligible individual may be entitled as medical benefits under subsection (d).

"(5) LIMITATIONS.—

"(A) DISABILITY BENEFITS.—No benefit is payable under paragraph (1) with respect to the disability of an eligible individual if—

"(i) a disability benefit is paid or payable with respect to such individual under Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.); or

"(ii) a death benefit is paid or payable with respect to such individual under paragraph (2) or the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.).

"(B) DEATH BENEFITS.—No benefit is payable under paragraph (2) with respect to the death of an eligible individual if—

"(i) a disability benefit is paid with respect to such individual under paragraph (1) or the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe

Streets Act of 1968 (42 U.S.C. 3796 et seq.); or

''(ii) a death benefit is paid or payable with respect to such individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.).

''(g) ADMINISTRATION.—

''(1) ADMINISTRATION BY AGREEMENT WITH OTHER AGENCY OR AGENCIES.—The Secretary may administer any or all of the provisions of this section through Memorandum of Agreement with the Attorney General or the Secretary of Labor.

''(2) REGULATIONS.—The head of the agency administering this section or any provisions thereof (including any agency head administering such section or provisions through a Memorandum of Agreement under paragraph (1)) may promulgate such implementing regulations as may be determined necessary and appropriate. Initial implementing regulations may be interim final regulations.

''(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for fiscal year 2003 and each succeeding fiscal

year to carry out this section, to remain available until expended, including administrative costs and costs of provision and payment of benefits.

''(i) RELATIONSHIP TO OTHER LAWS.—

''(1) NO PREEMPTION OF INDIVIDUAL RIGHTS.—Except as otherwise provided in this section, nothing in this section shall be construed to override or limit any rights an individual may have to seek compensation, benefits, or redress under any other provision of Federal or State law.

''(2) RELATIONSHIP TO THE FEDERAL TORT CLAIMS ACT.—

''(A) EXHAUSTION REQUIREMENT.—An individual may not seek any remedy that may be available under section 224(p) (providing a cause of action under the Federal Tort Claims Act for injuries resulting from administration of smallpox countermeasures under such section 224(p)) unless such individual has first filed a claim for payment or compensation under this section and has received a final determination with respect to such claim.

''(B) OFFSET OF COMPENSATION AGAINST FEDERAL TORT CLAIMS ACT RECOVERY.—The value of any compensation or benefits paid to

an individual, or the survivor or survivors of such an individual, or the estate of the individual pursuant to a claim under this section shall be offset against any amount to which such individual or the individual's survivor, survivors, or estate are entitled under section 224(p).

''(3) PREEMPTION OF STATE LAWS PROVIDING EXCLUSIVE REMEDY FOR WORK-RELATED INJURIES.—No provision of a State workers' compensation law or other State law shall be construed to bar claims or benefits under this section, to the extent that it purports to make such State law the exclusive remedy for a work-related injury or otherwise to make benefits under this section unavailable to an otherwise eligible individual.''.

TITLE II—PROJECT BIOSHIELD

SEC. 201. SHORT TITLE.

This title may be cited as the ''Project BioShield Act of 2003''.

SEC. 202. BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT AUTHORITIES.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409I. BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT.

"(a) IN GENERAL.—

"(1) AUTHORITY.—In carrying out research responsibilities under this Act, the Secretary may conduct and support research and development with respect to biomedical countermeasures.

"(2) IMPLEMENTATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (C), authorities assigned by this section to the Secretary shall be carried out through the Director of NIH and the Director of the National Institute of Allergy and Infectious Diseases.

"(B) LEAD INSTITUTE.—The National Institute of Allergy and Infectious Diseases shall be the lead institute for biomedical countermeasure research and development under this section.

"(C) CHEMICAL, RADIOLOGICAL, AND NUCLEAR AGENTS.—To the extent that an authority described in subparagraph (A) is exercised with respect to a chemical, radiological, or nuclear agent, the Secretary may authorize the Director of NIH to carry out the authority through any national research institute.

''(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 Federal Government and to use other agencies of the Department of Health and Human Services.

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

''(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 biomedical countermeasure research or development, 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 Adminis-

trative 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) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for procurements made under this paragraph, including requirements with respect to documenting the justification for use of the authority provided in this paragraph.

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

"(A) the procurement is as described by paragraph (1)(A); 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 meet the needs of the Secretary.

"(3) INCREASED MICROPURCHASE THRESHOLD.—

"(A) IN GENERAL.—For a procurement described by paragraph (1)(A), 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 procurements that are made 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 Federal Government purchase card method for purchases shall apply to procurements made under

this paragraph and that are greater than $2,500.

''(c) AUTHORITY TO EXPEDITE PEER REVIEW.—The Secretary may, as the Secretary determines necessary to respond to pressing 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, determines to be appropriate to obtain an assessment of scientific and technical merit and likely contribution to the field of biomedical countermeasure research, in place of the peer review and advisory council review procedures that would otherwise 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—

''(1) that is for performing, administering, or supporting biomedical countermeasure research and development; and

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

''(d) FACILITIES AUTHORITY.—

''(1) AGENCY FACILITIES.—In addition to any similar authority provided under any other provision

of law, in carrying out this section, the Secretary may—

"(A) acquire, lease, construct, improve, renovate, remodel, repair, operate, and maintain laboratories, other research facilities and equipment, and other real or personal property as the Secretary determines necessary for the purpose of performing, administering, and supporting biomedical countermeasure research and development; and

"(B) acquire, without regard to section 8141 of title 40, United States Code, by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia.

"(2) FACILITIES OF GRANTEE OR COOPERATIVE AGREEMENT PARTNER.—

"(A) IN GENERAL.—The Secretary may exercise the authorities described in section 481A with respect to biocontainment laboratories and other related or ancillary specialized research facilities as the Secretary determines necessary for the purpose of performing, administering, and supporting biomedical countermeasure research and development.

"(B) AVAILABILITY OF FACILITY TO SECRETARY.—A grant or cooperative agreement under subparagraph (A) 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.

"(C) TWENTY YEAR USE REQUIREMENT.—A grant or cooperative agreement under this paragraph shall include an agreement by the grantee or cooperative agreement partner that, for not less than 20 years after the completion of the acquisition, construction, or other work described in subparagraph (A), the facility will be used for the purposes of the research and development for which it is to be acquired, constructed, or otherwise improved.

"(D) AMOUNT OF GRANT; COST-SHARING; PAYMENTS.—The provisions of section 481A(e) shall apply to a grant or cooperative agreement under this paragraph, except that—

"(i) authorities exercised under that section by the Director of the National Center for Research Resources shall, for

purposes of this paragraph, be exercised by the Secretary; and

"(ii) for purposes of this paragraph, each of the percentages in subparagraphs (A) and (B) of section 481A(e)(1) shall be deemed to be 75 percent.

"(E) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant or cooperative agreement has been awarded under this paragraph, the facility shall cease to be used for the research and development purposes for which it was constructed (unless the Secretary determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so), the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the

cost of the construction, acquisition, or other improvement of such facility.

"(c) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

"(1) IN GENERAL.—For the purpose of performing, administering, and supporting biomedical countermeasure research and development, the Secretary may, as the Secretary determines necessary to respond to pressing 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.

"(2) FEDERAL TORT CLAIMS ACT COVERAGE.—

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

death, resulting from performance of functions under such contract.

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

"(3) INTERNAL CONTROLS TO BE INSTITUTED.—

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

"(B) DETERMINATION OF EMPLOYEE STATUS TO BE FINAL.—A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or governing board member of a person, is or is not deemed to be an employee of the Department of Health and

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

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

''(f) 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 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 biomedical countermeasure research and development in carrying out this section.

''(2) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate

internal controls for appointments under this subsection.

''(g) DEFINITION.—As used in this section, the term 'biomedical 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 is used—

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

''(2) 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 that is used as described in paragraph (1).

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

SEC. 203. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

Section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 300hh–12) is amended—

(1) by redesignating subsections (c) through (e) as subsections (d) through (f), respectively; and

(2) by inserting after subsection (b) the following:

"(c) BIOMEDICAL COUNTERMEASURES PROCUREMENT.—

"(1) DETERMINATION OF MATERIAL THREATS.—

"(A) RISK OF USE.—The Secretary, in consultation with the heads of other agencies as appropriate, shall on an ongoing basis—

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

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

"(B) PUBLIC HEALTH IMPACT.—The Secretary of Health and Human Services, in consultation with 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 countermeasures are necessary to protect the public health.

"(2) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—The Secretary of Health and Human Services, in consultation with the Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (1).

"(3) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR PROCUREMENT UNDER THIS SUBSECTION.—

"(A) IN GENERAL.—The Secretary of Health and Human Services, in accordance with this paragraph, shall identify specific countermeasures to threats identified under paragraph (1) that such Secretary determines, in consultation with the Secretary of Homeland Security, to be appropriate for procurement

with appropriations under this subsection for inclusion in the stockpile under subsection (a).

"(B) REQUIREMENTS.—In order for the Secretary of Health and Human Services to make the determination under subparagraph (A) with respect to a countermeasure, the following requirements must be met:

"(i) DETERMINATION OF QUALIFIED COUNTERMEASURE.—Such Secretary must determine that the product is a qualified countermeasure (as defined in paragraph (7)).

"(ii) DETERMINATION OF QUANTITIES NEEDED AND FEASIBILITY OF PRODUCTION AND DISTRIBUTION.—Such Secretary must determine—

"(I) the quantities of the product that will be needed to meet the needs of the stockpile; and

"(II) that production and delivery within 5 years of sufficient quantities of the product, as so determined, is reasonably expected to be feasible.

"(iii) DETERMINATION OF NO SIGNIFICANT COMMERCIAL MARKET.—Such Secretary shall—

"(I) determine that, at the time of the initial determination under this paragraph, there is not a significant commercial market for the product other than as a homeland security threat countermeasure; and

"(II) annually redetermine and report to the President, while a determination under subparagraph (A) remains in effect with respect to the product, whether a significant commercial market exists for the product other than as a homeland security threat countermeasure.

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

"(A) RECOMMENDATION FOR PROCUREMENT.—In the case of a countermeasure that the Secretary and the Secretary of Health and Human Services have determined is appropriate for procurement under this subsection for inclusion in the stockpile, in accordance with the

preceding provisions of this subsection, the Secretary and the Secretary of Health and Human Services shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation for procurement under this subsection.

"(B) PRESIDENTIAL APPROVAL.—A countermeasure may be procured under this subsection only if the President has approved a recommendation under subparagraph (A) with respect to such countermeasure.

"(C) NOTICE TO CONGRESS.—The Secretary shall notify Congress of each decision of the President to approve a recommendation under subparagraph (A).

"(5) PROCUREMENT.—The Secretary of Health and Human Services and the Secretary shall be responsible for the following, for purposes of procurement of qualified countermeasures for the stockpile under subsection (a), as approved by the President under paragraph (4):

"(A) INTERAGENCY AGREEMENTS.—

"(i) FOR PROCUREMENT.—The Secretary shall enter into an agreement with the Secretary of Health and Human Serv-

ices for the procurement of the countermeasure in accordance with the provisions of this paragraph. Amounts appropriated under paragraph (8) shall be available for the Secretary of Health and Human Service's costs of such procurement, other than as provided in clause (ii).

"(ii) FOR ADMINISTRATIVE COSTS.—The agreement entered into between the Secretary and the Secretary of Health and Human Services for managing the stockpile under subsection (a) shall provide for reimbursement of the Secretary of Health and Human Service's administrative costs relating to procurements under this subsection from appropriations to carry out such subsection (a).

"(B) PROCUREMENT.—

"(i) IN GENERAL.—The Secretary of Health and Human Services shall be responsible for—

"(I) arranging for procurement of the 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 otherwise specified in this clause, 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 Health and Human Services) of the total number of units contracted for.

"(II) DISCOUNTED PAYMENT FOR UNLICENSED PRODUCT.—The contract may provide for a discounted

price per unit of a product that is not licensed or approved as described in paragraph (7)(A) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed 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 or approval).

"(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 Government under the contract, for such period and under such terms and conditions as the Secretary of Health and Human Services may specify, and in such case amounts appropriated under paragraph (8) shall be available for costs of shipping, handling, storage, and related costs for such product.

"(IV) CONTRACT DURATION.—The contract shall be for a period not to exceed 5 years, renewable for additional periods none of which shall exceed 5 years.

"(V) TERMINATION FOR NONDELIVERY.—In addition to any other rights of the Secretary of Health and Human Services to terminate the contract, the contract may provide that such Secretary may terminate the contract for failure to deliver a reasonable number (as determined by such Secretary) of units of the product by 3 years after the date the contract is entered into, and may further provide that in such case the vendor shall not be entitled to any payment under the contract.

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

"(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.

"(iv) USE OF NONCOMPETITIVE PROCEDURES.—In addition to any other authority to use procedures other than competitive procedures, the Secretary of Health and Human Services 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 such Secretary's needs.

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

‘‘(I) IN GENERAL.—If, under this subsection, the Secretary of Health and Human Services enters into contracts with more than one person to procure a 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 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 persons' 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 RE-

VIEWABLE.—If the Secretary of Health and Human Services includes in each of a set of contracts a provision as described in clause (I), such Secretary's determination of the total quantity of 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 of Health and Human Services 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 of Health and Human Services 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 such Secretary may so exclude such a source.

''(6) INTERAGENCY COOPERATION.—

''(A) IN GENERAL.—In carrying out activities under this section, the Secretary and the Secretary of Health and Human Services 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 Secretary or to the Secretary of Health and Human Services.

''(7) DEFINITIONS.—In this subsection:

''(A) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' means a biomedical countermeasure—

''(i) that is approved under section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health

Service Act (42 U.S.C. 262) for use as such a countermeasure to a chemical, biological, radiological, or nuclear agent identified as a material threat under paragraph (1); or

"(ii) for which the Secretary of Health and Human Services determines that sufficient and satisfactory clinical experience or research data (including data, if available, from preclinical and clinical trials) support a reasonable conclusion that the product will qualify for approval or licensing as such a countermeasure within 5 years after the date of a determination under paragraph (3).

"(B) BIOMEDICAL COUNTERMEASURE.—The term 'biomedical 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))) or biological product (as that term is defined by section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))) that is used—

"(i) to treat, identify, or prevent harm from any biological, chemical, radiological,

or nuclear agent that may cause a public health emergency affecting national security; or

"(ii) 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 or biological product that is used as described in clause (i).

"(8) APPROPRIATIONS.—

"(A) IN GENERAL.— There are appropriated, out of any moneys in the Treasury not otherwise appropriated, for fiscal year 2003 and for each fiscal year thereafter, such sums as may be necessary for the costs incurred by the Secretary in the procurement of countermeasures under this subsection as approved by the President under paragraph (4) (other than costs specified in subparagraph (B)).

"(B) RESTRICTIONS.—Amounts appropriated under this paragraph shall not be available to pay—

"(i) costs for the purchase of vaccines under procurement contracts entered into before January 1, 2003;

''(ii) costs under new contracts, or costs of new obligations under contracts previously entered into, for procurement of a countermeasure after the date of a determination under paragraph (3)(B)(iii) that there is a significant commercial market for the countermeasure other than as a homeland security threat countermeasure; or

''(iii) administrative costs.''.

SEC. 204. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

(a) IN GENERAL.—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:

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

''(a) IN GENERAL.—Notwithstanding sections 505 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 solely for use in an actual or potential emergency.

‘‘(b) DECLARATION OF EMERGENCY.—

‘‘(1) IN GENERAL.—The Secretary may declare an emergency justifying the authorization of a drug or device under this subsection on the basis of a determination—

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

‘‘(B) by the Secretary of Defense, that there is a military emergency (or a significant potential of 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) by the Secretary of a public health emergency under section 319 of the Public Health Service Act, involving a specified disease or condition or a specified biological, chemical, radiological, or nuclear 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 1-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) 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 a product if 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, di-

agnosing, 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 detect, diagnose, prevent, or treat within the scope of the authorization; and

''(2) the Secretary's conclusions, 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.

''(e) CONDITIONS OF AUTHORIZATION.—

''(1) IN GENERAL.—The Secretary is authorized, by order or regulation, to impose such conditions on an authorization under this section as the Secretary determines are necessary or appropriate to protect the public health, including the following:

''(A) The Secretary shall impose requirements (including requirements concerning product labeling and the provision of information) designed to ensure that, to the maximum extent

feasible given the circumstances of the emergency, health care professionals administering the product are informed—

"(i) that the Secretary has authorized the product solely for emergency use;

"(ii) of the significant known and potential benefits and risks of 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.

"(B) The Secretary shall impose requirements (including requirements concerning product labeling and the provision of information) designed to ensure that, to the maximum extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed—

"(i) that the Secretary has authorized the product solely for emergency use;

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

‘‘(iii) of any option to accept or refuse administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

‘‘(C) The Secretary may impose limitations on which entities may distribute the product (including limitation to distribution by government entities), and on how distribution is to be performed.

‘‘(D) The Secretary may impose limitations on who may administer the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered.

‘‘(E) The Secretary may condition the authorization on the performance of studies, clinical trials, or other research needed to support marketing approval of the product.

‘‘(F) The Secretary may impose requirements concerning recordkeeping and reporting, including records access by the Secretary and publication of data.

‘‘(G) The Secretary may impose (or waive) requirements, with respect to the product, of current good manufacturing practice otherwise

applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act.

''(H) The Secretary may impose requirements for the monitoring and reporting of adverse events associated with use of the product.

''(2) WAIVER.—The Secretary may waive any condition imposed under this subsection.

''(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—

''(A) the conditions for such an authorization are no longer met; or

''(B) other circumstances make such revocation appropriate.

''(h) 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.

''(i) RECORDKEEPING.—

''(1) IN GENERAL.—The Secretary may by order or regulation require persons, including a person who holds an authorization under this section, or who manufactures, distributes, prescribes, or administers a product that is the subject of such an authorization, to establish and maintain—

''(A) data that is obtained from such activity and that pertains to the effectiveness or safety of such product;

''(B) such records as are necessary to determine, or facilitate a determination, whether there may be any violation of this section or of

a regulation promulgated under this section; and

''(C) such additional records as the Secretary may determine necessary.

''(2) ACCESS TO RECORDS BY SECRETARY.—

''(A) SAFETY AND EFFECTIVENESS INFORMATION.—The Secretary may by order or regulation require a person who holds an authorization under this section, or who manufactures, distributes, prescribes, or administers a product that is the subject of such an authorization to provide to the Secretary all data that is obtained from such activity and that pertains to the safety or effectiveness of such product.

''(B) OTHER INFORMATION.—Every person required under this section to establish or maintain records, and every person in charge or custody of such records, shall, upon request by the Secretary, permit the Secretary at all reasonable times to have access to, to copy, and to verify such records.

''(j) CIVIL MONETARY PENALTIES.—

''(1) IN GENERAL.—A person who violates a requirement of this section or of a regulation or order promulgated pursuant to this section shall be subject

to a civil money penalty of not more than $100,000 in the case of an individual, and not more than $250,000 in the case of any other person, for each violation, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

''(2) ASSESSMENT OF CIVIL PENALTIES.—Paragraphs (3), (4), and (5) of section 303(g) shall apply to a civil penalty under this subsection, and references in such paragraphs to 'paragraph (1) or (2)' shall, for purposes of this subsection, be deemed to refer to paragraph (1) of this subsection.

''(k) 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.

''(l) REGULATIONS.—The Secretary may promulgate regulations to implement this section.

''(m) 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; or

"(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.

"(n) APPLICATION TO MEMBERS OF ARMED FORCES.—

"(1) WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.—In the case of the administration of a countermeasure to members of the armed forces, a requirement, under subsection (c)(2)(C), 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) EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.—In the case of an authorization based on a determination by the Secretary of Defense under subsection (b)(1)(B), section 1107 of title 10, United States Code, shall not apply to use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

''(o) 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.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsection (e)—

(A) by striking ''504, 703'' and inserting ''504, 564, 703''; and

(B) by striking ''or 519'' and inserting ''519, or 564''; and

(2) by adding at the end the following:

''(hh)(1) Promotion or use of a product that is the subject of an authorization under section 564 other than as stated in the authorization, or other than during the period described by section 564(g), unless such promotion or use is permitted under another provision of this Act.

''(2) Failure to comply with an information requirement under section 564(e)(1).''.

SEC. 205. DEVELOPING NEW COUNTERMEASURES AND PROTECTING EXISTING COUNTERMEASURES AGAINST BIOTERRORISM.

Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended by adding at the end the following:

''(k) LIMITED ANTITRUST EXEMPTION.—

''(1) COUNTERMEASURES DEVELOPMENT MEETINGS.—

''(A) COUNTERMEASURES DEVELOPMENT MEETINGS AND CONSULTATIONS.—The Secretary may conduct meetings and consultations with parties involved in the development of countermeasures for the purpose of the development, manufacture, distribution, or sale of priority countermeasures consistent with the purposes of this title. The Secretary shall give notice of such meetings and consultations to the Attorney General and the Chairperson of the Federal Trade Commission (referred to in this subsection as the 'Chairperson').

''(B) MEETING AND CONSULTATION CONDITIONS.—A meeting or consultation conducted under subparagraph (A) shall—

‘‘(i) be chaired or, in the case of a consultation, facilitated by the Secretary or the designee of the Secretary;

‘‘(ii) be open to parties involved in the development, manufacture, distribution, purchase, or sale of priority countermeasures, as determined by the Secretary;

‘‘(iii) be open to the Attorney General and the Chairperson;

‘‘(iv) be limited to discussions involving the development, manufacture, distribution, or sale of priority countermeasures, consistent with the purposes of this title; and

‘‘(v) be conducted in such manner as to ensure that national security, confidential, and proprietary information is not disclosed outside the meeting or consultation.

‘‘(C) MINUTES.—The Secretary shall maintain minutes of meetings and consultations under this subsection, which shall not be disclosed under section 552 of title 5, United States Code.

‘‘(D) EXEMPTION.—The antitrust laws shall not apply to meetings and consultations

under this paragraph, except that any agreement that results from a meeting or consultation and that has been denied an exemption pursuant to this subsection shall be subject to the antitrust laws.

"(2) WRITTEN AGREEMENTS OR CONDUCT.—The Secretary or any party to an agreement or other conduct regarding covered activities entered into or undertaken pursuant to meetings or consultations conducted under paragraph (1), and that is consistent with this paragraph, shall file such written agreement or a description of the conduct involved with the Attorney General and the Chairperson for a determination of whether such agreement or conduct should be exempt from the antitrust laws. In addition to the proposed agreement or description of conduct itself, any such filing shall include—

"(A) an explanation of the intended purpose of the agreement or conduct;

"(B) a specific statement of the substance of the agreement or conduct;

"(C) a description of the methods that will be utilized to achieve the objectives of the agreement or conduct;

‘‘(D) an explanation of the necessity of a cooperative effort among the particular participating parties to achieve the objectives of the agreement or conduct; and

‘‘(E) any other relevant information reasonably requested by the Attorney General, in consultation with the Chairperson and the Secretary.

‘‘(3) DETERMINATION.—The Attorney General, in consultation with the Chairperson, shall determine whether an agreement or description of conduct submitted under paragraph (2) should be exempt from the antitrust laws.

‘‘(4) LIMITED ANTITRUST EXEMPTION.—

‘‘(A) IN GENERAL.—The Attorney General, in consultation with the Chairperson, may, within 30 days of the receipt of a notification pursuant to paragraph (2), revoke in whole or in part, the scope of any exemption granted by the Attorney General under a determination under paragraph (3).

‘‘(B) EXTENSION.—The Attorney General may extend the 35-day period referred to in subparagraph (A) for an additional period of not to exceed 20 days. Such additional period

may be further extended only by the United States district court, upon an application by the Attorney General after notice to the Secretary and the parties involved.

''(C) APPLICATION OF LAWS.—

''(i) IN GENERAL.—The antitrust laws shall not apply to an agreement or conduct (described in a description of conduct) that is submitted for review pursuant to paragraph (2) until such time as the Attorney General determines, pursuant to subparagraph (D), that such agreement or conduct should not, in whole or in part, be exempt from the antitrust laws.

''(ii) LIMITED LIABILITY.—No party to an agreement or conduct referred to in clause (i) shall be liable under the antitrust laws for any actions reasonably necessary to carry out the agreement or for conduct taken after the agreement or description has been submitted pursuant to paragraph (2) and prior to any revocation of the exemption by the Attorney General pursuant to subparagraph (D).

"(D) DETERMINATION.—In making a determination under this subparagraph, the Attorney General, in consultation with the Chairperson and the Secretary shall consider—

"(i) whether the agreement or conduct involved would facilitate the availability of priority countermeasures;

"(ii) whether the exemption from the antitrust laws would promote the public interest;

"(iii) the competitive impact to areas not directly related to the purposes of the agreement or conduct; and

"(iv) any other factors determined relevant by the Attorney General and the Chairperson.

"(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption provided under paragraphs (3) or (4) shall be limited to covered activities, and shall expire on the date that is 3 years after the date on which the exemption becomes effective (and at 3 year intervals thereafter, if renewed) unless the Attorney General in consultation with the Chairperson determines that the exemption should be renewed

(with modifications, as appropriate) considering the factors described in paragraph (4).

''(6) LIMITATION ON PARTIES.—Any exemption from the antitrust laws provided under this subsection shall not apply to the use of any information acquired in conducting exempted activities for any purposes other than those expressly specified in the antitrust exemption provided for by this subsection.

''(7) GUIDELINES.—The Attorney General and the Chairperson may develop and issue guidelines to implement this subsection.

''(8) REPORT.—Not later than 1 year after the date of enactment of this subsection, and annually thereafter, the Attorney General and the Chairperson shall report to the Committee on Health, Education, Labor, and Pensions and the Committee on the Judiciary of the Senate and the Committee on Energy and Commerce and the Committee on the Judiciary of the House of Representatives on the use and continuing need for the exemption from the antitrust laws provided by this subsection.

''(9) SUNSET.—The authority of any party to apply for or to obtain a limited antitrust exemption under this subsection shall expire at the end of the

6-year period that begins on the date of enactment of this subsection.

''(l) DEFINITIONS.—In this section:

''(1) ANTITRUST LAWS.—The term 'antitrust laws'—

''(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes the Act of June 19, 1936 (15 U.S.C. 13 et seq.) commonly known as the Robinson-Patman Act), and section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

''(B) includes any State law similar to the laws referred to in subparagraph (A).

''(2) COVERED ACTIVITIES.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered activities' means any group of activities or conduct, including attempting to make, making, or performing a contract or agreement or engaging in other conduct, for the purpose of—

''(i) theoretical analysis, experimentation, or the systematic study of phe-

nomena or observable facts related to the development of priority countermeasures;

''(ii) the development or testing of basic engineering techniques related to the development of priority countermeasures;

''(iii) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes related to the development of priority countermeasures;

''(iv) the production, distribution, or marketing of a product, process, or service related to the development of priority countermeasures;

''(v) the testing in connection with the production of a product, process, or service related to the development of priority countermeasures;

''(vi) the collection, exchange, and analysis of research or production information related to the development of priority countermeasures; or

‘‘(vii) any combination of the purposes described in clauses (i) through (vi);

and such term may include the establishment and operation of facilities for the conduct of covered activities described in clauses (i) through (vi), the conduct of such covered activities on a protracted and proprietary basis, and the processing of applications for patents and the granting of licenses for the results of such covered activities.

‘‘(B) EXCEPTION.—The term ‘covered activities’ shall not include the following activities involving 2 or more persons:

‘‘(i) Exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution of any product, process, or service if such information is not reasonably necessary to carry out the purposes of covered activities.

‘‘(ii) Entering into any agreement or engaging in any other conduct—

‘‘(I) to restrict or require the sale, licensing, or sharing of inventions, developments, products, proc-

esses, or services not developed through, produced by, or distributed or sold through such covered activities; or

"(II) to restrict or require participation by any person who is a party to such covered activities in other research and development activities, that is not reasonably necessary to prevent the misappropriation of proprietary information contributed by any person who is a party to such covered activities or of the results of such covered activities.

"(iii) Entering into any agreement or engaging in any other conduct allocating a market with a competitor that is not expressly exempted from the antitrust laws by a determination under subsection (k)(4).

"(iv) Exchanging information among competitors relating to production (other than production by such covered activities) of a product, process, or service if such information is not reasonably necessary to

carry out the purpose of such covered activities.

''(v) Except as otherwise provided in this subsection or subsection (k), entering into any agreement or engaging in any other conduct to restrict or require participation by any person who is a party to such activities, in any unilateral or joint activity that is not reasonably necessary to carry out the purpose of such covered activities.

''(3) DEVELOPMENT.—The term 'development' includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval, and any other actions related to preparation of a countermeasure.

''(4) PERSON.—The term 'person' has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)).

''(5) PRIORITY COUNTERMEASURE.—The term 'priority countermeasure' means a countermeasure, including a drug, medical device, biological product, or diagnostic test to treat, identify, or prevent infection by a biological agent or toxin on the list devel-

oped under section 351A(a)(1) and prioritized under subsection (a)(1).''.

TITLE III—IMPROVED VACCINE AFFORDABILITY AND AVAILABILITY

SEC. 301. SHORT TITLE.

This title may be cited as the ''Improved Vaccine Affordability and Availability Act''.

Subtitle A—State Vaccine Grants

SEC. 311. AVAILABILITY OF INFLUENZA VACCINE.

Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following:

''(3)(A) For the purpose of carrying out activities relating to influenza vaccine under the immunization program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 and 2004. Such authorization shall be in addition to amounts available under paragraphs (1) and (2) for such purpose.

''(B) The authorization of appropriations established in subparagraph (A) shall not be effective for a fiscal year unless the total amount appropriated under paragraphs (1) and (2) for the fiscal year is not less than such total for fiscal year 2000.

~~"(C) The purposes for which amounts appropriated under subparagraph (A) are available to the Secretary include providing for improved State and local infrastructure for influenza immunizations under this subsection in accordance with the following:~~

~~"(i) Increasing influenza immunization rates in populations considered by the Secretary to be at high risk for influenza-related complications and in their contacts.~~

~~"(ii) Recommending that health care providers actively target influenza vaccine that is available in September, October, and November to individuals who are at increased risk for influenza-related complications and to their contacts.~~

~~"(iii) Providing for the continued availability of influenza immunizations through December of such year, and for additional periods to the extent that influenza vaccine remains available.~~

~~"(iv) Encouraging States, as appropriate, to develop contingency plans (including plans for public and professional educational activities) for maximizing influenza immunizations for high-risk populations in the event of a delay or shortage of influenza vaccine.~~

''(D) The Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, periodic reports describing the activities of the Secretary under this subsection regarding influenza vaccine. The first such report shall be submitted not later than June 6, 2003, the second report shall be submitted not later than June 6, 2004, and subsequent reports shall be submitted biennially thereafter.''.

SEC. 312. PROGRAM FOR INCREASING IMMUNIZATION RATES FOR ADULTS AND ADOLESCENTS; COLLECTION OF ADDITIONAL IMMUNIZATION DATA.

(a) ACTIVITIES OF CENTERS FOR DISEASE CONTROL AND PREVENTION.—Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)), as amended by section 311, is further amended by adding at the end the following:

''(4)(A) For the purpose of carrying out activities to increase immunization rates for adults and adolescents through the immunization program under this subsection, and for the purpose of carrying out subsection (k)(2), there are authorized to be appropriated $50,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006. Such author-

ization is in addition to amounts available under paragraphs (1), (2), and (3) for such purposes.

"(B) In expending amounts appropriated under subparagraph (A), the Secretary shall give priority to adults and adolescents who are medically underserved and are at risk for vaccine-preventable diseases, including as appropriate populations identified through projects under subsection (k)(2)(E).

"(C) The purposes for which amounts appropriated under subparagraph (A) are available include (with respect to immunizations for adults and adolescents) the payment of the costs of storing vaccines, outreach activities to inform individuals of the availability of the immunizations, and other program expenses necessary for the establishment or operation of immunization programs carried out or supported by States or other public entities pursuant to this subsection.

"(5) The Secretary shall annually submit to Congress a report that—

"(A) evaluates the extent to which the immunization system in the United States has been effective in providing for adequate immunization rates for adults and adolescents, taking into account the applicable year 2010 health objectives established by

the Secretary regarding the health status of the people of the United States; and

''(B) describes any issues identified by the Secretary that may affect such rates.

''(6) In carrying out this subsection and paragraphs (1) and (2) of subsection (k), the Secretary shall consider recommendations regarding immunizations that are made in reports issued by the Institute of Medicine of the National Academy of Sciences.''.

(b) RESEARCH, DEMONSTRATIONS, AND EDUCATION.—Section 317(k) of the Public Health Service Act (42 U.S.C. 247b(k)) is amended—

(1) by redesignating paragraphs (2) through (4) as paragraphs (3) through (5), respectively;

(2) by inserting after paragraph (1) the following:

''(2)(A) The Secretary, directly and through grants under paragraph (1), shall provide for a program of research, demonstration projects, and education in accordance with the following:

''(i) The Secretary shall coordinate with public and private entities (including nonprofit private entities), and develop and disseminate guidelines, toward the goal of ensuring that immunizations are rou-

tinely offered to adults and adolescents by public and private health care providers.

''(ii) The Secretary shall cooperate with public and private entities to obtain information for the annual evaluations required in subsection (j)(5)(A).

''(iii) The Secretary shall (relative to fiscal year 2003) increase the extent to which the Secretary collects data on the incidence, prevalence, and circumstances of diseases and adverse events that are experienced by adults and adolescents and may be associated with immunizations, including collecting data in cooperation with commercial laboratories.

''(iv) The Secretary shall ensure that the entities with which the Secretary cooperates for purposes of subparagraphs (A) through (C) include managed care organizations, community-based organizations that provide health services, and other health care providers.

''(v) The Secretary shall provide for projects to identify racial and ethnic minority groups and other health disparity populations for which immunization rates for adults and adolescents are below such rates for the general population, and to determine the factors underlying such disparities.

''(B) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2003 through 2007.''.

SEC. 313. IMMUNIZATION AWARENESS.

(a) DEVELOPMENT OF INFORMATION CONCERNING MENINGITIS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this title referred to as the ''Secretary''), in consultation with the Director of the Centers for Disease Control and Prevention, shall develop and make available to entities described in paragraph (2) information concerning bacterial meningitis and the availability and effectiveness of vaccinations for populations targeted by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).

(2) ENTITIES.—An entity is described in this paragraph if the entity—

(A) is—

(i) a college or university; or

(ii) any other facility with a setting similar to a dormitory that houses age-ap-

propriate populations for whom the Advisory Committee on Immunization Practices recommends such a vaccination; and

(B) is determined appropriate by the Secretary.

(b) DEVELOPMENT OF INFORMATION CONCERNING HEPATITIS.—

(1) IN GENERAL.—The Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop and make available to entities described in paragraph (2) information concerning hepatitis A and B and the availability and effectiveness of vaccinations with respect to such diseases.

(2) ENTITIES.—An entity is described in this paragraph if the entity—

(A) is—

(i) a health care clinic that serves individuals diagnosed as being infected with HIV or as having other sexually transmitted diseases;

(ii) an organization or business that counsels individuals about international travel or who arranges for such travel;

(iii) a police, fire, or emergency medical services organization that responds to natural or man-made disasters or emergencies;

(iv) a prison or other detention facility;

(v) a college or university; or

(vi) a public health authority or children's health service provider in areas of intermediate or high endemicity for hepatitis A as defined by the Centers for Disease Control and Prevention; and

(B) is determined appropriate by the Secretary.

SEC. 314. SUPPLY OF VACCINES.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall prioritize, acquire, and maintain a supply of such prioritized vaccines sufficient to provide vaccinations throughout a 6-month period.

(b) PROCEEDS.—Any proceeds received by the Secretary of Health and Human Services from the sale of vaccines contained in the supply described in subsection (a), shall be available to the Secretary for the purpose of pur-

chasing additional vaccines for the supply. Such proceeds shall remain available until expended.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purpose of carrying out subsection (a) such sums as may be necessary for each of fiscal years 2003 through 2008.

SEC. 315. COMMUNICATION.

The Commissioner of Food and Drugs shall ensure that vaccine manufacturers receive all forms of compliance guidelines for vaccines and that such guidelines are kept up to date.

SEC. 316. FAST TRACK.

The Commissioner of Food and Drugs shall issue regulations to revise the policies of the Food and Drug Administration regarding fast-tracking and priority review approval of vaccine products currently under development, to allow for the use of new forms of existing vaccines in cases where a determination is made that applying such approvals is in the public health interest to address the unmet need of strengthening the overall vaccine supply.

SEC. 317. STUDY.

(a) IN GENERAL.—The Secretary shall contract with the Institute of Medicine of the National Academy of Sciences or another independent and competent authority, to conduct a study of the statutes, regulations, guidelines,

and compliance, inspection, and enforcement practices and policies of the Department of Health and Human Services and of the Food and Drug Administration that are applicable to vaccines intended for human use that are in periodic short supply in the United States.

(b) REQUIREMENTS.—The study under subsection (a) shall include a review of the regulatory requirements, guidelines, practices, and policies—

(1) for the development and licensing of vaccines and the licensing of vaccine manufacturing facilities;

(2) for inspections and other activities for maintaining compliance and enforcement of the requirements applicable to such vaccines and facilities; and

(3) that may have contributed to temporary or long-term shortages of vaccines.

(c) REPORT.—Not later than 6 months after the date of enactment of this Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that contains—

(1) the results of the study under subsection (a); and

(2) recommendations for modifications to the regulatory requirements, guidelines, practices, and policies described in subsection (b).

Subtitle B—Vaccine Injury Compensation Program

SEC. 321. ADMINISTRATIVE REVISION OF VACCINE INJURY TABLE.

Section 2114 of the Public Health Service Act (42 U.S.C. 300aa–14) is amended—

(1) by striking subsection (c)(1) and inserting the following:

"(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and for at least 60 days of public comment."; and

(2) in subsection (d), by striking "90 days" and inserting "60 days".

SEC. 322. EQUITABLE RELIEF.

Section 2111(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)(A)) is amended by striking "No person" and all that follows through "and—" and inserting the following: "No person may bring or maintain a civil action against a vaccine administrator or manufacturer in a Federal or State court for damages arising

from, or equitable relief relating to, a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988 and no such court may award damages or equitable relief for any such vaccine-related injury or death, unless the person proves past or present physical injury and a timely petition has been filed in accordance with section 2116 for compensation under the Program for such injury or death and—''.

SEC. 323. DERIVATIVE PETITIONS FOR COMPENSATION.

(a) LIMITATIONS ON DERIVATIVE PETITIONS.—Section 2111(a)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(2)) is amended—

(1) in subparagraph (B), by inserting ''or (B)'' after ''subparagraph (A)'';

(2) by redesignating subparagraph (B) as subparagraph (C); and

(3) by inserting after subparagraph (A) the following:

''(B)(i) No parent or other third party may bring or maintain a civil action against a vaccine administrator or manufacturer in a Federal or State court for damages or equitable relief relating to a vaccine-related injury or death, including without limitation damages for loss of consortium, society, companionship, or services, loss of earnings, medical

or other expenses, and emotional distress, and no court may award damages or equitable relief in such an action, unless—

"(I) the person who sustained the underlying vaccine-related injury or death upon which such parent's or other third party's claim is premised has timely filed a petition for compensation in accordance with section 2111;

"(II) such parent or other third party is the legal representative or spouse of the person who sustained the underlying vaccine-related injury or death, and such legal representative or spouse has filed a timely derivative petition, in accordance with section 2116; and

"(III)(aa) the United States Court of Federal Claims has issued judgment under section 2112 on the derivative petition, and such legal representative or spouse elects under section 2121(a) to file a civil action; or

"(bb) such legal representative or spouse elects to withdraw such derivative petition under section 2121(b) or such petition is considered withdrawn under such section.

"(ii) Any civil action brought in accordance with this subparagraph shall be subject to the stand-

ards and procedures set forth in sections 2122 and 2123, regardless of whether the action arises directly from a vaccine-related injury or death associated with the administration of a vaccine. In a case in which the person who sustained the underlying vaccine-related injury or death upon which such legal representative's or spouse's civil action is premised elects under section 2121(a) to receive the compensation awarded, such legal representative or spouse may not bring a civil action for damages or equitable relief, and no court may award damages or equitable relief, for any injury or loss of the type set forth in section 2115(a) or that might in any way overlap with or otherwise duplicate compensation of the type available under section 2115(a).''.

(b) ELIGIBLE PERSONS.—Section 2111(a)(9) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(9)) is amended by striking the period and inserting ''and to a parent or other third party to the extent such parent or other third party seeks damages or equitable relief relating to a vaccine-related injury or death sustained by a person who is qualified to file a petition for compensation under the Program.''.

(c) PETITIONERS.—Section 2111(b) of the Public Health Service Act (42 U.S.C. 300aa–11(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), by striking ''(B)'' and inserting ''(C)'';

(B) by redesignating subparagraph (B) as subparagraph (C); and

(C) by inserting after subparagraph (A) the following:

''(B) Except as provided in subparagraph (C), any legal representative or spouse of a person—

''(i) who has sustained a vaccine-related injury or death; and

''(ii) who has filed a petition for compensation under the Program (or whose legal representative has filed such a petition as authorized in subparagraph (A));

may, if such legal representative or spouse meets the requirements of subsection (d), file a derivative petition under this section.''; and

(2) in paragraph (2)—

(A) by inserting ''by or on behalf of the person who sustained the vaccine-related injury or death'' after ''filed''; and

(B) by adding at the end the following: ''A legal representative or spouse may file only 1 derivative petition with respect to each underlying petition.''.

(d) DERIVATIVE PETITION CONTENTS.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) is amended—

(1) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively; and

(2) by inserting after subsection (c) the following:

''(d) DERIVATIVE PETITIONS.—

''(1) If the legal representative or spouse of the person who sustained the vaccine-related injury or death seeks compensation under the Program, such legal representative or spouse shall file a timely derivative petition for compensation under the Program in accordance with this section.

''(2) Such a derivative petition shall contain—

''(A) except for records that are unavailable as described in subsection (c)(3), an affidavit, and supporting documentation, demonstrating that—

''(i) the child or spouse of such person has, in accordance with section 2111, time-

ly filed a petition for compensation for the underlying vaccine-related injury or death upon which such legal representative's or spouse's derivative petition is premised;

''(ii) the derivative petition was timely filed;

''(iii) such legal representative or spouse suffered a loss compensable under section 2115(b) as a result of the vaccine-related injury or death sustained by such person; and

''(iv) such legal representative or spouse has not previously collected an award or settlement of a civil action for damages for such loss; and

''(B) records establishing such legal representative's or spouse's relationship to the person who sustained the vaccine-related injury or death.''.

(c) DETERMINATION OF ELIGIBILITY FOR COMPENSATION.—Section 2113(a)(1) of the Public Health Service Act (42 U.S.C. 300aa–13(a)(1)) is amended—

(1) in subparagraph (A), by striking ''and'' and inserting ''or, as applicable, section 2111(d),'';

(2) in subparagraph (B), by striking the period and inserting ", and"; and

(3) by inserting before the flush matter at the end, the following:

"(C) in the case of a derivative petition, that the person who sustained the underlying vaccine-related injury or death upon which the derivative petition is premised has timely filed a petition for compensation in accordance with section 2111 and that, with respect to such underlying petition, the special master or court has made the findings specified in subparagraphs (A) and (B) of this paragraph.".

(f) COMPENSATION.—Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended—

(1) by redesignating subsections (b) through (j) as subsections (c) through (k), respectively;

(2) by inserting after subsection (a) the following:

"(b) DERIVATIVE PETITIONS.—

"(1) IN GENERAL.—Compensation awarded under the Program to a legal representative or spouse who files a derivative petition under section 2111 for a loss sustained as a result of a vaccine-related injury or death sustained by such petitioner's

child or spouse shall only include compensation for any loss of consortium, society, companionship, or services, in an amount not to exceed the lesser of $250,000 or the total amount of compensation awarded to the person who sustained the underlying vaccine-related injury or death.

''(2) MULTIPLE INDIVIDUALS.—Where more than 1 person files a derivative petition under section 2111 for losses sustained as a result of the same underlying vaccine-related injury or death, the aggregate compensation to such persons shall not exceed the lesser of $250,000, or the total amount of compensation awarded to the person who sustained the underlying vaccine-related injury or death. The special master or court shall apportion compensation among the derivative petitioners in proportion to their respective losses.'';

(3) in subsection (e)(2), as so redesignated by paragraph (1)—

(A) by striking ''(2) and (3)'' and inserting ''(2), (3), (4), (5), and (6)''; and

(B) by inserting ''and subsection (b),'' after ''(a),'';

(4) in subsection (g), as so redesignated by paragraph (1), in paragraph (4)(B), by striking ''subsection (j)'' and inserting ''subsection (k)'';

(5) in subsection (j), as so redesignated by paragraph (1)—

(A) in paragraph (1), by striking ''subsection (j)'' and inserting ''subsection (k)''; and

(B) in paragraph (2), by inserting '', or to a legal representative or spouse of a person who sustained a vaccine-related injury or death,'' after ''death''; and

(6) in subsection (k), as so redesignated by paragraph (1), by striking ''subsection (f)(4)(B)'' and inserting ''subsection (g)(4)(B)''.

SEC. 324. JURISDICTION TO DISMISS ACTIONS IMPROPERLY BROUGHT.

Section 2111(a)(3) of the Public Health Service Act (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the end the following: ''If any civil action which is barred under subparagraph (A) or (B) of paragraph (2) is filed or maintained in a State court, or any vaccine administrator or manufacturer is made a party to any civil action brought in State court (other than a civil action which may be brought under paragraph (2)) for damages or equitable relief for a vaccine-related injury or death associ-

ated with the administration of a vaccine after October 1, 1988, the civil action may be removed at any time before final judgment by the defendant or defendants to the United States Court of Federal Claims. Once removed, the United States Court of Federal Claims shall have jurisdiction solely for the purpose of adjudicating whether the civil action should be dismissed pursuant to this section. If the United States Court of Federal Claims determines that the civil action should not be dismissed, the court shall remand the action to the State Court. The notice required by section 1446 of title 28, United States Code, shall be filed with the United States Court of Federal Claims, and that court shall, except as otherwise provided in this section, proceed in accordance with sections 1446 through 1451 of title 28, United States Code.''.

SEC. 325. CLARIFICATION OF WHEN INJURY IS CAUSED BY FACTOR UNRELATED TO ADMINISTRATION OF VACCINE.

Section 2113(a)(2)(B) of the Public Health Service Act (42 U.S.C. 300aa–13(a)(2)(B)) is amended—

(1) by inserting ''structural lesions, genetic disorders,'' after ''and related anoxia),'';

(2) by inserting ''(without regard to whether the cause of the infection, toxin, trauma, structural

lesion, genetic disorder, or metabolic disturbance is known)'' after ''metabolic disturbances''; and

(3) by striking ''but'' and inserting ''and''.

SEC. 326. INCREASE IN AWARD IN THE CASE OF A VACCINE-RELATED DEATH AND FOR PAIN AND SUFFERING.

(a) IN GENERAL.—Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)) is amended—

(1) in paragraph (2), by striking ''$250,000'' and inserting ''$350,000''; and

(2) in paragraph (4), by striking ''$250,000'' and inserting ''$350,000''.

(b) DEATH AWARDS.—Section 2115(a)(2) of the Public Health Service Act (42 U.S.C. 300aa–15(a)(2)) is amended by inserting ''(if the deceased incurred unreimbursable expenses due to the vaccine-related injury prior to death in excess of $50,000, the award shall also include reimbursement for those unreimbursable expenses that exceed $50,000)'' before the period.

SEC. 327. BASIS FOR CALCULATING PROJECTED LOST EARNINGS.

Section 2115(a)(3)(B) of the Public Health Service Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by striking ''loss of earnings'' and all that follows and inserting

the following: ''loss of earnings determined on the basis of the annual estimate of the average (mean) gross weekly earnings of wage and salary workers age 18 and over (excluding the incorporated self-employed) in the private nonfarm sector (which includes all industries other than agricultural production crops and livestock), as calculated annually by the Bureau of Labor Statistics from the quarter sample data of the Current Population Survey, or as calculated by such similar method as the Secretary may prescribe by regulation, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.''.

SEC. 328. ALLOWING COMPENSATION FOR FAMILY COUNSELING EXPENSES AND EXPENSES OF ESTABLISHING AND MAINTAINING GUARDIANSHIP.

(a) FAMILY COUNSELING EXPENSES IN POST-1988 CASES.—Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)) is amended by adding at the end the following:

''(5) Actual unreimbursable expenses that have been or will be incurred for family counseling as is determined to be reasonably necessary and that result from the vaccine-related injury from which the petitioner seeks compensation.''.

(b) EXPENSES OF ESTABLISHING AND MAINTAINING GUARDIANSHIPS IN POST-1988 CASES.—Section 2115(a) of the Public Health Service Act (42 U.S.C. 300aa–15(a)), as amended by subsection (a), is further amended by adding at the end the following:

"(6) Actual unreimbursable expenses that have been, or will be reasonably incurred to establish and maintain a guardianship or conservatorship for an individual who has suffered a vaccine-related injury, including attorney fees and other costs incurred in a proceeding to establish and maintain such guardianship or conservatorship.".

(c) CONFORMING AMENDMENT FOR CASES FROM 1988 AND EARLIER.—Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended in subsection (c), as so redesignated by section 323(f)—

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

(2) in paragraph (3), by striking "(c)" and inserting "(f)";

(3) by redesignating paragraph (3) as paragraph (5); and

(4) by inserting after paragraph (2), the following:

''(3) family counseling expenses (as provided for in paragraph (5) of subsection (a));

''(4) expenses of establishing and maintaining guardianships (as provided for in paragraph (6) of subsection (a)); and''.

SEC. 329. ALLOWING PAYMENT OF INTERIM COSTS.

Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15) is amended in subsection (f), as so redesignated by section 323(f), by adding at the end the following:

''(4) A special master or court may make an interim award of costs subject to final adjustment if—

''(A) the case involves a vaccine administered on or after October 1, 1988;

''(B) the special master or court has determined that the petitioner is entitled to compensation under the Program;

''(C) the award is limited to other costs (within the meaning of paragraph (1)(B)) incurred in the proceeding;

''(D) not more than 1 prior award has been made with respect to such petition; and

''(E) the petitioner provides documentation verifying the expenditure of the amount for which compensation is sought.''.

SEC. 330. PROCEDURE FOR PAYING ATTORNEYS' FEES.

Section 2115 of the Public Health Service Act (42 U.S.C. 300aa–15), is amended in subsection (f), as so redesignated by section 323(f) and amended by section 329, by adding at the end the following:

"(5) When a special master or court awards attorney fees or costs under paragraph (1) or (4), it may order that such fees or costs be payable solely to the petitioner's attorney if—

"(A) the petitioner expressly consents; or

"(B) the special master or court determines, after affording to the Secretary and to all interested persons the opportunity to submit relevant information, that—

"(i) the petitioner cannot be located or refuses to respond to a request by the special master or court for information, and there is no practical alternative means to ensure that the attorney will be reimbursed for such fees or costs expeditiously; or

"(ii) there are otherwise exceptional circumstances and good cause for paying such fees or costs solely to the petitioner's attorney.".

SEC. 331. EXTENSION OF STATUTE OF LIMITATIONS.

(a) GENERAL RULE.—Section 2116(a) of the Public Health Service Act (42 U.S.C. 300aa–16(a)) is amended—

(1) in paragraph (2), by striking ''36 months'' and inserting ''6 years''; and

(2) in paragraph (3), by striking ''48 months'' and inserting ''6 years''.

(b) CLAIMS BASED ON REVISIONS TO TABLE.—Section 2116 of the Public Health Service Act (42 U.S.C. 300aa–16) is amended by striking subsection (b) and inserting the following:

''(b) EFFECT OF REVISED TABLE.—If at any time the Vaccine Injury Table is revised and the effect of such revision is to make an individual eligible for compensation under the program, where, before such revision, such individual was not eligible for compensation under the program, or to significantly increase the likelihood that an individual will be able to obtain compensation under the program, such person may, and shall before filing a civil action for equitable relief or monetary damages, notwithstanding section 2111(b)(2), file a petition for such compensation if—

''(1) the vaccine-related death or injury with respect to which the petition is filed occurred not more

than 10 years before the effective date of the revision of the table; and

"(2) either—

"(A) the petition satisfies the conditions described in subsection (a); or

"(B) the date of the occurrence of the first symptom or manifestation of onset of the injury occurred more than 4 years before the petition is filed, and the petition is filed not more than 2 years after the effective date of the revision of the table.".

(c) DERIVATIVE PETITIONS.—Section 2116 of the Public Health Service Act (42 U.S.C. 300aa–16) is amended by adding at the end the following:

"(d) DERIVATIVE PETITIONS.—No derivative petition may be filed for compensation under the Program later than the earlier of—

"(1) the last day on which the petition for compensation for the underlying claim of the person who sustained the vaccine-related injury or death upon which the derivative petition is premised may be timely filed; or

"(2) 60 days after the date on which the special master has issued a decision pursuant to section 2112(d)(3) on the underlying claim of the person

who sustained the vaccine-related injury or death upon which the derivative petition is premised.''.

(d) TIMELY RESOLUTIONS OF CLAIMS.—

(1) SPECIAL MASTER DECISION.—Section 2112(d)(3)(A) of the Public Health Service Act (42 U.S.C. 300aa–12(d)(3)(A)) is amended by adding at the end the following: ''For purposes of this subparagraph, the petition shall be deemed to be filed on the date on which the special master issues a certificate of completeness, indicating that all petition contents and supporting documents required under section 2111(c) and, when applicable, section 2111(d) and the Vaccine Rules of the United States Court of Federal Claims, such as an affidavit and supporting documentation, have been served on the Secretary and filed with the clerk of the United States Court of Federal Claims.''.

(2) DERIVATIVE PETITIONS.—Section 2112(d)(3)(C) of the Public Health Service Act (42 U.S.C. 300aa–12(d)(3)(C)) is amended by adding at the end the following: ''With respect to any derivative petition filed under section 2111, the period of time during which the petition for compensation for the underlying vaccine-related injury or death upon which such derivative petition is premised is pending

shall be treated as a suspension for purposes of this subparagraph.''.

(3) COURT OF FEDERAL CLAIMS DECISION.—Section 2121(b) of the Public Health Service Act (42 U.S.C. 300aa–21(b)) is amended by adding at the end the following: ''For purposes of this subsection, the petition shall be deemed to be filed on the date on which the special master issues a certificate of completeness, indicating that all petition contents and supporting documents required under section 2111(c) and, when applicable, section 2111(d) and the Vaccine Rules of the United States Court of Federal Claims, such as an affidavit and supporting documentation, have been served on the Secretary and filed with the clerk of the United States Court of Federal Claims.''.

SEC. 332. ADVISORY COMMISSION ON CHILDHOOD VACCINES.

(a) SELECTION OF PERSONS INJURED BY VACCINES AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of the Public Health Service Act (42 U.S.C. 300aa–19(a)(1)(B)) is amended by striking ''of whom'' and all that follows and inserting the following: ''of whom 1 shall be the legal representative of a child who has suffered a vaccine-related injury or death, and at least 1 other shall be either

the legal representative of a child who has suffered a vaccine-related injury or death or an individual who has personally suffered a vaccine-related injury.''.

(b) MANDATORY MEETING SCHEDULE ELIMINATED.—Section 2119(c) of the Public Health Service Act (42 U.S.C. 300aa–19(c)) is amended by striking ''not less often than four times per year and''.

SEC. 333. CLARIFICATION OF STANDARDS OF RESPONSIBILITY.

(a) GENERAL RULE.—Section 2122(a) of the Public Health Service Act (42 U.S.C. 300aa–22(a)) is amended by striking ''and (c) State law shall apply to a civil action brought for damages'' and inserting ''(d), and (f) State law shall apply to a civil action brought for damages or equitable relief''; and

(b) UNAVOIDABLE ADVERSE SIDE EFFECTS.—Section 2122(b)(1) of the Public Health Service Act (42 U.S.C. 300aa–22(b)(1)) is amended by inserting ''or equitable relief'' after ''for damages''.

(c) DIRECT WARNINGS.—Section 2122(c) of the Public Health Service Act (42 U.S.C. 300aa–22(c)) is amended by inserting ''or equitable relief'' after ''for damages''.

(d) CONSTRUCTION.—Section 2122(d) of the Public Health Service Act (42 U.S.C. 300aa–22(d)) is amended—

(1) by inserting ''or equitable relief'' after ''for damages''; and

(2) by inserting ''or relief'' after ''which damages''.

(c) PAST OR PRESENT PHYSICAL INJURY.—Section 2122 of the Public Health Service Act (42 U.S.C. 300aa–22) is amended—

(1) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively; and

(2) by inserting after subsection (c) the following:

''(d) PAST OR PRESENT PHYSICAL INJURY.—No vaccine manufacturer or vaccine administrator shall be liable in a civil action brought after October 1, 1988, for equitable or monetary relief absent proof of past or present physical injury from the administration of a vaccine, nor shall any vaccine manufacturer or vaccine administrator be liable in any such civil action for claims of medical monitoring, or increased risk of harm.''.

SEC. 334. CLARIFICATION OF DEFINITION OF MANUFACTURER.

Section 2133(3) of the Public Health Service Act (42 U.S.C. 300aa–33(3)) is amended—

(1) in the first sentence, by striking ''under its label any vaccine set forth in the Vaccine Injury

Table'' and inserting ''any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine''; and

(2) in the second sentence, by inserting ''including any component or ingredient of any such vaccine'' before the period.

SEC. 335. CLARIFICATION OF DEFINITION OF VACCINE-RELATED INJURY OR DEATH.

Section 2133(5) of the Public Health Service Act (42 U.S.C. 300aa–33(5)) is amended by adding at the end the following: ''For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label.''.

SEC. 336. CLARIFICATION OF DEFINITION OF VACCINE AND DEFINITION OF PHYSICAL INJURY.

Section 2133 of the Public Health Service Act (42 U.S.C. 300aa–33) is amended by adding at the end the following:

''(7) The term 'vaccine' means any preparation or suspension, including a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredi-

ents listed in the vaccine's product license application and product label.

''(8) The term 'physical injury' means a manifest physical illness, condition, or death, including a neurological disease or disorder.''.

SEC. 337. AMENDMENTS TO VACCINE INJURY COMPENSATION TRUST FUND.

(a) EXPANSION OF COMPENSATED LOSS.—Section 9510(c)(1)(A) of the Internal Revenue Code of 1986 is amended by inserting '', or related loss,'' after ''death''.

(b) INCREASE IN LIMIT ON ADMINISTRATIVE EXPENSES.—Subparagraph (B) of section 9510(c)(1) of the Internal Revenue Code of 1986 is amended—

(1) by striking ''(but not in excess of the base amount of $9,500,000 for any fiscal year)''; and

(2) by striking the period and inserting '', provided that such administrative costs shall not exceed the greater of—

''(i) the base amount of $9,500,000 for any fiscal year,

''(ii) 125 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 150 percent of the average number of claims pending in the preceding 5 years,

''(iii) 175 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 200 percent of the average number of claims pending in the preceding 5 years,

''(iv) 225 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 250 percent of the average number of claims pending in the preceding 5 years, or

''(v) 275 percent of the base amount for any fiscal year in which the total number of claims pending under such subtitle exceeds 300 percent of the average number of claims pending in the preceding 5 years.''.

(c) CONFORMING AMENDMENT.—Section 9510(c)(1)(A) of the Internal Revenue Code of 1986 is amended by striking ''October 18, 2000'' and inserting ''the date of enactment of the Improved Vaccine Affordability and Availability Act''.

SEC. 338. ONGOING REVIEW OF CHILDHOOD VACCINE DATA.

Part C of title XXI of the Public Health Service Act (42 U.S.C. 300a–25 et seq.) is amended by adding at the end the following:

"SEC. 2129A. ONGOING REVIEW OF CHILDHOOD VACCINE DATA.

"(a) IN GENERAL.—Not later than 6 months after the date of enactment of this section, the Secretary shall enter into a contract with the Institute of Medicine of the National Academy of Science under which the Institute shall conduct an ongoing, comprehensive review of new scientific data on childhood vaccines (according to priorities agreed upon from time to time by the Secretary and the Institute of Medicine).

"(b) REPORTS.—Not later than 3 years after the date on which the contract is entered into under subsection (a), the Institute of Medicine shall submit to the Secretary a report on the findings of the studies conducted under such contract, including findings as to any adverse events associated with childhood vaccines, including conclusions concerning causation of adverse events by such vaccines, and other appropriate recommendations, based on such findings and conclusions.

"(c) FAILURE TO ENTER INTO CONTRACT.—If the Secretary and the Institute of Medicine are unable to

enter into the contract described in subsection (a), the Secretary shall enter into a contract with another qualified nongovernmental scientific organization for the purposes described in subsections (a) and (b).

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003, 2004, 2005 and 2006.''.

SEC. 339. PENDING ACTIONS.

The amendments made by this title shall apply to all actions or proceedings pending on or after the date of enactment of this Act, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding.

SEC. 340. REPORT.

Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Advisory Commission on Childhood Vaccines shall report to the Secretary regarding the status of the Vaccine Injury Compensation Trust Fund, and shall make recommendations to the Secretary regarding the allocation of funds from the Vaccine Injury Compensation Trust Fund.

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 IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409J. BIOMEDICAL COUNTERMEASURE RESEARCH AND DEVELOPMENT.

"(a) IN GENERAL.—

"(1) AUTHORITY.—In carrying out research responsibilities under this Act, the Secretary may conduct and support research and development with respect to biomedical countermeasures.

"(2) IMPLEMENTATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (C), authorities assigned by this section to the Secretary shall be carried out through the Director of NIH.

"(B) LEAD INSTITUTE.—The National Institute of Allergy and Infectious Diseases shall be the lead institute for performing, administering, or supporting biomedical countermeasure research and development. The Director of NIH may delegate to the Director of the Institute au-

thorities as are necessary to carry out this function.

"(C) CHEMICAL, RADIOLOGICAL, AND NUCLEAR AGENTS.—To the extent that an authority described in subparagraph (A) is exercised with respect to a chemical, radiological, or nuclear agent, the Secretary may authorize the Director of NIH to carry out the authority through any national research institute.

"(D) 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 preforming, administering, and supporting biomedical countermeasures 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.

"(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 Federal Government and to use other agencies of the Department of Health and Human Services.

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

"(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 biomedical countermeasure research or development, 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) INTERNAL CONTROLS TO BE INSTITUTED.—The Secretary shall institute appropriate internal controls for procurements made under this paragraph, including requirements with respect to documenting the justification for use of the authority provided in this paragraph.

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

"(A) the procurement is as described by paragraph (1)(A); and

"(B) the property or services needed by the Secretary are available from only one responsible source or only from a limited number of respon-

sible sources, and no other type of property or services will meet the needs of the Secretary.

"(3) INCREASED MICROPURCHASE THRESHOLD.—

"(A) IN GENERAL.—For a procurement described by paragraph (1)(A), 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 procurements that are made 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 Federal Government purchase card method for purchases shall apply to procurements made under this paragraph and that are greater than $2,500.

"(c) AUTHORITY TO EXPEDITE PEER REVIEW.—The Secretary may, as the Secretary determines necessary to respond to pressing 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, determines to be appropriate to obtain an assessment of scientific and technical merit and likely contribution to the field of biomedical countermeasure research, in place of the peer review and advisory council review procedures that would otherwise 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—

"(1) that is for performing, administering, or supporting biomedical countermeasure research and development; and

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

"(d) AGENCY FACILITIES.—In addition to any similar authority provided under any other provision of law, in carrying out this section, the Secretary may—

"(1) acquire, lease, construct, improve, renovate, remodel, repair, operate, and maintain laboratories, other research facilities and equipment, and other real or personal property as the Secretary determines necessary for the purpose of performing, administering, and supporting biomedical countermeasure research and development; and

"(2) acquire, without regard to section 8141 of title 40, United States Code, by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia.

"(e) AUTHORITY FOR PERSONAL SERVICES CONTRACTS.—

"(1) IN GENERAL.—For the purpose of performing, administering, and supporting biomedical countermeasure research and development, the Secretary may, as the Secretary determines necessary to respond to pressing 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.

"(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 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 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 person, officer, employee, or governing board member to carry out any obligation or responsibility assumed by such

person, officer, employee, or governing board member under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of such person, officer, employee, or governing board member.

"(ii) VENUE.—The United States may maintain an action under this subparagraph against such person, officer, employee, or governing board member in the district court of the United States in which such person, officer, employee, or governing board member 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 Sec-

retary 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.

"(f) 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 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 biomedical counter-

measure research and development in carrying out this section.

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

"(g) DEFINITION.—As used in this section, the term 'biomedical 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 is used—

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

"(2) 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 that is used as described in paragraph (1).

"(h) 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"; and

(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".

SEC. 3. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

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

"SEC. 319A-1. BIOMEDICAL COUNTERMEASURES PROCUREMENT.

"(a) DETERMINATION OF MATERIAL THREATS.—

"(1) RISK OF USE.—The Secretary of Homeland Security, in consultation with the heads of other agencies as appropriate, shall on an ongoing basis—

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

"(B) determine which of such agents present a material risk of use against the United States population.

"(2) PUBLIC HEALTH IMPACT.—The Secretary, in consultation with the Secretary of Homeland Security, shall on an ongoing basis—

"(A) assess the potential public health consequences of use against the United States population of agents identified under paragraph (1)(B); and

"(B) determine, on the basis of such assessment, the agents for which countermeasures are necessary to protect the public health.

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

"(c) CALL FOR NECESSARY COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

"(1) PROPOSAL TO THE PRESIDENT.—Based on a determination of necessary countermeasures under subsection (a), and the assessment of availability and appropriateness of countermeasures under subsection (b), the Secretary of Homeland Security and the Secretary may jointly submit to the President a proposal to—

"(A) call for a necessary countermeasure that is not available; and

"(B) commit to make a recommendation for procurement under subsection (e) of the first such specific countermeasure that meets the conditions for procurement under subsection (d).

"(2) COUNTERMEASURE SPECIFICATIONS.—The Secretary of Homeland Security and the Secretary shall, to the extent practicable, include in the recommendation under paragraph (1)—

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

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

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

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

"(3) PRESIDENTIAL APPROVAL.—If the President has approved a request under paragraph (1), the Secretary of Homeland Security and the Secretary shall make known to persons who may respond to a call for the countermeasure—

"(A) the call for the countermeasure;

"(B) specifications for the countermeasure under paragraph (2); and

"(C) a commitment for a recommendation for procurement under subsection (e) of the first such specific countermeasure that meets the con-

ditions for procurement under subsection (d) and the specifications under paragraph (2).

"(4) SUBSEQUENT SPECIFIC COUNTERMEASURES.—Procurement under subsection (f) of the first such specific countermeasure, or any other such countermeasure, that meets the conditions for procurement under subsection (d) and the specifications under paragraph (2) shall not preclude the additional procurement under subsection (f) of a subsequent such countermeasure that meets the conditions of procurement under subsection (d) if such a 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.

"(d) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR PROCUREMENT UNDER THIS SECTION.—

"(1) IN GENERAL.—The Secretary, in accordance with this section, shall identify specific countermeasures to threats identified under subsection (a) that the Secretary determines, in consultation with the Secretary of Homeland Security, to be appropriate for procurement with appropriations under this subsection for inclusion in the stockpile under

section 121(a) of the Public Health and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 300hh-12(a)).

"(2) REQUIREMENTS.—In order for the Secretary to make the determination under paragraph (1) with respect to a countermeasure, the following requirements must be met:

"(A) DETERMINATION OF QUALIFIED COUNTERMEASURE.—The Secretary must determine that the product is a qualified countermeasure (as defined in subsection (h)).

"(B) DETERMINATION OF QUANTITIES NEEDED AND FEASIBILITY OF PRODUCTION AND DISTRIBUTION.—The Secretary must determine—

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

"(ii) that production and delivery within 5 years of sufficient quantities of the product, as so determined, is reasonably expected to be feasible.

"(C) DETERMINATION OF NO SIGNIFICANT COMMERCIAL MARKET.—The Secretary shall—

"(i) determine that, at the time of the initial determination under this subsection, there is not a significant commercial market for the product other than as a biomedical countermeasure; and

"(ii) annually redetermine and report to the President, while a determination under paragraph (1) remains in effect with respect to the product, whether a significant commercial market exists for the product other than as a biomedical countermeasure.

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

"(1) RECOMMENDATION FOR PROCUREMENT.—In the case of a countermeasure that the Secretary of Homeland Security and the Secretary have determined is appropriate for procurement under this section for inclusion in the stockpile, in accordance with the preceding provisions of this section, the Secretary of Homeland Security and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation for procurement under this section.

"(2) PRESIDENTIAL APPROVAL.—A countermeasure may be procured under this section only if

the President has approved a recommendation under paragraph (1) with respect to such countermeasure.

"(3) NOTICE TO CONGRESS.—The Secretary of Homeland Security shall notify Congress of each decision of the President to approve a recommendation under paragraph (1).

"(f) PROCUREMENT.—The Secretary and the Secretary of Homeland Security shall be responsible for the following, for purposes of procurement of qualified countermeasures for the stockpile under section 121(a) of the Public Health and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 300hh-12(a)), as approved by the President under subsection (e):

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

"(A) arranging for procurement of the 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 paragraph; and

"(B) promulgating regulations to implement subparagraphs (E), (F), and (G), and any other provisions of this section.

"(2) CONTRACT TERMS.—A contract for procurement under this section shall (or, as otherwise specified in this paragraph, may) include the following terms:

"(A) 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.

"(B) DISCOUNTED PAYMENT FOR UNLICENSED PRODUCT.—The contract may provide for a discounted price per unit of a product that is not licensed or approved as described in subsection (h)(1) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed 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 or approval).

"(C) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts appropriated under subsection (i) shall be available for costs of shipping, handling, storage, and related costs for such product.

"(D) CONTRACT DURATION.—The contract shall be for a period not to exceed 5 years, renewable for additional periods none of which shall exceed 5 years.

"(E) TERMINATION FOR NONDELIVERY.—In addition to any other rights of the Secretary to terminate the contract, the contract may provide that such Secretary may terminate the contract for failure to deliver a reasonable number (as determined by the Secretary) of units of the product by 3 years after the date the contract is entered into, and may further provide that in such case the vendor shall not be entitled to any payment under the contract.

"(F) 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 of all of this contract term on request of the vendor or on the initiative of the Secretary.

"(3) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—The amount of any procurement under this section 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—

"(A) 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

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

"(4) 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 section 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 such Secretary's needs.

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

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

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

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

"(B) DETERMINATION OF GOVERNMENT'S REQUIREMENT NOT REVIEWABLE.—If the Sec-

retary includes in each of a set of contracts a provision as described in subparagraph (A), such Secretary's determination of the total quantity of countermeasure required, and any amendment of such determination, is committed to agency discretion.

"(6) 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.

"(7) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this section, 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 such Secretary may so exclude such a source.

"(g) INTERAGENCY COOPERATION.—

"(1) IN GENERAL.—In carrying out activities under this section, the Secretary of Homeland Security and the Secretary are authorized, subject to paragraph (2), to enter into interagency agreements

and other collaborative undertakings with other agencies of the United States Government.

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

"(h) DEFINITIONS.—In this section:

"(1) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' means a biomedical countermeasure—

"(A) that is approved under section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of this Act (42 U.S.C. 262) or that is approved under section 515 or cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e and 360) for use as such a countermeasure to a chemical, biological, radiological, or nuclear agent identified as a material threat under subsection (a); or

"(B) for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from preclinical and clinical trials) sup-

port a reasonable conclusion that the product will qualify for approval or licensing as such a countermeasure within 5 years after the date of a determination under subsection (d).

"(2) BIOMEDICAL COUNTERMEASURE.—The term 'biomedical 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))), device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))), or biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))) that is used—

"(A) to 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) 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 or biological product that is used as described in subparagraph (A).

"(i) APPROPRIATIONS.—

"(1) IN GENERAL.— There are appropriated, out of any moneys in the Treasury not otherwise appro-

priated, for fiscal year 2003 and for each fiscal year thereafter, such sums as may be necessary for the costs incurred by the Secretary in the procurement of countermeasures under this subsection as approved by the President under subsection (e) (other than costs specified in paragraph (2)).

"(2) RESTRICTIONS.—Amounts appropriated under this subsection shall not be available to pay—

"(A) costs for the purchase of vaccines under procurement contracts entered into before January 1, 2003;

"(B) costs under new contracts, or costs of new obligations under contracts previously entered into, for procurement of a countermeasure after the date of a determination under subsection (d)(2)(C) that there is a significant commercial market for the countermeasure other than as a biomedical countermeasure; or

"(C) administrative costs.".

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

(a) IN GENERAL.—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:

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

"(a) IN GENERAL.—Notwithstanding sections 505, 510(k), and 515 of this Act and section 351 of the Public Health Service Act, and 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, biological product, or device intended solely for use in an actual or potential emergency.

"(b) DECLARATION OF EMERGENCY.—

"(1) IN GENERAL.—The Secretary may declare an emergency justifying the authorization of a drug, biological product, or device under this subsection on the basis of a determination—

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

"(B) by the Secretary of Defense, that there is a military emergency (or a significant potential of a military emergency) involving a heightened risk to United States military forces of at-

tack with a biological, chemical, radiological, or nuclear agent; or

"(C) 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 a specified disease or condition that may be attributable to such agent.

"(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 1-year period beginning on the date on which the declaration is made.

"(B) RENEWAL.—Notwithstanding subparagraph (A), the Secretary may renew a declara-

tion under this subsection, and this paragraph shall apply to any such renewal.

"(3) NOTIFICATION.—The Secretary shall promptly publish in the Federal Register, and shall notify the appropriate committees of Congress concerning, 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 a product if 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.—An authorization of a product under this section shall state—

"(1) each disease or condition and the intended use of the product within the scope of the authorization; and

"(2) the Secretary's conclusions, 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.

"(e) CONDITIONS OF AUTHORIZATION.—The Secretary is authorized to impose such conditions on an authorization under this section as the Secretary determines are necessary

or appropriate to protect the public health, including the following:

"(1) The Secretary shall impose requirements (including requirements concerning product labeling and the provision of information) designed to ensure that, to the maximum extent feasible given the circumstances of the emergency, health care professionals administering the product are informed—

"(A) that the Secretary has authorized the product solely for emergency use;

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

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

"(2) The Secretary shall impose requirements (including requirements concerning product labeling and the provision of information) designed to ensure that, to the maximum extent feasible given the circumstances of the emergency, individuals to whom the product is administered are informed—

"(A) that the Secretary has authorized the product solely for emergency use;

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

"(C) of any option to accept or refuse administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

"(3) The Secretary may impose limitations on which entities may distribute the product (including limitation to distribution by government entities), and on how distribution is to be performed.

"(4) The Secretary may impose limitations on who may administer the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered.

"(5) The Secretary may condition the authorization on the performance of studies, clinical trials, or other research needed to support marketing approval of the product.

"(6) The Secretary shall impose, to the extent feasible and appropriate given the circumstances of the emergency, requirements concerning recordkeeping and reporting, including records access by the Secretary and publication of data.

"(7) The Secretary may waive, to the extent appropriate given the circumstances of the emergency, requirements, with respect to the product, of current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act.

"(8) The Secretary shall, to the extent feasible and appropriate given the circumstances of the emergency, impose requirements for the monitoring and reporting of adverse events associated with use of the product.

"(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—

"(A) the conditions for such an authorization are no longer met; or

"(B) other circumstances make such revocation appropriate.

"(h) PUBLICATION.—The Secretary shall promptly publish in the Federal Register, and provide to the appropriate committees of Congress, a notice of each authorization, and each termination or revocation of an authorization, under this section.

"(i) RECORDKEEPING.—

"(1) IN GENERAL.—The Secretary may require persons, including a person who holds an authorization under this section, or who manufactures, distributes, prescribes, or administers a product that is the subject of such an authorization, to establish and maintain—

"(A) data that is obtained from such activity and that pertains to the effectiveness or safety of such product;

"(B) such records as are necessary to determine, or facilitate a determination, whether there may be any violation of this section or of a regulation promulgated under this section; and

"(C) such additional records as the Secretary may determine necessary.

"(2) ACCESS TO RECORDS BY SECRETARY.—

"(A) SAFETY AND EFFECTIVENESS INFORMATION.—The Secretary may require a person who holds an authorization under this section, or who manufactures, distributes, prescribes, or administers a product that is the subject of such an authorization to provide to the Secretary all data that is obtained from such activity and that pertains to the safety or effectiveness of such product.

"(B) OTHER INFORMATION.—Every person required under this section to establish or maintain records, and every person in charge or custody of such records, shall, upon request by the Secretary, permit the Secretary at all reasonable times to have access to, to copy, and to verify such records.

"(j) CIVIL MONETARY PENALTIES.—

"(1) IN GENERAL.—A person who violates a requirement of this section or of a regulation or order promulgated pursuant to this section shall be subject to a civil money penalty of not more than $100,000 in the case of an individual, and not more than $250,000 in the case of any other person, for each violation, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

"(2) ASSESSMENT OF CIVIL PENALTIES.—Paragraphs (3), (4), and (5) of section 303(g) shall apply to a civil penalty under this subsection, and references in such paragraphs to 'paragraph (1) or (2)' shall, for purposes of this subsection, be deemed to refer to paragraph (1) of this subsection.

"(k) 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.

"(l) REGULATIONS.—The Secretary may promulgate regulations to implement this section.

"(m) 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; or

"(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.

"(n) APPLICATION TO MEMBERS OF ARMED FORCES.—

"(1) WAIVER OF REQUIREMENT RELATING TO OPTION TO REFUSE.—In the case of the administration of a countermeasure to members of the armed forces, a requirement, under subsection (e)(2), 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) EFFECT ON STATUTE PERTAINING TO INVESTIGATIONAL NEW DRUGS.—In the case of an authorization based on a determination by the Secretary of Defense under subsection (b)(1)(B), section 1107 of title 10, United States Code, shall not apply to use of a product that is the subject of such authorization,

within the scope of such authorization and while such authorization is effective.

"(o) 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.".

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsection (e)—

(A) by striking "504, 703" and inserting "504, 564, 703"; and

(B) by striking "or 519" and inserting "519, or 564"; and

(2) by adding at the end the following:

"(hh)(1) Promotion or use of a product that is the subject of an authorization under section 564 other than as stated in the authorization, or other than during the period described by section 564(g), unless such promotion or use is permitted under another provision of this Act.

"(2) Failure to comply with an information requirement under section 564(e).".

SEC. 5. AMENDMENTS TO PROVISIONS OF THE HOMELAND SECURITY ACT.

(a) DECLARATION RECOMMENDING MAKING COUNTERMEASURE AVAILABLE TO INDIVIDUALS.—Section 224(p)(2)(A)(i) of the Public Health Service Act (42 U.S.C. 233(p)(2)(A)(i)) is amended—

(1) by striking "advisable the administration" and inserting the following: "advisable—

"(I) the administration";

(2) by striking the period and inserting "; or"; and

(3) by adding at the end the following:

"(II) making a covered countermeasure available to a category or categories of individuals who may wish to receive it.".

(b) AMENDMENT TO ACCIDENTAL VACCINIA INOCULATION PROVISION.—Section 224(p)(2)(C)(ii)(II) of the Public Health Service Act (42 U.S.C. 233(p)(2)(C)(ii)(II)) is amended by striking "resides or has resided with" and inserting "has resided with, or has had close contact with,".

(c) DEEMING ACTS AND OMISSIONS TO BE WITHIN SCOPE OF EMPLOYMENT.—Section 224(p)(2) of the Public

Health Service Act (42 U.S.C. 233(p)(2)) is amended by adding at the end the following:

"(D) ACTS AND OMISSIONS DEEMED TO BE WITHIN SCOPE OF EMPLOYMENT.—

"(i) IN GENERAL.—In the case of a claim arising out of alleged transmission of vaccinia from an individual described in clause (ii), acts or omissions by such individual shall be deemed to have been taken within the scope of such individual's office or employment for purposes of—

"(I) subsection (a); and

"(II) section 1346(b) and chapter 171 of title 28, United States Code.

"(ii) INDIVIDUALS TO WHOM DEEMING APPLIES.—An individual is described by this clause if—

"(I) vaccinia vaccine was administered to such individual as provided by paragraph (2)(B); and

"(II) such individual was within a category of individuals covered by a declaration under paragraph (2)(A)(i)(I).".

(d) REQUIREMENT TO COOPERATE WITH UNITED STATES.—Section 224(p)(5) of the Public Health Service Act (42 U.S.C. 233(p)(5)) is amended in paragraph heading by striking "DEFENDANT" and inserting "COVERED PERSON".

(e) AMENDMENT TO DEFINITION OF COVERED COUNTERMEASURE.—Subclause (II) of section 224(p)(7)(A)(i) of the Public Health Service Act (42 U.S.C. 233(p)(7)(A)(i)(II)) is amended to read as follows:

> *"(II) used to control or treat the adverse effects of vaccinia inoculation or of administration of another covered countermeasure; and".*

(f) AMENDMENT TO DEFINITION OF COVERED PERSON.—Section 224(p)(7)(B) of the Public Health Service Act (42 U.S.C. 233(p)(7)(B)) is amended—

(1) in the matter preceding clause (i), by striking "includes any person" and inserting "means a person";

(2) in clause (ii)—

(A) by striking "auspices such" and inserting the following: "auspices—

"(I) such"; and

(B) by adding at the end the following:

"(II) a determination was made as to whether, or under what circumstances, an individual should receive a covered countermeasure;

"(III) the immediate site of administration of a covered countermeasure was monitored, managed, or cared for; or

"(IV) an evaluation was made of whether the administration of a covered countermeasure was effective;";

(3) in clause (iii) by striking "or";

(4) by striking clause (iv) and inserting the following:

"(iv) a State, a political subdivision of a State, or an agency or official of a State or of such a political subdivision, if such State, subdivision, agency, or official has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance with respect to administration of such countermeasures;

"(v) in the case of a claim arising out of alleged transmission of vaccinia from an individual—

"(I) the individual who allegedly transmitted the vaccinia, if vaccinia vaccine was administered to such individual as provided by paragraph (2)(B) and such individual was within a category of individuals covered by a declaration under paragraph (2)(A)(i)(I); or

"(II) an entity that employs an individual described by clause (I) or where such individual has privileges to provide health care;

"(vi) an official, agent, or employee of a person described in clause (i), (ii), (iii), or (iv);

"(vii) a contractor of, or a volunteer working for, a person described in clause (i), (ii), or (iv), if the contractor or volunteer performs a function for which a person described in clause (i), (ii), or (iv) is a covered person; or

"(viii) an individual who has privileges to provide health care under the auspices of an entity described in clause (ii) or (v)(II).".

(g) AMENDMENT TO DEFINITION OF QUALIFIED PERSON.—Section 224(p)(7)(C) of the Public Health Service Act (42 U.S.C. 233(p)(7)(C)) is amended—

(1) by striking "who is authorized to" and inserting the following: "who—

"(i) is authorized to";

(2) by striking the period and inserting "; or"; and

(3) by adding at the end the following:

"(ii) is otherwise authorized by the Secretary to administer such countermeasure.".

(h) DEFINITION OF "ARISING OUT OF ADMINISTRATION OF A COVERED COUNTERMEASURE".—Section 224(p)(7) of the Public Health Service Act (42 U.S.C. 233(p)(7)) is amended by adding at the end the following:

"(D) ARISING OUT OF ADMINISTRATION OF A COVERED COUNTERMEASURE.—

"(i) IN GENERAL.—The term 'arising out of administration of a covered countermeasure', when used with respect to a claim or liability, includes, except as provided in clause (ii), a claim or liability arising out of—

"(I) determining whether, or under what conditions, an individual should receive a covered countermeasure;

"(II) obtaining informed consent of an individual to the administration of a covered countermeasure;

"(III) monitoring, management, or care of an immediate site of administration of a covered countermeasure, or evaluation of whether the administration of the countermeasure has been effective; or

"(IV) transmission of vaccinia virus by an individual to whom vaccinia vaccine was administered as provided by paragraph (2)(B).

"(ii) EXCEPTION.—Such term shall not include a claim or liability arising out of care for or treatment of complications arising out of the administration of the countermeasure.".

(i) TECHNICAL CORRECTION.—Section 224(p)(2)(A)(ii) of the Public Health Service Act (42

U.S.C. 233(p)(2)(A)(ii)) is amended by striking "paragraph (8)(A)" and inserting "paragraph (7)(A)".

(j) EFFECTIVE DATE.—This amendments made by this section shall take effect as if enacted on November 25, 2002.

SEC. 6. GAO REPORT.

Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report that—

(1) describes the activities conducted under the authorities provided for in section 409J(b)(1) of the Public Health Service Act (as added by section 2) and section 319A-1(f)(3) and (4) of such Act (as added by section 3);

(2) identifies any procurements that would have been prohibited except for the authorities provided in the sections described in paragraph (1); and

(3) assesses the adequacy of the internal controls established by the Secretary of Health and Human Services regarding procurements made under the authorities provided for in the sections described in paragraph (1).

Calendar No. 53

108TH CONGRESS
1ST SESSION

S. 15

A BILL

To amend the Public Health Service Act to provide for the payment of compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures, to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States, and to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program.

MARCH 25, 2003

Reported with an amendment