activity relating to the development, manufacture, distribution, purchase, or storage of a countermeasure or product.

''(B) EXCEPTION.—The term 'covered activities' shall not include, with respect to a meeting or consultation conducted under subsection (a)(1) or an agreement for which an exemption has been granted under subsection (a)(4), the following activities involving 2 or more persons:

''(i) Exchanging information among competitors relating to costs, profitability, or distribution of any product, process, or service if such information is not reasonably necessary to carry out covered activities—

''(I) with respect to a countermeasure or product regarding which such meeting or consultation is being conducted; or

''(II) that are described in the agreement as exempted.

''(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, processes, 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 participating in such covered activities, in other research and development activities, except as reasonably necessary to prevent the misappropriation of proprietary information contributed by any person participating in 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 under subsection (a)(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 such covered activities.

''(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not expressly exempted from the antitrust laws under subsection (a)(4).

''(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person participating in such covered activities, in any unilateral or joint activity that is not reasonably necessary to carry out such covered activities.

''(vii) Entering into any agreement or engaging in any other conduct restricting or setting the price at which a countermeasure or product is offered for sale, whether by bid or otherwise.''

OUTREACH

Pub. L. 108–276, § 6, July 21, 2004, 118 Stat. 862, provided that: ''The Secretary of Health and Human Services shall develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of Black or African Americans, American Indians, Appalachian Americans, Alaska Natives, Asians, Native Hawaiians, other Pacific Islanders, Hispanics or Latinos, or other underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under sections 2 and 3 of this Act [enacting this section and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, and 300aa–6 of this title and sections 312 and 313 of Title 6, renumbering section 300hh–12 of this title as section 247d–6b of this title, and enacting provisions set out as notes under this section and section 247d–6b of this title].''

RECOMMENDATION FOR EXPORT CONTROLS ON CERTAIN BIOMEDICAL COUNTERMEASURES

Pub. L. 108–276, § 7, July 21, 2004, 118 Stat. 863, provided that: ''Upon the award of any grant, contract, or cooperative agreement under section 2 or 3 of this Act [enacting this section and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, and 300aa–6 of this title and sections 312 and 313 of Title 6, renumbering section 300hh–12 of this title as section 247d–6b of this title, and enacting provisions set out as notes under this section and section 247d–6b of this title] for the research, development, or procurement of a qualified countermeasure or a security countermeasure (as those terms are defined in this Act [see Short Title of 2004 Amendments note set out under section 201 of this title]), the Secretary of Health and Human Services shall, in consultation with the heads of other appropriate Federal agencies, determine whether the countermeasure involved in such grant, contract, or cooperative agreement is subject to existing export-related controls and, if not, may make a recommendation to the appropriate Federal agency or agencies that such countermeasure should be included on the list of controlled items subject to such controls.''

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

Pub. L. 108–276, § 8, July 21, 2004, 118 Stat. 863, provided that:

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

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

## § 247d–6b. Strategic National Stockpile and security countermeasure procurements

### (a) Strategic National Stockpile

#### (1) In general

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

health emergency. The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review.

**(2) Procedures**

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

(A) consult with the working group under section 247d–6(a) of this title;

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

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

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

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

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

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

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

**(b) Smallpox vaccine development**

**(1) In general**

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

**(2) Rule of construction**

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

**(c) Additional authority regarding procurement of certain countermeasures; availability of special reserve fund**

**(1) In general**

**(A) Use of fund**

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

**(B) Security countermeasure**

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

(i)(I) the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

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

(III)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title; or

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

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3].

**(2) Determination of material threats**

**(A) Material threat**

The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—

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

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

**(B) Public health impact; necessary countermeasures**

The Secretary shall on an ongoing basis—

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

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

**(C) Notice to Congress**

The Secretary and the Homeland Security Secretary shall promptly notify the designated congressional committees (as defined in paragraph (10)) that a determination

has been made pursuant to subparagraph (A) or (B).

**(D) Assuring access to threat information**

In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 122 of title 6, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

**(3) Assessment of availability and appropriateness of countermeasures**

**(A) In general**

The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

**(B) Information**

The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—

(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or

(ii) would otherwise be exempt from disclosure under section 552 of title 5.

**(4) Call for development of countermeasures; commitment for recommendation for procurement**

**(A) Proposal to the President**

If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

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

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

**(B) Countermeasure specifications**

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

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

(ii) necessary measures of minimum safety and effectiveness;

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

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

**(C) Presidential approval**

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

(i) the call for the countermeasure;

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

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

**(5) Secretary's determination of countermeasures appropriate for funding from special reserve fund**

**(A) In general**

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

**(B) Requirements**

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

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

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

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

**(6) Recommendation for President's approval**

**(A) Recommendation for procurement**

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

**(B) Presidential approval**

The special reserve fund under paragraph (10) is available for a procurement of a secu-

rity countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

**(C) Notice to designated congressional committees**

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

**(D) Subsequent specific countermeasures**

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

**(E) Rule of construction**

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

**(7) Procurement**

**(A) In general**

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

**(B) Interagency agreement; cost**

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

**(C) Procurement**

**(i) In general**

The Secretary shall be responsible for—

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

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

**(ii) Contract terms**

A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

**(I) Payment conditioned on delivery**

The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

**(II) Discounted payment**

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

**(III) Contract duration**

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

**(IV) Storage by vendor**

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

**(V) Product approval**

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

**(VI) Non-stockpile transfers of security countermeasures**

The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

**(VII) Sales exclusivity**

The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 253(c)(1) of title 41.

**(VIII) Warm based surge capacity**

The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

**(IX) Contract terms**

The Secretary, in any contract for procurement under this section, may specify—

(aa) the dosing and administration requirements for countermeasures to be developed and procured;

(bb) the amount of funding that will be dedicated by the Secretary for development and acquisition of the countermeasure; and

(cc) the specifications the countermeasure must meet to qualify for procurement under a contract under this section.

**(iii) Availability of simplified acquisition procedures**

**(I) In general**

If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 403(11) of title 41, for purposes of application to such procurement, pursuant to section 252a(a) of title 41, of—

(aa) section 253(g)(1)(A) of title 41 and its implementing regulations; and

(bb) section 252a(b) of title 41 and its implementing regulations.

**(II) Application of certain provisions**

Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

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

(bb) Subsections (a) and (b) of section 57 of title 41.

(cc) Section 254d of title 41 (relating to the examination of contractor records).

(dd) Section 3131 of title 40 (relating to bonds of contractors of public buildings or works).

(ee) Subsection (a) of section 254 of title 41 (relating to contingent fees to middlemen).

(ff) Section 6962 of this title.

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

**(III) Internal controls to be established**

The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

**(IV) Authority to limit competition**

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

**(iv) Procedures other than full and open competition**

**(I) In general**

In using the authority provided in section 253(c)(1) of title 41 to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase ''available from only one responsible source'' in such section 253(c)(1) shall be deemed to mean ''available from only one responsible source or only from a limited number of responsible sources''.

**(II) Relation to other authorities**

The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

**(III) Applicable government-wide regulations**

The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 253(c)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

**(v) Premium provision in multiple award contracts**

**(I) In general**

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

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

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

**(II) Determination of Government's requirement not reviewable**

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

**(vi) Extension of closing date for receipt of proposals not reviewable**

A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

**(vii) Limiting competition to sources responding to request for information**

In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 253a(a)(1)(B) of title 41 if such request has given notice that the Secretary may so exclude such a source.

**(8) Interagency cooperation**

**(A) In general**

In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

**(B) Limitation**

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

**(9) Restrictions on use of funds**

Amounts in the special reserve fund under paragraph (10) shall not be used to pay—

(A) costs for the purchase of vaccines under procurement contracts entered into before July 21, 2004; or

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

**(10) Definitions**

**(A) Special reserve fund**

For purposes of this subsection, the term ''special reserve fund'' has the meaning given such term in section 510[1] of the Homeland Security Act of 2002.

**(B) Designated congressional committees**

For purposes of this section, the term ''designated congressional committees'' means the following committees of the Congress:

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

(ii) In the Senate: the appropriate committees.

**(d) Disclosures**

No Federal agency shall disclose under section 552 of title 5 any information identifying the location at which materials in the stockpile under subsection (a) of this section are stored.

**(e) Definition**

For purposes of subsection (a) of this section, the term ''stockpile'' includes—

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

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

**(f) Authorization of appropriations**

**(1) Strategic National Stockpile**

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

**(2) Smallpox vaccine development**

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

(July 1, 1944, ch. 373, title III, § 319F–2, formerly Pub. L. 107–188, title I, § 121, June 12, 2002, 116 Stat. 611; Pub. L. 107–296, title XVII, § 1705(a), Nov. 25, 2002, 116 Stat. 2316; renumbered § 319F–2 of act July 1, 1944, and amended Pub. L. 108–276, § 3(a), July 21, 2004, 118 Stat. 842; Pub. L. 109–417, title I, § 102(c), title IV, §§ 403(b), 406, Dec. 19, 2006, 120 Stat. 2834, 2874, 2879.)

[1] See References in Text note below.

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(1)(B)(i)(III)(aa), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended. Chapter V of the Act is classified generally to subchapter V (§ 351 et seq.) of chapter 9 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Project BioShield Act of 2004, referred to in subsec. (c)(7)(C)(iii)(IV), is Pub. L. 108–276, July 21, 2004, 118 Stat. 835. For complete classification of this Act to the Code, see Short Title of 2004 Amendments note set out under section 201 of this title and Tables.

Section 510 of the Homeland Security Act of 2002, referred to in subsec. (c)(10)(A), probably means section 510 of Pub. L. 107–296 as added by Pub. L. 108–276, which defines ''special reserve fund'', and which was renumbered section 521 of that Act by Pub. L. 109–295, title VI, § 611(7), Oct. 4, 2006, 120 Stat. 1395, and is classified to section 321j of Title 6, Domestic Security. Another section 510 of Pub. L. 107–296, relating to urban and other high risk area communications capabilities, was classified to section 321 of Title 6, prior to repeal by Pub. L. 109–295, title VI, § 611(5), Oct. 4, 2006, 120 Stat. 1395. Another section 510 of Pub. L. 107–296, relating to credentialing and typing, is classified to section 320 of Title 6.

CODIFICATION

Section was formerly classified to section 300hh–12 of this title prior to renumbering by Pub. L. 108–276.

AMENDMENTS

2006—Pub. L. 109–417, § 406(1), inserted ''and security countermeasure procurements'' after ''Stockpile'' in section catchline.

Subsec. (a)(1). Pub. L. 109–417, § 102(c), inserted ''in collaboration with the Director of the Centers for Disease Control and Prevention, and'' after ''The Secretary,'' and inserted at end ''The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review.''

Subsec. (c). Pub. L. 109–417, § 406(2)(A), struck out ''biomedical'' before ''countermeasures'' in heading.

Subsec. (c)(1)(B)(i)(I). Pub. L. 109–417, § 403(b), which directed amendment of section 319F–2(c)(1)(B) by substituting ''diagnose, mitigate, prevent, or treat'' for ''treat, identify, or prevent'' wherever appearing, was executed by making the substitution in two places in subsec. (c)(1)(B)(i)(I) of this section, which is section 319F–2 of the Public Health Service Act, to reflect the probable intent of Congress.

Subsec. (c)(3). Pub. L. 109–417, § 406(2)(B), designated existing provisions as subpar. (A), inserted heading, and added subpar. (B).

Subsec. (c)(4)(A). Pub. L. 109–417, § 406(2)(C), inserted ''not developed or'' after ''currently'' in introductory provisions.

Subsec. (c)(5)(B)(i). Pub. L. 109–417, § 406(2)(D), substituted ''to meet the stockpile needs'' for ''to meet the needs of the stockpile''.

Subsec. (c)(7)(B). Pub. L. 109–417, § 406(2)(E), substituted ''cost'' for ''costs'' in subpar. heading, struck out cl. (i) designation and heading before ''The Homeland'', and struck out heading and text of cl. (ii). Text read as follows: ''The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1) of this section.''

Subsec. (c)(7)(C)(ii)(I). Pub. L. 109–417, § 406(2)(F)(i), amended heading and text of subcl. (I) generally. Prior to amendment, text read as follows: ''The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law,

the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government.''

Subsec. (c)(7)(C)(ii)(VII) to (IX). Pub. L. 109–417, §406(2)(F)(ii), added subcls. (VII) to (IX).

Subsec. (c)(8)(A). Pub. L. 109–417, §406(2)(G), inserted at end ''Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.''

2004—Pub. L. 108–276, §3(a)(2), amended section generally. Prior to amendment, text related in subsec. (a) to Strategic National Stockpile, in subsec. (b) to smallpox vaccine development, in subsec. (c) to disclosures, in subsec. (d) to definition of ''stockpile'', and in subsec. (e) to authorization of appropriations.

2002—Subsec. (a)(1). Pub. L. 107–296, §1705(a)(1), substituted ''The Secretary of Homeland Security'' for ''The Secretary of Health and Human Services'' and inserted ''the Secretary of Health and Human Services and'' after ''in coordination with'' and ''of Health and Human Services'' after ''as are determined by the Secretary''.

Subsecs. (a)(2), (b)(1). Pub. L. 107–296, §1705(a)(2), inserted ''of Health and Human Services'' after ''Secretary'' wherever appearing.

CHANGE OF NAME

Committee on Government Reform of House of Representatives changed to Committee on Oversight and Government Reform of House of Representatives by House Resolution No. 6, One Hundred Tenth Congress, Jan. 5, 2007.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–296, title XVII, §1705(b), Nov. 25, 2002, 116 Stat. 2316, provided that: ''The amendments made by this section [amending this section] shall take effect on the date of transfer of the Strategic National Stockpile of the Department of Health and Human Services to the Department [of Homeland Security].''

STOCKPILE FUNCTIONS TRANSFERRED

Pub. L. 108–276, §3(c)(1),(2), July 21, 2004, 118 Stat. 853, provided that:

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

''(2) EXCEPTIONS.—

''(A) FUNCTIONS.—The transfer of functions pursuant to paragraph (1) shall not include such functions as are explicitly assigned to the Secretary of Homeland Security by this Act [see Short Title of 2004 Amendments note set out under section 201 of this title] (including the amendments made by this Act).

''(B) ASSETS AND UNEXPENDED BALANCES.—The transfer of assets and unexpended balances pursuant to paragraph (1) shall not include the funds appropriated under the heading 'BIODEFENSE COUNTERMEASURES' in the Department of Homeland Security Appropriations Act, 2004 (Public Law 108–90 [117 Stat. 1148]).''

POTASSIUM IODIDE

Pub. L. 107–188, title I, §127, June 12, 2002, 116 Stat. 615, provided that:

''(a) IN GENERAL.—Through the national stockpile under section 121 [now section 319F–2 of act July 1, 1944, this section], the President, subject to subsections (b) and (c), shall make available to State and local governments potassium iodide tablets for stockpiling and for distribution as appropriate to public facilities, such as schools and hospitals, in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant.

''(b) STATE AND LOCAL PLANS.—

''(1) IN GENERAL.—Subsection (a) applies with respect to a State or local government, subject to paragraph (2), if the government involved meets the following conditions:

''(A) Such government submits to the President a plan for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident.

''(B) The plan is accompanied by certifications by such government that the government has not already received sufficient quantities of potassium iodide tablets from the Federal Government.

''(2) LOCAL GOVERNMENTS.—Subsection (a) applies with respect to a local government only if, in addition to the conditions described in paragraph (1), the following conditions are met:

''(A) The State in which the locality involved is located—

''(i) does not have a plan described in paragraph (1)(A); or

''(ii) has a plan described in such paragraph, but the plan does not address populations at a distance greater than 10 miles from the nuclear power plant involved.

''(B) The local government has petitioned the State to modify the State plan to address such populations, not exceeding 20 miles from such plant, and 60 days have elapsed without the State modifying the State plan to address populations at the full distance sought by the local government through the petition.

''(C) The local government has submitted its local plan under paragraph (1)(A) to the State, and the State has approved the plan and certified that the plan is not inconsistent with the State emergency plan.

''(c) GUIDELINES.—Not later than one year after the date of the enactment of this Act [June 12, 2002], the President, in consultation with individuals representing appropriate Federal, State, and local agencies, shall establish guidelines for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident. Such tablets may not be made available under subsection (a) until such guidelines have been established.

''(d) INFORMATION.—The President shall carry out activities to inform State and local governments of the program under this section.

''(e) REPORTS.—

''(1) PRESIDENT.—Not later than six months after the date on which the guidelines under subsection (c) are issued, the President shall submit to the Congress a report—

''(A) on whether potassium iodide tablets have been made available under subsection (a) or other Federal, State, or local programs, and the extent to which State and local governments have established stockpiles of such tablets; and

''(B) the measures taken by the President to implement this section.

''(2) NATIONAL ACADEMY OF SCIENCES.—

''(A) IN GENERAL.—The President shall request the National Academy of Sciences to enter into an agreement with the President under which the Academy conducts a study to determine what is the most effective and safe way to distribute and administer potassium iodide tablets on a mass scale. If the Academy declines to conduct the study, the President shall enter into an agreement with another appropriate public or nonprofit private entity to conduct the study.

''(B) REPORT.—The President shall ensure that, not later than six months after the date of the enactment of this Act [June 12, 2002], the study required in subparagraph (A) is completed and a report describing the findings made in the study is submitted to the Congress.

''(f) APPLICABILITY.—Subsections (a) and (d) cease to apply as requirements if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.''

[Memorandum of President of the United States, July 3, 2007, 72 F.R. 37627, provided:

[Memorandum for the Secretary of Health and Human Services[,] the Secretary of Energy[,] the Secretary of Homeland Security[,] the Chairman of the Nuclear Regulatory Commission[, and] the Director of the Office of Science and Technology Policy

[By the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, and section 204(b) of the National Science and Technology Policy, Organization, and Priorities Act of 1976, as amended (42 U.S.C. 6613(b)), the functions of the President under section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) (42 U.S.C. 247d–6b note) are assigned as follows:

[(1) the function of making a determination under subsection 127(f) of Public Law 107–188 is assigned to the Director of the Office of Science and Technology Policy; and

[(2) the functions of the President under section 127 of Public Law 107–188 other than that assigned under subsection 127(f) are assigned to the Chairman of the Nuclear Regulatory Commission.

[In the performance of such functions the Chairman and the Director should consult each other and the Secretaries of Health and Human Services, Energy, and Homeland Security, as appropriate.

[The Director is authorized and directed to publish this memorandum in the Federal Register.]

DESIGNATION AND AUTHORIZATION TO PERFORM FUNCTIONS UNDER SECTION 319F–2 OF THE PUBLIC HEALTH SERVICE ACT

Memorandum of President of the United States, Oct. 21, 2004, 69 F.R. 70349, provided:

Memorandum for the Director of the Office of Management and Budget

By the authority vested in me by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby direct you to perform the functions vested in the President under section 319F–2(c)(6) of the Public Health Service Act, 42 U.S.C. 247d–6b(c)(6).

Any reference in this memorandum to the provision of any Act shall be deemed to include references to any hereafter-enacted provision of law that is the same or substantially the same as such provision.

You are authorized and directed to publish this memorandum in the Federal Register.

GEORGE W. BUSH.

## § 247d–6c. Reports regarding authorities under this Act

### (a) Secretary of Health and Human Services

#### (1) Annual reports on particular exercises of authority

##### (A) Relevant authorities

The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall submit reports in accordance with subparagraph (B) regarding the exercise of authority under the following provisions of law:

(i) With respect to section 247d–6a of this title:

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

(II) Subsection (b)(2) (relating to procedures other than full and open competition).

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

(ii) With respect to section 247d–6b of this title:

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

(II) Subsection (c)(7)(C)(iv) (relating to procedures other than full and open competition).

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

(iii) With respect to section 360bbb–3 of title 21:

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

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

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

##### (B) Contents of reports

The Secretary shall annually submit to the designated congressional committees a report that summarizes—

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

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

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity; and

(iv) whether, with respect to each procurement that is approved by the President under section 247d–6b(c)(6) of this