tack, including significant numbers of low-income or uninsured individuals, lack of affordable and accessible health care services, insufficient public and primary health care resources, lack of integration of Federal or State public health networks, workforce deficits, or other relevant characteristics;

''(E) the recommendations of the Secretary with respect to additional legislative authority that the Secretary determines is necessary to effectively strengthen rural communities, or medically underserved populations (as defined in section 330 of such Act); and

''(F) the need for and benefits of a National Disaster Response Medical Volunteer Service that would be a private-sector, community-based rapid response corps of medical volunteers.''

STUDY REGARDING COMMUNICATIONS ABILITIES OF PUBLIC HEALTH AGENCIES

Pub. L. 107–188, title I, §104(b), June 12, 2002, 116 Stat. 606, provided that: ''The Secretary of Health and Human Services, in consultation with the Federal Communications Commission, the National Telecommunications and Information Administration, and other appropriate Federal agencies, shall conduct a study to determine whether local public health entities have the ability to maintain communications in the event of a bioterrorist attack or other public health emergency. The study shall examine whether redundancies are required in the telecommunications system, particularly with respect to mobile communications, for public health entities to maintain systems operability and connectivity during such emergencies. The study shall also include recommendations to industry and public health entities about how to implement such redundancies if necessary.''

§ 247d–6a. Authority for use of certain procedures regarding qualified countermeasure research and development activities

(a) In general

(1) Authority

In conducting and supporting research and development activities regarding countermeasures under section 247d–6(h) of this title, the Secretary may conduct and support such activities in accordance with this section and, in consultation with the Director of the National Institutes of Health, as part of the program under section 285f of this title, if the activities concern qualified countermeasures.

(2) Definitions

In this section:

(A) Qualified countermeasure

The term ''qualified countermeasure'' means a drug (as that term is defined by section 321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21), that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6)—

(i) to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security;

(ii) 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 that is used as described in this subparagraph; or

(iii) is a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii).

(B) Infectious disease

The term ''infectious disease'' means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.

(3) Interagency cooperation

(A) In general

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

(B) Limitation

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

(4) Availability of facilities to the Secretary

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

(5) Transfers of qualified countermeasures

Each agreement for an award of a grant, contract, or cooperative agreement under section 247d–6(h) of this title for the development of a qualified countermeasure shall provide that the recipient of the award will comply with all applicable export-related controls with respect to such countermeasure.

(b) Expedited procurement authority

(1) Increased simplified acquisition threshold for qualified countermeasure procurements

(A) In general

For any procurement by the Secretary of property or services for use (as determined by the Secretary) in performing, administering, or supporting qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, the amount specified in section 134 of title 41, as applicable pursuant to section

3101(b)(1)(A) of title 41, shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

(i) section 3305(a)(1) of title 41 and its implementing regulations; and

(ii) section 3101(b)(1)(B) of title 41 and its implementing regulations.

(B) Application of certain provisions

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

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

(ii) Section 8703(a) of title 41.

(iii) Section 4706 of title 41 (relating to the examination of contractor records).

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

(v) Section 3901 of title 41 (relating to contingent fees to middlemen).

(vi) Section 6962 of this title.

(vii) 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).

(C) Internal controls to be instituted

The Secretary shall institute appropriate internal controls for procurements that are under this paragraph, including requirements with regard to documenting the justification for use of the authority in this paragraph with respect to the procurement involved.

(D) Authority to limit competition

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

(2) Procedures other than full and open competition

(A) In general

In using the authority provided in section 3304(a)(1) of title 41 to use procedures other than competitive procedures in the case of a procurement described in paragraph (1) of this subsection, the phrase ''available from only one responsible source'' in such section 3304(a)(1) shall be deemed to mean ''available from only one responsible source or only from a limited number of responsible sources''.

(B) Relation to other authorities

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

(C) Applicable government-wide regulations

The Secretary shall implement this paragraph in accordance with government-wide regulations implementing such section 3304(a)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(3) Increased micropurchase threshold

(A) In general

For a procurement described by paragraph (1), the amount specified in subsections (a), (d), and (e) of section 1902 of title 41 shall be deemed to be $15,000 in the administration of that section with respect to such procurement.

(B) Internal controls to be instituted

The Secretary shall institute appropriate internal controls for purchases that are under this paragraph and that are greater than $2,500.

(C) Exception to preference for purchase card mechanism

No provision of law establishing a preference for using a Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than $2,500.

(4) Review

(A) Review allowed

Notwithstanding subsection (f) of this section, section 1491 of title 28, and section 3556 of title 31, review of a contracting agency decision relating to a procurement described in paragraph (1) may be had only by filing a protest—

(i) with a contracting agency; or

(ii) with the Comptroller General under subchapter V of chapter 35 of title 31.

(B) Override of stay of contract award or performance committed to agency discretion

Notwithstanding section 1491 of title 28 and section 3553 of title 31, the following authorizations by the head of a procuring activity are committed to agency discretion:

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

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

(c) Authority to expedite peer review

(1) In general

The Secretary may, as the Secretary determines necessary to respond to pressing quali-

fied countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would be required under sections 241(a)(3), 284(b)(1)(B), 284(b)(2), 284a(a)(3)(A), 289a, and 289c of this title, as applicable to a grant, contract, or cooperative agreement—

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

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

(2) Subsequent phases of research

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

(d) Authority for personal services contracts

(1) In general

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

(2) Federal Tort Claims Act coverage

(A) In general

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

(B) Exclusivity of remedy

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

(C) Recourse in case of gross misconduct or contract violation

(i) In general

Should payment be made by the United States to any claimant bringing a claim under this paragraph, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover against any entity identified in subparagraph (B) for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any such entity to carry out any obligation or responsibility assumed by such entity under a contract with the United States or from any grossly negligent or reckless conduct or intentional or willful misconduct on the part of such entity.

(ii) Venue

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

(3) Internal controls to be instituted

(A) In general

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

(B) Determination of employee status to be final

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

(4) Number of personal services contracts limited

The number of experts and consultants whose personal services are obtained under paragraph (1) shall not exceed 30 at any time.

(e) Streamlined personnel authority

(1) In general

In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, without regard to those provisions of title 5 governing appointments in the competitive service, and without regard to the provisions of chapter 51

and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, not to exceed 30 such employees at any time, to positions in the National Institutes of Health to perform, administer, or support qualified countermeasure research and development activities in carrying out this section.

(2) Limitations

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

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

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

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

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

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

(3) Internal controls to be instituted

The Secretary shall institute appropriate internal controls for appointments under this subsection.

(f) Actions committed to agency discretion

Actions by the Secretary under the authority of this section are committed to agency discretion.

(July 1, 1944, ch. 373, title III, § 319F–1, as added Pub. L. 108–276, § 2(a), July 21, 2004, 118 Stat. 835; amended Pub. L. 109–417, title IV, § 403(a), Dec. 19, 2006, 120 Stat. 2874; Pub. L. 113–5, title IV, § 402(g)(1), Mar. 13, 2013, 127 Stat. 195.)

REFERENCES IN TEXT

The Project BioShield Act of 2004, referred to in subsec. (b)(1)(D), 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.

The Federal Tort Claims Act, referred to in subsec. (d)(2), is title IV of act Aug. 2, 1946, ch. 753, 60 Stat. 842, which was classified principally to chapter 20 (§§ 921, 922, 931–934, 941–946) of former Title 28, Judicial Code and Judiciary. Title IV of act Aug. 2, 1946, was substantially repealed and reenacted as sections 1346(b) and 2671 et seq. of Title 28, Judiciary and Judicial Procedure, by act June 25, 1948, ch. 646, 62 Stat. 992, the first section of which enacted Title 28. The Federal Tort Claims Act is also commonly used to refer to chapter 171 of Title 28, Judiciary and Judicial Procedure. For complete classification of title IV to the Code, see Tables. For distribution of former sections of Title 28 into the revised Title 28, see Table at the beginning of Title 28.

CODIFICATION

In subsec. (b)(1)(A), ''section 134 of title 41'' substituted for ''section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11))'' and ''section 3101(b)(1)(A) of title 41'' substituted for ''section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(A)(i), ''section 3305(a)(1) of title 41'' substituted for ''section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(A)(ii), ''section 3101(b)(1)(B) of title 41'' substituted for ''section 302A(b) of such Act (41 U.S.C. 252a(b))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(ii), ''Section 8703(a) of title 41'' substituted for ''Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(iii), ''Section 4706 of title 41'' substituted for ''Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(v), ''Section 3901 of title 41'' substituted for ''Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(2)(A), ''section 3304(a)(1) of title 41'' substituted for ''section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))'' and ''such section 3304(a)(1)'' substituted for ''such section 303(c)(1)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(2)(C), ''such section 3304(a)(1)'' substituted for ''such section 303(c)(1)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(3)(A), ''subsections (a), (d), and (e) of section 1902 of title 41'' substituted for ''subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428)'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2013—Subsec. (a)(2)(A). Pub. L. 113–5 struck out ''to'' before dash at end of introductory provisions, inserted ''to'' before ''diagnose'' in cls. (i) and (ii), and added cl. (iii).

2006—Subsec. (a)(2). Pub. L. 109–417 added par. (2) and struck out heading and text of former par. (2). Text read as follows: ''For purposes of this section, the term 'qualified countermeasure' means a drug (as that term is defined by section 321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21) that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to—

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

''(B) treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A).''

RULE OF CONSTRUCTION

Pub. L. 108–276, § 2(e), July 21, 2004, 118 Stat. 842, provided that: ''Nothing in this section [enacting this section and amending sections 247d–6, 287a–2, and 300aa–6

of this title] has any legal effect on sections 302(2), 302(4), 304(a), or 304(b) of the Homeland Security Act of 2002 [6 U.S.C. 182(2), (4), 184(a), (b)].''

COLLABORATION AND COORDINATION

Pub. L. 109–417, title IV, § 405, Dec. 19, 2006, 120 Stat. 2875, as amended by Pub. L. 113–5, § 402(e)(1), Mar. 13, 2013, 127 Stat. 195, provided that:

''(a) LIMITED ANTITRUST EXEMPTION.—

''(1) MEETINGS AND CONSULTATIONS TO DISCUSS SECURITY COUNTERMEASURES, QUALIFIED COUNTERMEASURES, OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT DEVELOPMENT.—

''(A) AUTHORITY TO CONDUCT MEETINGS AND CONSULTATIONS.—The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary'), in coordination with the Attorney General and the Secretary of Homeland Security, may conduct meetings and consultations with persons engaged in the development of a security countermeasure (as defined in section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b)) (as amended by this Act), a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a)) (as amended by this Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d)) for the purpose of the development, manufacture, distribution, purchase, or storage of a countermeasure or product. The Secretary may convene such meeting or consultation at the request of the Secretary of Homeland Security, the Attorney General, the Chairman of the Federal Trade Commission (referred to in this section as the 'Chairman'), or any interested person, or upon initiation by the Secretary. The Secretary shall give prior notice of any such meeting or consultation, and the topics to be discussed, to the Attorney General, the Chairman, and the Secretary of Homeland Security.

''(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;

''(ii) be open to persons involved in the development, manufacture, distribution, purchase, or storage of a countermeasure or product, as determined by the Secretary;

''(iii) be open to the Attorney General, the Secretary of Homeland Security, and the Chairman;

''(iv) be limited to discussions involving covered activities; and

''(v) be conducted in such manner as to ensure that no national security, confidential commercial, or proprietary information is disclosed outside the meeting or consultation.

''(C) LIMITATION.—The Secretary may not require participants to disclose confidential commercial or proprietary information.

''(D) TRANSCRIPT.—The Secretary shall maintain a complete verbatim transcript of each meeting or consultation conducted under this subsection. Such transcript (or a portion thereof) shall not be disclosed under section 552 of title 5, United States Code, to the extent that the Secretary, in consultation with the Attorney General and the Secretary of Homeland Security, determines that disclosure of such transcript (or portion thereof) would pose a threat to national security. The transcript (or portion thereof) with respect to which the Secretary has made such a determination shall be deemed to be information described in subsection (b)(3) of such section 552.

''(E) EXEMPTION.—

''(i) IN GENERAL.—Subject to clause (ii), it shall not be a violation of the antitrust laws for any person to participate in a meeting or consultation conducted in accordance with this paragraph.

''(ii) LIMITATION.—Clause (i) shall not apply to any agreement or conduct that results from a meeting or consultation and that is not covered by an exemption granted under paragraph (4).

''(2) SUBMISSION OF WRITTEN AGREEMENTS.—The Secretary shall submit each written agreement regarding covered activities that is made pursuant to meetings or consultations conducted under paragraph (1) to the Attorney General and the Chairman for consideration. In addition to the proposed agreement itself, any submission shall include—

''(A) an explanation of the intended purpose of the agreement;

''(B) a specific statement of the substance of the agreement;

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

''(D) an explanation of the necessity for a cooperative effort among the particular participating persons to achieve the objectives of the agreement; and

''(E) any other relevant information determined necessary by the Attorney General, in consultation with the Chairman and the Secretary.

''(3) EXEMPTION FOR CONDUCT UNDER APPROVED AGREEMENT.—It shall not be a violation of the antitrust laws for a person to engage in conduct in accordance with a written agreement to the extent that such agreement has been granted an exemption under paragraph (4), during the period for which the exemption is in effect.

''(4) ACTION ON WRITTEN AGREEMENTS.—

''(A) IN GENERAL.—The Attorney General, in consultation with the Chairman, shall grant, deny, grant in part and deny in part, or propose modifications to an exemption request regarding a written agreement submitted under paragraph (2), in a written statement to the Secretary, within 15 business days of the receipt of such request. An exemption granted under this paragraph shall take effect immediately.

''(B) EXTENSION.—The Attorney General may extend the 15-day period referred to in subparagraph (A) for an additional period of not to exceed 10 business days.

''(C) DETERMINATION.—An exemption shall be granted regarding a written agreement submitted in accordance with paragraph (2) only to the extent that the Attorney General, in consultation with the Chairman and the Secretary, finds that the conduct that will be exempted will not have any substantial anticompetitive effect that is not reasonably necessary for ensuring the availability of the countermeasure or product involved.

''(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4) shall be limited to covered activities, and such exemption shall be renewed (with modifications, as appropriate, consistent with the finding described in paragraph (4)(C)), on the date that is 3 years after the date on which the exemption is granted unless the Attorney General in consultation with the Chairman determines that the exemption should not be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

''(6) AUTHORITY TO OBTAIN INFORMATION.—Consideration by the Attorney General for granting or renewing an exemption submitted under this section shall be considered an antitrust investigation for purposes of the Antitrust Civil Process Act (15 U.S.C. 1311 et seq.).

''(7) LIMITATION ON PARTIES.—The use of any information acquired under an agreement for which an exemption has been granted under paragraph (4), for any purpose other than specified in the exemption, shall be subject to the antitrust laws and any other applicable laws.

''(8) REPORT.—Not later than one year after the date of enactment of this Act [Dec. 19, 2006] and biannually thereafter, the Attorney General and the Chairman shall report to Congress on the use of the exemption from the antitrust laws provided by this subsection.

''(b) SUNSET.—The applicability of this section shall expire at the end of the 12-year period that begins on the date of enactment of this Act [Dec. 19, 2006].

''(c) 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 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) COUNTERMEASURE OR PRODUCT.—The term 'countermeasure or product' refers to a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product (as those terms are defined in subsection (a)(1)).

''(3) COVERED ACTIVITIES.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered activities' includes any 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.''

[Pub. L. 113–5, title IV, §402(e)(2), Mar. 13, 2013, 127 Stat. 195, provided that: ''This subsection [amending section 405 of Pub. L. 109–417, set out above] shall take effect as if enacted on December 17, 2012.'']

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 consistent with section 300hh–10 of this title 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 and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security.

(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 and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment;

(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 as defined in subsection (h).

(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 10 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].