recombinant influenza vaccines relative to egg-based vaccines;

(B) explore options to expand the production capacity of cell-based vaccine candidates used by industry;

(C) develop a plan to expand domestic capacity for whole genome characterization of influenza viruses;

(D) increase influenza vaccine use through enhanced communication and by removing barriers to vaccination; and

(E) enhance communication to healthcare providers about the performance of influenza vaccines, in order to assist them in promoting the most effective vaccines for their patient populations; and

(v) through the Administrator of CMS, examine the current legal, regulatory, and policy framework surrounding payment for influenza vaccines and assess adoption of domestically manufactured vaccines that have positive attributes for pandemic response (such as scalability and speed of manufacturing).

(b) The Secretary of Defense shall:

(i) provide OMB with a cost estimate for transitioning DOD's annual procurement of influenza vaccines to vaccines manufactured both domestically and through faster, more scalable, and innovative technologies;

(ii) direct, in coordination with the VA, CDC, and other components of HHS, the conduct of epidemiological studies of vaccine effectiveness to improve knowledge of the clinical effect of the currently licensed influenza vaccines;

(iii) use DOD's network of clinical research sites to evaluate the effectiveness of licensed influenza vaccines, including methods of boosting their effectiveness;

(iv) identify opportunities to use DOD's vaccine research and development enterprise, in collaboration with HHS, to include both early discovery and design of influenza vaccines as well as later-stage evaluation of candidate influenza vaccines;

(v) investigate, in collaboration with HHS, alternative correlates of immune protection that could facilitate development of next-generation influenza vaccines;

(vi) direct the conduct of a study to assess the feasibility of using DOD's advanced manufacturing facility for manufacturing cell-based or recombinant influenza vaccines during a pandemic; and

(vii) accelerate, in collaboration with HHS, research regarding rapidly scalable prophylactic influenza antibody approaches to complement a universal vaccine initiative and address gaps in current vaccine coverage.

(c) The Secretary of VA shall provide OMB with a cost estimate for transitioning its annual procurement of influenza vaccines to vaccines manufactured both domestically and with faster, more scalable, and innovative technologies.

SEC. 5. *Termination*. The Task Force shall terminate upon direction from the President or, with the approval of the President, upon direction from the Task Force Co-Chairs.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

§ 247d–7f. Collaboration and coordination

(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, 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 247d–6b of this title), a qualified countermeasure (as defined in section 247d–6a of this title), or a qualified pandemic or epidemic product (as defined in section 247d–6d of this title) 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 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[1] 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 17-year period that begins on the date of enactment of this Act.[1]

(c) Definitions

In this section:

(1) Antitrust laws

The term ''antitrust laws''—

(A) has the meaning given such term in subsection (a) of section 12 of title 15, except that such term includes section 45 of title 15 to the extent such section 45 of title 15 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)).

[1] See References in Text note below.

(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.

(July 1, 1944, ch. 373, title III, § 319L–1, as added Pub. L. 116–22, title VII, § 701(e)(1)(C), (D), June 24, 2019, 133 Stat. 961.)

REFERENCES IN TEXT

The Antitrust Civil Process Act, referred to in subsec. (a)(6), is Pub. L. 87–664, Sept. 19, 1962, 76 Stat. 548, which is classified principally to chapter 34 (§ 1311 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1311 of Title 15 and Tables.

The date of enactment of this Act, referred to in subsecs. (a)(8) and (b), probably means the date of enactment of Pub. L. 109–417, which was approved Dec. 19, 2006. This section was originally enacted as section 405 of Pub. L. 109–417, prior to redesignation as section 319L–1 of act July 1, 1944, ch. 373. See Codification note below.

CODIFICATION

Section 405 of Pub. L. 109–417, formerly set out as a note under section 247d–6a of this title, which was redesignated as section 319L–1 of act July 1, 1944, ch. 373 and editorially reclassified as this section, was based on 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; Pub. L. 116–22, title VII, § 701(e)(1)(A), (B), June 24, 2019, 133 Stat. 961.

PRIOR PROVISIONS

A prior section 247d–7f, act July 1, 1944, ch. 373, title III, § 319M, as added Pub. L. 109–417, title IV, § 402, Dec. 19, 2006, 120 Stat. 2872; amended Pub. L. 113–5, title IV, § 404, Mar. 13, 2013, 127 Stat. 197, which related to National Biodefense Science Board and working groups, was transferred to section 247d–7g of this title.

AMENDMENTS

2019—Pub. L. 116–22 redesignated section 405 of Pub. L. 109–417 as this section. See Codification note above.

EFFECTIVE DATE OF 2013 AMENDMENT

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

§ 247d–7g. National Biodefense Science Board and working groups

(a) In general

(1) Establishment and function

The Secretary shall establish the National Biodefense Science Board (referred to in this section as the ''Board'') to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

(2) Membership

The membership of the Board shall be comprised of individuals who represent the Nation's preeminent scientific, public health, and medical experts, as follows—

(A) such Federal officials as the Secretary may determine are necessary to support the functions of the Board;

(B) four individuals representing the pharmaceutical, biotechnology, and device industries;