

countermeasures, including the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the appropriate agencies of the Department of Defense.

(June 25, 1938, ch. 675, §565, as added Pub. L. 109-417, title IV, §404, Dec. 19, 2006, 120 Stat. 2875; amended Pub. L. 113-5, title III, §§303-306, Mar. 13, 2013, 127 Stat. 185-190.)

AMENDMENTS

2013—Pub. L. 113-5, §304(1), substituted “Countermeasure development, review, and technical assistance” for “Technical assistance” in section catchline.

Pub. L. 113-5, §303, designated existing provisions as subsec. (b) and inserted heading.

Subsec. (a). Pub. L. 113-5, §303, added subsec. (a).

Subsec. (b). Pub. L. 113-5, §304(2), reenacted heading without change, substituted “In order to accelerate the development, stockpiling, approval, licensure, and clearance of qualified countermeasures, security countermeasures, and qualified pandemic or epidemic products, the Secretary, in consultation with the Assistant Secretary for Preparedness and Response, shall—” for “The Secretary, in consultation with the Commissioner of Food and Drugs, shall”, added pars. (1) to (4), and designated remainder of existing provisions as par. (5).

Subsecs. (c) to (e). Pub. L. 113-5, §304(3), added subsecs. (c) to (e).

Subsec. (f). Pub. L. 113-5, §305, added subsec. (f).

Subsec. (g). Pub. L. 113-5, §306, added subsec. (g).

PREDICTABLE REVIEW TIMELINES OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Pub. L. 114-255, div. A, title III, §3091, Dec. 13, 2016, 130 Stat. 1149, provided that:

“(a) CONSIDERATION OF NEW VACCINES.—Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the ‘Advisory Committee’) shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.

“(b) ADDITIONAL INFORMATION.—If the Advisory Committee does not make a recommendation with respect to the use of a vaccine at the Advisory Committee’s first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee shall provide an update on the status of such committee’s review.

“(c) CONSIDERATION FOR BREAKTHROUGH THERAPIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMERGENCY.—The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that—

“(1) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

“(2) could be used in a public health emergency.

“(d) DEFINITION.—In this section, the terms ‘Advisory Committee on Immunization Practices’ and ‘Advisory Committee’ mean the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.”

§ 360bbb-4a. Priority review to encourage treatments for agents that present national security threats

(a) Definitions

In this section:

(1) Human drug application

The term “human drug application” has the meaning given such term in section 379g(1) of this title.

(2) Priority review

The term “priority review”, with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

(3) Priority review voucher

The term “priority review voucher” means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] after the date of approval of the material threat medical countermeasure application.

(4) Material threat medical countermeasure application

The term “material threat medical countermeasure application” means an application that—

(A) is a human drug application for a drug intended for use—

(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F-2(c)(2)(A)(ii) of the Public Health Service Act [42 U.S.C. 247d-6b(c)(2)(A)(ii)]; or

(ii) to 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, or biological product against such agent; and

(B) the Secretary determines eligible for priority review;

(C) is approved after December 13, 2016; and

(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)].

(b) Priority review voucher

(1) In general

The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

(2) Transferability

The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] will be submitted after the date of the approval of the material threat medical counter-

measure application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

(3) Notification

(A) In general

The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(B) Transfer after notice

The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

(c) Priority review user fee

(1) In general

The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under subchapter VII.

(2) Fee amount

The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

(3) Annual fee setting

The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2016, for that fiscal year, the amount of the priority review user fee.

(4) Payment

(A) In general

The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for which the priority review voucher is used.

(B) Complete application

An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

(C) No waivers, exemptions, reductions, or refunds

The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) Offsetting collections

Fees collected pursuant to this subsection for any fiscal year—

(A)¹ shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(6)² shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

(d) Notice of issuance of voucher and approval of products under voucher

The Secretary shall publish a notice in the Federal Register and on the Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

(1) The Secretary issues a priority review voucher under this section.

(2) The Secretary approves a drug pursuant to an application submitted under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for which the sponsor of the application used a priority review voucher issued under this section.

(e) Eligibility for other programs

Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this chapter, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this chapter with respect to such drug.

(f) Relation to other provisions

The provisions of this section shall supplement, not supplant, any other provisions of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] that encourage the development of medical countermeasures.

(g) Sunset

The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.

(June 25, 1938, ch. 675, §565A, as added Pub. L. 114-255, div. A, title III, §3086, Dec. 13, 2016, 130 Stat. 1144.)

REFERENCES IN TEXT

Section 101(b) of the Food and Drug Administration Safety and Innovation Act, referred to in subsec. (a)(2), is section 101(b) of Pub. L. 112-144, which is set out as a note under section 379g of this title.

The Public Health Service Act, referred to in subsec. (f), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

¹ So in original. No subpar. (B) has been enacted.

² So in original. Probably should be designated as subpar. (B).

§ 360bbb-5. Critical Path Public-Private Partnerships

(a) Establishment

The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

(b) Eligible entity

In this section, the term “eligible entity” means an entity that meets each of the following:

- (1) The entity is—
 - (A) an institution of higher education (as such term is defined in section 1001 of title 20) or a consortium of such institutions; or
 - (B) an organization described in section 501(c)(3) of title 26 and exempt from tax under section 501(a) of such title.
- (2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.
- (3) The entity demonstrates to the Secretary’s satisfaction that the entity is capable of—
 - (A) developing and critically evaluating tools, methods, and processes—
 - (i) to increase efficiency, predictability, and productivity of medical product development; and
 - (ii) to more accurately identify the benefits and risks of new and existing medical products;
 - (B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and
 - (C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

(c) Funding

The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and

Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

(d) Annual report

Not later than 18 months after September 27, 2007, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

- (1) reviewing the operations and activities of the Partnerships in the previous year; and
- (2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

(e) Definition

In this section, the term “medical product” includes a drug, a biological product as defined in section 262 of title 42, a device, and any combination of such products.

(f) Authorization of appropriations

To carry out this section, there is authorized to be appropriated \$6,000,000 for each of fiscal years 2013 through 2017.

(June 25, 1938, ch. 675, §566, as added Pub. L. 110-85, title VI, §603, Sept. 27, 2007, 121 Stat. 898; amended Pub. L. 112-144, title XI, §1102, July 9, 2012, 126 Stat. 1108.)

AMENDMENTS

2012—Subsec. (f). Pub. L. 112-144 amended subsec. (f) generally. Prior to amendment, text read as follows: “To carry out this section, there are authorized to be appropriated \$5,000,000 for fiscal year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012.”

§ 360bbb-6. Risk communication

(a) Advisory Committee on Risk Communication

(1) In general

The Secretary shall establish an advisory committee to be known as the “Advisory Committee on Risk Communication” (referred to in this section as the “Committee”).

(2) Duties of Committee

The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.

(3) Members

The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations.

(4) Permanence of Committee

Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this subsection.

(b) Partnerships for risk communication

(1) In general

The Secretary shall partner with professional medical societies, medical schools, aca-