Editorial Notes

AMENDMENTS

2022—Subsec. (f). Pub. L. 117–328, which directed the substitution of ''$6,000,000 for each of fiscal years 2023 through 2027'' for ''$1,265,753 for the period beginning on October 1, 2022 and ending on December 23, 2022'', could not be executed because ''$1,265,753'' did not appear after the intervening amendment by section 301 of Pub. L. 117–229. See below.

Pub. L. 117–229 substituted ''$1,380,822 for the period beginning on October 1, 2022 and ending on December 23, 2022'' for ''$1,265,753 for the period beginning on October 1, 2022 and ending on December 16, 2022''.

Pub. L. 117–180 substituted ''$1,265,753 for the period beginning on October 1, 2022 and ending on December 16, 2022'' for ''$6,000,000 for each of fiscal years 2018 through 2022''.

2017—Subsec. (f). Pub. L. 115–52 substituted ''2018 through 2022'' for ''2013 through 2017''.

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–5a. Emerging technology program

(a) Program establishment

(1) In general

The Secretary shall establish a program to support the adoption of, and improve the development of, innovative approaches to drug design and manufacturing.

(2) Actions

In carrying out the program under paragraph (1), the Secretary may—

(A) facilitate and increase communication between public and private entities, consortia, and individuals with respect to innovative drug product design and manufacturing;

(B) solicit information regarding, and conduct or support research on, innovative approaches to drug product design and manufacturing;

(C) convene meetings with representatives of industry, academia, other Federal agencies, international agencies, and other interested persons, as appropriate;

(D) convene working groups to support drug product design and manufacturing research and development;

(E) support education and training for regulatory staff and scientists related to innovative approaches to drug product design and manufacturing;

(F) advance regulatory science related to the development and review of innovative approaches to drug product design and manufacturing;

(G) convene or participate in working groups to support the harmonization of international regulatory requirements related to innovative approaches to drug product design and manufacturing; and

(H) award grants or contracts to carry out or support the program under paragraph (1).

(3) Grants and contracts

To seek a grant or contract under this section, an entity shall submit an application—

(A) in such form and manner as the Secretary may require; and

(B) containing such information as the Secretary may require, including a description of—

(i) how the entity will conduct the activities to be supported through the grant or contract; and

(ii) how such activities will further research and development related to, or adoption of, innovative approaches to drug product design and manufacturing.

(b) Guidance

The Secretary shall—

(1) issue or update guidance to help facilitate the adoption of, and advance the development of, innovative approaches to drug product design and manufacturing; and

(2) include in such guidance descriptions of—

(A) any regulatory requirements related to the development or review of technologies related to innovative approaches to drug product design and manufacturing, including updates and improvements to such technologies after product approval; and

(B) data that can be used to demonstrate the identity, safety, purity, and potency of drugs manufactured using such technologies.

(c) Report to Congress

Not later than 4 years after December 29, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

(1) an annual accounting of the allocation of funds made available to carry out this section;

(2) a description of how Food and Drug Administration staff were utilized to carry out this section and, as applicable, any challenges or limitations related to staffing;

(3) the number of public meetings held or participated in by the Food and Drug Administration pursuant to this section, including meetings convened as part of a working group described in subparagraph (D) or (G) of subsection (a)(2), and the topics of each such meeting; and

(4) the number of drug products approved or licensed, after December 29, 2022, using an innovative approach to drug product design and manufacturing.

(June 25, 1938, ch. 675, § 566A, as added Pub. L. 117–328, div. FF, title III, § 3203, Dec. 29, 2022, 136 Stat. 5814.)

§ 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 1013 of title 5 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, academic medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers about emerging postmarket drug risks.

(2) Partnerships

The systems developed under paragraph (1) shall—

(A) account for the diversity among physicians in terms of practice, willingness to adopt technology, and medical specialty; and

(B) include the use of existing communication channels, including electronic communications, in place at the Food and Drug Administration.

(June 25, 1938, ch. 675, §567, as added Pub. L. 110–85, title IX, §917, Sept. 27, 2007, 121 Stat. 960; amended Pub. L. 117–286, §4(a)(157), Dec. 27, 2022, 136 Stat. 4323.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a)(4). Pub. L. 117–286 substituted ''Section 1013 of title 5'' for ''Section 14 of the Federal Advisory Committee Act''.

§ 360bbb–7. Notification

(a) Notification to Secretary

With respect to a drug, the Secretary may require notification to the Secretary by a regulated person if the regulated person knows—

(1) that the use of such drug in the United States may result in serious injury or death;

(2) of a significant loss or known theft of such drug intended for use in the United States; or

(3) that—

(A) such drug has been or is being counterfeited; and

(B)(i) the counterfeit product is in commerce in the United States or could be reasonably expected to be introduced into commerce in the United States; or

(ii) such drug has been or is being imported into the United States or may reasonably be expected to be offered for import into the United States.

(b) Manner of notification

Notification under this section shall be made in such manner and by such means as the Secretary may specify by regulation or guidance.

(c) Savings clause

Nothing in this section shall be construed as limiting any other authority of the Secretary to require notifications related to a drug under any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.].

(d) Definition

In this section, the term ''regulated person'' means—

(1) a person who is required to register under section 360 or 381(s) of this title;

(2) a wholesale distributor of a drug product; or

(3) any other person that distributes drugs except a person that distributes drugs exclusively for retail sale.

(June 25, 1938, ch. 675, §568, as added Pub. L. 112–144, title VII, §715(b), July 9, 2012, 126 Stat. 1075.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (c), 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.

§ 360bbb–8. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments

(a) In general

For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

(1) Consultation with stakeholders

Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (b).

(2) Consultation with external experts

(A) In general

The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (b). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (b), when such consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary's regulatory responsibilities and the necessary expertise can be provided by the external experts.