

(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.