

sified 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.

AMENDMENTS

2016—Subsec. (c). Pub. L. 114–255 inserted “or under the Public Health Service Act” before period at end.

**§ 360bbb–8b. Use of clinical investigation data from outside the United States**

**(a) In general**

In determining whether to approve, license, or clear a drug, biological product, or device pursuant to an application submitted under this subchapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that such data are adequate under applicable standards to support approval, licensure, or clearance of the drug, biological product, or device in the United States.

**(b) Notice to sponsor**

If the Secretary finds under subsection (a) that the data from clinical investigations conducted outside the United States, including in the European Union, are inadequate for the purpose of making a determination on approval, clearance, or licensure of a drug, biological product, or device pursuant to an application submitted under this subchapter, the Secretary shall provide written notice to the sponsor of the application of such finding and include the rationale for such finding.

(June 25, 1938, ch. 675, §569B, as added Pub. L. 112–144, title XI, §1123, July 9, 2012, 126 Stat. 1113; amended Pub. L. 114–255, div. A, title III, §3101(a)(2)(Q), Dec. 13, 2016, 130 Stat. 1155.)

AMENDMENTS

2016—Pub. L. 114–255 substituted “drug, biological product, or device” for “drug or device” wherever appearing.

**§ 360bbb–8c. Patient participation in medical product discussion**

**(a) Patient engagement in drugs and devices**

**(1) In general**

The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

(A) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

(B) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

**(2) Protection of proprietary information**

Nothing in this section shall be construed to alter the protections offered by laws, regulations, or policies governing disclosure of confidential commercial or trade secret information and any other information exempt from disclosure pursuant to section 552(b) of title 5

as such laws, regulations, or policies would apply to consultation with individuals and organizations prior to July 9, 2012.

**(3) Other consultation**

Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to July 9, 2012.

**(4) No right or obligation**

Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012. Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

**(5) Financial interest**

In this section, the term “financial interest” means a financial interest under section 208(a) of title 18.

**(b) Statement of patient experience**

**(1) In general**

Following the approval of an application that was submitted under section 355(b) of this title or section 262(a) of title 42 at least 180 days after December 13, 2016, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application.

**(2) Data and information**

The data and information referred to in paragraph (1) are—

(A) patient experience data;

(B) information on patient-focused drug development tools; and

(C) other relevant information, as determined by the Secretary.

**(c) Patient experience data**

For purposes of this section, the term “patient experience data” includes data that—

(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

(2) are intended to provide information about patients’ experiences with a disease or condition, including—

(A) the impact of such disease or condition, or a related therapy, on patients’ lives; and

(B) patient preferences with respect to treatment of such disease or condition.

(June 25, 1938, ch. 675, §569C, as added Pub. L. 112–144, title XI, §1137, July 9, 2012, 126 Stat. 1124; amended Pub. L. 114–255, div. A, title III, §3001, Dec. 13, 2016, 130 Stat. 1083.)

REFERENCES IN TEXT

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsec. (a)(4), is sec-