

Editorial Notes

REFERENCES IN TEXT

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsecs. (a)(1) and (f)(2), is section 101(b) of Pub. L. 112-144, which is set out as a note under section 379g of this title.

AMENDMENTS

2016—Subsec. (a)(2)(A). Pub. L. 114-255 substituted “subsection (b)” for “subsection (c)” before period in first sentence.

§ 360bbb–8a. Optimizing global clinical trials**(a) In general**

The Secretary shall—

(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage uniform, scientifically driven clinical trial standards with respect to medical products around the world; and

(2) enhance the commitment to provide consistent parallel scientific advice to manufacturers seeking simultaneous global development of new medical products in order to—

(A) enhance medical product development;

(B) facilitate the use of foreign data; and

(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or nonclinical studies.

(b) Medical product

In this section, the term “medical product” means a drug, as defined in subsection (g) of section 321 of this title, a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act [42 U.S.C. 262(i)].

(c) Savings clause

Nothing in this section shall alter the criteria for evaluating the safety or effectiveness of a medical product under this chapter or under the Public Health Service Act [42 U.S.C. 201 et seq.].

(June 25, 1938, ch. 675, §569A, 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)(P), Dec. 13, 2016, 130 Stat. 1154.)

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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.

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.)

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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