

(B) External experts

For purposes of subparagraph (A), external experts are individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

(b) Topics for consultation

Topics for consultation pursuant to this section may include—

- (1) rare diseases;
- (2) the severity of rare diseases;
- (3) the unmet medical need associated with rare diseases;
- (4) the willingness and ability of individuals with a rare disease to participate in clinical trials;
- (5) an assessment of the benefits and risks of therapies to treat rare diseases;
- (6) the general design of clinical trials for rare disease populations and subpopulations;
- (7) the demographics and the clinical description of patient populations; and
- (8) the science of small population studies.

(c) Classification as special government employees

The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18.

(d) Protection of confidential information and trade secrets**(1) Rule of construction**

Nothing in this section shall be construed to alter the protections offered by laws, regulations, and 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 provisions would be applied to consultation with individuals and organizations prior to July 9, 2012.

(2) Consent required for disclosure

The Secretary shall not disclose confidential commercial or trade secret information to an expert consulted under this section without the written consent of the sponsor unless the expert is a special government employee (as defined under section 202 of title 18) or the disclosure is otherwise authorized by law.

(e) 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.

(f) No right or obligation**(1) No right to consultation**

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.

(2) No altering of goals

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.

(3) No change to number of review cycles

Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

(g) No delay in product review**(1) In general**

Prior to a consultation with an external expert, as described in this section, relating to an investigational new drug application under section 355(i) of this title, a new drug application under section 355(b) of this title, or a biologics license application under section 262 of title 42, the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research (or appropriate Division Director), as appropriate, shall determine that—

(A) such consultation will—

- (i) facilitate the Secretary's ability to complete the Secretary's review; and
- (ii) address outstanding deficiencies in the application; or

(B) the sponsor authorized such consultation.

(2) Limitation

The requirements of this subsection shall apply only in instances where the consultation is undertaken solely under the authority of this section. The requirements of this subsection shall not apply to any consultation initiated under any other authority.

(June 25, 1938, ch. 675, § 569, as added Pub. L. 112–144, title IX, § 903, July 9, 2012, 126 Stat. 1088; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(O), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 117–328, div. FF, title III, § 3202(e), Dec. 29, 2022, 136 Stat. 5812.)

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

2022—Subsec. (b)(8). Pub. L. 117–328 added par. (8).

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.)

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.

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.)

Editorial Notes**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