Subtitle L—Priority Review for Breakthrough Devices

SEC. 2201. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 515(d)—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5); and

(2) by inserting after section 515A (21 U.S.C. 360e–1) the following:

"SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

"(a) IN GENERAL.—In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall establish a program to provide priority review for devices—

"(1) representing breakthrough technologies;

"(2) for which no approved alternatives exist;

"(3) offering significant advantages over existing approved or cleared alternatives, including the potential to, compared to existing approved or cleared alternatives, reduce or eliminate the need for

hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

"(4) the availability of which is in the best interest of patients.

"(b) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate the device for priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a petition for classification under section 513(f)(2), or a notification under section 510(k).

"(c) DESIGNATION PROCESS.—

"(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (a). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for priority review.

"(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and managers of the

Food and Drug Administration and is chaired by a senior manager.

"(3) DESIGNATION DETERMINATION.—A determination approving or denying a request under subsection (b) shall be considered a significant decision under section 517A and the Secretary shall provide a written, substantive summary of the basis for the determination in accordance with section 517A(a).

"(4) RECONSIDERATION.—

"(A) REQUEST FOR RECONSIDERATION.—Any person whose request under subsection (b) is denied may, within 30 days of the denial, request reconsideration of the denial in accordance with section 517A(b)—

"(i) based upon the submission of documents by such person; or

"(ii) based upon such documents and a meeting or teleconference.

"(B) RESPONSE.—Reconsideration of a designation determination under this paragraph shall be conducted in accordance with section 517A(b).

"(5) WITHDRAWAL.—If the Secretary approves a priority review designation for a device under this section, the Secretary may not withdraw the des-

ignation based on the fact that the criteria specified in subsection (a) are no longer met because of the subsequent clearance or approval of another device that was designated under—

"(A) this section; or

"(B) section 515(d)(5) (as in effect immediately prior to the enactment of the 21st Century Cures Act).

"(d) PRIORITY REVIEW.—

"(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (c), the Secretary shall—

"(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (b);

"(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (b) for the device;

"(C) adopt an efficient process for timely dispute resolution;

"(D) provide for interactive communication with the sponsor of the device during the review process;

"(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

"(F) disclose to the sponsor in advance the topics of any consultation concerning the sponsor's device that the Secretary intends to undertake with external experts or an advisory committee and provide the sponsor an opportunity to recommend such external experts;

"(G) for applications submitted under section 515(c), provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor); and

"(H) assign staff to be available within a reasonable time to address questions posed by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

"(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of

expediting the development and review of devices designated under subsection (c), the Secretary, in collaboration with the device sponsor, may, as appropriate—

"(A) coordinate with the sponsor regarding early agreement on a data development plan;

"(B) take steps to ensure that the design of clinical trials is as efficient as practicable, such as through adoption of shorter or smaller clinical trials, application of surrogate endpoints, and use of adaptive trial designs and Bayesian statistics, to the extent scientifically appropriate;

"(C) facilitate, to the extent scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection, with regard to applications for approval under section 515(c); and

"(D) agree to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

"(i) changes agreed to by the sponsor and the Secretary;

"(ii) changes that the Secretary determines are required to prevent an unreasonable risk to the public health; or

"(iii) the identification of a substantial scientific issue determined by the Secretary to be essential to the safety or effectiveness of the device involved.

"(e) PRIORITY REVIEW GUIDANCE.—

"(1) CONTENT.—The Secretary shall issue guidance on the implementation of this section. Such guidance shall include the following:

"(A) The process for a person to seek a priority review designation.

"(B) A template for requests under subsection (b).

"(C) The criteria the Secretary will use in evaluating a request for priority review.

"(D) The standards the Secretary will use in assigning a team of staff, including team leaders, to review devices designated for priority review, including any training required for such personnel on effective and efficient review.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall propose such guidance for public comment.

"(f) CONSTRUCTION.—

"(1) PURPOSE.—This section is intended to encourage the Secretary and provide the Secretary sufficient authorities to apply efficient and flexible approaches to expedite the development of, and prioritize the agency's review of, devices that represent breakthrough technologies.

"(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B), and consideration of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable. Nothing in this section alters the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary deems appropriate.".

(b) CONFORMING AMENDMENT RELATED TO DESIGNATION DETERMINATIONS.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–

1(a)(1)) is amended by inserting ''a request for designation under section 515B,'' after ''an application under section 515,''.

Subtitle M—Medical Device Regulatory Process Improvements

SEC. 2221. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

(a) ESTABLISHMENT OF THIRD-PARTY QUALITY SYSTEM ASSESSMENT PROGRAM.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 524A (21 U.S.C. 360n–1) the following new section:

''SEC. 524B. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.

''(a) ACCREDITATION AND ASSESSMENT.—

''(1) IN GENERAL; CERTIFICATION OF DEVICE QUALITY SYSTEM.—The Secretary shall, in accordance with this section, establish a third-party quality system assessment program—

''(A) to accredit persons to assess whether a requestor's quality system, including its design controls, can reasonably assure the safety and effectiveness of in-scope devices subject to device-related changes;

''(B) under which accredited persons shall (as applicable) certify that a requestor's quality system meets the criteria included in the guid-