Calendar No. 412

114TH CONGRESS
2D SESSION

S. 1077

To provide for expedited development of and priority review for breakthrough devices.

IN THE SENATE OF THE UNITED STATES

APRIL 23, 2015

Mr. BURR (for himself, Mr. BENNET, Mr. HATCH, and Mr. DONNELLY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 5, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To provide for expedited development of and priority review for breakthrough devices.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the "Advancing Breakthrough Devices for Patients Act of 2015".~~

SEC. 2. EXPEDITED DEVELOPMENT OF AND PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515A the following:

"SEC. 515B. EXPEDITED DEVELOPMENT OF AND 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 disease or conditions, the Secretary shall establish a program to expedite the development of and provide for the 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, compared to existing approved alternatives, to 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 expedited development and 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 expedited development and 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) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (a) no longer applying because of the subsequent clearance or approval of another device that—

"(A) was designated under this section; or

"(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the Advancing Breakthrough Devices for Patients Act of 2015.

"(d) EXPEDITED DEVELOPMENT AND 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 and timely communication with the sponsor of the device during the development program and review process;

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

"(F) disclose to the sponsor not less than 5 business days in advance the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

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

"(H) assign staff to be available within a reasonable time to address questions 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, when scientifically appropriate, such as through adoption of shorter or smaller clinical trials, application of surrogate endpoints, and the use of adaptive trial designs and Bayesian statistics, to the extent scientifically appropriate;

"(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely post-market data collection with regard to application for approval under section 515(c); and

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

"(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

"(ii) a decision, made by the director of the office responsible for reviewing the

device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

''(c) PRIORITY REVIEW GUIDANCE.—

''(1) CONTENT.—Not later than 1 year after the date of enactment of the Advancing Breakthrough Devices for Patients Act of 2015, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

''(A) set forth the process by which a person may seek a designation under subsection (c);

''(B) provide a template for requests under subsection (b);

''(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

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

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

"(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 Food and Drug Administration's review of, devices that represent breakthrough devices.

"(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

"(A) 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 and application

of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

"(B) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A); or

"(C) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate.".

(b) DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.—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 "application under section 515,".

(c) TERMINATION OF PREVIOUS PROGRAM.—

(1) IN GENERAL.—Section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5).

(2) CONFORMING AMENDMENT.—Section 737(5) of the Federal Food, Drug, and Cosmetics

~~Act (21 U.S.C. 379i(5)) is amended by striking "515(d)(6)" and inserting "515(d)(5)".~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Advancing Breakthrough Devices for Patients Act of 2016".

SEC. 2. EXPEDITED DEVELOPMENT OF AND PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515A the following:

"SEC. 515B. EXPEDITED DEVELOPMENT OF AND PRIORITY REVIEW FOR BREAKTHROUGH DEVICES.

"(a) PURPOSE.—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

"(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of and provide for the priority review for devices, as determined by the Secretary—

"(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

"(2)(A) that represent breakthrough technologies;

"(B) for which no approved or cleared alternatives exist;

"(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to 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

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

"(c) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate such device for expedited development and 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) or a petition for classification under section 513(f)(2).

"(d) DESIGNATION PROCESS.—

"(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria de-

scribed in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

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

"(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

"(A) was designated under this section; or

"(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the Advancing Breakthrough Devices for Patients Act of 2016.

"(e) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

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

"(A) assign a team of staff, including a team leader with appropriate subject matter ex-

pertise and experience, for each device for which a request is submitted under subsection (c);

"(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 (c) for the device;

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

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

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

"(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

"(G) provide for advisory committee input, as the Secretary determines appropriate (includ-

ing in response to the request of the sponsor) for applications submitted under section 515(c); and

"(H) assign staff to be available within a reasonable time to address questions 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 (d), 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 and flexible as practicable, when scientifically appropriate;

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

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

"(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

"(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

"(f) PRIORITY REVIEW GUIDANCE.—

"(1) CONTENT.—Not later than 1 year after the date of enactment of the Advancing Breakthrough Devices for Patients Act of 2016, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

"(A) set forth the process by which a person may seek a designation under subsection (d);

"(B) provide a template for requests under subsection (c);

"(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

"(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

"(1) 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 and application of the least burdensome means of evaluating device effec-

tiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

"(2) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A);

"(3) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate; or

"(4) the authority of the Secretary with respect to postmarket surveillance under sections 519(h) and 522.".

(b) DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.—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 "application under section 515,".

(c) TERMINATION OF PREVIOUS PROGRAM.—

(1) IN GENERAL.—Section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5).

(2) CONFORMING AMENDMENT.—Section 737(5) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 379i(5)) is amended by striking "515(d)(6)" and inserting "515(d)(5)".

(d) REPORT.—On January 1, 2017, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) on the program under section 515B of Federal Food, Drug, and Cosmetic Act, as added by this Act, in bringing safe and effective devices included in such program to patients as soon as possible; and

(2) that includes recommendations, if any, to strengthen the program to better meet patient device needs in a manner as timely as possible.

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