

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Advancing Break-
5 through Devices for Patients Act of 2015”.

1 **SEC. 2. EXPEDITED DEVELOPMENT OF AND PRIORITY RE-**
 2 **VIEW FOR BREAKTHROUGH DEVICES.**

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

6 **“SEC. 515B. EXPEDITED DEVELOPMENT OF AND PRIORITY**
 7 **REVIEW FOR BREAKTHROUGH DEVICES.**

8 “(a) IN GENERAL.—In order to provide for more ef-
 9 fective treatment or diagnosis of life-threatening or irre-
 10 versibly debilitating human disease or conditions, the Sec-
 11 retary shall establish a program to expedite the develop-
 12 ment of and provide for the priority review for devices—

- 13 “(1) representing breakthrough technologies;
- 14 “(2) for which no approved alternatives exist;
- 15 “(3) offering significant advantages over exist-
 16 ing approved or cleared alternatives, including the
 17 potential, compared to existing approved alter-
 18 natives, to reduce or eliminate the need for hos-
 19 pitalization, improve patient quality of life, facilitate
 20 patients’ ability to manage their own care (such as
 21 through self-directed personal assistance), or estab-
 22 lish long-term clinical efficiencies; or
- 23 “(4) the availability of which is in the best in-
 24 terest of patients.

25 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
 26 device may request that the Secretary designate the device

1 for expedited development and priority review under this
 2 section. Any such request for designation may be made
 3 at any time prior to the submission of an application
 4 under section 515(c), a petition for classification under
 5 section 513(f)(2), or a notification under section 510(k).

6 “(c) DESIGNATION PROCESS.—

7 “(1) IN GENERAL.—Not later than 60 calendar
 8 days after the receipt of a request under subsection
 9 (b), the Secretary shall determine whether the device
 10 that is the subject of the request meets the criteria
 11 described in subsection (a). If the Secretary deter-
 12 mines that the device meets the criteria, the Sec-
 13 retary shall designate the device for expedited devel-
 14 opment and priority review.

15 “(2) REVIEW.—Review of a request under sub-
 16 section (b) shall be undertaken by a team that is
 17 composed of experienced staff and managers of the
 18 Food and Drug Administration and is chaired by a
 19 senior manager.

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

25 “(A) was designated under this section; or

1 “(B) was given priority review under sec-
2 tion 515(d)(5), as in effect prior to the date of
3 enactment of the Advancing Breakthrough De-
4 vices for Patients Act of 2015.

5 “(d) EXPEDITED DEVELOPMENT AND PRIORITY RE-
6 VIEW.—

7 “(1) ACTIONS.—For purposes of expediting the
8 development and review of devices designated under
9 subsection (c) the Secretary shall—

10 “(A) assign a team of staff, including a
11 team leader with appropriate subject matter ex-
12 pertise and experience, for each device for
13 which a request is submitted under subsection
14 (b);

15 “(B) provide for oversight of the team by
16 senior agency personnel to facilitate the effi-
17 cient development of the device and the efficient
18 review of any submission described in sub-
19 section (b) for the device;

20 “(C) adopt an efficient process for timely
21 dispute resolution;

22 “(D) provide for interactive and timely
23 communication with the sponsor of the device
24 during the development program and review
25 process;

1 “(E) expedite the Secretary’s review of
2 manufacturing and quality systems compliance,
3 as applicable;

4 “(F) disclose to the sponsor not less than
5 5 business days in advance the topics of any
6 consultation the Secretary intends to undertake
7 with external experts or an advisory committee
8 concerning the sponsor’s device and provide the
9 sponsor the opportunity to recommend such ex-
10 ternal experts;

11 “(G) provide for advisory committee input,
12 as the Secretary determines appropriate (in-
13 cluding in response to the request of the spon-
14 sor) for applications submitted under section
15 515(e); and

16 “(H) assign staff to be available within a
17 reasonable time to address questions by institu-
18 tional review committees concerning the condi-
19 tions and clinical testing requirements applica-
20 ble to the investigational use of the device pur-
21 suant to an exemption under section 520(g).

22 “(2) ADDITIONAL ACTIONS.—In addition to the
23 actions described in paragraph (1), for purposes of
24 expediting the development and review of devices
25 designated under subsection (c), the Secretary, in

1 collaboration with the device sponsor, may, as appro-
2 priate—

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

5 “(B) take steps to ensure that the design
6 of clinical trials is as efficient as practicable;
7 when scientifically appropriate, such as through
8 adoption of shorter or smaller clinical trials, ap-
9 plication of surrogate endpoints, and the use of
10 adaptive trial designs and Bayesian statistics;
11 to the extent scientifically appropriate;

12 “(C) facilitate, when scientifically appro-
13 priate, expedited and efficient development and
14 review of the device through utilization of time-
15 ly post-market data collection with regard to
16 application for approval under section 515(c);
17 and

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

21 “(i) changes to such protocols agreed
22 to in writing by the sponsor and the Sec-
23 retary; or

24 “(ii) a decision, made by the director
25 of the office responsible for reviewing the

1 device submission, that a substantial sci-
 2 entific issue essential to determining the
 3 safety or effectiveness of such device exists,
 4 provided that such decision is in writing,
 5 and is made only after the Secretary pro-
 6 vides to the device sponsor or applicant an
 7 opportunity for a meeting at which the di-
 8 rector and the sponsor or applicant are
 9 present and at which the director docu-
 10 ments the substantial scientific issue.

11 ~~“(e) PRIORITY REVIEW GUIDANCE.—~~

12 ~~“(1) CONTENT.—Not later than 1 year after~~
 13 ~~the date of enactment of the Advancing Break-~~
 14 ~~through Devices for Patients Act of 2015, the Sec-~~
 15 ~~retary shall issue guidance on the implementation of~~
 16 ~~this section. Such guidance shall—~~

17 ~~“(A) set forth the process by which a per-~~
 18 ~~son may seek a designation under subsection~~
 19 ~~(e);~~

20 ~~“(B) provide a template for requests under~~
 21 ~~subsection (b);~~

22 ~~“(C) identify the criteria the Secretary will~~
 23 ~~use in evaluating a request for designation~~
 24 ~~under this section; and~~

1 “(D) identify the standards the Secretary
 2 will use in assigning a team of staff, including
 3 team leaders, to review devices designated for
 4 expedited development and priority review, in-
 5 cluding any training required for such per-
 6 sonnel to ensure effective and efficient review.

7 “(2) PROCESS.—Prior to finalizing the guid-
 8 ance under paragraph (1), the Secretary shall seek
 9 public comment on a proposed guidance.

10 “(f) CONSTRUCTION.—

11 “(1) PURPOSE.—This section is intended to en-
 12 courage the Secretary and provide the Secretary suf-
 13 ficient authorities to apply efficient and flexible ap-
 14 proaches to expedite the development of, and
 15 prioritize the Food and Drug Administration’s re-
 16 view of, devices that represent breakthrough devices.

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

19 “(A) the criteria and standards for evalu-
 20 ating an application pursuant to section 515(e),
 21 a report and request for classification under
 22 section 513(f)(2), or a report under section
 23 510(k), including the recognition of valid sci-
 24 entific evidence as described in section
 25 513(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

1 Act (~~21 U.S.C. 379i(5)~~) is amended by striking
 2 “515(d)(6)” and inserting “515(d)(5)”.

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Advancing Breakthrough*
 5 *Devices for Patients Act of 2016”.*

6 **SEC. 2. EXPEDITED DEVELOPMENT OF AND PRIORITY RE-**
 7 **VIEW FOR BREAKTHROUGH DEVICES.**

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

11 **“SEC. 515B. EXPEDITED DEVELOPMENT OF AND PRIORITY**
 12 **REVIEW FOR BREAKTHROUGH DEVICES.**

13 “(a) *PURPOSE.*—The purpose of this section is to en-
 14 courage the Secretary, and provide the Secretary with suffi-
 15 cient authority, to apply efficient and flexible approaches
 16 to expedite the development of, and prioritize the Food and
 17 Drug Administration’s review of, devices that represent
 18 breakthrough technologies.

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

23 “(1) that provide for more effective treatment or
 24 diagnosis of life-threatening or irreversibly debili-
 25 tating human disease or conditions; and

1 “(2)(A) that represent breakthrough technologies;

2 “(B) for which no approved or cleared alter-
3 natives exist;

4 “(C) that offer significant advantages over exist-
5 ing approved or cleared alternatives, including the
6 potential, compared to existing approved alternatives,
7 to reduce or eliminate the need for hospitalization,
8 improve patient quality of life, facilitate patients’
9 ability to manage their own care (such as through
10 self-directed personal assistance), or establish long-
11 term clinical efficiencies; or

12 “(D) the availability of which is in the best in-
13 terest of patients.

14 “(c) *REQUEST FOR DESIGNATION*.—A sponsor of a de-
15 vice may request that the Secretary designate such device
16 for expedited development and priority review under this
17 section. Any such request for designation may be made at
18 any time prior to the submission of an application under
19 section 515(c) or a petition for classification under section
20 513(f)(2).

21 “(d) *DESIGNATION PROCESS*.—

22 “(1) *IN GENERAL*.—Not later than 60 calendar
23 days after the receipt of a request under subsection
24 (c), the Secretary shall determine whether the device
25 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-

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

3 *“(B) provide for oversight of the team by*
4 *senior agency personnel to facilitate the efficient*
5 *development of the device and the efficient review*
6 *of any submission described in subsection (c) for*
7 *the device;*

8 *“(C) adopt an efficient process for timely*
9 *dispute resolution;*

10 *“(D) provide for interactive and timely*
11 *communication with the sponsor of the device*
12 *during the development program and review*
13 *process;*

14 *“(E) expedite the Secretary’s review of*
15 *manufacturing and quality systems compliance,*
16 *as applicable;*

17 *“(F) disclose to the sponsor, not less than 5*
18 *business days in advance, the topics of any con-*
19 *sultation the Secretary intends to undertake with*
20 *external experts or an advisory committee con-*
21 *cerning the sponsor’s device and provide the*
22 *sponsor the opportunity to recommend such ex-*
23 *ternal experts;*

24 *“(G) provide for advisory committee input,*
25 *as the Secretary determines appropriate (includ-*

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

3 *“(H) assign staff to be available within a*
4 *reasonable time to address questions by institu-*
5 *tional review committees concerning the condi-*
6 *tions and clinical testing requirements applica-*
7 *ble to the investigational use of the device pursu-*
8 *ant to an exemption under section 520(g).*

9 *“(2) ADDITIONAL ACTIONS.—In addition to the*
10 *actions described in paragraph (1), for purposes of*
11 *expediting the development and review of devices des-*
12 *ignated under subsection (d), the Secretary, in col-*
13 *laboration with the device sponsor, may, as appro-*
14 *priate—*

15 *“(A) coordinate with the sponsor regarding*
16 *early agreement on a data development plan;*

17 *“(B) take steps to ensure that the design of*
18 *clinical trials is as efficient and flexible as prac-*
19 *ticable, when scientifically appropriate;*

20 *“(C) facilitate, when scientifically appro-*
21 *priate, expedited and efficient development and*
22 *review of the device through utilization of timely*
23 *postmarket data collection with regard to appli-*
24 *cation for approval under section 515(c); and*

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

4 “(i) changes to such protocols agreed to
5 in writing by the sponsor and the Sec-
6 retary; or

7 “(ii) a decision, made by the director
8 of the office responsible for reviewing the de-
9 vice submission, that a substantial scientific
10 issue essential to determining the safety or
11 effectiveness of such device exists, provided
12 that such decision is in writing, and is
13 made only after the Secretary provides to
14 the device sponsor or applicant an oppor-
15 tunity for a meeting at which the director
16 and the sponsor or applicant are present
17 and at which the director documents the
18 substantial scientific issue.

19 “(f) *PRIORITY REVIEW GUIDANCE.*—

20 “(1) *CONTENT.*—Not later than 1 year after the
21 date of enactment of the Advancing Breakthrough De-
22 vices for Patients Act of 2016, the Secretary shall
23 issue guidance on the implementation of this section.
24 Such guidance shall—

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

3 “(B) provide a template for requests under
4 subsection (c);

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

8 “(D) identify the criteria and processes the
9 Secretary will use to assign a team of staff, in-
10 cluding team leaders, to review devices des-
11 ignated for expedited development and priority
12 review, including any training required for such
13 personnel to ensure effective and efficient review.

14 “(2) *PROCESS.*—Prior to finalizing the guidance
15 under paragraph (1), the Secretary shall seek public
16 comment on a proposed guidance.

17 “(g) *RULE OF CONSTRUCTION.*—Nothing in this sec-
18 tion shall be construed to affect—

19 “(1) the criteria and standards for evaluating an
20 application pursuant to section 515(c), a report and
21 request for classification under section 513(f)(2), or a
22 report under section 510(k), including the recognition
23 of valid scientific evidence as described in section
24 513(a)(3)(B) and consideration and application of
25 the least burdensome means of evaluating device effec-

1 *tiveness or demonstrating substantial equivalence be-*
 2 *tween devices with differing technological characteris-*
 3 *tics, as applicable;*

4 *“(2) the authority of the Secretary with respect*
 5 *to clinical holds under section 520(g)(8)(A);*

6 *“(3) the authority of the Secretary to act on an*
 7 *application pursuant to section 515(d) before comple-*
 8 *tion of an establishment inspection, as the Secretary*
 9 *determines appropriate; or*

10 *“(4) the authority of the Secretary with respect*
 11 *to postmarket surveillance under sections 519(h) and*
 12 *522.”.*

13 *(b) DOCUMENTATION AND REVIEW OF SIGNIFICANT*
 14 *DECISIONS.—Section 517A(a)(1) of the Federal Food,*
 15 *Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is*
 16 *amended by inserting “a request for designation under sec-*
 17 *tion 515B,” after “application under section 515,”.*

18 *(c) TERMINATION OF PREVIOUS PROGRAM.—*

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

22 *(A) by striking paragraph (5); and*

23 *(B) by redesignating paragraph (6) as*
 24 *paragraph (5).*

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

5 (d) *REPORT.*—On January 1, 2017, the Secretary of
 6 *Health and Human Services, acting through the Commis-*
 7 *sioner of Food and Drugs, shall issue a report to the Com-*
 8 *mittee on Health, Education, Labor, and Pensions of the*
 9 *Senate and the Committee on Energy and Commerce of the*
 10 *House of Representatives—*

11 (1) *on the program under section 515B of Fed-*
 12 *eral Food, Drug, and Cosmetic Act, as added by this*
 13 *Act, in bringing safe and effective devices included in*
 14 *such program to patients as soon as possible; and*

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

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A BILL

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