

114TH CONGRESS
1ST 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, and Mr. HATCH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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”.

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 amend-
10 ed by inserting after section 515A the following:

1 **“SEC. 515B. EXPEDITED DEVELOPMENT OF AND PRIORITY**
2 **REVIEW FOR BREAKTHROUGH DEVICES.**

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

8 “(1) representing breakthrough technologies;

9 “(2) for which no approved alternatives exist;

10 “(3) offering significant advantages over exist-
11 ing approved or cleared alternatives, including the
12 potential, compared to existing approved alter-
13 natives, to reduce or eliminate the need for hos-
14 pitalization, improve patient quality of life, facilitate
15 patients’ ability to manage their own care (such as
16 through self-directed personal assistance), or estab-
17 lish long-term clinical efficiencies; or

18 “(4) the availability of which is in the best in-
19 terest of patients.

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

1 “(c) DESIGNATION PROCESS.—

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

10 “(2) REVIEW.—Review of a request under sub-
11 section (b) shall be undertaken by a team that is
12 composed of experienced staff and managers of the
13 Food and Drug Administration and is chaired by a
14 senior manager.

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

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

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

1 “(d) EXPEDITED DEVELOPMENT AND PRIORITY RE-
2 VIEW.—

3 “(1) ACTIONS.—For purposes of expediting the
4 development and review of devices designated under
5 subsection (c) the Secretary shall—

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

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

16 “(C) adopt an efficient process for timely
17 dispute resolution;

18 “(D) provide for interactive and timely
19 communication with the sponsor of the device
20 during the development program and review
21 process;

22 “(E) expedite the Secretary’s review of
23 manufacturing and quality systems compliance,
24 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—

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

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

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

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

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

22 “(ii) a decision, made by the director
23 of the office responsible for reviewing the
24 device submission, that a substantial sci-
25 entific issue essential to determining the

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

9 “(e) PRIORITY REVIEW GUIDANCE.—

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

15 “(A) set forth the process by which a per-
16 son may seek a designation under subsection
17 (c);

18 “(B) provide a template for requests under
19 subsection (b);

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

23 “(D) identify the standards the Secretary
24 will use in assigning a team of staff, including
25 team leaders, to review devices designated for

1 expedited development and priority review, in-
2 cluding any training required for such per-
3 sonnel to ensure effective and efficient review.

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

7 “(f) CONSTRUCTION.—

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

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

16 “(A) the criteria and standards for evalu-
17 ating an application pursuant to section 515(c),
18 a report and request for classification under
19 section 513(f)(2), or a report under section
20 510(k), including the recognition of valid sci-
21 entific evidence as described in section
22 513(a)(3)(B) and consideration and application
23 of the least burdensome means of evaluating de-
24 vice effectiveness or demonstrating substantial

1 equivalence between devices with differing tech-
 2 nological characteristics, as applicable;

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

6 “(C) the authority of the Secretary to act
 7 on an application pursuant to section 515(d)
 8 before completion of an establishment inspec-
 9 tion, as the Secretary determines appropriate.”.

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

15 (c) TERMINATION OF PREVIOUS PROGRAM.—

16 (1) IN GENERAL.—Section 515(d) of the Fed-
 17 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 18 360e(d)) is amended—

19 (A) by striking paragraph (5); and

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

22 (2) CONFORMING AMENDMENT.—Section
 23 737(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)”.

