

114TH CONGRESS
1ST SESSION

H. R. 2337

To amend the Federal Food, Drug, and Cosmetic Act to authorize priority review for breakthrough devices.

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2015

Mr. PITTS introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize 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. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
4 **VICES.**

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

7 (1) in section 515(d)—

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

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

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

3 **“SEC. 515B. PRIORITY REVIEW FOR BREAKTHROUGH DE-**
4 **VICES.**

5 “(a) IN GENERAL.—In order to provide for more ef-
6 fective treatment or diagnosis of life-threatening or irre-
7 versibly debilitating human diseases or conditions, the
8 Secretary shall establish a program to provide priority re-
9 view for devices—

10 “(1) representing breakthrough technologies;

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

12 “(3) offering significant advantages over exist-
13 ing approved or cleared alternatives, including the
14 potential to, compared to existing approved or
15 cleared alternatives, reduce or eliminate the need for
16 hospitalization, improve patient quality of life, facili-
17 tate patients’ ability to manage their own care (such
18 as through self-directed personal assistance), or es-
19 tablish long-term clinical efficiencies; or

20 “(4) the availability of which is in the best in-
21 terest of patients.

22 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
23 device may request that the Secretary designate the device
24 for priority review under this section. Any such request
25 for designation may be made at any time prior to the sub-

1 mission of an application under section 515(c), a petition
2 for classification under section 513(f)(2), or a notification
3 under section 510(k).

4 “(c) DESIGNATION PROCESS.—

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

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

17 “(3) DESIGNATION DETERMINATION.—A deter-
18 mination approving or denying a request under sub-
19 section (b) shall be considered a significant decision
20 under section 517A and the Secretary shall provide
21 a written, substantive summary of the basis for the
22 determination in accordance with section 517A(a).

23 “(4) RECONSIDERATION.—

24 “(A) REQUEST FOR RECONSIDERATION.—

25 Any person whose request under subsection (b)

1 is denied may, within 30 days of the denial, re-
2 quest reconsideration of the denial in accord-
3 ance with section 517A(b)—

4 “(i) based upon the submission of
5 documents by such person; or

6 “(ii) based upon such documents and
7 a meeting or teleconference.

8 “(B) RESPONSE.—Reconsideration of a
9 designation determination under this paragraph
10 shall be conducted in accordance with section
11 517A(b).

12 “(5) WITHDRAWAL.—If the Secretary approves
13 a priority review designation for a device under this
14 section, the Secretary may not withdraw the des-
15 ignation based on the fact that the criteria specified
16 in subsection (a) are no longer met because of the
17 subsequent clearance or approval of another device
18 that was designated under—

19 “(A) this section; or

20 “(B) section 515(d)(5) (as in effect imme-
21 diately prior to the enactment of the 21st Cen-
22 tury Cures Act).

23 “(d) PRIORITY REVIEW.—

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

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

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

14 “(C) adopt an efficient process for timely
15 dispute resolution;

16 “(D) provide for interactive communication
17 with the sponsor of the device during the review
18 process;

19 “(E) expedite the Secretary’s review of
20 manufacturing and quality systems compliance,
21 as applicable;

22 “(F) disclose to the sponsor in advance the
23 topics of any consultation concerning the spon-
24 sor’s device that the Secretary intends to under-
25 take with external experts or an advisory com-

mittee 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 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 end-

1 points, and use of adaptive trial designs and
2 Bayesian statistics, to the extent scientifically
3 appropriate;

4 “(C) facilitate, to the extent scientifically
5 appropriate, expedited and efficient develop-
6 ment and review of the device through utiliza-
7 tion of timely postmarket data collection, with
8 regard to applications for approval under sec-
9 tion 515(c); and

10 “(D) agree to clinical protocols that the
11 Secretary will consider binding on the Secretary
12 and the sponsor, subject to—

13 “(i) changes agreed to by the sponsor
14 and the Secretary;

15 “(ii) changes that the Secretary deter-
16 mines are required to prevent an unreason-
17 able risk to the public health; or

18 “(iii) the identification of a substan-
19 tial scientific issue determined by the Sec-
20 retary to be essential to the safety or effec-
21 tiveness of the device involved.

22 “(e) PRIORITY REVIEW GUIDANCE.—

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

1 “(A) The process for a person to seek a
2 priority review designation.

3 “(B) A template for requests under sub-
4 section (b).

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

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

12 “(2) PROCESS.—Prior to finalizing the guid-
13 ance under paragraph (1), the Secretary shall pro-
14 pose such guidance for public comment.

15 “(f) CONSTRUCTION.—

16 “(1) PURPOSE.—This section is intended to en-
17 courage the Secretary and provide the Secretary suf-
18 ficient authorities to apply efficient and flexible ap-
19 proaches to expedite the development of, and
20 prioritize the agency’s review of, devices that rep-
21 resent breakthrough technologies.

22 “(2) CONSTRUCTION.—Nothing in this section
23 shall be construed to alter the criteria and standards
24 for evaluating an application pursuant to section
25 515(c), a report and request for classification under

1 section 513(f)(2), or a report under section 510(k),
2 including the recognition of valid scientific evidence
3 as described in section 513(a)(3)(B), and consider-
4 ation of the least burdensome means of evaluating
5 device effectiveness or demonstrating substantial
6 equivalence between devices with differing techno-
7 logical characteristics, as applicable. Nothing in this
8 section alters the authority of the Secretary to act
9 on an application pursuant to section 515(d) before
10 completion of an establishment inspection, as the
11 Secretary deems appropriate.”.

12 (b) CONFORMING AMENDMENT RELATED TO DES-
13 IGNATION DETERMINATIONS.—Section 517A(a)(1) of the
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–
15 1(a)(1)) is amended by inserting “a request for designa-
16 tion under section 515B,” after “an application under sec-
17 tion 515,”.

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