

114TH CONGRESS
1ST SESSION

H. R. 2427

To amend the Federal Food, Drug, and Cosmetic Act with respect to advisory committee process.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. SHIMKUS 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 with respect to advisory committee process.

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. ADVISORY COMMITTEE PROCESS.**

4 (a) CLASSIFICATION PANELS.—Paragraph (5) of sec-
5 tion 513(b) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 360c(b)) is amended—

7 (1) by striking “(5)” and inserting “(5)(A)”;

8 and

9 (2) by adding at the end the following:

1 “(B) For review by a classification panel of
2 a premarket submission for a device, the Sec-
3 retary shall—

4 “(i) provide an opportunity for the
5 person whose premarket submission is sub-
6 ject to panel review to provide rec-
7 ommendations on the expertise needed
8 among the voting members of the panel;
9 and

10 “(ii) give due consideration to such
11 recommendations and ensure that adequate
12 expertise is represented on advisory panels
13 to assess—

14 “(I) the disease or condition for
15 which the device is intended to cure,
16 treat, mitigate, prevent, or diagnose;
17 and

18 “(II) the technology of the de-
19 vice.

20 “(C) For purposes of subparagraph (B)(ii),
21 the term ‘adequate expertise’ means that the
22 membership of the classification panel reviewing
23 a premarket submission includes—

1 “(i) two or more voting members, with
2 a specialty or other expertise clinically rel-
3 evant to the device under review; and

4 “(ii) at least one voting member who
5 is knowledgeable about the technology of
6 the device.”.

7 (b) PANEL REVIEW PROCESS.—Section 513(b)(6) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 360c(b)(6)) is amended—

10 (1) in subparagraph (A)(iii), by inserting before
11 the period at the end “, including by designating a
12 representative who will be provided a time during
13 the panel meeting to address the panel individually
14 (or accompanied by experts selected by such rep-
15 resentative) for the purpose of correcting
16 misstatements of fact or providing clarifying infor-
17 mation, subject to the discretion of panel chair-
18 person.”.

19 (2) by striking subparagraph (B) and inserting
20 the following new subparagraph:

21 “(B)(i) Any meeting of a classification
22 panel with respect to the review of a premarket
23 submission for a device shall—

24 “(I) provide adequate time for initial
25 presentations by the person whose pre-

1 market submission is specifically the sub-
2 ject of such review and by the Secretary;
3 and

4 “(II) encourage free and open partici-
5 pation by all interested persons.

6 “(ii) Following the initial presentations de-
7 scribed in clause (i), the panel may—

8 “(I) pose questions to a designated
9 representative described in subparagraph
10 (A)(iii); and

11 “(II) consider the responses to such
12 questions in the panel’s review of the pre-
13 market submission.”.

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