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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

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A BILL

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

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

SECTION 1. ADVISORY COMMITTEE PROCESS.

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

(1) by striking ''(5)'' and inserting ''(5)(A)''; and

(2) by adding at the end the following:

''(B) For review by a classification panel of a premarket submission for a device, the Secretary shall—

''(i) provide an opportunity for the person whose premarket submission is subject to panel review to provide recommendations on the expertise needed among the voting members of the panel; and

''(ii) give due consideration to such recommendations and ensure that adequate expertise is represented on advisory panels to assess—

''(I) the disease or condition for which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

''(II) the technology of the device.

''(C) For purposes of subparagraph (B)(ii), the term 'adequate expertise' means that the membership of the classification panel reviewing a premarket submission includes—

''(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

''(ii) at least one voting member who is knowledgeable about the technology of the device.''.

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

(1) in subparagraph (A)(iii), by inserting before the period at the end '', including by designating a representative who will be provided a time during the panel meeting to address the panel individually (or accompanied by experts selected by such representative) for the purpose of correcting misstatements of fact or providing clarifying information, subject to the discretion of panel chairperson.''.

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

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

''(I) provide adequate time for initial presentations by the person whose pre-

market submission is specifically the subject of such review and by the Secretary; and

''(II) encourage free and open participation by all interested persons.

''(ii) Following the initial presentations described in clause (i), the panel may—

''(I) pose questions to a designated representative described in subparagraph (A)(iii); and

''(II) consider the responses to such questions in the panel's review of the premarket submission.''.

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