

114TH CONGRESS
1ST SESSION

H. R. 2428

To amend the Federal Food, Drug, and Cosmetic Act with respect to humanitarian device exemption applications.

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 humanitarian device exemption applications.

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. HUMANITARIAN DEVICE EXEMPTION APPLICA-**
4 **TION.**

5 (a) IN GENERAL.—Section 520(m) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amend-
7 ed—

8 (1) in paragraph (1) by striking “fewer than
9 4,000” and inserting “not more than 8,000”;

1 (2) in paragraph (2)(A) by striking “fewer than
2 4,000” and inserting “not more than 8,000”; and
3 (3) in paragraph (6)(A)(ii), by striking “4,000”
4 and inserting “8,000”.

5 (b) GUIDANCE DOCUMENT ON PROBABLE BEN-
6 EFIT.—Not later than 18 months after the date of enact-
7 ment of this Act, the Secretary of Health and Human
8 Services, acting through the Commissioner of Food and
9 Drugs, shall publish a draft guidance document that de-
10 fines the criteria for establishing “probable benefit” as
11 that term is used in section 520(m)(2)(C) of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

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