

114TH CONGRESS  
1ST SESSION

# H. R. 2428

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

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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 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9           Drugs, shall publish a draft guidance document that de-  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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