114TH CONGRESS
1ST SESSION

S. 2188

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 21, 2015

Mr. GARDNER (for himself and Mr. DONNELLY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Rare Disease Innovation Act''.

SEC. 2. HUMANITARIAN DEVICE EXEMPTION APPLICATION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

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

(2) in paragraph (2)(A) by striking ''fewer than 4,000'' and inserting ''not more than 8,000''; and

(3) in paragraph (6)(A)(ii), by striking ''4,000'' and inserting ''8,000''.

(b) GUIDANCE DOCUMENT ON PROBABLE BENEFIT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance document that defines the criteria for establishing ''probable benefit'' as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

(c) REPORTS TO CONGRESS.—Five years after the date of enactment of this Act and every 5 years thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the effect of the amendments made by subsection (a).

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