112TH CONGRESS
1ST SESSION

S. 1865

To improve patient access to medical innovation.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 15, 2011

Mr. FRANKEN (for himself, Mr. ALEXANDER, Mr. KERRY, and Mrs. HAGAN) 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 improve patient access to medical innovation.

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 ''Patient Access to Medical Innovation Act''.

SEC. 2. HUMANITARIAN USE DEVICE EXEMPTIONS.

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

(1) in paragraph (6)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''subparagraph (D)'' and inserting ''subparagraph (C)'';

(ii) by striking clause (i) and inserting the following:

''(i) The device with respect to which the exemption is granted was approved under this subsection before, on, or after the date of enactment of the Patient Access to Medical Innovation Act.'';

(iii) by striking clause (ii) and inserting the following:

''(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the number of such devices needed to treat, diagnose, or cure a population of 4,000 individuals in the United States (referred to in this paragraph as the 'annual distribution number').''; and

(iv) in clause (iv), by striking ''2012'' and inserting ''2017'';

(B) by striking subparagraph (C);

(C) by redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively;

(D) in subparagraph (C), as so redesignated, by striking ''and modified under subparagraph (C), if applicable,''; and

(E) in subparagraph (D), as so redesignated, by adding at the end the following:

''(iii) In this subsection, the term 'pediatric device' means a device with respect to which the exemption is granted that is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.'';

(2) in paragraph (7), by striking ''regarding a device'' and inserting ''regarding a pediatric device''; and

(3) in paragraph (8), by striking ''of all devices described in paragraph (6)'' and inserting ''of all pediatric devices granted an exemption under paragraph (2)''.

(b) REPORT.—Not later than 5 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that evaluates and describes—

(1) the effectiveness of the amendments made by subsection (a)(1) in stimulating innovation with respect to medical devices; and

(2) the effect of such amendments on patients described in such section 520(m) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)).

SEC. 3. CONFLICTS OF INTEREST.

Section 712 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–1) is amended—

(1) by striking subsection (b);

(2) by redesignating subsection (c) as subsection (b);

(3) in subsection (b), as so redesignated, by striking paragraph (2)(C) and inserting the following:

''(C) CONSIDERATION BY SECRETARY.—The Secretary shall ensure that each determination under subparagraph (B) considers the scope and magnitude of the financial interest at issue with the public health need for the expertise of the member on the advisory committee.''; and

(4) by redesignating subsection (d) as subsection (c);

(5) in subsection (c), as so redesignated, by striking ''subsection (c)(3)'' and inserting ''subsection (b)(3)''; and

(6) by striking subsections (e) and (f).

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