

112TH CONGRESS
1ST SESSION

S. _____

To improve patient access to medical innovation.

IN THE SENATE OF THE UNITED STATES

Mr. FRANKEN (for himself and Mr. ALEXANDER) introduced the following bill;
which was read twice and referred to the Committee on

A BILL

To improve patient access to medical innovation.

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. SHORT TITLE.**

4 This Act may be cited as the “Patient Access to Med-
5 ical Innovation Act”.

6 **SEC. 2. HUMANITARIAN USE DEVICE EXEMPTIONS.**

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

10 (1) in paragraph (6)—

11 (A) in subparagraph (A)—

1 (i) in the matter preceding clause (i),
2 by striking “subparagraph (D)” and in-
3 sserting “subparagraph (C)”;

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

6 “(i) The device with respect to which the ex-
7 emption is granted was approved under this sub-
8 section before, on, or after the date of enactment of
9 the Patient Access to Medical Innovation Act.”;

10 (iii) by striking clause (ii) and insert-
11 ing the following:

12 “(ii) During any calendar year, the number of
13 such devices distributed during that year under each
14 exemption granted under this subsection does not
15 exceed the number of such devices needed to treat,
16 diagnose, or cure a population of 4,000 individuals
17 in the United States (referred to in this paragraph
18 as the ‘annual distribution number’).”; and

19 (iv) in clause (iv), by striking “2012”
20 and inserting “2017”;

21 (B) by striking subparagraph (C);

22 (C) by redesignating subparagraphs (D)
23 and (E) as subparagraphs (C) and (D), respec-
24 tively;

1 (D) in subparagraph (C), as so redesignated,
2 nated, by striking “and modified under sub-
3 paragraph (C), if applicable,”; and

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

6 “(iii) In this subsection, the term ‘pediatric device’
7 means a device with respect to which the exemption is
8 granted that is intended for the treatment or diagnosis
9 of a disease or condition that occurs in pediatric patients
10 or in a pediatric subpopulation, and such device is labeled
11 for use in pediatric patients or in a pediatric subpopula-
12 tion in which the disease or condition occurs.”;

13 (2) in paragraph (7), by striking “regarding a
14 device” and inserting “regarding a pediatric device”;
15 and

16 (3) in paragraph (8), by striking “of all devices
17 described in paragraph (6)” and inserting “of all pe-
18 diatric devices granted an exemption under para-
19 graph (2)”.

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

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

4 (2) the effect of such amendments on patients
5 described in such section 520(m) of the Federal
6 Food, Drug, and Cosmetic Act (as amended by sub-
7 section (a)).

8 **SEC. 3. CONFLICTS OF INTEREST.**

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

11 (1) by striking subsection (b);

12 (2) by redesignating subsection (c) as sub-
13 section (b);

14 (3) in subsection (b), as so redesignated, by
15 striking paragraph (2)(C) and inserting the fol-
16 lowing:

17 “(C) CONSIDERATION BY SECRETARY.—

18 The Secretary shall ensure that each determina-
19 tion under subparagraph (B) considers the
20 scope and magnitude of the financial interest at
21 issue with the public health need for the exper-
22 tise of the member on the advisory committee.”;

23 and

24 (4) by redesignating subsection (d) as sub-
25 section (c);

1 (5) in subsection (c), as so redesignated, by
2 striking “subsection (c)(3)” and inserting “sub-
3 section (b)(3)”; and
4 (6) by striking subsections (e) and (f).