

115TH CONGRESS
1ST SESSION

S. 1093

To amend the Federal Food, Drug, and Cosmetic Act to improve pediatric medical device application procedures.

IN THE SENATE OF THE UNITED STATES

MAY 10, 2017

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve pediatric medical device application procedures.

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 “Pediatric Device Devel-
5 opment Act”.

6 **SEC. 2. PEDIATRIC USES OF DEVICES.**

7 Section 515A of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 360e–1) is amended—

9 (1) in subsection (a)(3)—

1 (A) by redesignating subparagraphs (B)
2 through (D) as subparagraphs (D) through (F),
3 respectively;

4 (B) by inserting after subparagraph (A)
5 the following:

6 “(B) an assessment of pediatric device la-
7 beling needs, based on a review of real world
8 evidence on the off-label use of medical devices
9 in children, drawn from data available to the
10 Food and Drug Administration;

11 “(C) the number of devices that receive a
12 humanitarian use exemption under section
13 520(m);”;

14 (C) in subparagraph (E) (as so redesign-
15 ated), by striking “; and” and inserting “;”;

16 (D) in subparagraph (F) (as so redesign-
17 ated), by striking “(B), and (C).” and insert-
18 ing “(C), (D), and (E); and”;

19 (E) by adding at the end the following:

20 “(G) the number of devices for which ex-
21 trapolation was used to support the approval of
22 pediatric labeling of such devices.

23 For the items described in this paragraph, such re-
24 port shall disaggregate the number of devices by pe-
25 diatric subpopulation.”;

1 (2) by redesignating subsection (c) as sub-
2 section (d); and

3 (3) by inserting after subsection (b), the fol-
4 lowing:

5 “(c) PEDIATRIC DEVICE INNOVATION.—

6 “(1) IN GENERAL.—The Secretary shall, not
7 later than 1 year after the date of enactment of the
8 Pediatric Device Development Act, establish within
9 the Center for Devices and Radiological Health a
10 structure to—

11 “(A) provide assistance to device manufac-
12 turers, in coordination with the relevant review
13 committees, as appropriate, that would result in
14 the development, approval, and labeling of med-
15 ical devices for children;

16 “(B) oversee an internal pediatrics team
17 that—

18 “(i) is comprised of—

19 “(I) employees of the Food and
20 Drug Administration with expertise in
21 pediatrics and appropriate expertise
22 pertaining to the relevant devices
23 under review; and

24 “(II) other individuals designated
25 by the Secretary; and

1 “(ii) provides expertise and consulta-
2 tion on—

3 “(I) the application of subsection
4 (b), section 520(m), section 510(k),
5 and section 522 of this Act and sec-
6 tion 402 of the Public Health Service
7 Act to pediatric devices; and

8 “(II) pediatrics, as it pertains to
9 reviewing devices, to all applicable di-
10 visions within the Center for Devices
11 and Radiological Health;

12 “(C) coordinate pediatric activities within
13 the Center for Devices and Radiological Health;
14 and

15 “(D) collaborate with other programs, of-
16 fices, and centers of the Food and Drug Admin-
17 istration, including the consortia program au-
18 thorized under section 305 of the Pediatric
19 Medical Device Safety and Improvement Act of
20 2007.

21 “(2) STAFF.—Such structure shall include a
22 chief pediatric medical officer and other appropriate
23 individuals as the Secretary determines necessary.”.

1 **SEC. 3. HUMANITARIAN DEVICE EXEMPTION.**

2 Section 520(m) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360j(m)) is amended—

4 (1) in paragraph (4)—

5 (A) by striking “an institutional review
6 committee” each place such term appears and
7 inserting “an institutional review board or an
8 appropriate local committee”; and

9 (B) by striking “the institutional review
10 committee” and inserting “the institutional re-
11 view board or the appropriate local committee”;
12 and

13 (2) in paragraph (6)(A)(iv), by striking “2017”
14 and inserting “2022”.

15 **SEC. 4. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**
16 **ATRIC AVAILABILITY.**

17 Section 305 of the Pediatric Medical Device Safety
18 and Improvement Act of 2007 (Public Law 110–85; 42
19 U.S.C. 282 note) is amended—

20 (1) in subsection (c)—

21 (A) in paragraph (4), by striking “and” at
22 the end;

23 (B) in paragraph (5), by striking the pe-
24 riod and inserting “; and”; and

25 (C) by adding at the end the following:

1 “(6) providing regulatory consultation to device
 2 sponsors in support of the submission of an applica-
 3 tion for a pediatric device, where appropriate.”; and
 4 (2) in subsection (e), by striking “2017” and
 5 inserting “2022”.

6 **SEC. 5. MEETING ON PEDIATRIC DEVICE DEVELOPMENT.**

7 (a) IN GENERAL.—Not later than 1 year after the
 8 date of enactment of this Act, the Secretary of Health and
 9 Human Services shall convene a public meeting regarding
 10 opportunities and barriers to the development, approval,
 11 and labeling of pediatric medical devices. Such meeting
 12 shall include representatives from the medical device in-
 13 dustry, academia, recipients of funding under section 305
 14 of the Pediatric Medical Device Safety and Improvement
 15 Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note),
 16 medical provider organizations, and organizations rep-
 17 resenting patients and consumers.

18 (b) TOPICS.—The meeting described in subsection (a)
 19 shall include consideration of ways to—

20 (1) improve research infrastructure and re-
 21 search networks to facilitate the conduct of clinical
 22 studies of devices for children that would result in
 23 the approval and labeling of medical devices for chil-
 24 dren;

1 (2) appropriately use extrapolation under sec-
2 tion 515A(b) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360e–1(b));

4 (3) enhance the appropriate use of postmarket
5 registries and data to increase pediatric medical de-
6 vice labeling;

7 (4) increase Food and Drug Administration as-
8 sistance to medical device manufacturers in devel-
9 oping devices for children that are approved and la-
10 beled for their use; and

11 (5) identify current barriers to pediatric device
12 development and incentives to address such barriers.

13 (c) REPORT.—Not later than 6 months after the
14 meeting described in subsection (a), the Secretary of
15 Health and Human Services shall submit to the Com-
16 mittee on Energy and Commerce of the House of Rep-
17 resentatives and the Committee on Health, Education,
18 Labor, and Pensions of the Senate, and publish, including
19 on the Internet website of the Food and Drug Administra-
20 tion, a report that summarizes and responds to the rec-
21 ommendations raised in such meeting.

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