

110TH CONGRESS
1ST SESSION

S. 830

To improve the process for the development of needed pediatric medical devices.

IN THE SENATE OF THE UNITED STATES

MARCH 8, 2007

Mr. DODD introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve the process for the development of needed pediatric medical devices.

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 Medical De-
5 vice Safety and Improvement Act of 2007”.

6 **SEC. 2. TRACKING PEDIATRIC DEVICE APPROVALS.**

7 Chapter V of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 351 et seq.) is amended by inserting after
9 section 515 the following:

1 **“SEC. 515A. PEDIATRIC USES OF DEVICES.**

2 “(a) NEW DEVICES.—

3 “(1) IN GENERAL.—A person that submits to
4 the Secretary an application under section 520(m),
5 or an application (or supplement to an application)
6 or a product development protocol under section
7 515, shall include in the application or protocol the
8 information described in paragraph (2).

9 “(2) REQUIRED INFORMATION.—The applica-
10 tion or protocol described in paragraph (1) shall in-
11 clude, with respect to the device for which approval
12 is sought and if readily available—

13 “(A) a description of any pediatric sub-
14 populations that suffer from the disease or con-
15 dition that the device is intended to treat, diag-
16 nose, or cure; and

17 “(B) the number of affected pediatric pa-
18 tients.

19 “(3) ANNUAL REPORT.—Not later than 18
20 months after the date of enactment of this section,
21 and annually thereafter, the Secretary shall submit
22 to the Committee on Health, Education, Labor, and
23 Pensions of the Senate and the Committee on En-
24 ergy and Commerce of the House of Representatives
25 a report that includes—

1 “(A) the number of devices approved in the
 2 year preceding the year in which the report is
 3 submitted, for which there is a pediatric sub-
 4 population that suffers from the disease or con-
 5 dition that the device is intended to treat, diag-
 6 nose, or cure;

7 “(B) the number of devices approved in
 8 the year preceding the year in which the report
 9 is submitted, labeled for use in pediatric pa-
 10 tients;

11 “(C) the number of pediatric devices ap-
 12 proved in the year preceding the year in which
 13 the report is submitted, exempted from a fee
 14 pursuant to section 738(a)(2)(B)(v); and

15 “(D) the review time for each device de-
 16 scribed in subparagraphs (A), (B), and (C).

17 “(b) DETERMINATION OF PEDIATRIC EFFECTIVE-
 18 NESS BASED ON SIMILAR COURSE OF DISEASE OR CONDI-
 19 TION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

20 “(1) IN GENERAL.—If the course of the disease
 21 or condition and the effects of the device are suffi-
 22 ciently similar in adults and pediatric patients, the
 23 Secretary may conclude that adult data may be used
 24 to support a determination of a reasonable assur-

1 ance of effectiveness in pediatric populations, as ap-
2 propriate.

3 “(2) **EXTRAPOLATION BETWEEN SUBPOPULA-**
4 **TIONS.**—A study may not be needed in each pedi-
5 atric subpopulation if data from one subpopulation
6 can be extrapolated to another subpopulation.

7 “(c) **PEDIATRIC SUBPOPULATION.**—In this section,
8 the term ‘pediatric subpopulation’ has the meaning given
9 the term in section 520(m)(6)(E)(ii).”.

10 **SEC. 3. MODIFICATION TO HUMANITARIAN DEVICE EXEMP-**
11 **TION.**

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

15 (1) in paragraph (3), by striking “No” and in-
16 serting “Except as provided in paragraph (6), no”;

17 (2) in paragraph (5)—

18 (A) by inserting “, if the Secretary has
19 reason to believe that the requirements of para-
20 graph (6) are no longer met,” after “public
21 health”; and

22 (B) by adding at the end the following: “If
23 the person granted an exemption under para-
24 graph (2) fails to demonstrate continued com-
25 pliance with the requirements of this sub-

1 section, the Secretary may suspend or withdraw
2 the exemption from the effectiveness require-
3 ments of sections 514 and 515 for a humani-
4 tarian device only after providing notice and an
5 opportunity for an informal hearing.”;

6 (3) by striking paragraph (6) and inserting the
7 following:

8 “(6)(A) Except as provided in subparagraph (D), the
9 prohibition in paragraph (3) shall not apply with respect
10 to a person granted an exemption under paragraph (2)
11 if each of the following conditions apply:

12 “(i)(I) The device with respect to which the ex-
13 emption is granted is intended for the treatment or
14 diagnosis of a disease or condition that occurs in pe-
15 diatric patients or in a pediatric subpopulation, and
16 such device is labeled for use in pediatric patients or
17 in a pediatric subpopulation in which the disease or
18 condition occurs.

19 “(II) The device was not previously approved
20 under this subsection for the pediatric patients or
21 the pediatric subpopulation described in subclause
22 (I) prior to the date of enactment of the Pediatric
23 Medical Device Safety and Improvement Act of
24 2007.

1 “(ii) During any calendar year, the number of
2 such devices distributed during that year does not
3 exceed the annual distribution number specified by
4 the Secretary when the Secretary grants such ex-
5 emption. The annual distribution number shall be
6 based on the number of individuals affected by the
7 disease or condition that such device is intended to
8 treat, diagnose, or cure, and of that number, the
9 number of individuals likely to use the device, and
10 the number of devices reasonably necessary to treat
11 such individuals. In no case shall the annual dis-
12 tribution number exceed the number identified in
13 paragraph (2)(A).

14 “(iii) Such person immediately notifies the Sec-
15 retary if the number of such devices distributed dur-
16 ing any calendar year exceeds the annual distribu-
17 tion number referred to in clause (ii).

18 “(iv) The request for such exemption is sub-
19 mitted on or before October 1, 2013.

20 “(B) The Secretary may inspect the records relating
21 to the number of devices distributed during any calendar
22 year of a person granted an exemption under paragraph
23 (2) for which the prohibition in paragraph (3) does not
24 apply.

1 “(C) A person may petition the Secretary to modify
2 the annual distribution number specified by the Secretary
3 under subparagraph (A)(ii) with respect to a device if ad-
4 ditional information on the number of individuals affected
5 by the disease or condition arises, and the Secretary may
6 modify such number but in no case shall the annual dis-
7 tribution number exceed the number identified in para-
8 graph (2)(A).

9 “(D) If a person notifies the Secretary, or the Sec-
10 retary determines through an inspection under subpara-
11 graph (B), that the number of devices distributed during
12 any calendar year exceeds the annual distribution number,
13 as required under subparagraph (A)(iii), and modified
14 under subparagraph (C), if applicable, then the prohibi-
15 tion in paragraph (3) shall apply with respect to such per-
16 son for such device for any sales of such device after such
17 notification.

18 “(E)(i) In this subsection, the term ‘pediatric pa-
19 tients’ means patients who are 21 years of age or younger
20 at the time of the diagnosis or treatment.

21 “(ii) In this subsection, the term ‘pediatric sub-
22 population’ means 1 of the following populations:

23 “(I) Neonates.

24 “(II) Infants.

25 “(III) Children.

1 “(IV) Adolescents.”; and

2 (4) by adding at the end the following:

3 “(7) The Secretary shall refer any report of an ad-
4 verse event regarding a device for which the prohibition
5 under paragraph (3) does not apply pursuant to para-
6 graph (6)(A) that the Secretary receives to the Office of
7 Pediatric Therapeutics, established under section 6 of the
8 Best Pharmaceuticals for Children Act (Public Law 107–
9 109)). In considering the report, the Director of the Office
10 of Pediatric Therapeutics, in consultation with experts in
11 the Center for Devices and Radiological Health, shall pro-
12 vide for periodic review of the report by the Pediatric Ad-
13 visory Committee, including obtaining any recommenda-
14 tions of such committee regarding whether the Secretary
15 should take action under this Act in response to the re-
16 port.”.

17 (b) REPORT.—Not later than January 1, 2012, the
18 Comptroller General of the United States shall submit to
19 the Committee on Health, Education, Labor, and Pen-
20 sions of the Senate and the Committee on Energy and
21 Commerce of the House of Representatives a report on
22 the impact of allowing persons granted an exemption
23 under section 520(m)(2) of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a
25 device to profit from such device pursuant to section

1 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amend-
2 ed by subsection (a)), including—

3 (1) an assessment of whether such section
4 520(m)(6) (as amended by subsection (a)) has in-
5 creased the availability of pediatric devices for condi-
6 tions that occur in small numbers of children, in-
7 cluding any increase or decrease in the number of—

8 (A) exemptions granted under such section
9 520(m)(2) for pediatric devices; and

10 (B) applications approved under section
11 515 of such Act (21 U.S.C. 360e) for devices
12 intended to treat, diagnose, or cure conditions
13 that occur in pediatric patients or for devices
14 labeled for use in a pediatric population;

15 (2) the conditions or diseases the pediatric de-
16 vices were intended to treat or diagnose and the esti-
17 mated size of the pediatric patient population for
18 each condition or disease;

19 (3) the costs of the pediatric devices, based on
20 a survey of children's hospitals;

21 (4) the extent to which the costs of such devices
22 are covered by health insurance;

23 (5) the impact, if any, of allowing profit on ac-
24 cess to such devices for patients;

1 (6) the profits made by manufacturers for each
2 device that receives an exemption;

3 (7) an estimate of the extent of the use of the
4 pediatric devices by both adults and pediatric popu-
5 lations for a condition or disease other than the con-
6 dition or disease on the label of such devices;

7 (8) recommendations of the Comptroller Gen-
8 eral of the United States regarding the effectiveness
9 of such section 520(m)(6) (as amended by sub-
10 section (a)) and whether any modifications to such
11 section 520(m)(6) (as amended by subsection (a))
12 should be made;

13 (9) existing obstacles to pediatric device devel-
14 opment; and

15 (10) an evaluation of the demonstration grants
16 described in section 5.

17 (c) GUIDANCE.—Not later than 180 days after the
18 date of enactment of this Act, the Commissioner of Food
19 and Drugs shall issue guidance for institutional review
20 committees on how to evaluate requests for approval for
21 devices for which a humanitarian device exemption under
22 section 520(m)(2) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 360j(m)(2)) has been granted.

1 **SEC. 4. ENCOURAGING PEDIATRIC MEDICAL DEVICE RE-**
2 **SEARCH.**

3 (a) ACCESS TO FUNDING.—The Director of the Na-
4 tional Institutes of Health shall designate a contact point
5 or office at the National Institutes of Health to help
6 innovators and physicians access funding for pediatric
7 medical device development.

8 (b) PLAN FOR PEDIATRIC MEDICAL DEVICE RE-
9 SEARCH.—

10 (1) IN GENERAL.—Not later than 180 days
11 after the date of enactment of this Act, the Commis-
12 sioner of Food and Drugs, in collaboration with the
13 Director of the National Institutes of Health and the
14 Director of the Agency for Healthcare Research and
15 Quality, shall submit to the Committee on Health,
16 Education, Labor, and Pensions of the Senate and
17 the Committee on Energy and Commerce of the
18 House of Representatives a plan for expanding pedi-
19 atric medical device research and development. In
20 developing such plan, the Commissioner of Food and
21 Drugs shall consult with individuals and organiza-
22 tions with appropriate expertise in pediatric medical
23 devices.

24 (2) CONTENTS.—The plan under paragraph (1)
25 shall include—

1 (A) the current status of federally funded
 2 pediatric medical device research;

3 (B) any gaps in such research, which may
 4 include a survey of pediatric medical providers
 5 regarding unmet pediatric medical device needs,
 6 as needed; and

7 (C) a research agenda for improving pedi-
 8 atric medical device development and Food and
 9 Drug Administration clearance or approval of
 10 pediatric medical devices, and for evaluating the
 11 short- and long-term safety and effectiveness of
 12 pediatric medical devices.

13 **SEC. 5. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**
 14 **ATRIC DEVICE AVAILABILITY.**

15 (a) IN GENERAL.—

16 (1) REQUEST FOR PROPOSALS.—Not later than
 17 90 days after the date of enactment of this Act, the
 18 Secretary of Health and Human Services shall issue
 19 a request for proposals for 1 or more grants or con-
 20 tracts to nonprofit consortia for demonstration
 21 projects to promote pediatric device development.

22 (2) DETERMINATION ON GRANTS OR CON-
 23 TRACTS.—Not later than 180 days after the date the
 24 Secretary of Health and Human Services issues a
 25 request for proposals under paragraph (1), the Sec-

1 retary shall make a determination on the grants or
2 contracts under this section.

3 (b) APPLICATION.—A nonprofit consortium that de-
4 sires to receive a grant or contract under this section shall
5 submit an application to the Secretary of Health and
6 Human Services at such time, in such manner, and con-
7 taining such information as the Secretary may require.

8 (c) USE OF FUNDS.—A nonprofit consortium that re-
9 ceives a grant or contract under this section shall—

10 (1) encourage innovation by connecting quali-
11 fied individuals with pediatric device ideas with po-
12 tential manufacturers;

13 (2) mentor and manage pediatric device
14 projects through the development process, including
15 product identification, prototype design, device devel-
16 opment, and marketing;

17 (3) connect innovators and physicians to exist-
18 ing Federal resources, including resources from the
19 Food and Drug Administration, the National Insti-
20 tutes of Health, the Small Business Administration,
21 the Department of Energy, the Department of Edu-
22 cation, the National Science Foundation, the De-
23 partment of Veterans Affairs, the Agency for
24 Healthcare Research and Quality, and the National
25 Institute of Standards and Technology;

1 (4) assess the scientific and medical merit of
2 proposed pediatric device projects;

3 (5) assess business feasibility and provide busi-
4 ness advice;

5 (6) provide assistance with prototype develop-
6 ment; and

7 (7) provide assistance with postmarket needs,
8 including training, logistics, and reporting.

9 (d) COORDINATION.—

10 (1) NATIONAL INSTITUTES OF HEALTH.—Each
11 consortium that receives a grant or contract under
12 this section shall—

13 (A) coordinate with the National Institutes
14 of Health’s pediatric device contact point or of-
15 fice, designated under section 4; and

16 (B) provide to the National Institutes of
17 Health any identified pediatric device needs
18 that the consortium lacks sufficient capacity to
19 address or those needs in which the consortium
20 has been unable to stimulate manufacturer in-
21 terest.

22 (2) FOOD AND DRUG ADMINISTRATION.—Each
23 consortium that receives a grant or contract under
24 this section shall coordinate with the Commissioner
25 of Food and Drugs and device companies to facili-

1 tate the application for approval or clearance of de-
 2 vices labeled for pediatric use.

3 (e) AUTHORIZATION OF APPROPRIATIONS.—There
 4 are authorized to be appropriated to carry out this section
 5 \$6,000,000 for each of fiscal years 2008 through 2012.

6 **SEC. 6. AMENDMENTS TO OFFICE OF PEDIATRIC THERA-**
 7 **PEUTICS AND PEDIATRIC ADVISORY COM-**
 8 **MITTEE.**

9 (a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section
 10 6(b) of the Best Pharmaceuticals for Children Act (21
 11 U.S.C. 393a(b)) is amended by inserting “, including in-
 12 creasing pediatric access to medical devices” after “pedi-
 13 atric issues”.

14 (b) PEDIATRIC ADVISORY COMMITTEE.—Section 14
 15 of the Best Pharmaceuticals for Children Act (42 U.S.C.
 16 284m note) is amended—

17 (1) in subsection (a), by inserting “(including
 18 drugs and biological products) and medical devices”
 19 after “therapeutics”; and

20 (2) in subsection (b)—

21 (A) in paragraph (1), by inserting “(in-
 22 cluding drugs and biological products) and med-
 23 ical devices” after “therapeutics”; and

24 (B) in paragraph (2)—

1 (i) in subparagraph (A), by striking
 2 “and 505B” and inserting “505B, 510(k),
 3 515, and 520(m)”;

4 (ii) by striking subparagraph (B) and
 5 inserting the following:

6 “(B) identification of research priorities re-
 7 lated to therapeutics (including drugs and bio-
 8 logical products) and medical devices for pedi-
 9 atric populations and the need for additional
 10 diagnostics and treatments for specific pediatric
 11 diseases or conditions; and”; and

12 (iii) in subparagraph (C), by inserting
 13 “(including drugs and biological products)
 14 and medical devices” after “therapeutics”.

15 **SEC. 7. STUDIES.**

16 (a) POSTMARKET STUDIES.—Section 522 of the Fed-
 17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is
 18 amended—

19 (1) in subsection (a)—

20 (A) by inserting “, or as a condition to ap-
 21 proval of an application (or a supplement to an
 22 application) or a product development protocol
 23 under section 515 or as a condition to clearance
 24 of a premarket notification under section

1 510(k),” after “The Secretary may by order”;
2 and

3 (B) by inserting “, that is expected to have
4 significant use in pediatric populations,” after
5 “health consequences”; and
6 (2) in subsection (b)—

7 (A) by striking “(b) SURVEILLANCE AP-
8 PROVAL.—Each” and inserting the following:

9 “(b) SURVEILLANCE APPROVAL.—
10 “(1) IN GENERAL.—Each”;

11 (B) by striking “The Secretary, in con-
12 sultation” and inserting “Except as provided in
13 paragraph (2), the Secretary, in consultation”;

14 (C) by striking “Any determination” and
15 inserting “Except as provided in paragraph (2),
16 any determination”; and

17 (D) by adding at the end the following:

18 “(2) LONGER STUDIES FOR PEDIATRIC DE-
19 VICES.—The Secretary may by order require a pro-
20 spective surveillance period of more than 36 months
21 with respect to a device that is expected to have sig-
22 nificant use in pediatric populations if such period of
23 more than 36 months is necessary in order to assess
24 the impact of the device on growth and development,
25 or the effects of growth, development, activity level,

1 or other factors on the safety or efficacy of the de-
2 vice.”.

3 (b) DATABASE.—

4 (1) IN GENERAL.—

5 (A) ESTABLISHMENT.—The Secretary of
6 Health and Human Services, acting through the
7 Commissioner of Food and Drugs, shall estab-
8 lish a publicly accessible database of studies of
9 medical devices that includes all studies and
10 surveillances, described in paragraph (2)(A),
11 that were in progress on the date of enactment
12 of this Act or that began after such date.

13 (B) ACCESSIBILITY.—Information included
14 in the database under subparagraph (A) shall
15 be in language reasonably accessible and under-
16 stood by individuals without specific expertise in
17 the medical field.

18 (2) STUDIES AND SURVEILLANCES.—

19 (A) INCLUDED.—The database described
20 in paragraph (1) shall include—

21 (i) all postmarket surveillances or-
22 dered under section 522(a) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C.
24 360l(a)) or agreed to by the manufacturer;
25 and

(ii) all studies agreed to by the manufacturer of a medical device as part of—

(I) the premarket approval of such device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e);

(II) the clearance of a premarket notification report under section 510(k) of such Act (21 U.S.C. 360(k)) with respect to such device; or

(III) the submission of an application under section 520(m) of such Act (21 U.S.C. 360j(m)) with respect to such device.

(B) EXCLUDED.—The database described in paragraph (1) shall not include any studies with respect to a medical device that were completed prior to the initial approval of such device.

(3) CONTENTS OF STUDY AND SURVEILLANCE.—For each study or surveillance included in the database described in paragraph (1), the database shall include—

(A) information on the status of the study or surveillance;

1 (B) basic information about the study or
2 surveillance, including the purpose, the primary
3 and secondary outcomes, and the population
4 targeted;

5 (C) the expected completion date of the
6 study or surveillance;

7 (D) public health notifications, including
8 safety alerts; and

9 (E) any other information the Secretary of
10 Health and Human Services determines appro-
11 priate to protect the public health.

12 (4) ONCE COMPLETED OR TERMINATED.—In
13 addition to the information described in paragraph
14 (3), once a study or surveillance has been completed
15 or if a study or surveillance is terminated, the data-
16 base shall also include—

17 (A) the actual date of completion or termi-
18 nation;

19 (B) if the study or surveillance was termi-
20 nated, the reason for termination;

21 (C) if the study or surveillance was sub-
22 mitted but not accepted by the Food and Drug
23 Administration because the study or surveil-
24 lance did not meet the requirements for such

1 study or surveillance, an explanation of the rea-
2 sons and any follow-up action required;

3 (D) information about any labeling
4 changes made to the device as a result of the
5 study or surveillance findings;

6 (E) information about any other decisions
7 or actions of the Food and Drug Administra-
8 tion that result from the study or surveillance
9 findings;

10 (F) lay and technical summaries of the
11 study or surveillance results and key findings,
12 or an explanation as to why the results and key
13 findings do not warrant public availability;

14 (G) a link to any peer reviewed articles on
15 the study or surveillance; and

16 (H) any other information the Secretary of
17 Health and Human Services determines appro-
18 priate to protect the public health.

19 (5) PUBLIC ACCESS.—The database described
20 in paragraph (1) shall be—

21 (A) accessible to the general public; and

22 (B) easily searchable by multiple criteria,
23 including whether the study or surveillance in-
24 volves pediatric populations.

○