

**[Committee Print]**

110TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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

\_\_\_\_\_  
IN THE HOUSE OF REPRESENTATIVES

M\_\_\_\_. \_\_\_\_\_ introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**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.**—For purposes of  
8           this section, the term ‘pediatric subpopulation’ has the  
9           meaning given 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.”; and

6 (3) by striking paragraph (6) and inserting  
7 after paragraph (5) the following new paragraphs:

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

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

21 “(II) The device was not previously ap-  
22 proved under this subsection for the pediatric  
23 patients or the pediatric subpopulation de-  
24 scribed in subclause (I) prior to the date of en-

1 actment of the Pediatric Medical Device Safety  
2 and Improvement Act of 2007.

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

17 “(iii) Such person immediately notifies the  
18 Secretary if the number of such devices distrib-  
19 uted during any calendar year exceeds the an-  
20 nual distribution number referred to in clause  
21 (ii).

22 “(iv) The request for such exemption is  
23 submitted on or before October 1, 2013.

24 “(B) The Secretary may inspect the records re-  
25 lating to the number of devices distributed during

1 any calendar year of a person granted an exemption  
2 under paragraph (2) for which the prohibition in  
3 paragraph (3) does not apply.

4 “(C) A person may petition the Secretary to  
5 modify the annual distribution number specified by  
6 the Secretary under subparagraph (A)(ii) with re-  
7 spect to a device if additional information on the  
8 number of individuals affected by the disease or con-  
9 dition arises, and the Secretary may modify such  
10 number but in no case shall the annual distribution  
11 number exceed the number identified in paragraph  
12 (2)(A).

13 “(D) If a person notifies the Secretary, or the  
14 Secretary determines through an inspection under  
15 subparagraph (B), that the number of devices dis-  
16 tributed during any calendar year exceeds the an-  
17 nual distribution number, as required under sub-  
18 paragraph (A)(iii), and modified under subpara-  
19 graph (C), if applicable, then the prohibition in  
20 paragraph (3) shall apply with respect to such per-  
21 son for such device for any sales of such device after  
22 such notification.

23 “(E)(i) In this subsection, the term ‘pediatric  
24 patients’ means patients who are 21 years of age or  
25 younger at the time of the diagnosis or treatment.

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

3                   “(I) Neonates.

4                   “(II) Infants.

5                   “(III) Children.

6                   “(IV) Adolescents.

7           “(7) The Secretary shall refer any report of an  
8           adverse event regarding a device for which the prohi-  
9           bition under paragraph (3) does not apply pursuant  
10          to paragraph (6)(A) that the Secretary receives to  
11          the Office of Pediatric Therapeutics, established  
12          under section 6 of the Best Pharmaceuticals for  
13          Children Act (Public Law 107–109)). In considering  
14          the report, the Director of the Office of Pediatric  
15          Therapeutics, in consultation with experts in the  
16          Center for Devices and Radiological Health, shall  
17          provide for periodic review of the report by the Pedi-  
18          atric Advisory Committee, including obtaining any  
19          recommendations of such committee regarding  
20          whether the Secretary should take action under this  
21          Act in response to the report.

22          “(8) In consultation with the Office of Pediatric  
23          Therapeutics and the Center for Devices and Radio-  
24          logical Health, the Secretary shall provide for an an-  
25          nual review by the Pediatric Advisory Committee of

1 all devices described in paragraph (6) to ensure that  
2 the exemption under paragraph (2) remains appro-  
3 priate for the pediatric populations for which it is  
4 granted.”.

5 (b) REPORT.—Not later than January 1, 2012, the  
6 Comptroller General of the United States shall submit to  
7 the Committee on Health, Education, Labor, and Pen-  
8 sions of the Senate and the Committee on Energy and  
9 Commerce of the House of Representatives a report on  
10 the impact of allowing persons granted an exemption  
11 under section 520(m)(2) of the Federal Food, Drug, and  
12 Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a  
13 device to profit from such device pursuant to section  
14 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amend-  
15 ed by subsection (a)), including—

16 (1) an assessment of whether such section  
17 520(m)(6) (as amended by subsection (a)) has in-  
18 creased the availability of pediatric devices for condi-  
19 tions that occur in small numbers of children, in-  
20 cluding any increase or decrease in the number of—

21 (A) exemptions granted under such section  
22 520(m)(2) for pediatric devices; and

23 (B) applications approved under section  
24 515 of such Act (21 U.S.C. 360e) for devices  
25 intended to treat, diagnose, or cure conditions

1           that occur in pediatric patients or for devices  
2           labeled for use in a pediatric population;

3           (2) the conditions or diseases the pediatric de-  
4           vices were intended to treat or diagnose and the esti-  
5           mated size of the pediatric patient population for  
6           each condition or disease;

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

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

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

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

15          (7) an estimate of the extent of the use of the  
16          pediatric devices by both adults and pediatric popu-  
17          lations for a condition or disease other than the con-  
18          dition or disease on the label of such devices;

19          (8) recommendations of the Comptroller Gen-  
20          eral of the United States regarding the effectiveness  
21          of such section 520(m)(6) (as amended by sub-  
22          section (a)) and whether any modifications to such  
23          section 520(m)(6) (as amended by subsection (a))  
24          should be made;

1 (9) existing obstacles to pediatric device devel-  
2 opment; and

3 (10) an evaluation of the demonstration grants  
4 described in section 5.

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

12 **SEC. 4. ENCOURAGING PEDIATRIC MEDICAL DEVICE RE-**  
13 **SEARCH.**

14 (a) ACCESS TO FUNDING.—The Director of the Na-  
15 tional Institutes of Health shall designate a contact point  
16 or office at the National Institutes of Health to help  
17 innovators and physicians access funding for pediatric  
18 medical device development.

19 (b) PLAN FOR PEDIATRIC MEDICAL DEVICE RE-  
20 SEARCH.—

21 (1) IN GENERAL.—Not later than 180 days  
22 after the date of enactment of this Act, the Commis-  
23 sioner of Food and Drugs, in collaboration with the  
24 Director of the National Institutes of Health and the  
25 Director of the Agency for Healthcare Research and

1       Quality, shall submit to the Committee on Health,  
2       Education, Labor, and Pensions of the Senate and  
3       the Committee on Energy and Commerce of the  
4       House of Representatives a plan for expanding pedi-  
5       atric medical device research and development. In  
6       developing such plan, the Commissioner of Food and  
7       Drugs shall consult with individuals and organiza-  
8       tions with appropriate expertise in pediatric medical  
9       devices.

10           (2) CONTENTS.—The plan under paragraph (1)  
11       shall include—

12           (A) the current status of federally funded  
13       pediatric medical device research;

14           (B) any gaps in such research, which may  
15       include a survey of pediatric medical providers  
16       regarding unmet pediatric medical device needs,  
17       as needed; and

18           (C) a research agenda for improving pedi-  
19       atric medical device development and Food and  
20       Drug Administration clearance or approval of  
21       pediatric medical devices, and for evaluating the  
22       short- and long-term safety and effectiveness of  
23       pediatric medical devices.

1 **SEC. 5. DEMONSTRATION GRANTS FOR IMPROVING PEDI-**  
2 **ATRIC DEVICE AVAILABILITY.**

3 (a) IN GENERAL.—

4 (1) REQUEST FOR PROPOSALS.—Not later than  
5 90 days after the date of enactment of this Act, the  
6 Secretary of Health and Human Services shall issue  
7 a request for proposals for 1 or more grants or con-  
8 tracts to nonprofit consortia for demonstration  
9 projects to promote pediatric device development.

10 (2) DETERMINATION ON GRANTS OR CON-  
11 TRACTS.—Not later than 180 days after the date the  
12 Secretary of Health and Human Services issues a  
13 request for proposals under paragraph (1), the Sec-  
14 retary shall make a determination on the grants or  
15 contracts under this section.

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

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

23 (1) encourage innovation by connecting quali-  
24 fied individuals with pediatric device ideas with po-  
25 tential manufacturers;

1           (2) mentor and manage pediatric device  
2 projects through the development process, including  
3 product identification, prototype design, device devel-  
4 opment, and marketing;

5           (3) connect innovators and physicians to exist-  
6 ing Federal resources, including resources from the  
7 Food and Drug Administration, the National Insti-  
8 tutes of Health, the Small Business Administration,  
9 the Department of Energy, the Department of Edu-  
10 cation, the National Science Foundation, the De-  
11 partment of Veterans Affairs, the Agency for  
12 Healthcare Research and Quality, and the National  
13 Institute of Standards and Technology;

14           (4) assess the scientific and medical merit of  
15 proposed pediatric device projects;

16           (5) assess business feasibility and provide busi-  
17 ness advice;

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

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

22 (d) COORDINATION.—

23           (1) NATIONAL INSTITUTES OF HEALTH.—Each  
24 consortium that receives a grant or contract under  
25 this section shall—

1 (A) coordinate with the National Institutes  
2 of Health's pediatric device contact point or of-  
3 fice, designated under section 4; and

4 (B) provide to the National Institutes of  
5 Health any identified pediatric device needs  
6 that the consortium lacks sufficient capacity to  
7 address or those needs in which the consortium  
8 has been unable to stimulate manufacturer in-  
9 terest.

10 (2) FOOD AND DRUG ADMINISTRATION.—Each  
11 consortium that receives a grant or contract under  
12 this section shall coordinate with the Commissioner  
13 of Food and Drugs and device companies to facili-  
14 tate the application for approval or clearance of de-  
15 vices labeled for pediatric use.

16 (e) AUTHORIZATION OF APPROPRIATIONS.—There  
17 are authorized to be appropriated to carry out this section  
18 \$6,000,000 for each of fiscal years 2008 through 2012.

19 **SEC. 6. AMENDMENTS TO OFFICE OF PEDIATRIC THERA-  
20 PEUTICS AND PEDIATRIC ADVISORY COM-  
21 MITTEE.**

22 (a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section  
23 6(b) of the Best Pharmaceuticals for Children Act (21  
24 U.S.C. 393a(b)) is amended by inserting “, including in-

1 creasing pediatric access to medical devices” after “pedi-  
2 atric issues”.

3 (b) PEDIATRIC ADVISORY COMMITTEE.—Section 14  
4 of the Best Pharmaceuticals for Children Act (42 U.S.C.  
5 284m note) is amended—

6 (1) in subsection (a), by inserting “(including  
7 drugs and biological products) and medical devices”  
8 after “therapeutics”; and

9 (2) in subsection (b)—

10 (A) in paragraph (1), by inserting “(in-  
11 cluding drugs and biological products) and med-  
12 ical devices” after “therapeutics”; and

13 (B) in paragraph (2)—

14 (i) in subparagraph (A), by striking  
15 “and 505B” and inserting “505B, 510(k),  
16 515, and 520(m)”;

17 (ii) by striking subparagraph (B) and  
18 inserting the following:

19 “(B) identification of research priorities re-  
20 lated to therapeutics (including drugs and bio-  
21 logical products) and medical devices for pedi-  
22 atric populations and the need for additional  
23 diagnostics and treatments for specific pediatric  
24 diseases or conditions;” and

1 (iii) in subparagraph (C), by inserting  
2 “(including drugs and biological products)  
3 and medical devices” after “therapeutics”.

4 **SEC. 7. STUDIES.**

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

8 (1) in subsection (a)—

9 (A) by inserting “, or as a condition to ap-  
10 proval of an application (or a supplement to an  
11 application) or a product development protocol  
12 under section 515 or as a condition to clearance  
13 of a premarket notification under section  
14 510(k),” after “The Secretary may by order”;  
15 and

16 (B) by inserting “, that is expected to have  
17 significant use in pediatric populations,” after  
18 “health consequences”; and

19 (2) in subsection (b)—

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

22 “(b) SURVEILLANCE APPROVAL.—

23 “(1) IN GENERAL.—Each”;

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

4 (C) by striking “Any determination” and  
5 inserting “Except as provided in paragraph (2),  
6 any determination”; and

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

8 “(2) LONGER STUDIES FOR PEDIATRIC DE-  
9 VICES.—The Secretary may by order require a pro-  
10 spective surveillance period of more than 36 months  
11 with respect to a device that is expected to have sig-  
12 nificant use in pediatric populations if such period of  
13 more than 36 months is necessary in order to assess  
14 the impact of the device on growth and development,  
15 or the effects of growth, development, activity level,  
16 or other factors on the safety or efficacy of the de-  
17 vice.”.

18 (b) DATABASE.—

19 (1) IN GENERAL.—

20 (A) ESTABLISHMENT.—The Secretary of  
21 Health and Human Services, acting through the  
22 Commissioner of Food and Drugs, shall estab-  
23 lish a publicly accessible database of studies of  
24 medical devices that includes all studies and  
25 surveillances, described in paragraph (2)(A),

1           that were in progress on the date of enactment  
2           of this Act or that began after such date.

3                   (B) ACCESSIBILITY.—Information included  
4           in the database under subparagraph (A) shall  
5           be in language reasonably accessible and under-  
6           stood by individuals without specific expertise in  
7           the medical field.

8           (2) STUDIES AND SURVEILLANCES.—

9                   (A) INCLUDED.—The database described  
10          in paragraph (1) shall include—

11                   (i) all postmarket surveillances or-  
12           dered under section 522(a) of the Federal  
13           Food, Drug, and Cosmetic Act (21 U.S.C.  
14           360l(a)) or agreed to by the manufacturer;  
15           and

16                   (ii) all studies agreed to by the manu-  
17           facturer of a medical device in conjunction  
18           with—

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

23                   (II) the clearance of a premarket  
24           notification report under section

1                   510(k) of such Act (21 U.S.C.  
2                   360(k)) with respect to such device; or  
3                   (III) the submission of an appli-  
4                   cation under section 520(m) of such  
5                   Act (21 U.S.C. 360j(m)) with respect  
6                   to such device.

7                   (B) EXCLUDED.—The database described  
8                   in paragraph (1) shall not include any studies  
9                   with respect to a medical device that were com-  
10                  pleted prior to the initial approval of such de-  
11                  vice.

12                  (3) CONTENTS OF STUDY AND SURVEIL-  
13                  LANCE.—For each study or surveillance included in  
14                  the database described in paragraph (1), the data-  
15                  base shall include—

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

18                   (B) basic information about the study or  
19                   surveillance, including the purpose, the primary  
20                   and secondary outcomes, and the population  
21                   targeted;

22                   (C) the expected completion date of the  
23                   study or surveillance;

24                   (D) public health notifications, including  
25                   safety alerts; and

1 (E) any other information the Secretary of  
2 Health and Human Services determines appro-  
3 priate to protect the public health.

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

9 (A) the actual date of completion or termi-  
10 nation;

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

13 (C) if the study or surveillance was sub-  
14 mitted but not accepted by the Food and Drug  
15 Administration because the study or surveil-  
16 lance did not meet the requirements for such  
17 study or surveillance, an explanation of the rea-  
18 sons and any follow-up action required;

19 (D) information about any labeling  
20 changes made to the device as a result of the  
21 study or surveillance findings;

22 (E) information about any other decisions  
23 or actions of the Food and Drug Administra-  
24 tion that result from the study or surveillance  
25 findings;

1 (F) lay and technical summaries of the  
2 study or surveillance results and key findings,  
3 or an explanation as to why the results and key  
4 findings do not warrant public availability;

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

7 (H) any other information the Secretary of  
8 Health and Human Services determines appro-  
9 priate to protect the public health.

10 (5) PUBLIC ACCESS.—The database described  
11 in paragraph (1) shall be—

12 (A) accessible to the general public; and

13 (B) easily searchable by multiple criteria,  
14 including whether the study or surveillance in-  
15 volves pediatric populations.