II

109TH CONGRESS
2D SESSION

S. 4098

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

IN THE SENATE OF THE UNITED STATES

DECEMBER 6, 2006

Mr. DODD (for himself and Mr. DEWINE) 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 the process for the development of needed pediatric medical devices.

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 ''Pediatric Medical Device Safety and Improvement Act of 2006''.

SEC. 2. TRACKING PEDIATRIC DEVICE APPROVALS.

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

"SEC. 515A. PEDIATRIC USES OF DEVICES.

"(a) NEW DEVICES.—

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

"(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

"(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

"(B) the number of affected pediatric patients.

"(3) ANNUAL REPORT.—Not later than 18 months after the date of enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

"(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

"(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

"(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v); and

"(D) the review time for each device described in subparagraphs (A), (B), and (C).

"(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

"(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assur-

ance of effectiveness in pediatric populations, as appropriate.

''(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.''.

SEC. 3. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.

(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 (3), by striking ''No'' and inserting ''Except as provided in paragraph (6), no'';

(2) in paragraph (5)—

(A) by inserting '', if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met,'' after ''public health''; and

(B) by adding at the end the following: ''If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humani-

tarian device only after providing notice and an opportunity for an informal hearing.'';

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

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

''(i)(I) The device with respect to which the exemption is granted 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.

''(II) The device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subclause (I) prior to the date of enactment of the Pediatric Medical Device Safety and Improvement Act of 2006.

''(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the Secretary when the Secretary grants such ex-

emption. The annual distribution number shall be based on the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number, the number of individuals likely to use the device, and the number of devices reasonably necessary to treat such individuals. In no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

''(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

''(iv) The request for such exemption is submitted on or before October 1, 2012.

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

''(C) A person may petition the Secretary to modify the annual distribution number specified by the Secretary under subparagraph (A)(ii) with respect to a device if additional information on the number of individuals affected by the disease or condition arises, and the Secretary may

modify such number but in no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

''(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

''(E)(i) In this subsection, the term 'pediatric patients' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

''(ii) In this subsection, the term 'pediatric subpopulation' means 1 of the following populations:

''(I) Neonates.

''(II) Infants.

''(III) Children.

''(IV) Adolescents.''; and

(4) by adding at the end the following:

''(7) The Secretary shall refer any report of an adverse event regarding a device for which the prohibition under paragraph (3) does not apply pursuant to para-

graph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109)). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.''.

(b) REPORT.—Not later than January 1, 2011, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a device to profit from such device pursuant to section 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amended by subsection (a)), including—

(1) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for condi-

tions that occur in small numbers of children, including any increase or decrease in the number of—

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

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

(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated size of the pediatric patient population for each condition or disease;

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

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

(5) the impact, if any, of allowing profit on access to such devices for patients;

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

(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

(8) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and whether any modifications to such section 520(m)(6) (as amended by subsection (a)) should be made;

(9) existing obstacles to pediatric device development; and

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

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

SEC. 4. ENCOURAGING PEDIATRIC MEDICAL DEVICE RESEARCH.

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

(b) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs, in collaboration with the Director of the National Institutes of Health and the Director of the Agency for Healthcare Research and Quality, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a plan for expanding pediatric medical device research and development. In developing such plan, the Commissioner of Food and Drugs shall consult with individuals and organizations with appropriate expertise in pediatric medical devices.

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

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

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

(C) a research agenda for improving pediatric medical device development and Food and Drug Administration clearance or approval of pediatric medical devices, and for evaluating the short- and long-term safety and effectiveness of pediatric medical devices.

SEC. 5. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

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

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and

Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall—

(1) encourage innovation by connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentor and manage pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connect innovators and physicians to existing Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

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

(5) assess business feasibility and provide business advice;

(6) provide assistance with prototype development; and

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

(d) COORDINATION.—

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

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

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $6,000,000 for each of fiscal years 2007 through 2011.

SEC. 6. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section 6(b) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(b)) is amended by inserting ", including increasing pediatric access to medical devices" after "pediatric issues".

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

(1) in subsection (a), by inserting "(including drugs and biological products) and medical devices" after "therapeutics"; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting "(including drugs and biological products) and medical devices" after "therapeutics"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "and 505B" and inserting "505B, 510(k), 515, and 520(m)";

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

''(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions; and''; and

(iii) in subparagraph (C), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

SEC. 7. STUDIES.

(a) POSTMARKET STUDIES.—Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) in subsection (a)—

(A) by inserting '', or as a condition to approval of an application (or a supplement to an application) or a product development protocol under section 515 or as a condition to clearance of a premarket notification report under section 510(k),'' after ''The Secretary may by order''; and

(B) by inserting ", that is expected to have significant use in pediatric populations," after "health consequences"; and

(2) in subsection (b)—

(A) by striking "(b) SURVEILLANCE APPROVAL.—Each" and inserting the following:

"(b) SURVEILLANCE APPROVAL.—

"(1) IN GENERAL.—Each";

(B) by striking "The Secretary, in consultation" and inserting "Except as provided in paragraph (2), the Secretary, in consultation";

(C) by striking "Any determination" and inserting "Except as provided in paragraph (2), any determination"; and

(D) by adding at the end the following:

"(2) LONGER STUDIES FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device.".

(b) DATABASE.—

(1) IN GENERAL.—

(A) ESTABLISHMENT.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall establish a publicly accessible database of studies of medical devices that includes all studies and surveillances, described in paragraph (2)(A), that were in progress on the date of enactment of this Act or that began after such date.

(B) ACCESSIBILITY.—Information included in the database under subparagraph (A) shall be in language reasonably accessible and understood by individuals without specific expertise in the medical field.

(2) STUDIES AND SURVEILLANCES.—

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

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

(ii) all other studies completed by the manufacturer with respect to a medical device after—

(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) 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;

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

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

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

(E) any other information the Secretary of Health and Human Services determines appropriate to protect the public health.

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

(A) the actual date of completion or termination;

(B) if the study or surveillance was terminated, the reason for termination;

(C) if the study or surveillance was submitted but not accepted by the Food and Drug Administration because the study or surveil-

lance did not meet the requirements for such study or surveillance, an explanation of the reasons and any follow-up action required;

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

(E) information about any other decisions or actions of the Food and Drug Administration that result from the study or surveillance findings;

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

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

(H) any other information the Secretary of Health and Human Services determines appropriate to protect the public health.

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

(A) accessible to the general public; and

(B) easily searchable by multiple criteria, including whether the study or surveillance involves pediatric populations.

(c) MEDICAL DEVICE CODING.—The Secretary of Health and Human Services, in consultation with the Commissioner of Food and Drugs, shall adopt voluntary national standards for medical device coding. In adopting voluntary national standards for medical device coding, the Secretary of Health and Human Services shall coordinate with other efforts by the Secretary to adopt and implement standards for the electronic exchange of health information.

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