



# Pediatric Medical Device Safety and Improvement Act of 2007

## Text of Legislation and Summary of Provisions

110th Congress: H.R. 3580, Public Law 110-85

Text	Summary of Provisions
<p><b>TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007</b></p> <p><b>SEC. 301. SHORT TITLE.</b></p> <p>This title may be cited as the 'Pediatric Medical Device Safety and Improvement Act of 2007'.</p> <p><b>SEC. 302. TRACKING PEDIATRIC DEVICE APPROVALS.</b></p> <p>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:</p> <p><b>SEC. 515A. PEDIATRIC USES OF DEVICES.</b></p> <p>(a) NEW DEVICES—</p> <p>(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).</p> <p>(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—</p> <p>(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</p> <p>(B) the number of affected pediatric patients.</p> <p>(3) ANNUAL REPORT—Not later than 18 months after the date of the 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—</p> <p>(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;</p> <p>(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;</p>	<p><b>TRACKING PEDIATRIC DEVICE APPROVALS</b></p> <p><b>Increases Tracking of Pediatric Device Approvals</b> Creates a mechanism to allow the Food and Drug Administration (FDA) to track the number and types of devices approved specifically for children or for conditions that occur in children, as well as the approval times for premarket approvals and humanitarian device exemptions. Requires annual reports to Congress on the results.</p>

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<p>(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</p> <p>(D) the review time for each device described in subparagraphs (A), (B), and (C).</p> <p>(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS—</p> <p>(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 assurance of effectiveness in pediatric populations, as appropriate.</p> <p>(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.</p> <p>(c) PEDIATRIC SUBPOPULATION—For purposes of this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).</p> <p><b>SEC. 303. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.</b></p> <p>(a) IN GENERAL—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—</p> <p>(1) in paragraph (3), by striking 'No' and inserting 'Except as provided in paragraph (6), no';</p> <p>(2) in paragraph (5)—</p> <p>(A) by inserting ', if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met,' after 'public health'; and</p> <p>(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 humanitarian device only after providing notice and an opportunity for an informal hearing.'; and</p> <p>(3) by striking paragraph (6) and inserting after paragraph (5) the following new paragraphs:</p> <p>(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:</p> <p>(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.</p> <p>(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 the enactment of the Pediatric Medical Device Safety and Improvement Act of 2007.</p> <p>(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the</p>	<p><b>Allows Extrapolation of Adult Data</b> Provides specific authority to FDA to allow appropriate extrapolation of adult data to support a pediatric indication.</p> <p><b>MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION</b></p> <p><b>Incentivize Pediatric Device Development By Modifying Humanitarian Device Exemption</b> Allows profit for devices approved under the humanitarian device exemption (HDE) that are specifically designed to meet a pediatric need.</p>

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<p>Secretary when the Secretary grants such exemption. 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).</p> <p>`(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).</p> <p>`(iv) The request for such exemption is submitted on or before October 1, 2012.</p> <p>`(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.</p> <p>`(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).</p> <p>`(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.</p> <p>`(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.</p> <p>`(ii) In this subsection, the term `pediatric subpopulation' means 1 of the following populations:</p> <p>`(I) Neonates.</p> <p>`(II) Infants.</p> <p>`(III) Children.</p> <p>`(IV) Adolescents.</p> <p>`(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 paragraph (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.</p> <p>`(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (6) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.'</p> <p>(b) REPORT—Not later than January 1, 2012, the Comptroller General of the</p>	<p><b>Sunset</b>  Sunsets HDE provision in 2012 to coincide with Medical Device User Fee Act.</p> <p><b>Adverse Event Reporting</b>  Requires adverse event reports for pediatric HDE devices to be referred to the Office of Pediatric Therapeutics. Provides for the review of adverse event reports by the Pediatric Advisory Committee.</p> <p><b>GAO Report</b></p>

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<p>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—</p> <p>(1) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—</p> <p>(A) exemptions granted under such section 520(m)(2) for pediatric devices; and</p> <p>(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;</p> <p>(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;</p> <p>(3) the costs of purchasing pediatric devices, based on a representative sampling of children's hospitals;</p> <p>(4) the extent to which the costs of such devices are covered by health insurance;</p> <p>(5) the impact, if any, of allowing profit on access to such devices for patients;</p> <p>(6) the profits made by manufacturers for each device that receives an exemption;</p> <p>(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;</p> <p>(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;</p> <p>(9) existing obstacles to pediatric device development; and</p> <p>(10) an evaluation of the demonstration grants described in section 305, which shall include an evaluation of the number of pediatric medical devices—</p> <p>(A) that have been or are being studied in children; and</p> <p>(B) that have been submitted to the Food and Drug Administration for approval, clearance, or review under such section 520(m) (as amended by this Act) and any regulatory actions taken.</p> <p>(c) GUIDANCE—Not later than 180 days after the date of the 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.</p> <p><b>SEC. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RESEARCH.</b></p>	<p>Requires the Government Accountability Office to assess the success and impact of removing the HDE profit restriction by January 1, 2012. The report will also address the cost, availability, and access to these devices.</p> <p><b>Institutional Review Guidance</b> Directs FDA to issue guidance to institutional review committees for responding to HDEs.</p> <p><b>ENCOURAGING PEDIATRIC MEDICAL DEVICE</b></p>

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<p>(a) CONTACT POINT FOR AVAILABLE FUNDING—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—</p> <p>(1) in paragraph (21), by striking `and' after the semicolon at the end;</p> <p>(2) in paragraph (22), by striking the period at the end and inserting `; and'; and</p> <p>(3) by inserting after paragraph (22) the following:</p> <p>`(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.'</p> <p>(b) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH—</p> <p>(1) IN GENERAL—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, 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 Secretary of Health and Human Services shall consult with individuals and organizations with appropriate expertise in pediatric medical devices.</p> <p>(2) CONTENTS—The plan under paragraph (1) shall include—</p> <p>(A) the current status of federally funded pediatric medical device research;</p> <p>(B) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and</p> <p>(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.</p> <p><b>SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.</b></p> <p>(a) IN GENERAL—</p> <p>(1) REQUEST FOR PROPOSALS—Not later than 90 days after the date of the 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.</p> <p>(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.</p> <p>(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.</p> <p>(c) USE OF FUNDS—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—</p>	<p><b>RESEARCH</b></p> <p><b>Pediatric Device Contact Point</b> Requires the NIH director to designate an office to serve as a contact point to help innovators and physicians access existing funding for pediatric medical device development.</p> <p><b>Plan for Pediatric Medical Device Research</b> Directs the NIH, FDA, and AHRQ to submit a plan within 180 days of enactment for pediatric medical device research that identifies gaps and proposes a research agenda for addressing them. As needed, the plan can include a survey of pediatric medical providers to identify unmet pediatric medical device needs.</p> <p><b>DEVICE DEVELOPMENT CONSORTIA</b></p> <p><b>Establishes Non-Profit Consortia to Stimulate Pediatric Device Development</b> Establishes demonstration grants for non-profit consortia to facilitate the development, production, approval, and distribution of pediatric medical devices.</p>

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<p>(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;</p> <p>(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;</p> <p>(3) connecting innovators and physicians to existing Federal and non-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;</p> <p>(4) assessing the scientific and medical merit of proposed pediatric device projects; and</p> <p>(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.</p> <p>(d) COORDINATION—</p> <p>(1) NATIONAL INSTITUTES OF HEALTH—Each consortium that receives a grant or contract under this section shall—</p> <p>(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act, as added by section 304(a) of this Act; and</p> <p>(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.</p> <p>(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.</p> <p>(3) EFFECTIVENESS AND OUTCOMES—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.</p> <p>(e) AUTHORIZATION OF APPROPRIATIONS—There are authorized to be appropriated to carry out this section \$6,000,000 for each of fiscal years 2008 through 2012.</p> <p><b>SEC. 306. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.</b></p> <p>(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'.</p> <p>(b) PEDIATRIC ADVISORY COMMITTEE—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—</p> <p>(1) in subsection (a), by inserting `(including drugs and biological products) and medical devices' after `therapeutics'; and</p> <p>(2) in subsection (b)—</p>	<p><b>NIH Identification of Research Issues</b> Requires consortia to coordinate with the National Institutes of Health (NIH) to identify research issues that require further study and with the FDA to facilitate approval of pediatric devices.</p> <p><b>Authorization of Appropriations</b> Authorizes \$6 million for each of fiscal years 2008 through 2012.</p> <p><b>PEDIATRIC ADVISORY COMMITTEE</b></p> <p><b>Pediatric Advisory Committee Review</b> Grants explicit authority to FDA's Pediatric Advisory Committee to monitor pediatric devices and make recommendations for improving their availability and safety.</p>

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<p>(A) in paragraph (1), by inserting `(including drugs and biological products and medical devices' after `therapeutics'; and</p> <p>(B) in paragraph (2)—</p> <p>(i) in subparagraph (A), by striking `and 505B' and inserting `505B, 510(k), 515, and 520(m)';</p> <p>(ii) by striking subparagraph (B) and inserting the following:</p> <p>`(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</p> <p>(iii) in subparagraph (C), by inserting `(including drugs and biological products and medical devices' after `therapeutics'.</p> <p><b>SEC. 307. POSTMARKET SURVEILLANCE.</b></p> <p>Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360I) is amended—</p> <p>(1) by amending the section heading and designation to read as follows:</p> <p><b>`SEC. 522. POSTMARKET SURVEILLANCE.';</b></p> <p>(2) by striking subsection (a) and inserting the following:</p> <p>`(a) POSTMARKET SURVEILLANCE—</p> <p>`(1) IN GENERAL—</p> <p>`(A) CONDUCT—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—</p> <p>`(i) the failure of which would be reasonably likely to have serious adverse health consequences;</p> <p>`(ii) that is expected to have significant use in pediatric populations; or</p> <p>`(iii) that is intended to be—</p> <p>`(I) implanted in the human body for more than 1 year; or</p> <p>`(II) a life-sustaining or life-supporting device used outside a device user facility.</p> <p>`(B) CONDITION—The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).</p> <p>`(2) RULE OF CONSTRUCTION—The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act.'; and</p> <p>(3) in subsection (b)—</p> <p>(A) by striking `(b) SURVEILLANCE APPROVAL—Each' and inserting the following:</p> <p>`(b) SURVEILLANCE APPROVAL—</p> <p>`(1) IN GENERAL—Each';</p>	<p><b>POSTMARKET SURVEILLANCE</b></p> <p><b>Authority to Require Postmarket Surveillance</b> For a devices that are expected to have significant use in pediatric populations, allows FDA to require a manufacturer to conduct postmarket surveillance for any class II or class III device.</p> <p><b>Postmarket Studies as Condition of Approval</b> For a devices that are expected to have significant use in pediatric populations, allows FDA to require postmarket studies as a condition of approval.</p>

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<p>(B) by striking 'The Secretary, in consultation' and inserting 'Except as provided in paragraph (2), the Secretary, in consultation';</p> <p>(C) by striking 'Any determination' and inserting 'Except as provided in paragraph (2), any determination'; and</p> <p>(D) by adding at the end the following:</p> <p><b>(2) LONGER SURVEILLANCE FOR PEDIATRIC DEVICES</b>—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.</p> <p><b>(c) DISPUTE RESOLUTION</b>—A manufacturer may request review under section 562 of any order or condition requiring postmarket surveillance under this section. During the pendency of such review, the device subject to such a postmarket surveillance order or condition shall not, because of noncompliance with such order or condition, be deemed in violation of section 301(q)(1)(C), adulterated under section 501(f)(1), misbranded under section 502(t)(3), or in violation of, as applicable, section 510(k) or section 515, unless deemed necessary to protect the public health.'</p>	<p><b>Longer Studies Allowed</b></p> <p>Gives the FDA the ability to require a prospective surveillance period longer than the current standard of 36 months for a device that is expected to have significant use in pediatric populations when necessary to assess the long-term impact on growth and development in children.</p>