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112TH CONGRESS
2D SESSION

H. R. 3975

To amend title V of the Federal Food, Drug, and Cosmetic Act to extend the provisions of the Pediatric Medical Device Safety and Improvement Act.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2012

Mr. ROGERS of Michigan (for himself and Mr. MARKEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title V of the Federal Food, Drug, and Cosmetic Act to extend the provisions of the Pediatric Medical Device Safety and Improvement Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. EXTENSION OF PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT.

(a) HUMANITARIAN DEVICE EXEMPTION EXTENSION.—Section 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking ''2012'' and inserting ''2017''.

(b) DEMONSTRATION GRANTS TO IMPROVE PEDIATRIC DEVICE AVAILABILITY.—Section 305(e) of Pedi-

atric Medical Device Safety and Improvement Act (Public Law 110–85; 42 U.S.C. 282 note)) is amended by striking ''2012'' and inserting ''2017''.

(c) EFFECTIVE DATE FOR RULE RELATING TO TRACKING OF PEDIATRIC USES OF DEVICES.—Notwithstanding subchapter II of chapter 5, and chapter 7, of title 5, the United States Code (commonly known as the ''Administrative Procedures Act'') and any other provision of law, the proposed rule issued by the Commissioner of Food and Drugs entitled ''Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure,'' 75 Fed. Reg. 16365 (April 1, 2010), shall take effect on January 1, 2013, unless such Commissioner issues the final rule before such date.

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