

## HR 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.

**Congress:** 112 (2011–2013, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Feb 8, 2012

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (Feb 10, 2012)

**Official Text:** <https://www.congress.gov/bill/112th-congress/house-bill/3975>

### Sponsor

**Name:** Rep. Rogers, Mike J. [R-MI-8]

**Party:** Republican • **State:** MI • **Chamber:** House

### Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Markey, Edward J. [D-MA-7]	D · MA		Feb 8, 2012

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 10, 2012

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

*No related bills are listed.*

Amends the Pediatric Medical Device Safety and Improvement Act to authorize appropriations through FY2017 for grants for demonstration projects to promote pediatric device development.

Amends the Federal Food, Drug, and Cosmetic Act to allow an exception to the prohibition against selling a device that is designed to treat or diagnose a disease or condition which affects fewer than 4,000 individuals in the United States and that is exempt from the effectiveness requirements of such Act for an amount that exceeds the costs of research and development, fabrication, and distribution of the device where the request for such exemption is submitted on or before October 1, 2017 (currently, October 1, 2012).

Requires the proposed rule issued by the Commissioner of Food and Drugs (FDA) 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" to take effect on January 1, 2013, unless such Commissioner issues the final rule before such date.

### **Actions Timeline**

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- **Feb 10, 2012:** Referred to the Subcommittee on Health.
- **Feb 8, 2012:** Introduced in House
- **Feb 8, 2012:** Referred to the House Committee on Energy and Commerce.