

## HR 2428

To amend the Federal Food, Drug, and Cosmetic Act with respect to humanitarian device exemption applications.

**Congress:** 114 (2015–2017, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** May 19, 2015

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

**Latest Action:** Referred to the Subcommittee on Health. (May 22, 2015)

**Official Text:** <https://www.congress.gov/bill/114th-congress/house-bill/2428>

### Sponsor

**Name:** Rep. Shimkus, John [R-IL-15]

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

### Cosponsors

No cosponsors are listed for this bill.

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 22, 2015

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
114 HR 34	Related bill	Dec 13, 2016: Became Public Law No: 114-255.
114 S 2188	Related bill	Oct 21, 2015: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 HR 6	Related bill	Jul 13, 2015: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

### Summary (as of May 19, 2015)

This bill amends the Federal Food, Drug, and Cosmetic Act to expand the humanitarian device exemption to authorize the Food and Drug Administration (FDA) to exempt from effectiveness requirements certain medical devices intended to benefit fewer than 8,000 individuals. Currently, the FDA may exempt devices intended to benefit fewer than 4,000 individuals.

Within 18 months of enactment of this Act, the FDA must define “probable benefit” for these devices.

## Actions Timeline

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- **May 22, 2015:** Referred to the Subcommittee on Health.
- **May 19, 2015:** Introduced in House
- **May 19, 2015:** Referred to the House Committee on Energy and Commerce.