

## S 2188

Rare Disease Innovation Act

**Congress:** 114 (2015–2017, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Oct 21, 2015

**Current Status:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

**Latest Action:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Oct 21, 2015)

**Official Text:** <https://www.congress.gov/bill/114th-congress/senate-bill/2188>

### Sponsor

**Name:** Sen. Gardner, Cory [R-CO]

**Party:** Republican • **State:** CO • **Chamber:** Senate

### Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Donnelly, Joe [D-IN]	D · IN		Oct 21, 2015

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Oct 21, 2015

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
114 HR 34	Related bill	<b>Dec 13, 2016:</b> Became Public Law No: 114-255.
114 HR 6	Related bill	<b>Jul 13, 2015:</b> Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 HR 2428	Related bill	<b>May 22, 2015:</b> Referred to the Subcommittee on Health.

## **Rare Disease Innovation Act**

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.

The FDA must report every five years on the effect of this expansion of the humanitarian device exception.

## **Actions Timeline**

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- **Oct 21, 2015:** Introduced in Senate
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