

## S 320

### Medical Innovation Act of 2015

**Congress:** 114 (2015–2017, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Jan 29, 2015

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

**Latest Action:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Sponsor introductory remarks on measure: CR S657-658) (Jan 29, 2015)

**Official Text:** <https://www.congress.gov/bill/114th-congress/senate-bill/320>

### Sponsor

**Name:** Sen. Warren, Elizabeth [D-MA]

**Party:** Democratic • **State:** MA • **Chamber:** Senate

### Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Baldwin, Tammy [D-WI]	D · WI		Jan 29, 2015
Sen. Brown, Sherrod [D-OH]	D · OH		Jan 29, 2015
Sen. Cardin, Benjamin L. [D-MD]	D · MD		Jan 29, 2015
Sen. Franken, Al [D-MN]	D · MN		May 5, 2015

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jan 29, 2015

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
114 HR 744	Identical bill	Feb 6, 2015: Referred to the Subcommittee on Health.

## Medical Innovation Act of 2015

This bill amends the Public Health Service Act to require certain drug manufacturers to make payments to fund research supported by the Food and Drug Administration (FDA) and the National Institutes of Health (NIH).

A drug manufacturer with over \$1 billion in net income in a fiscal year that has entered into a settlement agreement in the previous five years with a federal agency regarding specified violations must pay 1% of its net income to the Department of Health and Human Services (HHS) for each of its covered blockbuster drugs. A covered blockbuster drug is a drug that has at least \$1 billion in net sales in a year and was developed, in whole or in part, through federal investments in medical research, including a drug for which a patent contains information that relates to, or is based upon, federally-funded research.

Each fiscal year, HHS must publish a list of manufacturers that make payments, each manufacturer's covered blockbuster drugs, and payment amounts.

Payments are divided between the FDA and the NIH in proportion to the discretionary funding of those agencies, excluding FDA user fees. Payments are not disbursed if appropriations for the FDA or the NIH are lower than in the prior fiscal year.

The FDA's priority use for payments must include advancing regulatory science for medical products.

The NIH's priority use for payments must include supporting: (1) research that fosters radical innovation, (2) research that advances fundamental knowledge, (3) research related to diseases that disproportionately account for federal health care spending, and (4) early career scientists.

A covered blockbuster drug for which a manufacturer has not made a required payment is considered misbranded and cannot be sold until payment is made.

## Actions Timeline

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- **Jan 29, 2015:** Introduced in Senate
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