

## S 2055

Medical Countermeasure Innovation Act of 2016

**Congress:** 114 (2015–2017, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Sep 17, 2015

**Current Status:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 388.

**Latest Action:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 388. (Mar 14, 2016)

**Official Text:** <https://www.congress.gov/bill/114th-congress/senate-bill/2055>

### Sponsor

**Name:** Sen. Burr, Richard [R-NC]

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

### Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Casey, Robert P., Jr. [D-PA]	D · PA		Sep 17, 2015
Sen. Isakson, Johnny [R-GA]	R · GA		Oct 26, 2015
Sen. Roberts, Pat [R-KS]	R · KS		Nov 19, 2015
Sen. Alexander, Lamar [R-TN]	R · TN		Mar 15, 2016

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Mar 14, 2016

### 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.

## Medical Countermeasure Innovation Act of 2016

(Sec. 2) This bill amends the Public Health Service Act to require the Department of Health and Human Services (HHS) to ensure the issuance of timely and accurate guidelines regarding the use of medical products for countering public health emergencies or material threats. HHS must report on funding for procurement of medical countermeasures when available funds are below a specified amount.

(Sec. 3) The Biomedical Advanced Research and Development Authority's (BARDA's) contracting authority for procurement of medical countermeasures under Project BioShield is codified.

(Sec. 4) The Office of the Assistant Secretary for Preparedness and Response must annually publish its budget plan for medical countermeasures.

(Sec. 5) BARDA may enter an agreement with an independent, nongovernmental nonprofit to foster and accelerate the development and innovation of medical countermeasures and related technologies. BARDA must direct and oversee the nonprofit's work and ensure transparency and accountability.

(Sec. 6) BARDA's procurement of medical countermeasures no longer requires Presidential approval or an agreement between HHS and the Department of Homeland Security.

(Sec. 7) This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to award, upon approval, a priority review voucher to the sponsor of a drug or biological product that: (1) is a significant improvement in the prevention, diagnosis, or treatment of a serious condition; and (2) can be used as a medical countermeasure to a material threat. The transferable voucher entitles the holder to have an application for a new medication acted upon by the FDA within six months.

The sponsor of a medication that is subject to a voucher must pay a user fee based on the FDA's cost for the priority review process.

The FDA must publish a notice each time it issues a voucher or a voucher is used.

(Sec. 8) The Government Accountability Office must report on the effectiveness of this priority review voucher program in providing incentives for the development of material threat medical countermeasures.

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## Actions Timeline

- **Mar 14, 2016:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander with an amendment in the nature of a substitute. Without written report.
- **Mar 14, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 388.
- **Mar 9, 2016:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Sep 17, 2015:** Introduced in Senate
- **Sep 17, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.