



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

August 8, 2016

S. 2055

Medical Countermeasure Innovation Act of 2016

*As reported by the Senate Committee on Health, Education, Labor, and Pensions
on March 14, 2016*

SUMMARY

S. 2055 would authorize two programs to invest in research and to provide incentives for developing medical countermeasures. One program would authorize the Secretary of Health and Human Services (HHS) to enter into an agreement with an independent entity that fosters the development of medical countermeasures. The bill also would create an incentive program that awards vouchers for priority review to companies that obtain Food and Drug Administration (FDA) approval of certain drugs that can be used to counter the effects of biological, chemical, radiological, or nuclear agents. The bill also would require HHS to prepare a five-year budget plan for medical countermeasures. CBO estimates that implementing S. 2055 would cost \$94 million over the 2017-2021 period, assuming appropriation of the necessary amounts. Pay-as-you-go procedures do not apply to this legislation because it would not affect direct spending or revenues.

CBO estimates that enacting S. 2055 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

S. 2055 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of S. 2055 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					2017-2021
	2017	2018	2019	2020	2021	
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	24	25	24	23	23	120
Estimated Outlays	7	19	22	23	23	94

Notes: Components do not sum to totals because of rounding.

BASIS OF ESTIMATE

For this estimate, CBO assumes that the bill will be enacted near the beginning of fiscal year 2017 and that the necessary amounts will be appropriated each year.

HHS

S. 2055 would authorize the Secretary of HHS to enter into an agreement with a non-profit entity that aims to advance research and development on medical countermeasures. Based on a similar proposal in the 2017 budget request for HHS, CBO estimates that implementing this provision and developing the five-year budget plan would cost \$76 million over the 2017-2021 period.

FDA

The bill would create an incentive program that awards vouchers for priority review to companies when they obtain FDA approval of certain drugs to counter the effects from biological, chemical, radiological, or nuclear agents. Such vouchers can be used to accelerate review of a future drug application. To redeem the voucher, a sponsor must pay an extra fee set by FDA each year to cover the agency's cost for the accelerated review. Such fees would be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. (Estimated collections and related spending offset each other in the year fees are paid by sponsors.)

To establish the new voucher program, CBO expects FDA would issue guidance containing the definition of the types of products that would be eligible for a voucher. Based on an analysis of information from FDA for similar programs, CBO estimates that those activities would require on average of 11 employees to establish and maintain the

program. Assuming appropriation of the necessary amounts, CBO estimates implementing the new voucher program would cost FDA \$18 million over the 2017-2021 period.

PAY-AS-YOU-GO CONSIDERATIONS: None

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

S. 2055 contains no intergovernmental or private-sector mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

ESTIMATE PREPARED BY:

Federal Costs: Andrea Noda and Ellen Werble
Impact on State, Local, and Tribal Governments: J'nell Blanco Suchy
Impact on the Private Sector: Amy Petz

ESTIMATE APPROVED BY:

Holly Harvey
Deputy Assistant Director for Budget Analysis