CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

September 7, 2016

H.R. 3299
Strengthening Public Health Emergency Response Act of 2016

As ordered reported by the House Committee on Energy and Commerce on July 13, 2016

SUMMARY

H.R. 3299 would establish an incentive program that awards vouchers for priority review to companies that obtain approval from the Food and Drug Administration (FDA) for certain drugs that can be used to counter the effects of biological, chemical, radiological, or nuclear agents. The bill also would make several changes to the processes used to procure medical countermeasures in the Department of Health and Human Services (HHS). Finally, the Government Accountability Office (GAO) would be required to report on programs to improve state, local, and hospital preparedness. CBO estimates that implementing H.R. 3299 would cost $20 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 H.R. 3299 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

H.R. 3299 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 H.R. 3299 is shown in the following table. The costs of this legislation fall primarily within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2017	2018	2019	2020	2021	2017-2021
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	5	5	4	4	4	21
Estimated Outlays	4	4	4	4	4	20

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.

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 about 10 employees to establish and to 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.

HHS

The Office of the Assistant Secretary for Preparedness and Response (ASPR) within HHS is required to work with other HHS agencies to issue a Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan (SIP) each year. The SIP outlines a strategy and an accompanying implementation plan for medical

countermeasures to address chemical, biological, radiological, and nuclear threats. H.R. 3299 would require ASPR to include specific information about pandemic influenza in the SIP. It also would require ASPR to report on the amount of time it takes the Biomedical Advanced Research and Development Authority (BARDA) to award contracts once requests for proposals are issued. Based on information from HHS, CBO estimates that including these new elements in the SIP would require one employee to implement. Assuming appropriation of the necessary amounts, CBO estimates this section would cost HHS about $1 million over the 2017-2021 period.

GAO

H.R. 3299 would require GAO to report on programs to improve state, local, and hospital preparedness for public health emergencies. CBO estimates implementing that provision would cost about $500,000 over the 2017-2021 period; such spending would be subject to the availability of appropriated funds.

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

H.R. 3299 contains no intergovernmental or private-sector mandates as defined in the UMRA and would not affect the budgets of state, local, or tribal governments.

PREVIOUS CBO ESTIMATES

On August 8, 2016, CBO transmitted a cost estimate for S. 2055, the Medical Countermeasure Innovation Act of 2016, as reported by the Senate Committee on Health, Education, Labor, and Pensions on March 14, 2016. Several provisions are similar to provisions in H.R. 3299; however, S. 2055 would also authorize an additional program to invest in research and provide incentives for the development of medical countermeasures and would require HHS to prepare a five-year budget plan for such countermeasures. H.R. 3299 would authorize one program and modify existing requirements for an annual

strategy and implementation plan. CBO's estimate of the budgetary effects reflects those differences.

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