



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

August 8, 2016

S. 185

Promise for Antibiotics and Therapeutics for Health Act

*As reported by the Senate Committee on Health, Education, Labor, and Pensions
on April 18, 2016*

SUMMARY

S. 185 would require the Food and Drug Administration (FDA) to establish a program to approve certain antibacterial drugs for a limited population of patients with unmet needs. The bill also would require FDA to study the effectiveness of the new program. CBO estimates that implementing S. 185 would cost \$27 million over the 2017-2021 period, assuming appropriation of the necessary amounts. Pay-as-you-go procedures do not apply because enacting S. 185 would not affect direct spending or revenues.

CBO estimates that enacting S. 185 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

S. 185 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of S. 185 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	3	5	7	7	7	30
Estimated Outlays	2	4	6	7	7	27

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

BASIS OF ESTIMATE

S. 185 would require FDA to establish a program to approve certain antibiotics for a limited population of patients with unmet needs. Based on an analysis of information provided by FDA, CBO estimates that establishing and maintaining that program would require the equivalent of about 20 employees. The Government Accountability Office also would be required to report on the effectiveness of the new program. Based on historical spending patterns for similar activities and assuming appropriation of the necessary amounts, CBO estimates implementing the bill would cost \$27 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. 185 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

PREVIOUS CBO ESTIMATES

On June 23, 2015, CBO transmitted a cost estimate for H.R. 6, the 21st Century Cures Act as ordered reported by the House Energy and Commerce Committee. That legislation included similar language in section 2121; however, H.R. 6 specified timelines for FDA interactions with industry. Those timelines are not included in S. 185. CBO's estimate of S. 185 reflects those differences.

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