



## CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

July 7, 2016

### **S. 1878** **Advancing Hope Act of 2016**

*As reported by the Senate Committee on Health, Education, Labor, and Pensions  
on April 5, 2016*

#### **SUMMARY**

S. 1878 would amend and extend an incentive program administered by the Food and Drug Administration (FDA) that awards priority review vouchers to companies for obtaining FDA approval for drugs and biologics that target rare pediatric diseases. Such vouchers allow a recipient to receive expedited FDA review of a future drug application. CBO estimates that implementing S. 1878 would cost \$12 million over the 2017-2021 period, assuming appropriation of the necessary amounts. Pay-as-you-go procedures do not apply to the bill because enacting it would not affect direct spending or revenues.

CBO estimates that enacting S. 1878 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

S. 1878 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. 1878 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	
<b>INCREASES IN SPENDING SUBJECT TO APPROPRIATION</b>						
Estimated Authorization Level	2	3	3	3	3	13
Estimated Outlays	2	2	3	3	3	12

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

## **BASIS OF ESTIMATE**

Under current law, sponsors of a drug application for the treatment of a rare pediatric disease can receive a voucher from FDA for priority review of a subsequent new drug application. The vouchers are intended to provide incentives to drug companies to develop new treatments for drugs and biologics that target rare diseases affecting children. FDA’s authority to issue such vouchers expires on September 30, 2016.

S. 1878 would authorize FDA to award vouchers through September 30, 2027, for drugs designated to be eligible by September 30, 2022. To redeem the voucher, a sponsor must pay an extra fee set by FDA each year to cover the agency’s cost for 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. CBO estimates that, assuming appropriation action consistent with the bill, the net budgetary effect of implementing this provision would be negligible over the 2017-2021 period because FDA is already authorized to collect fees sufficient to defray the costs of priority review vouchers. (Estimated collections and related spending offset each other in the year fees are paid by sponsors.)

S. 1878 would also broaden the definition of rare pediatric disease in this program. CBO estimates such an expansion would increase the number of applications from drug sponsors seeking eligibility under the voucher program and thus would increase FDA’s workload. The bill would also require the Government Accountability Office (GAO) to review and report on the voucher program no later than January 31, 2022. Based on the number of applications received for the current program, CBO estimates that implementing S. 1878 would require the equivalent of about six additional full-time employees each year to review the additional applications. That expansion and the GAO report would cost \$12 million over the 2017-2021 period, assuming appropriation of the necessary amounts, CBO estimates.

**PAY-AS-YOU-GO CONSIDERATIONS:** None.

### **INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS**

CBO estimates that enacting S. 1878 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. 1878 contains no intergovernmental or private-sector mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

### **PREVIOUS CBO ESTIMATE**

On July 7, 2015, CBO transmitted a cost estimate for the Rules Committee print of H.R. 6, the 21st Century Cures Act. That legislation included language in section 2152 that similarly expanded and extended the voucher program. However, H.R. 6 would extend the program through December 2018. S. 1878 would extend the program through September 30, 2027, for drugs that are designated to be eligible for the award by September 30, 2022. CBO's estimate of S. 1878 reflects those differences.

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