



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

July 12, 2016

S. 1622 **FDA Device Accountability Act of 2016**

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

SUMMARY

S. 1622 would require the Food and Drug Administration (FDA) to train certain employees to determine the least burdensome means for medical device sponsors to demonstrate the effectiveness of a device. S. 1622 would also require the agency's ombudsman to audit that training, and FDA would be required to revise guidance on addressing approaches clinical laboratories can use to demonstrate a test's accuracy. CBO estimates that implementing S. 1622 would cost \$7 million over the 2017-2021 period, subject to the availability of appropriated funds. Pay-as-you-go procedures do not apply because enacting S. 1622 would not affect direct spending or revenues.

CBO estimates that enacting S. 1622 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

S. 1622 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. 1622 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	2	2	1	1	1	8
Estimated Outlays	1	2	1	1	1	7

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

BASIS OF ESTIMATE

Under current law, FDA is required to consider the least burdensome means for a device manufacturer to demonstrate that a medical device is safe and effective. S. 1622 would require FDA employees who review the submissions to receive training on those requirements and to provide a written rationale for certain determinations about the implementation of those requirements; FDA’s ombudsman would be required to audit the training. The bill would also require FDA to revise guidance for device manufacturers seeking to obtain a waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which regulates laboratory testing. Based on information from the agency, CBO estimates that implementing S. 1622 would require roughly five employees each year to update guidance, revise and conduct training, and provide written responses; implementation costs would total \$7 million over the 2017-2021 period, 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 S. 1622 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. 1622 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 Committee on Energy and Commerce on May 21, 2015. In title II of that legislation, there are several sections—2223, 2228 and 2262—similar to the provisions in S. 1622. However, S. 1622 would require FDA to provide a written rationale for certain determinations about the consideration and implementation of the requirements. CBO’s estimate of implementing S. 1622 reflects those differences.

On July 7, 2015, CBO transmitted a table for the Rules Committee print of H.R. 6, the 21st Century Cures Act. In title II of that legislation, there are several sections similar to the provisions in S. 1622; however, the activities authorized in S. 1622 would be subject to appropriation. The Rules Committee print of H.R. 6 would create a new fund—the Cures Innovation Fund—and would make those funds available for provisions in section 2223 of the bill. CBO determined those funds would be direct spending.

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