



CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

November 25, 2014

S. 2917

Adding Ebola to the FDA Priority Review Voucher Program Act

*As reported by the Senate Committee on Health, Education, Labor, and Pensions
on November 19, 2014*

S. 2917 would make several changes to an incentive program administered by the Food and Drug Administration (FDA) that awards priority review vouchers to companies for obtaining FDA approval of certain drug products for the prevention and treatment of qualifying tropical diseases. Such vouchers can be used for a future drug application. The agency's goal for reviewing a marketing application under priority review is six months. 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 of the application. Such fees can be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts.

S. 2917 would add Filoviruses, a family of viruses that includes Ebola and Marburg viruses, to the list of qualifying tropical diseases. It also would authorize FDA to expand the list of qualifying diseases through administrative order (rather than through formal rulemaking). The legislation would remove the limitation on the number of times vouchers can be sold or transferred and would reduce the period required between notice by a sponsor and use of a voucher from one year to 90 days.

CBO estimates that the net budgetary effect of implementing S. 2917 would be negligible over the 2015-2019 period because FDA is authorized to collect fees sufficient to defray the costs of priority review vouchers, assuming appropriation action consistent with the bill. (Estimated authorizations for the collections and spending of fees offset each other in the year fees are paid by sponsors.) Enacting S. 2917 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Julia Christensen. The estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.