

H.R. 1499, Protecting Consumer Access to Generic Drugs Act of 2019

As ordered reported by the House Committee on Energy and Commerce on April 3, 2019

Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-193	-520
Revenues	0	34	93
Deficit Effect	0	-227	-613
Spending Subject to Appropriation (Outlays)	0	-24	n.e.
Pay-as-you-go procedures apply?	Yes	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Over Threshold
n.e. = not estimated.			

H.R. 1499 would prohibit certain agreements that are used to settle claims of patent infringement between sponsors of brand-name, generic, or biosimilar drugs relating to the sale of a drug or biological product. The bill also would create civil penalties for parties to settlement agreements that violate the bill's requirements.

CBO expects that the bill would accelerate the availability of lower-priced generic or biosimilar drugs that would have been affected by agreements prohibited under the bill and reduce the average price of drugs paid by federal health programs that purchase drugs or provide health insurance that covers drugs. In total, CBO estimates that enacting H.R. 1499 would decrease the deficit by \$613 million over the 2019-2029 period. That amount includes a \$520 million reduction in direct spending and a \$93 million increase in revenues.

CBO also estimates that implementing H.R. 1499 would decrease spending subject to appropriation by \$24 million over the 2019-2024 period, assuming appropriation actions consistent with the bill. That decrease would result primarily because lower estimated drug prices would reduce costs for discretionary health programs.

By prohibiting certain agreements between sponsors of brand-name, generic, or biosimilar drugs, H.R. 1499 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates the cost of the mandate, in the form of lost revenues to patent holders, would exceed the threshold for private-sector mandates



established in UMRA (\$164 million in 2019, adjusted annually for inflation) in at least two of the first five years the mandate is in effect.

Details of the estimated budgetary effect of H.R 1499 are shown in Table 1. Those effects fall primarily within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

**Table 1.
Estimated Budgetary Effects of H.R. 1499**

	By Fiscal Year, Millions of Dollars											2019-2024	2019-2029
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029		
Decreases in Direct Spending													
Estimated Budget Authority	0	0	-21	-53	-63	-56	-58	-61	-65	-74	-69	-193	-520
Estimated Outlays	0	0	-21	-53	-63	-56	-58	-61	-65	-74	-69	-193	-520
On-Budget	0	0	-21	-53	-63	-56	-58	-61	-65	-74	-69	-192	-518
Off-Budget ^a	0	0	*	*	*	*	*	*	*	*	*	-1	-2
Increases in Revenues													
Estimated Revenues	0	0	3	9	11	11	10	11	12	12	13	34	93
On-Budget	0	0	3	6	8	8	7	8	9	9	10	25	69
Off-Budget	0	0	1	2	3	3	3	3	3	3	3	9	24
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	0	-24	-62	-74	-67	-68	-72	-77	-86	-82	-227	-613
On-Budget	0	0	-23	-59	-71	-64	-66	-69	-74	-83	-78	-217	-587
Off-Budget	0	0	-1	-3	-3	-3	-3	-3	-3	-3	-4	-10	-26
Increases or Decreases (-) in Spending Subject to Appropriation													
Estimated Authorization	0	*	-3	-6	-8	-7	n.e.	n.e.	n.e.	n.e.	n.e.	-24	n.e.
Estimated Outlays	0	*	-3	-6	-8	-7	n.e.	n.e.	n.e.	n.e.	n.e.	-24	n.e.

Components may not sum to totals because of rounding; n.e. = not estimated; * = between -\$500,000 and \$500,000.

a. Includes off-budget effects on the operating costs of the U.S. Postal Service.

The CBO staff contact for this estimate is Julia Christensen. The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.