

## H.R. 938, Bringing Low-cost Options and Competition while Keeping Incentives for New Generics 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	-124	-374
Revenues	0	23	68
Deficit Effect	0	-147	-442
Spending Subject to Appropriation (Outlays)	0	-17	n.e.
Pay-as-you-go procedures apply?	Yes	<b>Mandate Effects</b>	
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?	No
n.e. = not estimated.			

Under current law, manufacturers of generic drugs may seek approval from the Food and Drug Administration (FDA) to market a generic drug before the expiration of a patent listed with the FDA for the brand-name product. The first generic applicant that submits a substantially complete application to the FDA challenging an innovator's patent claim may be awarded 180 days of generic market exclusivity. (The FDA cannot approve any other generic versions of the drug during that 180-day period.) If certain conditions are met, the exclusivity period begins upon the first applicant's commercial marketing.

H.R. 938 would allow the FDA to approve a subsequent generic drug application that is ready for full approval if no first applicant has received final approval and other conditions are satisfied. In such cases, the exclusivity period would be triggered and would run for 180 days after which time the subsequent applicant could enter the market.

CBO expects that the bill's provisions would allow generic drugs to enter the market earlier, on average, than they would under current law. Because of the earlier entry of lower-priced generic drugs, CBO estimates, enacting the legislation would reduce federal spending on prescription drugs and subsidies for health insurance. In total, CBO estimates that enacting H.R. 938 would decrease the deficit by \$442 million over the 2019-2029 period. That amount includes a \$374 million reduction in direct spending and a \$68 million increase in revenues.



CBO also estimates that implementing H.R. 938 would decrease spending subject to appropriation by \$17 million over the 2019-2024 period, assuming appropriation actions consistent with the bill. That decrease would occur primarily because lower estimated drug prices would reduce costs for discretionary health programs.

Details of the estimated budgetary effect of H.R. 938 are shown in Table 1. The effects of the legislation fall primarily within budget functions 550 (health) and 570 (Medicare).

**Table 1.  
Estimated Budgetary Effects of H.R. 938**

	By Fiscal Year, Millions of Dollars											2019-2024	2019-2029
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029		
<b>Decreases in Direct Spending</b>													
Estimated Outlays <sup>a</sup>	0	0	-12	-34	-38	-39	-44	-47	-49	-57	-53	-124	-374
On-Budget	0	0	-12	-34	-38	-39	-44	-47	-49	-56	-53	-124	-373
Off-Budget <sup>b</sup>	0	0	*	*	*	*	*	*	*	*	*	-1	-2
<b>Increases in Revenues</b>													
Estimated Revenues	0	0	3	6	7	7	8	8	9	9	11	23	68
On-Budget	0	0	2	4	5	5	6	6	7	7	8	16	50
Off-Budget	0	0	1	2	2	2	2	2	2	2	3	7	18
<b>Net Decrease in the Deficit From Changes in Direct Spending and Revenues</b>													
Effect on the Deficit	0	0	-15	-40	-46	-46	-52	-55	-58	-66	-64	-147	-442
On-budget	0	0	-14	-38	-43	-44	-50	-53	-56	-63	-61	-140	-423
Off-budget	0	0	-1	-2	-2	-2	-2	-2	-2	-2	-3	-8	-20
<b>Decreases in Spending Subject to Appropriation</b>													
Estimated Authorization	0	0	-2	-5	-5	-5	n.e.	n.e.	n.e.	n.e.	n.e.	-17	n.e.
Estimated Outlays	0	0	-2	-5	-5	-5	n.e.	n.e.	n.e.	n.e.	n.e.	-17	n.e.

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

a. Budget Authority equals Outlays.

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

The CBO staff contacts for this estimate are Ellen Werble and Julia Christensen. The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.