Congressional Budget Office
Cost Estimate

May 8, 2019

H.R. 2375, Preserve Access to Affordable Generics and Biosimilars Act

As ordered reported by the House Committee on the Judiciary on April 30, 2019

By Fiscal Year, 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. 2375 would make certain agreements—used to settle claims of patent infringement between sponsors of brand-name, generic, or biosimilar drugs and relating to the sale of a drug or biological product—presumptively illegal under antitrust law. The bill would require particular types of agreements arising from proceedings conducted by the Patent Trial and Appeal Board (PTAB) to be reported to Federal Trade Commission (FTC) and the Department of Justice (DOJ). H.R. 2375 also would establish the authority to impose civil penalties when a party to a settlement is found to have violated 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 targeted by 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. 2375 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. 2375 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.

Details of the estimated budgetary effect of H.R 2375 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. 2375

	By Fiscal Year, Millions of Dollars												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019-2024	2019-2029
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 zero.

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

By enhancing FTC authority to restrict certain agreements between sponsors of brand-name, generic, or biosimilar drugs, H.R. 2375 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). The bill also would impose a private-sector mandate by requiring those manufacturers to notify the FTC of agreements that resolve PTAB proceedings. CBO estimates the cost of the mandate, particularly in the form of lost revenues, 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.

On April 26, 2019, CBO transmitted an estimate for H.R. 1499, the Protecting Consumer Access to Generic Drugs Act of 2019, as ordered reported by the House Committee on Energy and Commerce on April 3, 2019. CBO's estimates of the effect on the deficit through 2029 for the two bills are the same. In different ways, both H.R. 2375 and H.R. 1499 would modify the conduct of enforcement actions by FTC against parties to certain agreements to

settle a claim of patent infringement and would impose significant restrictions on the terms of compensation in affected agreements. H.R. 2375 also would require particular types of agreements relating to PTAB proceedings to be filed with FTC and the DOJ; H.R. 1499 does not contain a comparable provision. CBO expects that both bills would accelerate, on average, the availability of lower-priced generic and biosimilar drugs to a similar extent and would generate an equivalent amount of budgetary savings from 2020 through 2029.

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