Congressional Budget Office
Cost Estimate

June 6, 2022

Under S. 1428, certain agreements that are 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 would presumptively be considered illegal under antitrust law.

Estimated Budgetary Effects of S. 1428, the Preserve Access to Affordable Generics and Biosimilars Act

As reported by the Senate Committee on the Judiciary on December 9, 2021

	By Fiscal Year, Millions of Dollars												
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2022-2027	2022-2032
Decreases in Direct Spending													
Estimated Budget Authority	0	-11	-30	-45	-53	-56	-62	-57	-65	-68	-72	-195	-519
Estimated Outlays	0	-11	-30	-45	-53	-56	-62	-57	-65	-68	-72	-195	-519
Increases in Revenues													
Estimated Revenues	0	0	10	16	18	19	19	19	20	22	23	63	166
On-Budget Revenues	*0*	*0*	*7*	*11*	*13*	*14*	*14*	*14*	*15*	*16*	*17*	*45*	*121*
Off-Budget Revenues	*0*	*0*	*3*	*5*	*5*	*5*	*5*	*5*	*5*	*6*	*6*	*18*	*45*
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	-11	-40	-61	-71	-75	-81	-76	-85	-90	-95	-258	-685
On-Budget Deficit	*0*	*-11*	*-37*	*-56*	*-66*	*-70*	*-76*	*-71*	*-80*	*-84*	*-89*	*-240*	*-640*
Off-Budget Deficit	*0*	*0*	*-3*	*-5*	*-5*	*-5*	*-5*	*-5*	*-5*	*-6*	*-6*	*-18*	*-45*

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Under S. 1428, certain agreements that are 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 would presumptively be considered illegal under antitrust law. Based on discussions with drug industry experts, CBO expects that the bill would accelerate the availability of lower-priced generic or biosimilar drugs that would be affected by agreements under the bill and reduce the average prices for drugs that are paid by federal health programs that purchase or provide health insurance that covers drugs.

The areas of significant uncertainty for this estimate include CBO's estimates of sales, market effects, and timing of introductions of new pharmaceutical products.

S. 1428 would impose private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) by enhancing the authority of the Federal Trade Commission (FTC) to restrict certain agreements between sponsors of brand-name, generic, or biosimilar drugs and by requiring those sponsors to notify the FTC of agreements that resolve Patent Trial and Appeal Board proceedings. CBO estimates the cost of the mandates would not exceed the threshold for private-sector mandates established in UMRA ($184 million in 2022, adjusted annually for inflation).