

Under H.R. 2891, 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 H.R. 2891, the Preserve Access to Affordable Generics and Biosimilars Act**  
**As ordered reported by the House Committee on the Judiciary on September 29, 2021**

	By Fiscal Year, Millions of Dollars											2022-2027	2022-2032
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032		
<b>Decreases in Direct Spending</b>													
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
<b>Increases in Revenues</b>													
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
<b>Net Decrease in the Deficit From Changes in Direct Spending and Revenues</b>													
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

Components may not sum to total because of rounding.

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Under H.R. 2891, 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 such agreements. The estimated budgetary effects would stem from lower average prices for federal health programs that purchase prescription drugs and lower costs of health insurance subsidies.

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

CBO has not completed an estimate of the effects of H.R. 2891 on spending subject to appropriation.

H.R. 2891 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).

H.R. 2891 contains no intergovernmental mandates.



On June 6, 2022, CBO transmitted a [cost estimate for S. 1428](#), the Preserve Access to Affordable Generics and Biosimilars Act, as reported by the Senate Committee on the Judiciary on December 9, 2021. The two versions of the bill are similar, and their estimated costs are the same.