Congressional Budget Office
Cost Estimate

June 6, 2022

S. 1435 would establish a statutory framework for the Federal Trade Commission to undertake litigation against manufacturers that engage in "product hopping" and limit the number of patents that could be included in infringement claims for biological products.

Estimated Budgetary Effects of S. 1435, the Affordable Prescriptions for Patients Act of 2021

As ordered reported by the Senate Committee on the Judiciary on July 29, 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	-9	-23	-50	-76	-84	-97	-99	-123	-133	-142	-242	-836
Estimated Outlays	0	-9	-23	-50	-76	-84	-97	-99	-123	-133	-142	-242	-836
Increases in Revenues													
Estimated Revenues	0	0	7	18	27	28	31	35	39	42	46	80	273
On-Budget Revenues	*0*	*0*	*5*	*13*	*20*	*21*	*23*	*26*	*29*	*31*	*33*	*59*	*201*
Off-Budget Revenues	*0*	*0*	*2*	*5*	*7*	*7*	*8*	*9*	*10*	*11*	*13*	*21*	*72*
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	-9	-30	-68	-103	-112	-128	-134	-162	-175	-188	-322	-1,109
On-Budget Deficit	*0*	*-9*	*-28*	*-63*	*-96*	*-105*	*-120*	*-125*	*-152*	*-164*	*-175*	*-301*	*-1,037*
Off-Budget Deficit	*0*	*0*	*-2*	*-5*	*-7*	*-7*	*-8*	*-9*	*-10*	*-11*	*-13*	*-21*	*-72*

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S. 1435 would define "product hopping" under the Federal Trade Commission Act and establish a statutory framework for the authority of the Federal Trade Commission (FTC) to undertake litigation against manufacturers that engage in that practice. Product hopping refers to an attempt by a brand product manufacturer to impede the availability of generic competition or to renew market exclusivity periods by reformulating a product. The bill also would allow the FTC to impose civil penalties and seek other relief in district court from parties that violate antitrust law in that area. Finally, S. 1435 would limit to 20 the number of patents that could be included in infringement claims under the Biologics Price Competition and Innovation Act of 2009.

On the basis of an examination of past cases and discussions with stakeholders, CBO anticipates that more generic or biosimilar drugs would enter the market earlier, on average, under S. 1435 than would be the case under current law. This would result in lower federal spending for prescription drugs and for 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.

S. 1435 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by limiting the number of patents that may be asserted in infringement claims for biological products. CBO estimates the cost of the mandate would not exceed the threshold for private-sector mandates established in UMRA ($184 million in 2022, adjusted annually for inflation).