Congressional Budget Office
Cost Estimate

March 13, 2024

At a Glance

S. 148, Stop STALLING Act

As reported by the Senate Committee on the Judiciary on March 1, 2023

By Fiscal Year, Millions of Dollars	2024	2024-2029	2024-2034
Direct Spending (Outlays)	0	-101	-311
Revenues	0	31	90
Decrease (-) in the Deficit	0	-132	-401
Spending Subject to Appropriation (Outlays)	*	*	not estimated

Increases *net direct spending* in any of the four consecutive 10-year periods beginning in 2035?	No	Statutory pay-as-you-go procedures apply?	Yes
Increases *on-budget deficits* in any of the four consecutive 10-year periods beginning in 2035?	No	**Mandate Effects**	
		Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

* = between zero and $500,000.

The bill would

- Authorize the Federal Trade Commission to initiate a civil action against any person or entity that submits a baseless petition to the Food and Drug Administration (FDA) with the intent that the FDA's review of the petition would delay the approval of a generic drug, a biosimilar biological product, or certain other new drugs

Estimated budgetary effects would mainly stem from

- Generic drugs or biosimilar biological products entering the market earlier than under current law, resulting in lower federal spending on prescription drugs and health insurance subsidies

Areas of significant uncertainty include

- Predicting the number of petitions and the amount of drug and biological product sales affected by the bill
- Forecasting the bill's effects on the timing of FDA approval and the timing of the introduction of some generic drugs and biosimilar biological products

Detailed estimate begins on the next page.

See also
CBO's Cost Estimates Explained, *CBO Describes Its Cost-Estimating Process*, *Glossary*

Bill Summary

S. 148 would authorize the Federal Trade Commission (FTC) to initiate a civil action against any person or entity that submits a petition to the Food and Drug Administration (FDA) with respect to certain pending prescription drug applications that is objectively baseless and that was submitted with the intent to use the FDA's review process to delay approval of the application. In any civil action initiated under the bill, the FTC would face the burden of demonstrating that a petition was impermissible unless the FDA determined that it had been submitted with the primary purpose of delaying the approval of a covered application, the FDA referred the petition to the FTC in writing, and the petition was submitted as part of a series of covered petitions; in those cases, the burden of proof would shift to the person or entity who submitted the petition. The bill would allow the FTC to seek monetary penalties and other appropriate relief.

Under current law, the FDA can summarily deny any petition that does not on its face raise valid scientific or regulatory questions and that the FDA has determined was submitted for the primary purpose of delaying the approval of another application. The FDA can refer such petitions to the FTC, and the FTC can seek injunctive relief (but not monetary penalties). Any petition that the FTC challenges is presumed permissible unless the FTC demonstrates otherwise.

Estimated Federal Cost

The estimated budgetary effect of S. 148 is shown in Table 1. The costs of the legislation fall within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

Basis of Estimate

For this estimate, CBO assumes that S. 148 will be enacted near the middle of fiscal year 2024 and would apply to any covered petition submitted on or after the enactment date. CBO's estimates are informed by historical data on how competition from generic drugs and biosimilar biological products affects total spending across a brand-name drug and its generic competitors (in the case of generic competition), or across a brand-name biological product and its biosimilar competitors (in the case of biosimilar competition).

Table 1.
Estimated Budgetary Effects of S. 148

	By Fiscal Year, Millions of Dollars												
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2024-2029	2024-2034
Decreases in Direct Spending													
Estimated Budget Authority	0	-1	-11	-25	-32	-32	-38	-39	-42	-46	-45	-101	-311
Estimated Outlays	0	-1	-11	-25	-32	-32	-38	-39	-42	-46	-45	-101	-311
On-Budget	0	-1	-11	-25	-32	-32	-38	-38	-42	-46	-45	-101	-310
Off-Budget	0	*	*	*	*	*	*	-1	*	*	*	*	-1
Increases in Revenues													
Estimated Revenues	0	*	4	8	9	10	12	11	12	12	12	31	90
On-Budget	0	*	3	6	6	8	9	8	9	8	10	23	67
Off-Budget	0	*	1	2	3	2	3	3	3	4	2	8	23
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	-1	-15	-33	-41	-42	-50	-50	-54	-58	-57	-132	-401
On-Budget	0	-1	-14	-31	-38	-40	-47	-46	-51	-54	-55	-124	-377
Off-Budget	0	*	-1	-2	-3	-2	-3	-4	-3	-4	-2	-8	-24
Increases in Spending Subject to Appropriation													
Estimated Authorization	*	*	0	0	0	0	n.e.	n.e.	n.e.	n.e.	n.e.	*	n.e.
Estimated Outlays	*	*	0	0	0	0	n.e.	n.e.	n.e.	n.e.	n.e.	*	n.e.

n.e. = not estimated; * = between -$500,000 and $500,000.

Direct Spending and Revenues

Using information from federal agencies and drug industry experts, CBO expects that the reduced burden of proof and the threat of substantial penalties under the bill would deter some parties from submitting petitions that would otherwise delay FDA's approval of generic drugs or biosimilar biological products. As a result, CBO expects earlier marketing of some lower-cost generic drugs or biosimilar biological products, which would reduce federal spending on prescription drugs and reduce health insurance subsidies provided through the tax code. Based on CBO's analysis of past petitions submitted to the FDA, the agency projects that enacting the bill would accelerate initial competition from generic drugs or biosimilar biological products by about nine months, on average, for affected drugs and biological products. CBO estimates that the drugs and biological products that would be affected during the 2024-2034 period total about $2 billion in annual sales. CBO expects that companies would generally comply with the new requirements, and that any additional revenues collected as penalties over the 2024-2034 period would be insignificant. In total,

CBO estimates that enacting the bill would reduce direct spending by $311 million and increase revenues by $90 million over the 2024-2034 period, for a net decrease in the deficit of $401 million.

Spending Subject to Appropriation

Based on administrative costs for similar activities, CBO estimates that it would cost less than $500,000 for the FTC to issue rules or provide guidance in the first year after enactment under the bill; any spending would be subject to the availability of appropriated funds.

Uncertainty

Areas of significant uncertainty for this estimate include:

- The number of petitions that would be submitted under current law but not under S. 148,
- The effect that avoiding the submission of those petitions would have on the timing of the FDA's approval of the affected generic drugs and biosimilar biological products,
- The effect of earlier FDA approval on the timing of market entry for the affected generic drugs and biosimilar biological products, and
- The total sales of prescription drugs and biological products that would face earlier competition from generic drugs and biosimilar biological products under the bill than under current law.

Pay-As-You-Go Considerations

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays and revenues that are subject to those pay-as-you-go procedures are shown in Table 2.

Table 2.
CBO's Estimate of the Statutory Pay-As-You-Go Effects of S. 148, the Stop STALLING Act, as Reported by the Senate Committee on the Judiciary on March 1, 2023

	By Fiscal Year, Millions of Dollars												
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2024-2029	2024-2034
	Net Decrease in the On-Budget Deficit												
Pay-As-You-Go Effect	0	-1	-14	-31	-38	-40	-47	-46	-51	-54	-55	-124	-377
Memorandum:													
Changes in Outlays	0	-1	-11	-25	-32	-32	-38	-38	-42	-46	-45	-101	-310
Changes in Revenues	0	0	3	6	6	8	9	8	9	8	10	23	67

Changes to off-budget outlays and revenues are exempt from pay-as-you-go procedures and are excluded from Table 2. CBO estimates that enacting S. 148 would reduce private health insurance premiums. That reduction would shift a portion of employees' compensation from tax-favored health insurance to taxable wages and in turn increase Social Security revenues, which are classified as off-budget. Additionally, lower premiums would reduce outlays for health care programs for active Postal Service employees, which are also classified as off-budget.

Increase in Long-Term Net Direct Spending and Deficits

CBO estimates that enacting S. 148 would not increase net direct spending or deficits in any of the four consecutive 10-year periods beginning in 2034.

Mandates

The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act.

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