Congressional Budget Office
Cost Estimate

March 13, 2024

At a Glance

S. 142, Preserve Access to Affordable Generics and Biosimilars 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)	-1	-447	-1,280
Revenues	0	135	366
Decrease (-) in the Deficit	-1	-582	-1,646
Spending Subject to Appropriation (Outlays)	*	5	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?	Yes, Over Threshold

* = between zero and $500,000.

The bill would

- Prohibit certain anticompetitive settlement agreements that resolve patent infringement claims against manufacturers of generic drugs or biosimilar biological products
- Create a framework under which the Federal Trade Commission (FTC) could block prohibited settlement agreements and seek penalties from parties to those agreements
- Require parties to certain settlement agreements arising from proceedings conducted by the Patent Trial and Appeal Board (PTAB) to report them to the FTC and the Department of Justice
- Impose private-sector mandates by enhancing the FTC's authority to restrict certain agreements and by requiring pharmaceutical manufacturers to notify the FTC of agreements that settle PTAB proceedings

Estimated budgetary effects would mainly stem from

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

Areas of significant uncertainty include

- Predicting the extent to which manufacturers of drugs or biosimilar biological products would continue to enter into anticompetitive settlement agreements
- Determining the number of settlement agreements permitted under current law that would be prohibited under the bill
- Estimating the total sales of drugs and biological products whose manufacturers would enter into prohibited settlement agreements regarding those drugs or biological products under current law but not under the bill

Detailed estimate begins on the next page.

Bill Summary

S. 142 would create a framework through which the Federal Trade Commission (FTC) could initiate proceedings against the parties to agreements used to settle claims of patent infringement involving prescription drugs or biological products. Any such agreement would presumptively be considered illegal under antitrust law if a generic drug applicant or biosimilar biological product applicant that was party to the agreement received anything of value—excluding three permissible types of compensation specified in the bill—and if that applicant agreed to "limit or forgo research, development, manufacturing, marketing, or sales" of the drug or biological product. The parties to the agreement could override the presumption of illegality by demonstrating either that the "thing of value" was compensation for goods or services provided or that the pro-competitive benefits of the agreement outweigh its anticompetitive effects. Under the bill, the FTC would be authorized to issue cease-and-desist orders and to seek civil penalties from each party to such an agreement.

Parties to certain agreements related to the manufacturing, marketing, or sale of generic drugs or biosimilar biological products and arising from proceedings conducted by the Patent Trial and Appeal Board would be required to report those agreements to the FTC and the Department of Justice. CBO expects that enactment of the bill would result in earlier marketing of lower-cost generic drugs or biosimilar biological products, which would reduce total sales of drugs and biological products.

Estimated Federal Cost

The estimated budgetary effect of S. 142 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. 142 will be enacted in the middle of fiscal year 2024 and that the bill would apply to settlements reached on or after the enactment date. CBO's estimates are informed by historical data on the effect of competition from generic drugs on total spending for brand-name drugs and generic competitors and the effect of competition from biosimilar biological products on total spending for brand-name biological products and biosimilar competitors.

Table 1.
Estimated Budgetary Effects of S. 142

	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	-1	-17	-59	-103	-137	-130	-148	-159	-161	-184	-181	-447	-1,280
Estimated Outlays	-1	-17	-59	-103	-137	-130	-148	-159	-161	-184	-181	-447	-1,280
On-Budget	-1	-17	-59	-102	-137	-130	-147	-159	-160	-184	-180	-446	-1,276
Off-Budget	0	*	*	-1	*	*	-1	*	-1	*	-1	-1	-4
Increases in Revenues													
Estimated Revenues	0	3	17	34	39	42	46	44	47	47	47	135	366
On-Budget	0	2	13	25	29	31	34	33	35	34	36	100	272
Off-Budget	0	1	4	9	10	11	12	11	12	13	11	35	94
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	-1	-20	-76	-137	-176	-172	-194	-203	-208	-231	-228	-582	-1,646
On-Budget	-1	-19	-72	-127	-166	-161	-181	-192	-195	-218	-216	-546	-1,548
Off-Budget	0	-1	-4	-10	-10	-11	-13	-11	-13	-13	-12	-36	-98
Increases in Spending Subject to Appropriation													
Estimated Authorization	*	1	1	1	1	1	n.e.	n.e.	n.e.	n.e.	n.e.	5	n.e.
Estimated Outlays	*	1	1	1	1	1	n.e.	n.e.	n.e.	n.e.	n.e.	5	n.e.

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

Direct Spending and Revenues

On the basis of information from federal agencies and experts on the prescription drug industry, CBO expects that the penalties under S. 142 would provide an incentive to pharmaceutical companies to avoid settlement agreements under which a manufacturer of generic drugs or biosimilar biological products delays market entry in return for a payment or something else of value. Consequently, enacting the bill would result in 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 settlement agreements, the agency projects that enacting the bill would accelerate initial competition from generic drugs or biosimilar biological products by about 17 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 between $4 billion and $5 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 $1.3 billion and increase revenues by $366 million over the 2024-2034 period, for a net decrease in the deficit of $1.6 billion.

Spending Subject to Appropriation
CBO estimates that it would cost $5 million over the 2024-2029 period for the FTC to implement S. 142; any spending would be subject to the availability of appropriated funds. Based on the administrative costs of similar activities, CBO expects that in the first year after enactment the FTC would need the equivalent of three employees, at an average annual cost of $225,000 per employee, to issue rules and guidance to pharmaceutical manufacturers. In each subsequent year, the FTC would need three employees to enforce the prohibition on banned settlements. Finally, the FTC would need one employee in the first year after enactment to make the required recommendations to the Congress.

Uncertainty

CBO's estimate of the budgetary effects of S. 142 is subject to uncertainty in three major areas.

First, the budgetary effects of the bill would depend on how broadly pharmaceutical manufacturers, the FTC, and the courts interpret the bill's limitations on negotiated settlements; how aggressively the FTC pursues infringing settlements; and the extent to which pharmaceutical manufacturers would circumvent those limitations.

Second, CBO's estimate of the number of affected settlement agreements is subject to uncertainty because of constraints on the availability of data. Pharmaceutical companies generally do not release settlement agreements publicly, and court records for previously challenged settlements may not cover all agreements that would have been challenged under the bill. Additionally, the FTC's currently available reports on pharmaceutical settlement agreements cover settlements only through fiscal year 2017.

Finally, federal spending on prescription drugs and biological products is highly concentrated. The budgetary effects of S. 142 could be larger or smaller than estimated if the settlement agreements affected by the bill correspond to drugs and biological products with particularly high or low sales.

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. 142, the Preserve Access to Affordable Generics and Biosimilars 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	-1	-19	-72	-127	-166	-161	-181	-192	-195	-218	-216	-546	-1,548
Memorandum:													
Changes in Outlays	-1	-17	-59	-102	-137	-130	-147	-159	-160	-184	-180	-446	-1,276
Changes in Revenues	0	2	13	25	29	31	34	33	35	34	36	100	272

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. 142 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. 142 would not increase net direct spending or deficits by more than $2.5 billion in any of the four consecutive 10-year periods beginning in 2034.

Mandates

S. 142 would impose private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) by enhancing the FTC's authority to restrict certain agreements between sponsors of brand-name drugs or biological products and sponsors of generic drugs or biosimilar biological products and by requiring those manufacturers to notify the FTC of agreements that resolve, settle, or withdraw challenges that are the subject of proceedings conducted by the Patent Trial and Appeal Board. Enactment of the bill could result in earlier marketing of lower-cost generic or biosimilar drugs, which would reduce revenues from the sales of brand-name drugs and biological products. CBO estimates that the cost of the mandate would exceed the threshold for private-sector mandates established in UMRA in at least three of the first five years that the mandate would be in effect ($200 million in 2024, adjusted annually for inflation).

The bill would not impose any intergovernmental mandates as defined in UMRA.

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