Congressional Budget Office
Cost Estimate

June 13, 2024

At a Glance

S. 150, Affordable Prescriptions for Patients Act of 2023

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)	*	-597	-2,434
Revenues	0	162	585
Increase or Decrease (-) in the Deficit	*	-759	-3,019
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 -$500,000 and $500,000.

The bill would

- Prohibit “product hopping” by manufacturers of original (not generic or biosimilar) drugs and biological products
- Limit the number of patents of a certain type that a company may assert that another company has infringed on or would infringe on by manufacturing, importing, or marketing a biosimilar version of the first company’s original biological product
- Impose private-sector mandates by limiting assertions of patent infringement

Estimated budgetary effects would mainly stem from

- Lower federal spending for prescription drugs and biological products
- Lower spending on federal subsidies for health insurance programs that cover drugs and biological products

Areas of significant uncertainty include

- Predicting the amount in sales of drugs and biological products that would be affected by the bill
- Predicting manufacturers’ decisions concerning litigation and the introduction and promotion of follow-on products
- Anticipating the effects of those decisions on competition

Detailed estimate begins on the next page.

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

Bill Summary

S. 150 would amend the Federal Trade Commission Act to prohibit "product hopping." Under the bill, a manufacturer of an original drug or biological product (that is, not a generic drug or a biosimilar biological product) would be considered to have engaged in product hopping if it marketed a reformulation or other follow-on product to treat the same or substantively similar condition and withdrew, discontinued, or otherwise unfairly placed the original product at a competitive disadvantage to the follow-on product.

A manufacturer of an original drug or biological product would be prohibited from product hopping once that manufacturer is notified that the Food and Drug Administration (FDA) has received an application for a generic version of the drug or a biosimilar version of the biological product. That prohibition would be lifted either three years after the manufacturer of the original product first markets the follow-on product or 180 days after a competing generic drug or biosimilar biological product is first marketed, whichever is earlier.

S. 150 would establish a statutory framework under which the Federal Trade Commission (FTC) could seek remedies from companies that engage in product hopping. S. 150 specifies the justifications that a manufacturer may use to defend against an accusation of product hopping; identifies the criteria that the FTC must meet to rebut any justifications; and affirms that the promotion of a follow-on product or the absence of promotion for an original product do not, on their own, amount to product hopping.

S. 150 also would limit the number of patents that a sponsor of an approved application for an original biological product (that is, the entity that submitted the application) may assert (that is, allege infringement of) against an applicant seeking FDA approval for a biosimilar version of the biological product. A patent would count against the limit only if it met two criteria:

- The patent must claim exclusive rights to the biological product, a use of the product, or a method or product used in the manufacture of the product; and
- Either the patent must have been filed more than four years after the original biological product was approved or the patent must claim exclusive rights to a manufacturing process that is not used by the sponsor of the original biological product.

Estimated Federal Cost

The estimated budgetary effect of S. 150 is shown in Table 1. The costs of the legislation fall within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

Table 1.
Estimated Budgetary Effects of S. 150

	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	*	-17	-52	-111	-189	-228	-289	-328	-360	-420	-440	-597	-2,434
Estimated Outlays	*	-17	-52	-111	-189	-228	-289	-328	-360	-420	-440	-597	-2,434
On-Budget	*	*-17*	*-52*	*-111*	*-188*	*-227*	*-288*	*-327*	*-360*	*-419*	*-439*	*-595*	*-2,428*
Off-Budget	*0*	*	*	*	*-1*	*-1*	*-1*	*-1*	*	*-1*	*-1*	*-2*	*-6*
Increases in Revenues													
Estimated Revenues	0	1	16	33	48	64	71	80	83	93	96	162	585
On-Budget	*0*	*1*	*12*	*24*	*35*	*47*	*54*	*59*	*62*	*69*	*70*	*119*	*433*
Off-Budget	*0*	*	*4*	*9*	*13*	*17*	*17*	*21*	*21*	*24*	*26*	*43*	*152*
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	*	-18	-68	-144	-237	-292	-360	-408	-443	-513	-536	-759	-3,019
On-Budget	*	*-18*	*-64*	*-135*	*-223*	*-274*	*-343*	*-385*	*-422*	*-488*	*-509*	*-714*	*-2,861*
Off-Budget	*0*	*	*-4*	*-9*	*-14*	*-18*	*-17*	*-23*	*-21*	*-25*	*-27*	*-45*	*-158*
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.

Off-budget effects would come from increases in Social Security revenues and decreases in outlays for health care programs for active Postal Service employees; n.e = not estimated; * = between -$500,000 and $500,000.

Basis of Estimate

For this estimate, CBO assumes that S. 150 will be enacted in the middle of fiscal year 2024. The estimate is informed by historical data on the effects of competition from generic drugs on total spending for original drugs and their generic competitors and on the effects of competition from biosimilar biological products on total spending for original biological products and their biosimilar competitors.

Direct Spending and Revenues

On the basis of information from federal agencies and experts on the prescription drug industry, CBO expects that enacting the bill would reduce average prices for prescription drugs and biological products. Those price reductions would result in lower federal spending for prescription drugs and biological products, including spending on federal subsidies for health insurance programs that cover prescription drugs and biological products. CBO

anticipates that under the bill, outlays would be reduced for Medicare, Medicaid, the Federal Employees Health Benefits Program, the health insurance exchanges created under the Affordable Care Act, and for other, smaller, programs that are subsidized through direct spending.

CBO also expects that enacting S. 150 would reduce spending for prescription drugs by employment-based health insurance plans, thus allowing those plans to reduce premiums. That reduction would shift a portion of employees' compensation from tax-favored health insurance to taxable wages and, as a result, increase federal revenues.

CBO estimates that enacting the bill would reduce direct spending by $2.4 billion and increase revenues by $585 million over the 2024-2034 period, for a net decrease in the deficit of $3.0 billion (see Table 2).

Section 2, Product Hopping. Section 2 would establish a statutory framework under which the FTC could seek equitable remedies from any company that engages in product hopping. Those remedies could include injunctions, restitution, and disgorgement. Restitution requires violators to compensate victims for their monetary loss; disgorgement strips violators of monetary profits obtained from illegal activity. When the FTC cannot return those amounts to harmed consumers, the money is remitted to the Treasury and thus increases revenues.

CBO expects that enacting section 2 would reduce spending for prescription drugs through two mechanisms.

First, on the basis of information from experts on the drug industry, CBO expects that some instances of product hopping that the courts would block under current law would be blocked about six months sooner, on average, under the bill. (Under current antitrust law, courts may block some instances and allow others.) Based on CBO's analysis of instances of product hopping that the courts have blocked in recent years, CBO estimates that the drugs and biological products that would be affected through this mechanism during the 2024-2034 period total about $2 billion in annual sales. CBO anticipates that the accelerated litigation in those cases would result in earlier competition from lower-cost generic drugs and biosimilar biological products under the bill than under current law; that competition would be expected to reduce average prices for drugs and biological products.

Second, CBO expects that—to avoid the risk of a court staying an action or imposing a penalty—some manufacturers of original drugs and biological products would limit themselves to actions that are less anticompetitive in promoting follow-on products under the bill than those manufacturers might pursue under current law. Based on CBO's analysis of past actions that might be considered product hopping, CBO estimates that the drugs and biological products that would be affected through this mechanism during the 2024-2034 period total about $2 billion in annual sales.

Table 2.
Estimated Changes in Direct Spending, Revenues, and the Deficit Under S.150

	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													
Section 2. Product Hopping													
Estimated Budget Authority	*	-9	-25	-48	-71	-84	-102	-118	-133	-160	-167	-237	-917
Estimated Outlays	*	-9	-25	-48	-71	-84	-102	-118	-133	-160	-167	-237	-917
On-Budget	*	*-9*	*-25*	*-48*	*-71*	*-83*	*-102*	*-117*	*-133*	*-160*	*-166*	*-236*	*-914*
Off-Budget	*0*	*	*	*	*	*-1*	*	*-1*	*	*	*-1*	*-1*	*-3*
Section 3. Title 35 Amendments													
Estimated Budget Authority	*	-8	-27	-63	-118	-144	-187	-210	-227	-260	-273	-360	-1,517
Estimated Outlays	*	-8	-27	-63	-118	-144	-187	-210	-227	-260	-273	-360	-1,517
On-Budget	*	*-8*	*-27*	*-63*	*-117*	*-144*	*-186*	*-210*	*-227*	*-259*	*-273*	*-359*	*-1,514*
Off-Budget	*0*	*	*	*	*-1*	*	*-1*	*	*	*-1*	*	*-1*	*-3*
Total Decreases													
Estimated Budget Authority	*	-17	-52	-111	-189	-228	-289	-328	-360	-420	-440	-597	-2,434
Estimated Outlays	*	-17	-52	-111	-189	-228	-289	-328	-360	-420	-440	-597	-2,434
On-Budget	*	*-17*	*-52*	*-111*	*-188*	*-227*	*-288*	*-327*	*-360*	*-419*	*-439*	*-595*	*-2,428*
Off-Budget	*0*	*	*	*	*-1*	*-1*	*-1*	*-1*	*	*-1*	*-1*	*-2*	*-6*
Increases in Revenues													
Section 2. Product Hopping													
Revenues	0	*	9	16	21	29	31	37	40	46	48	75	277
On-Budget	*0*	*	*7*	*12*	*15*	*21*	*24*	*27*	*30*	*34*	*35*	*55*	*205*
Off-Budget	*0*	*	*2*	*4*	*6*	*8*	*7*	*10*	*10*	*12*	*13*	*20*	*72*
Section 3. Title 35 Amendments													
Revenues	0	1	7	17	27	35	40	43	43	47	48	87	308
On-Budget	*0*	*1*	*5*	*12*	*20*	*26*	*30*	*32*	*32*	*35*	*35*	*64*	*228*
Off-Budget	*0*	*	*2*	*5*	*7*	*9*	*10*	*11*	*11*	*12*	*13*	*23*	*80*
Total Increases													
Revenues	0	1	16	33	48	64	71	80	83	93	96	162	585
On-Budget	*0*	*1*	*12*	*24*	*35*	*47*	*54*	*59*	*62*	*69*	*70*	*119*	*433*
Off-Budget	*0*	*	*4*	*9*	*13*	*17*	*17*	*21*	*21*	*24*	*26*	*43*	*152*
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	*	-18	-68	-144	-237	-292	-360	-408	-443	-513	-536	-759	-3,019
On-Budget	*	*-18*	*-64*	*-135*	*-223*	*-274*	*-343*	*-385*	*-422*	*-488*	*-509*	*-714*	*-2,861*
Off-Budget	*0*	*	*-4*	*-9*	*-14*	*-18*	*-17*	*-23*	*-21*	*-25*	*-27*	*-45*	*-158*

Off-budget effects would come from increases in Social Security revenues and decreases in outlays for health care programs for active Postal Service employees; * = between -$500,000 and $500,000.

CBO expects that in such cases fewer patients would switch to follow-on products (about one-third), on average, than would switch under current law (about two-thirds). More patients would continue to use the original products, which would face competition from lower-cost generic drugs or biosimilar biological products, and that competition would be expected to reduce average prices by about 85 percent for original drugs and their generic competitors and by about half as much for original biological products and their biosimilar competitors.

CBO estimates that enacting section 2 would reduce direct spending by $917 million and increase revenues by $277 million over the 2024-2034 period, for a net decrease in the deficit of $1.2 billion.

Section 3, Title 35 Amendments. Section 3 would revise title 35 of the U.S. Code to limit the number of patents that the sponsor of an original biological product may assert that the sponsor of a biosimilar biological product application has infringed on or would infringe on by manufacturing, importing, or marketing the biosimilar biological product. Only certain patents would count against the limit.

CBO expects that enacting section 3 would force some manufacturers of original biological products to assert fewer patents than they would under current law. CBO anticipates that, under the bill, some manufacturers would not assert one or more patents that a court would have upheld in litigation if the manufacturer had asserted them. CBO also anticipates that some of those patents could have a later expiration date than that of any asserted patent upheld by the court. In those cases, the manufacturer of the biosimilar biological product could start marketing earlier under section 3 (upon expiration of the last upheld, asserted patent) than under current law.

CBO also anticipates that some manufacturers of original biological products and manufacturers of biosimilar biological products that would resolve patent litigation through settlements under current law would agree to an earlier first-marketing date for the biosimilar biological product under section 3 than under current law because enacting section 3 would reduce the original manufacturer’s negotiating leverage relative to that of the biosimilar manufacturer. In particular:

- CBO anticipates that manufacturers of biosimilar biological products would receive more favorable treatment from a court under section 3 than they would under current law. Manufacturers of original biological products would have more to lose by waiting for a court decision, so they would be more willing to resolve a dispute through a settlement.

- CBO anticipates that enacting section 3 would reduce the cost of patent litigation for both parties by reducing the number of litigated patents. Manufacturers of original products generally are more willing to accept high litigation costs because they stand to lose more profits from biosimilar competition than manufacturers of biosimilar biological products stand to gain.

Based on CBO's analysis of lists of patents that sponsors of original biological products have indicated might reasonably be asserted against biosimilar competitors, CBO anticipates that enacting section 3 would accelerate initial competition from biosimilar biological products by about two years, on average, for affected biological products. CBO estimates that the biological products that would be affected during the 2024-2034 period total about $7 billion in annual sales. CBO anticipates that enacting section 3 would reduce the price of affected biological products by about 20 percent on average, relative to current law. CBO expects that gap to shrink over time as prices for each biological product approach the same long-run price under section 3 as under current law.

CBO estimates that enacting section 3 would reduce direct spending by $1.5 billion and increase revenues by $308 million over the 2024-2034 period, for a net decrease in the deficit of $1.8 billion.

Spending Subject to Appropriation

CBO estimates that it would cost $5 million over the 2024-2029 period for the FTC to implement section 2 (see Table 3). Any related spending would be subject to the availability of appropriated funds.

Table 3.
Estimated Increases in Spending Subject to Appropriation Under S. 150

	By Fiscal Year, Millions of Dollars						
	2024	2025	2026	2027	2028	2029	2024-2029
Section 2. Product Hopping							
Estimated Authorization	*	1	1	1	1	1	5
Estimated Outlays	*	1	1	1	1	1	5
Section 3. Title 35 Amendments							
Estimated Authorization	0	0	0	0	0	0	0
Estimated Outlays	0	0	0	0	0	0	0
Total Changes							
Estimated Authorization	*	1	1	1	1	1	5
Estimated Outlays	*	1	1	1	1	1	5

* = between zero and $500,000.

Based on the 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 drug and biological product manufacturers. In

each subsequent year, the FTC would need three employees to enforce the bill's provisions by initiating administrative and judicial proceedings, among other actions.

Uncertainty

This estimate is subject to significant uncertainty involving CBO's projections in several areas. The amount of sales affected by each section of the bill could be larger or smaller than CBO anticipates. Decisions by manufacturers of original products with respect to the introduction and promotion of follow-on products could differ from what CBO anticipates, as could the choices of manufacturers of original biological products with respect to prioritizing which patents to assert in infringement litigation. Finally, the effects of each section on the timing of the introduction of generic drugs and biosimilar biological products may differ from CBO's projections, as could the implications of enacting section 2 for the effectiveness of manufacturers' actions to switch patients to follow-on products.

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 4.

Changes to off-budget outlays and revenues are exempt from pay-as-you-go procedures and are excluded from Table 4. CBO estimates that enacting S. 150 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 would 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; those amounts also are classified as off-budget.

Table 4.
CBO's Estimate of the Statutory Pay-As-You-Go Effects of S. 150, the Affordable Prescriptions for Patients Act of 2023, 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	-18	-64	-135	-223	-274	-343	-385	-422	-488	-509	-714	-2,861
Memorandum:													
Changes in Outlays	0	-17	-52	-111	-188	-227	-288	-327	-360	-419	-439	-595	-2,428
Changes in Revenues	0	1	12	24	35	47	54	59	62	69	70	119	433

Increase in Long-Term Net Direct Spending and Deficits

CBO estimates that enacting S. 150 would not increase net direct spending or deficits in any of the four consecutive 10-year periods beginning in 2035.

Mandates

S. 150 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 patent infringement litigation involving biological products. Those limits would result in earlier marketing of lower-cost biosimilar biological products, which would in turn reduce manufacturers' revenues from original biological products. CBO estimates that the cost of the mandate would exceed the threshold for private-sector mandates established in UMRA ($200 million in 2024, adjusted annually for inflation) in at least two of the first five years that the mandate would be in effect.

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

Estimate Prepared By

Federal Costs:

Ezra Cohn (for federal health programs)
David Hughes (for the Federal Trade Commission)

Revenues: Ezra Cohn

Mandates: Andrew Laughlin

Estimate Reviewed By

Sean Dunbar
Chief, Low-Income Health Programs and Prescription Drugs Cost Estimates Unit

Justin Humphrey
Chief, Finance, Housing, and Education Cost Estimates Unit

Kathleen FitzGerald
Chief, Public and Private Mandates Unit

Chad Chirico
Director of Budget Analysis

Estimate Approved By

Phillip L. Swagel
Director, Congressional Budget Office