# Congressional Budget Office
## Cost Estimate

June 6, 2022

S. 1425 would authorize the Federal Trade Commission to take civil action against individuals or entities involved in submitting certain petitions to the Food and Drug Administration.

### Estimated Budgetary Effects of S. 1425, the Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (Stop STALLING) Act

**As reported by the Senate Committee on the Judiciary on December 8, 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 | -1 | -5 | -7 | -9 | -9 | -10 | -9 | -10 | -13 | -13 | -31 | -86 |
| Estimated Outlays | 0 | -1 | -5 | -7 | -9 | -9 | -10 | -9 | -10 | -13 | -13 | -31 | -86 |
| **Increases in Revenues** | | | | | | | | | | | | | |
| Estimated Revenues | 0 | 0 | 1 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 11 | 31 |
| *On-Budget Revenues* | *0* | *0* | *1* | *2* | *2* | *3* | *3* | *3* | *3* | *3* | *3* | *8* | *23* |
| *Off-Budget Revenues* | *0* | *0* | *0* | *1* | *1* | *1* | *1* | *1* | *1* | *1* | *1* | *3* | *8* |
| **Net Decrease (-) in the Deficit From Changes in Direct Spending and Revenues** | | | | | | | | | | | | | |
| Effect on the Deficit | 0 | -1 | -6 | -10 | -12 | -13 | -14 | -13 | -14 | -17 | -17 | -42 | -117 |
| *On-Budget Deficit* | *0* | *-1* | *-6* | *-9* | *-11* | *-12* | *-13* | *-12* | *-13* | *-16* | *-16* | *-39* | *-109* |
| *Off-Budget Deficit* | *0* | *0* | *0* | *-1* | *-1* | *-1* | *-1* | *-1* | *-1* | *-1* | *-1* | *-3* | *-8* |

Staff Contacts: Ryan Greenfield, Ellen Werble

Under S. 1425, the Federal Trade Commission could take civil action against individuals or entities involved in submitting petitions to the Food and Drug Administration (FDA) that the FDA finds are intended primarily to delay approval of a pending marketing application, including applications submitted for the marketing of lower-priced generic or biosimilar drugs. Under current law and FDA guidance, the FDA may summarily deny petitions that do not on their face raise valid scientific or regulatory issues. Under the bill, such petitions would presumptively be considered illegal under the Federal Trade Commission Act, unless the petitioner could prove the petition's merits.

On the basis of CBO's examination of past cases involving petitions to the FDA, CBO expects that the threat of substantial penalties under the bill would deter some parties from submitting petitions that would otherwise delay the marketing of lower-priced drugs. The estimated budgetary effects would stem from more generic or biosimilar drugs' entering the market earlier, on average, than would be the case under current law, resulting 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 the timing of introductions of new pharmaceutical products.