Congressional Budget Office
Cost Estimate

May 13, 2019

H.R. 2374, Stop STALLING Act

As ordered reported by the House Committee on the Judiciary on April 30, 2019

By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-42	-98
Revenues	0	8	18
Deficit Effect	0	-50	-117
Spending Subject to Appropriation (Outlays)	0	-7	n.e.

Pay-as-you-go procedures apply?	Yes	**Mandate Effects**	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

n.e. = not estimated.

H.R. 2374 would authorize the Federal Trade Commission (FTC) to initiate a civil action against any persons involved with submitting certain petitions to the Food and Drug Administration (FDA) that are objectively without merit and who use the agency's administrative review process for the purpose of interfering with the business of a competitor. Such persons would be liable for violating the FTC Act. (Under the bill, the term "persons" includes individuals or entities.)

Under current law, section 505(q) of the Federal Food, Drug, and Cosmetic Act governs how certain petitions submitted to FDA are treated. Such petitions request FDA to take or refrain from taking an action by the agency that could delay approval of pending marketing applications, including applications for lower priced generic and biosimilar drugs. FDA's draft guidance details how FDA assesses whether a petition is submitted with the primary purpose of delaying the approval of an application. If such a determination is made, FDA may summarily deny the petition if it also does not on its face raise valid scientific or regulatory issues. FDA may refer such cases to the FTC, although a recent appellate court ruling limits FTC's litigation authority in this area.

In addition to establishing a statutory framework for FTC's litigation authority, the bill also would allow FTC to impose civil penalties and seek other appropriate relief in district court from parties that violate antitrust law in this area. If FDA determines that a petition was submitted primarily to delay approval of a marketing application and refers it to the FTC, the

bill would make such petitions presumptively illegal under the FTC Act, unless the defendant proves by preponderance of the evidence that the petition is not a sham.

Enacting H.R. 2374 would make it easier for the FTC to bring cases alleging that certain petitions are unlawful and to impose penalties. CBO expects the threat of substantial penalties would deter some parties from submitting petitions to FDA that would otherwise delay marketing of lower priced drugs.

To estimate the effects of reducing the number of sham petitions, CBO examined information about past cases involving petitions that potentially delayed the marketing approval for a competitor's drug. CBO estimates that the bill would affect between $1 billion and $2 billion of brand-name sales for drugs over the 2019-2029 period and would accelerate initial competition from generic or biosimilar products for affected drugs by six months, on average. Because CBO expects the bill would accelerate the availability of lower-priced drugs that would otherwise have been delayed, enacting H.R. 2374 would reduce the average price of drugs paid by federal health programs that purchase drugs or provide health insurance that covers drugs. As result, CBO estimates that the legislation would reduce mandatory spending by $98 million over the 2019-2029 period. By lowering the average cost for prescription drugs, we also estimate that premiums for some private health insurance plans would decrease under the bill. Lower premiums would reduce federal subsidies for insurance purchased through the marketplaces and shift compensation from tax-favored health insurance to taxable wages. Taken together, such changes would increase federal revenues by $18 million over the 2019-2029 period. In total, CBO estimates that enacting H.R. 2374 would decrease the deficit by $117 million over the 2019-2029 period.

CBO also estimates that implementing H.R. 2374 would decrease spending subject to appropriation by $7 million over the 2019-2024 period, assuming appropriation actions consistent with the bill. That decrease would result primarily because lower estimated drug prices would reduce costs for discretionary health programs.

The uncertainty in this estimate is driven primarily by the difficulty in predicting the number of frivolous petitions that are likely to be submitted to FDA through 2029 under current law and under the bill and estimating the amount of brand-name sales for drugs facing competition affected by such petitions. If fewer sham petitions were submitted to the FDA under the bill, its enactment could lead to earlier market entry by lower-priced drugs when both approval of the generic or biosimilar application and marketing of the drug hinge on the date that a petition is adjudicated by FDA. If patent-related issues would delay entry of generic or biosimilar drugs regardless of the date on which a petition is resolved, such cases would not be affected by the bill. The timing and results of those legal proceedings are inherently uncertain. Such effects could differ from those included in CBO's analyses, depending on pharmaceutical companies' decisionmaking and the outcome of court proceedings.

Details of the estimated budgetary effect of H.R 2374 are shown in Table 1. Those effects fall primarily within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

Table 1.
Estimated Budgetary Effects of H.R. 2374

	By Fiscal Year, Millions of Dollars												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019-2024	2019-2029
Decreases in Direct Spending													
Estimated Outlays[a]	0	-5	-9	-10	-9	-9	-10	-11	-11	-13	-12	-42	-98
On-Budget	0	-5	-9	-10	-9	-9	-10	-11	-11	-13	-12	-42	-98
Off-Budget[b]	0	*	*	*	*	*	*	*	*	*	*	*	*
Increases in Revenues													
Estimated Revenues	0	1	2	2	2	2	2	2	2	2	2	8	18
On-Budget	0	1	1	1	1	1	1	1	2	2	2	6	13
Off-Budget	0	*	*	*	*	*	*	1	1	1	1	2	5
Net Decrease in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	-6	-11	-11	-11	-10	-12	-13	-13	-15	-14	-50	-117
On-Budget	0	-6	-11	-11	-10	-10	-11	-12	-13	-14	-14	-48	-111
Off-Budget	0	*	-1	-1	-1	-1	-1	-1	-1	-1	-1	-2	-5
Increases or Decreases (-) in Spending Subject to Appropriation													
Estimated Authorization	0	-1	-1	-1	-1	-1	n.e.	n.e	n.e	n.e	n.e	-7	n.e
Estimated Outlays	0	-1	-1	-1	-1	-1	n.e.	n.e	n.e	n.e	n.e	-7	n.e

Components may not sum to totals because of rounding; n.e. = not estimated; * = between -$500,000 and $500,000.

a. Budget authority equals outlays.

b. Includes off-budget effects on the operating costs of the U.S. Postal Service.

The CBO staff contact for this estimate is Julia Christensen. The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.