CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

December 7, 2018

S. 2315
Over-the-Counter Drug Safety, Innovation, and Reform Act

As reported by the Senate Committee on Health, Education, Labor, and Pensions on May 14, 2018

SUMMARY

S. 2315 would change the oversight of the commercial marketing of over-the-counter (OTC) medicines by the Food and Drug Administration (FDA). The bill would authorize the collection and spending of fees through 2023 to cover the costs of expediting the FDA's administrative procedures for certain regulatory activities relating to OTC products. Such fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts.

Assuming appropriation actions consistent with the bill, CBO estimates that implementing S. 2315 would increase fee collections and related spending. Over the 2019-2023 period, spending would lag collections by $10 million.

S. 2315 also would grant two years of exclusive market protection for certain qualifying OTC drugs, thus delaying the entry of other versions of the same qualifying OTC product. Because Medicaid currently provides some coverage for OTC medicines, and such delays could affect the average net price paid by Medicaid, that provision could affect direct spending; therefore, pay-as-you go procedures apply. CBO estimates that the effect on Medicaid spending would be negligible over the 2019-2028 period. Enacting the bill would not affect revenues.

CBO estimates that enacting S. 2315 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

S. 2315 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring developers and manufacturers of OTC products to pay certain fees to the FDA. CBO estimates that the costs of the mandates would not exceed the annual threshold for private-sector mandates ($160 million in 2018, adjusted annually for inflation) in any year during that period.

The bill contains no intergovernmental mandates as defined in UMRA.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of S. 2315 is shown in the following table. The costs of the legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2019	2020	2021	2022	2023	2019-2023
INCREASES OR DECREASES (-) IN SPENDING SUBJECT TO APPROPRIATION						
Collections						
Estimated Authorization Level	-22	-22	-26	-35	-42	-147
Estimated Outlays	-22	-22	-26	-35	-42	-147
Spending						
Estimated Authorization Level	22	22	26	35	42	147
Estimated Outlays	3	19	30	44	41	137
Net Effect on FDA						
Estimated Authorization Level	0	0	0	0	0	0
Estimated Outlays	-19	-3	4	9	*	-10

Components may not sum to totals because of rounding.

* = less than $500,000.

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 2315 will be enacted early in 2019, that the full amounts estimated will be collected and appropriated for each year, and that outlays will follow historical patterns for the similar fee programs.

Spending Subject to Appropriation

S. 2315 would change the FDA's oversight of the commercial marketing of OTC medicines and authorize the collection and spending of fees through 2023 to cover the costs of expediting the FDA's administrative procedures for certain regulatory activities relating to OTC products. Under the bill, CBO estimates, the FDA would assess about $147 million in fees over the 2019-2023 period that could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. CBO expects that spending would lag behind collections. Assuming appropriation action consistent with the bill, CBO estimates that over the 2019-2023

period collections would total $147 million and spending would total $137 million. (CBO expects that remaining amounts would spend in years after 2023.)

Direct Spending

S. 2315 would authorize FDA to grant two years of exclusive market protection for certain qualifying OTC drugs, thus delaying the entry of other versions of the same qualifying OTC product. Medicaid currently provides some coverage for OTC medicines, but only if a medicine is the least costly alternative in its drug class. On the basis of stakeholder feedback, CBO expects that delaying the availability of additional OTC versions of a drug would not significantly affect the average net price paid by Medicaid. As a result, CBO estimates that enacting the exclusivity provision would have a negligible effect on the federal budget.

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 changes in outlays that are subject to those pay-as-you-go procedures would be negligible, CBO estimates.

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting S. 2315 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

MANDATES

S. 2315 would impose a private-sector mandate as defined in UMRA. The bill would require developers and manufacturers of OTC drugs to pay facility fees and fees to request a monograph order for an OTC drug to the FDA. CBO estimates that about $30 million would be collected annually, on average, and that the cost of the mandate would not exceed the annual threshold for private-sector mandates ($160 million in 2018, adjusted annually for inflation) in any year during that period.

The bill contains no intergovernmental mandates as defined in UMRA.

PREVIOUS CBO ESTIMATE

On June 6, 2018, CBO issued a cost estimate for H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, as ordered reported by the House Committee on Energy and Commerce on May 9, 2018. CBO's estimates for implementing the fee program authorized by the two bills are the same. H.R. 5333 would also require the Government Accountability Office (GAO) to study exclusive market protections for certain qualifying OTC drugs authorized by the bill; S. 2315 does not contain a similar provision. (CBO estimates that producing the report would cost GAO less than $500,000.)

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