S. 4348 would reauthorize the collection and spending of user fees by the Food and Drug Administration for activities related to the approval and marketing of prescription drugs and medical devices. The bill also would amend the Federal Food, Drug, and Cosmetic Act in part to change processes and procedures for regulating, manufacturing, and marketing certain prescription drugs, medical devices, and other products.

## Estimated Direct Spending and Revenue Effects of S. 4348, the Food and Drug Administration Safety and Landmark Advancements Act of 2022, as Reported by the Senate Committee on Health, Education, Labor, and Pensions on July 13, 2022

www.congress.gov/117/bills/s4348/BILLS-117s4348rs.pdf

| | | By Fiscal Year, Millions of Dollars | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2022-2027 | 2022-2032 |
| | | Increases or Decreases (-) in Direct Spending | | | | | | | | | | | | |
| Sec. 509 | Generic Drug Labeling Changes | | | | | | | | | | | | | |
| | Estimated Budget Authority | 0 | -1 | -3 | -3 | -4 | -4 | -5 | -5 | -6 | -6 | -6 | -15 | -43 |
| | Estimated Outlays | 0 | -1 | -3 | -3 | -4 | -4 | -5 | -5 | -6 | -6 | -6 | -15 | -43 |
| Sec. 511 | Ensuring Timely Access to Generics | | | | | | | | | | | | | |
| | Estimated Budget Authority | 0 | -10 | -15 | -16 | -20 | -21 | -24 | -23 | -25 | -26 | -27 | -82 | -207 |
| | Estimated Outlays | 0 | -10 | -15 | -16 | -20 | -21 | -24 | -23 | -25 | -26 | -27 | -82 | -207 |
| Sec. 512 | Increasing Transparency in Generic Drug Applications | | | | | | | | | | | | | |
| | Estimated Budget Authority | 0 | -12 | -29 | -35 | -41 | -43 | -48 | -44 | -51 | -54 | -57 | -160 | -414 |
| | Estimated Outlays | 0 | -12 | -29 | -35 | -41 | -43 | -48 | -44 | -51 | -54 | -57 | -160 | -414 |
| Sec. 515 | 180-Day Exclusivity Period | | | | | | | | | | | | | |
| | Estimated Budget Authority | 0 | 0 | 0 | -8 | -30 | -46 | -58 | -56 | -65 | -69 | -74 | -84 | -406 |
| | Estimated Outlays | 0 | 0 | 0 | -8 | -30 | -46 | -58 | -56 | -65 | -69 | -74 | -84 | -406 |
| Sec. 605 | Reauthorization of Provision Pertaining to Drugs Containing Single Enantiomers | | | | | | | | | | | | | |
| | Estimated Budget Authority | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 4 | 6 | 6 | 0 | 17 |
| | Estimated Outlays | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 4 | 6 | 6 | 0 | 17 |
| **Total Changes in Direct Spending** | | | | | | | | | | | | | | |
| | **Estimated Budget Authority** | **0** | **-23** | **-47** | **-62** | **-95** | **-114** | **-135** | **-127** | **-143** | **-149** | **-158** | **-341** | **-1,053** |
| | **Estimated Outlays** | **0** | **-23** | **-47** | **-62** | **-95** | **-114** | **-135** | **-127** | **-143** | **-149** | **-158** | **-341** | **-1,053** |

## Estimated Direct Spending and Revenue Effects of S. 4348, the Food and Drug Administration Safety and Landmark Advancements Act of 2022, as Reported by the Committee on Health, Education, Labor, and Pensions on July 13, 2022

www.congress.gov/117/bills/s4348/BILLS-117s4348rs.pdf

| | | By Fiscal Year, Millions of Dollars | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2022-2027 | 2022-2032 |
| | | **Increases or Decreases (-) in Revenues** | | | | | | | | | | | | |
| Sec. 509 | Generic Drug Labeling Changes | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 4 | 9 |
| | *On-Budget Revenues* | *0* | *0* | *1* | *1* | *1* | *1* | *1* | *1* | *1* | *1* | *1* | *4* | *9* |
| | *Off-Budget Revenues* | *0* | *0* | * | * | * | * | * | * | * | * | * | * | * |
| Sec. 511 | Ensuring Timely Access to Generics | 0 | 2 | 4 | 6 | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 26 | 64 |
| | *On-Budget Revenues* | *0* | *1* | *3* | *4* | *5* | *5* | *5* | *5* | *6* | *6* | *6* | *18* | *46* |
| | *Off-Budget Revenues* | *0* | *1* | *1* | *2* | *2* | *2* | *2* | *2* | *2* | *2* | *2* | *8* | *18* |
| Sec. 512 | Increasing Transparency in Generic Drug Applications | 0 | 0 | 9 | 13 | 14 | 15 | 15 | 15 | 16 | 17 | 18 | 51 | 132 |
| | *On-Budget Revenues* | *0* | *0* | *6* | *9* | *10* | *11* | *11* | *11* | *12* | *13* | *13* | *36* | *96* |
| | *Off-Budget Revenues* | *0* | *0* | *3* | *4* | *4* | *4* | *4* | *4* | *4* | *4* | *5* | *15* | *36* |
| Sec. 515 | 180-Day Exclusivity Period | 0 | 0 | 0 | 3 | 10 | 15 | 18 | 19 | 20 | 22 | 23 | 28 | 130 |
| | *On-Budget Revenues* | *0* | *0* | *0* | *2* | *7* | *11* | *13* | *14* | *15* | *16* | *17* | *20* | *95* |
| | *Off-Budget Revenues* | *0* | *0* | *0* | *1* | *3* | *4* | *5* | *5* | *5* | *6* | *6* | *8* | *35* |
| Sec. 605 | Reauthorization of Provision Pertaining to Drugs Containing Single Enantiomers | 0 | 0 | 0 | 0 | 0 | 0 | 0 | * | -1 | -1 | -1 | 0 | -3 |
| | *On-Budget Revenues* | *0* | *0* | *0* | *0* | *0* | *0* | *0* | * | *-1* | *-1* | *-1* | *0* | *-3* |
| | *Off-Budget Revenues* | *0* | *0* | *0* | *0* | *0* | *0* | *0* | * | * | * | * | * | * |
| **Total Changes in Revenues** | | **0** | **2** | **14** | **23** | **32** | **38** | **41** | **42** | **44** | **47** | **49** | **109** | **332** |
| | *On-Budget Revenues* | *0* | *1* | *10* | *16* | *23* | *28* | *30* | *31* | *33* | *35* | *36* | *78* | *243* |
| | *Off-Budget Revenues* | *0* | *1* | *4* | *7* | *9* | *10* | *11* | *11* | *11* | *12* | *13* | *31* | *89* |

## Estimated Direct Spending and Revenue Effects of S. 4348, the Food and Drug Administration Safety and Landmark Advancements Act of 2022, as Reported by the Committee on Health, Education, Labor, and Pensions on July 13, 2022

www.congress.gov/117/bills/s4348/BILLS-117s4348rs.pdf

| | By Fiscal Year, Millions of Dollars | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2022-2027 | 2022-2032 |
| | Net Decrease (-) in the Deficit From Changes in Direct Spending and Revenues | | | | | | | | | | | | |
| **Effect on the Deficit** | **0** | **-25** | **-61** | **-85** | **-127** | **-152** | **-176** | **-169** | **-187** | **-196** | **-207** | **-450** | **-1,385** |
| *On-Budget Deficit* | *0* | *-24* | *-57* | *-78* | *-118* | *-142* | *-165* | *-158* | *-176* | *-184* | *-194* | *-419* | *-1,296* |
| *Off-Budget Deficit* | *0* | *-1* | *-4* | *-7* | *-9* | *-10* | *-11* | *-11* | *-11* | *-12* | *-13* | *-31* | *-89* |

* = between -$500,000 and $500,000.

Staff Contacts: Ryan Greenfield, Ellen Werble

Sources: Congressional Budget Office; staff of the Joint Committee on Taxation.

Section 509 would authorize the Food and Drug Administration (FDA) to approve a marketing application for a generic drug whose label differs from that of the reference brand product when the reference product's label changes within 90 days of the date on which the generic application would otherwise have been eligible for approval. The sponsor of the generic drug would be required to update that drug's label within 60 days of approval. Based on conversations with stakeholders, CBO expects that the provision would accelerate the availability of lower-priced generic drugs because manufacturers would bring them to market earlier than under current law. Therefore, CBO anticipates, the provision would reduce the average prices for those drugs that are paid for by federal health programs.

Section 511 would allow the FDA to deny a citizen petition if the agency determines that the petition was submitted with the primary purpose of delaying the approval of an application or if the petition does not raise valid scientific or regulatory issues. The bill also would require a petition to be submitted within 60 days after the petitioner knew, or reasonably should have known, the information that forms the basis of the petition. CBO expects that the new timely-submission requirement and related changes to the dismissal procedures involving civil actions would further enhance the FDA's ability to expeditiously deny petitions that otherwise would have delayed the marketing approval of generic or biosimilar applications. Based on past cases involving petitions that potentially delayed drug-marketing approvals, CBO anticipates that the provision would accelerate the availability of lower-priced drugs and reduce the average prices for those drugs that are paid for by federal health programs.

Section 512 would authorize the FDA to disclose qualitative and quantitative information on the inactive ingredients of a reference brand drug in response to a request in a controlled correspondence from a generic drug manufacturer. Based on conversations with stakeholders, CBO expects that this provision would accelerate the availability of lower-priced generic drugs because manufacturers would bring them to market earlier than under current law. Therefore, CBO anticipates, the provision would reduce the average prices for those drugs that are paid for by federal health programs.

Section 515 would allow the FDA to approve a subsequent generic drug application, under certain conditions, if the first applicant that is eligible for 180 days of generic market exclusivity has not yet begun marketing. Based on conversations with stakeholders, CBO expects that the provision would accelerate the availability of lower-priced generic drugs because manufacturers would bring them to market earlier than under current law. Therefore, CBO anticipates, the provision would reduce the average prices for those drugs that are paid for by federal health programs.

**Estimated Direct Spending and Revenue Effects of S. 4348, the Food and Drug Administration Safety and Landmark Advancements Act of 2022, as Reported by the Committee on Health, Education, Labor, and Pensions on July 13, 2022**

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Section 605 would reauthorize through 2027 a provision that allows sponsors of drugs developed from a particular type of molecule called an enantiomer to elect five-year data exclusivity under certain circumstances; under current law, the maximum period of data exclusivity would revert to 3 years in 2023. (Data exclusivity begins when a drug is approved by the FDA. During that time, the agency does not accept applications for marketing approval for generic versions of the drug.) Based on historical data, CBO expects that extending market exclusivity for prescription drugs developed from enantiomers would, in some cases, delay the entry of lower-priced generic versions of those drugs.

Other provisions in S. 4348 would have insignificant effects on direct spending and revenues. The areas of significant uncertainty for this table include CBO's estimates of sales, market effects, and timing of introductions of new pharmaceutical products.

S. 4348 would authorize programs that would be funded through discretionary appropriations. CBO has not estimated the costs of implementing those programs.

S. 4348 would impose private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). Among other mandates, the bill would impose fees on developers and manufacturers of drugs, biological products, and devices; expand requirements for the application and approval of certain products; ban electrical stimulation devices; and impose significant new regulations on developers and manufacturers of cosmetics and in vitro clinical tests. CBO estimates the cost of the mandates would exceed the annual private-sector threshold established in UMRA ($184 million in 2022, adjusted annually for inflation).

The bill also would impose an intergovernmental mandate by preempting state and local laws that conflict with the new requirements imposed on developers and manufacturers of cosmetics and in vitro clinical tests. CBO estimates that the cost of the mandate would not exceed the annual intergovernmental threshold ($92 million in 2022, adjusted annually for inflation).