CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

September 18, 2018

S. 974
Creating and Restoring Equal Access to Equivalent Samples Act of 2018

As reported by the Senate Committee on the Judiciary on June 21, 2018

SUMMARY

S. 974 would create a private right of action that allows developers of generic drugs or biosimilar products to bring civil lawsuits against manufacturers of brand-name drugs if sufficient quantities of reference samples of a branded product are not made available for premarket testing. (To obtain marketing approval of their products from the Food and Drug Administration (FDA), developers of generic or biosimilar drugs currently must purchase reference samples to conduct the testing required to demonstrate that their drugs meet the FDA's approval criteria.)

The bill also would remove a statutory requirement that manufacturers of generic or biosimilar versions of certain drugs that carry a significant risk of serious side effects use the same risk management system as the brand-name reference drug to ensure safe use of the product. Instead, it would provide the FDA with more discretion to allow those manufacturers to use comparable safety systems on a case-by-case basis. CBO expects that the bill's provisions would allow generic drugs (including biosimilar versions of biologics) to enter the market earlier, on average, than they would under current law. Because of the earlier entry of lower-priced generic drugs, CBO estimates, enacting the legislation would reduce federal spending on prescription drugs.

CBO and the staff of the Joint Committee on Taxation (JCT) estimate that implementing S. 974 would:

- Reduce direct spending by $3.3 billion over the 2019-2028 period;
- Increase revenues by $0.6 billion over the 2019-2028 period;
- Reduce unified budget deficits by $3.9 billion over the 2019-2028 period; and
- Reduce spending subject to appropriation, on net, by $87 million over the 2019-2023 period, assuming appropriation actions consistent with those estimated reductions in costs.

Because enacting S. 974 would affect direct spending and revenues, pay-as-you-go procedures apply.

CBO estimates that enacting S. 974 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2029.

S. 974 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated mandatory effects of S. 974 are shown in Table 1. The costs of the legislation fall within budget function 550 (health) and 570 (Medicare).

TABLE 1. SUMMARY OF MANDATORY EFFECTS OF S. 974

	By Fiscal Year, in Millions of Dollars												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019-2023	2019-2028
DECREASES (-) IN DIRECT SPENDING													
Estimated Budget Authority	0	0	-43	-155	-317	-381	-391	-446	-476	-510	-581	-895	-3,299
Estimated Outlays	0	0	-43	-155	-317	-381	-391	-446	-476	-510	-581	-895	-3,299
INCREASES IN REVENUES													
Estimated Revenues	0	0	8	28	52	66	71	76	86	92	97	155	577
On-Budget	0	0	6	20	38	47	51	55	63	69	73	111	422
Off-Budget	0	0	2	8	15	19	20	21	22	23	25	44	155
NET DECREASE (-) IN THE DEFICIT FROM INCREASES OR DECREASES IN DIRECT SPENDING AND REVENUES													
Effect on the Deficit	0	0	-51	-183	-369	-447	-462	-521	-562	-602	-678	-1,050	-3,876
On-Budget	0	0	-48	-175	-354	-428	-442	-500	-539	-579	-654	-1,006	-3,721
Off-Budget	0	0	-2	-8	-15	-19	-20	-21	-22	-23	-25	-44	-155

Components may not sum to totals because of rounding. Effects on discretionary spending can be found in Table 2.

BASIS OF ESTIMATE

CBO estimates that enacting S. 974 would, on average, accelerate the availability of lower-priced drugs and reduce costs for public and private purchasers of prescription drugs. Because the federal government funds programs that pay for prescription drugs

and that provide subsidies for the purchase of health insurance, those effects would reduce direct spending and increase revenues. For similar reasons, CBO estimates that the bill would reduce spending subject to appropriation, assuming appropriation actions consistent with the legislation.

Direct Spending

Accelerating the market entry of lower-priced drugs would reduce spending by federal health programs that either purchase drugs or provide insurance that includes prescription benefits. CBO estimates that if the bill is enacted direct spending for mandatory health programs—including Medicare, Medicaid, subsidies for coverage obtained through the marketplaces established by the Affordable Care Act, payments for annuitant premiums under the Federal Employees Health Benefits (FEHB) program, and the Defense Department's TRICARE for Life program—would fall by $3.3 billion over the 2020-2028 period.

Private Right of Action Against Sponsors of Brand-Name Drugs for Failure to Provide Sufficient Quantities of a Drug for Premarket Testing. S. 974 would create a private right of action to allow developers of generic drugs or biosimilar products to bring civil suits against manufacturers of brand-name drugs if sufficient amounts of reference samples of the branded product were not available to purchase for premarket testing. Under current law, before submitting an application for FDA approval, manufacturers of generic and biosimilar products must complete tests to show that their products meet all approval criteria. Although the tests require manufacturers to use reference samples of brand-name drugs, brand-name manufacturers have little incentive to sell their samples to competitors and, as a result, the market entry of lower-priced generic or biosimilar products can be delayed.

S. 974 would create a legal pathway in federal court to adjudicate disputes over the sale of samples to generic drug manufacturers. It also would establish a statutory process to allow generic product developers who wished to obtain reference samples for certain drugs that carry a significant risk of serious side effects to ask the FDA to supply written authorization stating that providing such reference samples would not violate the requirements of a risk management plan approved by the FDA for the brand-name product. (That new protocol would replace the agency's current process.)

Under the bill, if the developer of the generic product sued and prevailed in court, that entity could receive immediate injunctive relief and an award of reasonable attorney fees and other costs of the civil action. In addition, if the court found that a brand-name drug manufacturer delayed providing sufficient quantities of the reference product without a legitimate business justification to do so, or failed to comply with a court order to provide the product on commercially reasonable terms, the court would be directed to award the

generic drug sponsor an amount that could equal but not exceed the revenues earned by the brand-name drug manufacturer during the period of delay.

S. 974 stipulates that penalties should be large enough to deter brand-name drug manufacturers from failing to provide sufficient samples for testing, so CBO expects that any penalty assessed at the court's discretion could be very high to deter such activity in the future. The potential for large penalties also would provide an incentive for generic drug manufacturers to aggressively pursue federal litigation to a final decision if they could not gain access to sufficient samples for testing. CBO anticipates that brand-name drug manufacturers without a strong business justification for delaying the sale of the reference products would change their business practices in the face of the possibility of having to pay substantial penalties.

Because the penalties would be based on revenues earned during a period of delayed market entry, the incentive for the brand-name manufacturer to maximize profits by extending that delay would be reduced. As a result, CBO expects, the sale of sufficient quantities of reference products would occur more often as a private business transaction (and in a more timely fashion, relative to current law), reducing the need to bring civil claims in federal court under the private right of action established under the bill.

Because CBO expects that the legislation would result in earlier access to testing samples for sponsors of generic drugs, we anticipate that the bill would allow them to submit their marketing applications to the FDA earlier relative to current law. As a result, over the next 10 years, establishing a private right of action would promote the timely entry of lower-priced generic products onto the market and thereby reduce the average price of certain prescription drugs. CBO estimates that enacting a private right of action would reduce mandatory spending for federal health programs by $3.1 billion over the 2020-2028 period. (Detail on the basis of the estimate can be found in the section below titled: Estimated Effects of S. 974 on Spending for Prescription Drugs.)

Changes to the FDA's Requirement for a Single, Shared System. S. 974 would change the current law requirement that manufacturers of a generic drug use the same risk management system approved by the FDA for the brand-name reference drug. Instead, the bill would provide the FDA more discretion to allow manufacturers of generic products to use a comparable safety system. Under current law, the FDA can require the sponsors of certain brand-name drugs that cause serious side effects to develop a risk management strategy to ensure that the drug's benefits outweigh its risks. Such a plan details ways to ensure the product's safe use—for example, by requiring specific language in package inserts or establishing a limited-distribution system. Current law also requires that manufacturers of generic drugs use the reference drug's risk management system unless the FDA waives the requirement for a single, shared system.

Although the FDA currently can waive the requirement and allow separate but comparable systems, that authority requires the agency to make several determinations before issuing a waiver. Negotiations between brand-name and generic drug manufacturers to share systems can be lengthy and delay the market entry of generic drugs. CBO expects that the time frame for approving risk management plans of sponsors of generic drugs would be shorter under S. 974 than under the current procedures, which require the FDA to consider a complex set of criteria in evaluating a sponsor's waiver request. As a result, the streamlined review process under the bill would lead to earlier market entry of some generic drugs than would occur under current law. CBO estimates that enacting those changes to the requirement for a single, shared system would reduce direct spending for mandatory health programs by $0.2 billion over the 2020-2028 period.

Estimated Effects of S. 974 on Spending for Prescription Drugs. To estimate the bill's effects on total expenditures for prescription drugs, CBO estimated the share of national spending for prescription drugs that might both first experience competition from generic or biosimilar versions over the next 10 years and face safety requirements or other restrictions that lead to barriers for competing manufacturers to obtain reference samples. On the basis of historical information, CBO expects that roughly half of drug spending potentially affected by S. 974 would be for drugs facing additional safety requirements; the remainder would be for drugs for which the brand-name manufacturer voluntarily restricted access to reference samples.

CBO estimates that the value of the spending on brand-name drugs affected through 2028 would be about $20 billion, or about 0.4 percent of the total U.S. prescription drug market over the 2020-2028 period. That estimate incorporates the probability that the expected market entry date for certain generic or biosimilar drugs would not be affected by the legislation because patents and other market exclusivities would otherwise prevent their entry over that period. For products affected by the legislation, CBO expects that the bill would accelerate the entry of generic or biosimilar products by one to two years, on average. When generic drugs enter the market, the health programs that cover drugs realize savings as patients shift their use from brand-name to generic versions. CBO estimates that the accelerated availability of lower-priced versions of the drug would reduce total spending for a given drug by about 50 percent during the period of earlier access to the generic version.

To project the effects of S. 974 on federal spending by health programs that pay for prescription drugs, CBO allocated the expected rate of savings generated nationally to each program, taking into account the differences in prices paid by federal programs and by private payers for brand-name prescription drugs. In total, CBO estimates that enacting the bill would reduce direct spending by $3.3 billion over the 2020-2028 period.

Revenues

CBO and JCT estimate that enacting S. 974 would increase federal revenues by $0.6 billion over the 2020-2028 period. That estimate accounts for effects on the subsidies for insurance purchased through the marketplaces and effects that arise from lower premiums for employment-based health insurance. Because the bill would reduce the average cost for prescription drugs, CBO estimates that premiums for some private health insurance plans would decrease. Lower premiums would both reduce federal subsidies for insurance purchased through the marketplaces and shift compensation from tax-favored health insurance to taxable wages. That change would increase federal revenues from income and payroll taxes. Social Security payroll taxes, which are off-budget, would account for about 25 percent of the total change in revenues.

Spending Subject to Appropriation

CBO estimates that implementing administrative requirements at the FDA under S. 974 would increase spending subject to appropriation but that lower drug prices generated under the bill also would reduce costs for discretionary health programs and cause spending subject to appropriation to decline, assuming that appropriation actions reflected similar declines. In total, CBO estimates, implementing S. 974 would reduce spending subject to appropriation by $87 million, on net, over the 2019-2023 period (see Table 2).

TABLE 2. CHANGES IN SPENDING SUBJECT TO APPROPRIATION IN S. 974

	By Fiscal Year, in Millions of Dollars						
	2018	2019	2020	2021	2022	2023	2019-2023
INCREASES OR DECREASES (-) IN SPENDING SUBJECT TO APPROPRIATION							
Administrative Costs of the Food and Drug Administration							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
Spending by Federal Health Programs for Prescription Drugs							
Estimated Authorization Level	0	0	-4	-14	-34	-40	-91
Estimated Outlays	0	0	-4	-14	-34	-40	-91
Total							
Estimated Authorization Level	0	1	-3	-13	-33	-39	-87
Estimated Outlays	0	1	-3	-13	-33	-39	-87

Components may not sum to totals because of rounding.

Administrative Costs of the Food and Drug Administration. S. 974 would establish a statutory process by which the FDA provides written authorization to product developers who wish to obtain samples of certain reference products. Currently, developers can receive the FDA's written authorization to help obtain such samples in certain cases. Because CBO expects that this provision would be likely to increase the number of requests, CBO estimates that the FDA would require the equivalent of three full-time employees to cover the increased workload at an average annual cost of roughly $300,000 per employee. Using information from the agency, CBO estimates that the provision would cost about $4 million to implement over the 2019-2023 period, assuming appropriation of the necessary amounts.

Spending by Federal Health Programs for Prescription Drugs. Accelerating the entry of lower-priced drugs into the market would reduce the costs of certain discretionary health programs, including programs in the Veterans Health Administration, the Department of Defense, and the Indian Health Service. S. 974 also would reduce payments by federal agencies for health insurance premiums for FEHB program enrollees. CBO estimates that implementing S. 974 would reduce such discretionary spending by about $91 million over the 2019-2023 period, assuming appropriation actions that reflect the estimated reduction in costs.

Uncertainty

CBO endeavors to develop estimates that are in the middle of the distribution of potential budgetary outcomes. In this case, the overall uncertainty in that estimate is driven primarily by uncertainty about the quantity and pace that new pharmaceutical products are introduced to the market and the number of affected products and manufacturers.

In addition, S. 974 would permit developers of generic drugs or biosimilar products to bring civil action against manufacturers of brand-name products in certain circumstances. 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.

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 procedures are shown in Table 3. Only on-budget changes to outlays or revenues are subject to pay-as-you-go procedures.

TABLE 3. CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR S. 974, THE CREATING AND RESTORING EQUAL ACCESS TO EQUIVALENT SAMPLES ACT OF 2018, AS REPORTED BY THE SENATE COMMITTEE ON THE JUDICIARY ON JUNE 21, 2018

	By Fiscal Year, in Millions of Dollars												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2018-2023	2018-2028
NET DECREASE (-) IN THE ON-BUDGET DEFICIT													
Statutory Pay-As-You-Go Effect	0	0	-48	-175	-354	-428	-442	-500	-539	-579	-654	-1,006	-3,721
Memorandum:													
Changes in Outlays	0	0	-43	-155	-317	-381	-391	-446	-476	-510	-581	-895	-3,299
Changes in Revenues	0	0	6	20	38	47	51	55	63	69	73	111	422

Components may not sum to totals because of rounding.

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting S. 974 would not increase net direct spending in any of the four consecutive 10-year periods beginning in 2029.

MANDATES

S. 974 contains no intergovernmental or private-sector mandates as defined in UMRA. Because the bill would accelerate the entry of generic drug and biosimilar products onto the market, sales of brand-name drugs and biological products are likely to fall. Any effects on manufacturers of those products that result from a change in market competition would not be mandates.

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