116TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPT. 116–55
Part 3

CREATING AND RESTORING EQUAL ACCESS TO EQUIVALENT SAMPLES ACT OF 2019

MAY 16, 2019.—Ordered to be printed

Mr. NADLER, from the Committee on the Judiciary, submitted the following

SUPPLEMENTAL REPORT

[To accompany H.R. 965]

CORRECTION—CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

Pursuant to clause 3(a)(2) of rule XIII of the Rules of the House of Representatives for the 116th Congress, the Committee on the Judiciary is filing this supplemental report to correct an error in the report to accompany H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (H. Rept. 116-55, Part 2).

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 8, 2019.

Hon. JERROLD NADLER,
Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 965, the CREATES Act of 2019.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

KEITH HALL,
Director.

Enclosure

cc: Honorable Doug Collins
Ranking Member

H.R. 965, the CREATES Act of 2019
As ordered reported by the House Committee on the Judiciary on April 30, 2019

Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-901	-3,299
Revenues	0	165	609
Deficit Effect	0	-1,066	-3,908
Spending Subject to Appropriation (Outlays)	0	-118	n.e.

		Mandate Effects	
Pay-as-you-go procedures apply?	Yes		
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. 965 would create a private right of action that would allow 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 and subsidies for health insurance. In total, CBO estimates that enacting H.R. 965 would decrease the deficit by $3.9 billion over the 2019–2029 period. That amount includes a $3.3 billion reduction in direct spending and a $0.6 billion increase in revenues.

CBO also estimates that implementing H.R. 965 would decrease spending subject to appropriation by $118 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 estimated budgetary effect of H.R. 965 is shown in Table 1. The effects of the legislation fall primarily within budget functions 550 (health), and 570 (Medicare).

TABLE 1.—ESTIMATED BUDGETARY EFFECTS OF H.R. 965

	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	0	−47	−179	−310	−365	−424	−450	−478	−542	−503	−901	−3,299
On-budget	0	0	−47	−178	−308	−363	−423	−448	−476	−540	−501	−897	−3,284
Off-budget[b]	0	0	*	−1	−2	−2	−2	−2	−2	−2	−2	−5	−15
Increases in Revenues													
Estimated Revenues	0	0	9	31	56	70	76	85	91	95	99	165	609
On-budget	0	0	6	22	40	50	55	63	68	71	74	119	448
Off-budget	0	0	2	9	16	20	21	22	23	24	25	46	161
Net Decrease (−) in the Deficit From Changes in Direct Spending and Revenues													
Effect on the Deficit	0	0	−55	−210	−366	−435	−500	−535	−568	−637	−602	−1,066	−3,908
On-budget	0	0	−53	−200	−348	−414	−477	−511	−544	−611	−575	−1,015	−3,732
Off-budget	0	0	−3	−9	−17	−21	−23	−24	−25	−26	−27	−51	−175
Increases or Decreases (−) in Spending Subject to Appropriation													
Estimated Authorization	0	1	−7	−23	−41	−47	n.e.	n.e.	n.e.	n.e.	n.e.	−118	n.e.
Estimated Outlays	0	1	−7	−23	−41	−47	n.e.	n.e.	n.e.	n.e.	n.e.	−118	n.e.

Components may not sum to totals because of rounding; n.e. = not estimated; * = between −$500,000 and zero.
a. Budget authority equals outlays.
b. Includes off-budget effects on the operating costs of the U.S. Postal Service.

Previous CBO Estimate

On April25, 2019, CBO transmitted a cost estimate for H.R. 965, the CREATES Act of 2019, as ordered reported by the House Committee on Energy and Commerce on April 3, 2019 (https://www.cbo.gov/publication/55181). While there are differences in the language, CBO's estimates of the budgetary effects for the two versions are the same.

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

○