For an updated estimate of the bill's budgetary effects through fiscal year 2020, relative to CBO's March 2010 baseline and reflecting the enactment of health care legislation, see the table produced by the agency on June 16, 2010.

CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

January 28, 2010

S. 369
Preserve Access to Affordable Generics Act

As reported by the Senate Committee on the Judiciary on October 15, 2009

SUMMARY

S. 369 would impose significant restrictions on certain agreements to settle a claim of patent infringement between manufacturers of brand-name and generic drugs relating to the sale of a drug product. CBO anticipates that enacting S. 369 would accelerate, on average, the availability of lower-priced generic drugs affected by such agreements and generate savings to public and private purchasers of prescription drugs.

CBO estimates that implementing S. 369 would:

- Reduce direct spending by $0.7 billion over the 2010-2014 period and by $1.8 billion over the 2010-2019 period.
- Increase federal revenues by $0.1 billion over the 2010-2014 period and by $0.2 billion over the 2010-2019 period. (Social Security payroll taxes, which are off-budget, would account for almost 30 percent of those totals.)
- Reduce spending subject to appropriation by $0.1 billion over the 2010-2014 period and by $0.2 billion over the 2010-2019 period, assuming that appropriation action reflects the estimated reductions in costs.

Considering both the direct spending and revenue effects, CBO estimates that enacting S. 369 would reduce unified budget deficits by approximately $0.8 billion over the 2010-2014 period and by roughly $2.0 billion over the 2010-2019 period.

Pursuant to section 311 of S. Con. Res. 70 (110th Congress), CBO estimates that S. 369 would not cause a net increase in deficits in excess of $5 billion in any of the four 10-year periods beginning after fiscal year 2019.

S. 369 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

S. 369 would impose a mandate on the private sector by limiting agreements between brand-name and generic drug manufacturers to settle a claim of patent infringement. CBO estimates that the aggregate direct cost of complying with this mandate would exceed the threshold established by UMRA for private-sector mandates ($141 million in 2010, adjusted annually for inflation) in each year, beginning with 2010.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 369 is shown in the following table. The costs of this legislation fall primarily within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare).

CBO expects that enacting S. 369 would accelerate, on average, the availability of generic drugs that are the subject of specific types of agreements to settle a claim of patent infringement between manufacturers of brand-name and generic drugs. The legislation would affect settlement agreements entered into after November 15, 2009, that involve certain kinds of compensation flowing from the manufacturer of a brand-name drug to the manufacturer of the generic version of the drug. Earlier entry of lower-priced generic drugs would reduce the average price of prescription drugs over the next 10 years. CBO expects that lower drug prices would reduce the costs of federal programs that purchase prescription drugs or provide health insurance that covers prescription drugs. CBO estimates that savings to mandatory health programs—such as Medicare and Medicaid and for health insurance provided to certain retirees by the Federal Employees Health Benefits (FEHB) program and TRICARE for Life program operated by the Department of Defense—would total $0.7 billion over the 2010-2014 period and $1.8 billion over the 2010-2019 period.

Lower prices would also generate savings to federal health programs subject to appropriation—such as health insurance provided to federal employees through the FEHB program, and the health programs of the Departments of Veterans Affairs and Defense—totaling $0.1 billion over the 2010-2014 period and $0.2 billion over the 2010-2019 period. CBO estimates that the Federal Trade Commission (FTC) would also realize discretionary savings because of lower administrative expenses for the agency under the bill of $7 million over the 2010-2019 period.

	By Fiscal Year, in Millions of Dollars											
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010-2014	2010-2019
CHANGES IN DIRECT SPENDING												
Estimated Budget Authority	-30	-170	-160	-170	-140	-120	-110	-220	-290	-340	-670	-1,750
Estimated Outlays	-30	-170	-160	-170	-140	-120	-110	-220	-290	-340	-670	-1,750
CHANGES IN REVENUES												
Effect from Health Insurance Premiums												
On-budget	5	10	10	10	10	10	10	15	20	20	45	120
Off-budget	3	5	5	5	5	5	5	5	10	10	23	58
Subtotal	8	15	15	15	15	15	15	20	30	30	68	178
Collection of Civil Penalties	0	0	2	5	5	5	5	5	4	4	12	35
Total Changes in Revenues												
On-budget	5	10	12	15	15	15	15	20	24	24	57	155
Off-budget	3	5	5	5	5	5	5	5	10	10	23	58
Total Changes	8	15	17	20	20	20	20	25	34	34	80	213
NET IMPACT ON THE DEFICIT FROM CHANGES IN DIRECT SPENDING AND REVENUES												
Net Change in the Deficit[a]												
On-budget	-35	-180	-172	-185	-155	-135	-125	-240	-314	-364	-727	-1,905
Off-budget	-3	-5	-5	-5	-5	- 5	-5	-5	-10	-10	-23	-58
Total Changes	-38	-185	-177	-190	-160	-140	-130	-245	-324	-374	-750	-1,963
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
Federal Health Programs												
Estimated Authorization Level	-5	-20	-25	-20	-20	-15	-10	-25	-35	-35	-90	-210
Estimated Outlays	-5	-20	-25	-20	-20	-15	-10	-25	-35	-35	-90	-210
Federal Trade Commission												
Estimated Authorization Level	*	*	*	-1	-1	-1	-1	-1	-1	-1	-2	-7
Estimated Outlays	*	*	*	-1	-1	-1	-1	-1	-1	-1	-2	-7
Total Changes												
Estimated Authorization Level	-5	-20	-25	-21	-21	-16	-11	-26	-36	-36	-92	-217
Estimated Outlays	-5	-20	-25	-21	-21	-16	-11	-26	-36	-36	-92	-217

* = between 0 and -$500,000.

a. Negative numbers indicate a reduction in budget deficits.

S. 369 would affect revenues in two ways. First, the bill would increase governmental receipts (i.e., revenues) because it would create new civil penalties for parties that violate the bill's requirements. Secondly, the bill would also affect revenues because CBO expects that lower prices for prescription drugs would reduce premiums for private health insurance and we assume that part of the savings from lower health insurance costs would be passed on to workers as increases in taxable compensation. Taken together, CBO estimates that the bill would increase federal revenues by $0.1 billion over the 2010-2014 period and by $0.2 billion over the 2010-2019 period.

BASIS OF ESTIMATE

S. 369 would impose significant restrictions on settlement agreements to resolve patent litigation between manufacturers of brand-name and generic drugs relating to the sale of a drug product. Under current law, such settlement agreements must be reported to the FTC. The FTC may challenge those agreements in court by alleging that they constitute an illegal restraint of trade.

S. 369 would limit agreements to settle a claim of patent infringement where the manufacturer of the generic version of the drug receives anything of value from the manufacturer of the brand name drug and the generic drug manufacturer agrees to limit or forego research, development, manufacturing, marketing, or sale of the generic drug for any period of time. The bill would allow the FTC to initiate an enforcement proceeding where such settlement agreements between drug companies would be presumed anti-competitive and unlawful; they would only be allowed if the parties can demonstrate by clear and convincing evidence that the competitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

The bill, however, would permit a brand manufacturer to grant certain types of consideration to the manufacturer of the generic version of the drug under settlement agreements. Such exemptions include the right to market the generic drug before the expiration of patents or statutory exclusivities that aim to prevent such marketing. The legislation also would allow the FTC to establish additional exemptions through rulemaking procedures.

S. 369 also would establish significant penalties to deter parties from entering into certain settlement agreements. Such penalties include the assessment of civil penalties and the forfeiture by a violator of any rights to the award of 180 days of market exclusivity to the generic drug company granted such exclusivity by the Food and Drug Administration (FDA) for meeting certain statutory requirements. The new restrictions under S. 369 would apply to all agreements entered into after November 15, 2009. (Provisions relating

to civil penalties, however, only apply to agreements entered into after the date of enactment.) For the estimate, CBO assumes that S. 369 will be enacted in early 2010.

Based on discussions with drug industry experts, CBO expects that limiting the compensation of manufacturers of generic drugs within settlement agreements between drug companies in the manner specified by S. 369 would lead to the earlier entry of some generic drugs. Since profits of manufacturers of brand-name drugs are so high relative to those of generic drug manufacturers, CBO believes that there is an incentive for brand manufacturers to compensate generic manufacturers for delaying the availability of the generic drug within such agreements. If the generic company that is party to such an agreement is eligible for 180 days of marketing exclusivity, plans to enter the market by competing generic manufacturers could also be delayed.

Under the restricted terms of compensation allowed under S. 369, we anticipate that the expected date of market entry for generic drugs affected by such agreements, on average, would be earlier regardless of whether that date is ultimately determined by a court ruling (because the parties decide to litigate instead of settling with an agreement subject to those new terms) or by a different settlement agreement negotiated between the parties.

Direct Spending

Through imposing significant restrictions on certain types of compensation in agreements to settle a claim of patent infringement between manufacturers of brand-name and generic drugs, enactment of S. 369 would accelerate the availability of lower-priced generic drugs. CBO estimates that change would reduce federal direct spending for mandatory health programs such as Medicare, Medicaid, payments for annuitant premiums under the FEHB program, and the Defense Department's TRICARE for Life program by $0.7 billion over the 2010-2014 period and by $1.8 billion over the 2010-2019 period.

To estimate the savings from earlier entry of generics, CBO focused on the share of national spending for prescription drugs that might both face competition by generic products over the next 10 years and involve settlement agreements of patent litigation with terms of compensation limited by the bill. We assumed that those products make up roughly one-quarter of the current market that may face competition by generic drugs. (CBO estimates that the value of the total drug market in the United States that may experience generic competition through 2019 is greater than $100 billion.) Based on information from FTC, CBO assumes that S. 369 would accelerate the entry of generic drugs affected by the bill by roughly 17 months, on average. During that period, CBO expects that the availability of lower-priced generic drugs would reduce total spending for the drug by roughly one-half. After accounting for the fact that S. 369 would only restrict settlement agreements entered into after November 15, 2009, CBO estimates that

earlier entry of generic drugs affected by the bill would reduce total drug expenditures in the United States by roughly $8 billion over the 2010-2019 period.

A settlement agreement with compensation flowing from the brand manufacturer to the generic manufacturer is just one of several possible outcomes to patent litigation. Limiting such settlement agreements would cause the expected rewards from challenging a patent to decline, on average. CBO expects that such a decline in expected returns would lead to fewer challenges of patents. In some instances, fewer generic challengers would lead to a higher average price following generic entry. CBO estimates that such price increases would increase total drug spending in the United States by roughly $2 billion over the 2010-2019 period. On net, CBO estimates that S. 369 would reduce total expenditures on prescription drugs in the United States by about $6 billion over the 10-year period.

To estimate the net effect of the bill on federal spending by health programs that pay for prescription drugs, CBO applied the expected rate of savings generated nationally to each program. (We also took into account that prices paid by federal programs are generally lower than prices paid by private payers for brand-name prescription drugs.) CBO estimates that enacting S. 369 would reduce direct spending for federal health programs by $0.7 billion over the 2010-2014 period and by $1.8 billion over the 2010-2019 period.

Revenues

CBO estimates that enacting S. 369 would increase federal revenues by $0.1 billion over the 2010-2014 period and by $0.2 billion over the 2010-2019 period. That estimate reflects two effects:

- Higher federal tax revenues resulting from employers passing lower costs for employer-sponsored health insurance to workers as increases in taxable compensation; and

- Collection of civil penalties associated with violations of new requirements imposed by the bill that would be recorded as federal revenues.

Health Insurance Premiums. As explained above, CBO expects that enacting S. 369 would reduce the average cost for prescription drugs. That change would lower costs for private health insurance plans. CBO anticipates that the reduction in costs for private health insurance plans would result in lower insurance premiums, thus reducing the amount spent by employers for tax-favored health insurance and increasing the amount spent on taxable wages. That wage effect would increase federal revenues from income taxes and payroll taxes by an estimated $0.1 billion over the 2010-2014 period and

$0.2 billion over the 2010-2019 period. Social Security payroll taxes, which are off-budget, would account for about 30 percent of those totals.

Collection of Civil Penalties. Under the bill, the FTC would have the authority to assess civil penalties on entities that enter into a settlement agreement that is subsequently ruled anti-competitive. The magnitude of those penalties would be tied to the value received by the parties to the agreement. CBO assumes that cases for which penalties would be assessed would take two or more years to resolve, thus we anticipate that the collection of penalties would start in 2012. CBO assumes that some firms would initially test the evidentiary standards for lawful agreements, and as those standards become clearer, fewer agreements would trigger penalties. Based on our estimates of profits garnered by firms who enter such agreements, CBO estimates that the bill would increase collections of civil penalties by about $35 million over the 2012-2019 period.

Spending Subject to Appropriation

CBO estimates that implementing S. 369 would reduce spending subject to appropriation by $0.1 billion over the 2010-2014 period and by $0.2 billion over the 2010-2019 period.

Spending by Federal Health Programs for Prescription Drugs. Accelerating the entry of the lower-priced generic drugs would reduce the costs to administer certain discretionary health programs, including those of the Veterans Health Administration, the Indian Health Service, and the Department of Defense. It also would lower payments by federal agencies for health insurance premiums for employees enrolled in the FEHB program. CBO estimates that implementing S. 369 would reduce discretionary spending by those programs by about $0.1 billion over the 2010-2014 period and by $0.2 billion over the 2010-2019 period, assuming that appropriation actions reflect the estimated reductions in costs.

Administrative Costs of the Federal Trade Commission. Based on information from the FTC, CBO expects that the agency's rulemaking and enforcement activities relating to settlement agreements between drug companies would decrease over time as the number of settlements requiring enforcement activities declines. CBO estimates that any resulting cost reductions would be insignificant for the first three years after enactment of S. 369; thereafter, CBO estimates the agency's costs would be reduced by about $1 million per year. Assuming that appropriation actions reflect these reductions, CBO estimates that discretionary spending would fall by about $2 million over the 2010-2014 period and by $7 million over the 2010-2019 period.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 369 contains no intergovernmental mandates as defined in UMRA. CBO estimates that enactment of this bill would result in a decline in state Medicaid spending of less than $50 million over the 2010-2014 period.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 369 would impose a mandate on brand-name and generic drug manufacturers by limiting agreements to settle a claim of patent infringement if, in those agreements, the generic manufacturer receives anything of value and agrees to limit or forgo research, development, manufacturing, marketing, or sale of the generic drug for any period of time. Such agreements would be presumed illegal unless drug manufacturers present clear and convincing evidence that the competitive benefits of the agreement outweigh the anticompetitive effects.

CBO anticipates that limiting such agreements would result in earlier generic entry into the market and, as a result of lower drug prices, decreased profits for drug manufacturers. Under UMRA, the cost of this mandate to drug manufacturers would be the forgone profit, which CBO estimates to be about $350 million in 2010 and $2.4 billion over the 2010-2014 period. Thus, the costs of the mandate would significantly exceed the threshold established by UMRA for private-sector mandates ($141 million in 2010, adjusted annually for inflation).

PREVIOUS CBO ESTIMATE

On November 20, 2009, CBO transmitted a cost estimate for H.R. 3962, the Affordable Health Care for America Act, as passed by the House of Representatives on November 7, 2009. H.R. 3962 also contains a provision that would impose restrictions on certain settlement agreements between manufacturers of brand-name and generic drugs. (That provision can be found in section 2573 of the bill.)

Differences in the estimated costs of the provision in H.R. 3962 and S. 369 reflect differences in the legislation. A key difference in the proposals is that the provision in H.R. 3962 would not allow the parties the opportunity to demonstrate that the competitive benefits of the settlement agreement outweigh the anticompetitive effects. CBO's estimate for the provision in H.R. 3962 also reflects interactions with other policies in the bill (such as the expansion of health insurance coverage and other drug policies.)

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