CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

November 7, 2011

S. 27
Preserve Access to Affordable Generics Act

As reported by the Senate Committee on the Judiciary on July 22, 2011

SUMMARY

S. 27 would impose significant restrictions on certain agreements, relating to the sale of a drug product, used to settle a claim of patent infringement between manufacturers of brand-name and generic drugs. CBO anticipates that enacting S. 27 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 and the staff of the Joint Committee on Taxation (JCT) estimate that implementing S. 27 would:

- Reduce direct spending by $1.1 billion over the 2012-2016 period and by $4.0 billion over the 2012-2021 period.

- Increase federal revenues by $0.2 billion over the 2012-2016 period and by $0.8 billion over the 2012-2021 period. (Social Security payroll taxes, which are off-budget, would account for almost 25 percent of those totals.)

- Reduce spending subject to appropriation by $0.1 billion over the 2012-2016 period and by $0.4 billion over the 2012-2021 period, assuming that appropriation actions reflect the estimated reductions in costs.

Considering both the direct spending and revenue effects, we estimate that enacting S. 27 would reduce unified budget deficits by approximately $1.4 billion over the 2012-2016 period and by nearly $4.8 billion over the 2012-2021 period.

Pay-as-you-go procedures apply because enacting the legislation would affect direct spending and revenues.

S. 27 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

S. 27 would impose a private-sector mandate 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 2011, adjusted annually for inflation) in each year, beginning with 2012.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

CBO expects that 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 would accelerate, on average, the availability of lower-priced generic drugs and generate savings to federal health programs that pay for prescription drugs. The legislation would affect settlement agreements entered into after November 15, 2009, that involve certain kinds of compensation flowing from the manufacturer of the brand-name drug to the manufacturer of the generic version of the drug. CBO estimates that savings to mandatory health programs—including Medicare and Medicaid, subsidies for enrollees in health insurance exchanges, and health insurance provided to certain retirees by the Federal Employees Health Benefits (FEHB) program and the TRICARE for Life program operated by the Department of Defense—would total $4.0 billion over the 2012-2021 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 $0.4 billion over the 2012-2021 period. CBO estimates that the Federal Trade Commission (FTC) would initially face slightly higher administrative expenses to implement the bill in the first few years following enactment but would ultimately realize discretionary savings because of lower administrative costs for the agency under the bill. In total, costs for FTC would be reduced by $17 million over the 2012-2021 period.

The estimated budgetary impact of S. 27 is shown in the following table. The effects of this legislation fall primarily within budget functions 370 (commerce and housing credit), 550 (health), and 570 (Medicare). For the estimate, CBO assumes that S. 27 will be enacted by the end of calendar year 2011.

	By Fiscal Year, in Millions of Dollars											
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2012-2016	2012-2021
CHANGES IN DIRECT SPENDING												
Estimated Budget Authority	-50	-220	-260	-290	-330	-410	-510	-620	-660	-690	-1,140	-4,020
Estimated Outlays	-50	-220	-260	-290	-330	-410	-510	-620	-660	-690	-1,140	-4,020
CHANGES IN REVENUES												
Exchange Subsidies	0	0	1	2	3	5	6	6	6	6	6	35
Indirect Effect on Private Health Insurance Premiums												
On-budget	2	25	40	40	45	55	70	75	80	80	152	512
Off-budget[a]	1	10	15	15	15	20	25	25	30	30	56	186
Subtotal	3	35	55	55	60	75	95	100	110	110	208	698
Collection of Civil Penalties	0	2	4	4	4	4	4	4	3	3	14	32
Total Changes in Revenues												
On-budget	2	27	45	46	52	64	80	85	89	89	172	579
Off-budget[a]	1	10	15	15	15	20	25	25	30	30	56	186
Total	3	37	60	61	67	84	105	110	119	119	228	765
NET INCREASE OR DECREASE (-) IN THE BUDGET DEFICIT FROM CHANGES IN DIRECT SPENDING AND RECEIPTS												
Impact on Deficit												
On-budget	-52	-247	-305	-336	-382	-474	-590	-705	-749	-779	-1,312	-4,599
Off-budget[a]	-1	-10	-15	-15	-15	-20	-25	-25	-30	-30	-56	-186
Net Change in Deficit	-53	-257	-320	-351	-397	-494	-615	-730	-779	-809	-1,368	-4,785
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
Spending by Federal Health Programs												
Estimated Authorization Level	-10	-20	-25	-30	-30	-35	-45	-50	-55	-60	-115	-360
Estimated Outlays	-10	-20	-25	-30	-30	-35	-45	-50	-55	-60	-115	-360
Federal Trade Commission												
Estimated Authorization Level	*	*	*	*	-3	-3	-3	-3	-3	-3	-2	-18
Estimated Outlays	*	*	*	*	-3	-3	-3	-3	-3	-3	-2	-17
Total Changes												
Estimated Authorization Level	-10	-20	-25	-30	-33	-38	-48	-53	-58	-63	-117	-378
Estimated Outlays	-10	-20	-25	-30	-33	-38	-48	-53	-58	-63	-117	-377

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

Note: Numbers may not sum to totals because of rounding; * = between -$500,000 and $500,000.

a. Social Security payroll taxes are classified as "off budget."

S. 27 would affect revenues in three ways. First, lower prices for prescription drugs under the bill would reduce the cost of health insurance available through plans participating in health insurance exchanges, and therefore would lower tax subsidies provided to individuals who purchase insurance through such exchanges.[1] Second, CBO expects that lower prices for prescription drugs would reduce premiums for private health insurance. Because part of those savings from lower health insurance costs would be passed onto workers as increases in taxable compensation, revenues would be expected to rise. Lastly, the bill would create new civil penalties for parties that violate the bill's requirements. Taken together, CBO estimates that the bill would increase federal revenues by $0.8 billion over the 2012-2021 period.

BASIS OF ESTIMATE

Background

Under current law, certain agreements to settle litigation related to drug patents 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. 27 would modify how FTC conducts enforcement proceedings against parties to an agreement to settle a claim of patent infringement in specific cases. Under the bill, certain 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 pro-competitive benefits of the agreement outweigh the anti-competitive effects of the agreement. The agreements affected by the bill are ones in which 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 forgo research, development, manufacturing, marketing, or sale of the generic drug for any period of time.

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 other statutory restrictions that aim to prevent such marketing. The legislation also would allow FTC to establish additional exemptions through rulemaking procedures.

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1. A portion of those subsidies for exchange plans are provided to individuals via reduced tax liabilities; those amounts are recorded as revenues. Premium assistance tax credits are refundable, thus credits that exceed an individual's tax liability are recorded as outlays.

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. 27 would lead to the earlier entry of generic drugs, on average. Since profits of manufacturers of brand-name drugs are 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, competing generic manufacturers' plans to enter the market can also be delayed.

Under the restricted terms of compensation allowed under S. 27, 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 than would have been negotiated under current law.

S. 27 also contains 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.

Effect of S. 27 on Spending for Prescription Drugs

CBO estimates that enacting S. 27 would reduce total expenditures on prescription drugs in the United States, on net, by about $11 billion over the 2012-2021 period. Of that amount, we estimate that federal programs would save about $4 billion.

To estimate the effect of S. 27 on total expenditures for prescription drugs, 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 ligation with terms of compensation limited by the bill. We anticipate 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 2021 is between $100 billion and $150 billion.) Based on information from FTC, CBO expects that S. 27 would accelerate the entry of generic drugs affected by the bill by roughly 17 months, on average. During that period, CBO estimates a generic savings rate of about 50 percent—that is, the availability of lower-priced generic drugs would reduce total spending for a given drug by roughly one-half. After accounting for the fact that S. 27 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 $11 billion over the 2012-2021 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. However, it is an outcome that is profitable for the generic manufacturer. Banning 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 likely would lead to fewer challenges of patents for a small number of drugs. In such cases, fewer generic challengers could lead to a higher average price for affected drugs. CBO estimates that such offsetting costs would increase total drug spending in the United States by about $0.3 billion over the 2012-2021 period.

Direct Spending

Accelerating the entry of lower-priced generic drugs into the market would reduce spending by federal health programs that purchase drugs or provide health insurance that covers drugs. Consequently, CBO expects that direct spending for mandatory health programs—including Medicare, Medicaid, subsidies for enrollees in health insurance exchanges, payments for annuitant premiums under the FEHB program, and the Defense Department's TRICARE for Life program—would fall under the bill.

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. 27 would reduce direct spending for federal health programs by $1.1 billion over the 2012-2016 period and by $4.0 billion over the 2012-2021 period.

Revenues

CBO and JCT estimate that enacting S. 27 would increase federal revenues by $0.2 billion over the 2012-2016 period and by $0.8 billion over the 2012-2021 period.

Exchange Subsidies. CBO expects that enacting S. 27 would reduce the average cost for prescription drugs resulting in 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. Lowering of health insurance premiums would reduce federal subsidies for premium assistance provided for health insurance purchased through an exchange. Under current law, beginning in 2014, refundable tax credits will be available to certain individuals and families to subsidize health insurance purchased through new health insurance exchanges. (The portion of those tax credits that exceed taxpayers'

liabilities are classified as outlays, while the portions that reduce taxpayers' liabilities are recorded as reductions in revenues.) We estimate that the bill would increase federal revenues from lowering such subsidies by $35 million over the 2014-2021 period.

Indirect Effect on Private Health Insurance Premiums. CBO anticipates that enacting S. 27 would reduce the average costs for prescription drugs paid by consumers and would lower health insurance premiums. We expect the reduction in health insurance premiums to shift compensation from tax-favored health insurance to taxable wages. That change would increase federal revenues from income taxes and payroll taxes by an estimated $0.7 billion over the 2012-2021 period. Social Security payroll taxes, which are off-budget, would account for about 25 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 and would only apply to agreements entered into after the date of enactment. CBO anticipates that the collection of penalties would start in 2013. 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 $32 million over the 2013-2021 period.

Spending Subject to Appropriation

CBO estimates that implementing S. 27 would reduce spending subject to appropriation by $0.1 billion over the 2012-2016 period and by $0.4 billion over the 2012-2021 period.

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 increase slightly for the first few years after enactment, but then decrease over time as the number of settlements requiring enforcement activities declines. CBO estimates that any resulting changes in spending would be insignificant for the first four years after enactment of S. 27; thereafter, CBO estimates the agency's costs would be reduced by about $3 million per year. Assuming that appropriation actions reflect these changes, CBO estimates that discretionary spending would fall by $17 million over the 2012-2021 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. (See the discussion of the effect of the bill on spending by federal health programs for prescription drugs in the section on direct spending.) CBO estimates that implementing S. 27 would reduce discretionary spending by those programs by about $0.4 billion over the 2012-2021 period, assuming that appropriation actions reflect the estimated reductions in costs.

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 pay-as-you-go procedures are shown in the following table. Only on-budget changes to outlays or revenues are subject to pay-as-you-go procedures.

CBO Estimate of Pay-As-You-Go Effects for S.27, as reported by the Senate Committee on the Judiciary on July 22, 2011

	By Fiscal Year, in Millions of Dollars											
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2012-2016	2012-2021
NET INCREASE OR DECREASE (-) IN THE ON-BUDGET DEFICIT												
Statutory Pay-As-You-Go Impact	-52	-247	-305	-336	-382	-474	-590	-705	-749	-779	-1,312	-4,599
Memorandum:												
Changes in Outlays	-50	-220	-260	-290	-330	-410	-510	-620	-660	-690	-1,140	-4,020
Changes in Revenues	2	27	45	46	52	64	80	85	89	89	172	579

Note: Components may not sum to totals because of rounding.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 27 contains no intergovernmental mandates as definite in UMRA. CBO estimates that enacting this bill would result in a decline in state and local government spending for Medicaid of about $85 million over the 2012-2016 period.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 27 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. All agreements reached after November 15, 2009, would be affected by the mandate.

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 $450 million in 2012 and $4.2 billion over the 2012-2016 period. Thus, the costs of the mandate would significantly exceed the threshold established by UMRA for private-sector mandates ($141 million in 2011, adjusted annually for inflation).

ESTIMATE PREPARED BY:

Federal Spending:
  Federal Health Programs—Julia Christensen and Anna Cook
  Federal Trade Commission—Susan Willie
Federal Revenues: Kalyani Parthasarathy
Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum
Impact on the Private Sector: Anna Cook and Michael Levine

ESTIMATE APPROVED BY:

Holly Harvey
Deputy Assistant Director for Budget Analysis