Estimated Cost of FDA's Proposed Generic Drug Labeling Rule: Updated for 2017–2024

MATRIX GLOBAL ADVISORS, LLC

July 2016

In November 2013, the Food and Drug Administration (FDA) released a Proposed Rule that would permit any generic drug manufacturer to unilaterally make changes to its products' labels. Expected to be finalized in April 2017, this rule would drastically alter the existing legal landscape by exposing generic manufacturers, who supply 84 percent of all prescriptions, to failure-to-warn product liability lawsuits. As upheld by the Supreme Court, state failure-to-warn claims against generic drug manufacturers are preempted by the federal requirement that a generic drug have the same label as its reference product. Previous research, Brill (2014), estimated that the Proposed Rule would increase public and private spending by $4 billion due to the new liability costs that will be imposed on generic manufacturers.[1] The updated analysis presented here revises that estimate using more recent data and concludes that the Proposed Rule would increase public and private generic drug spending by $5.6 billion in 2017, rising to $8.6 billion in 2024.

BACKGROUND

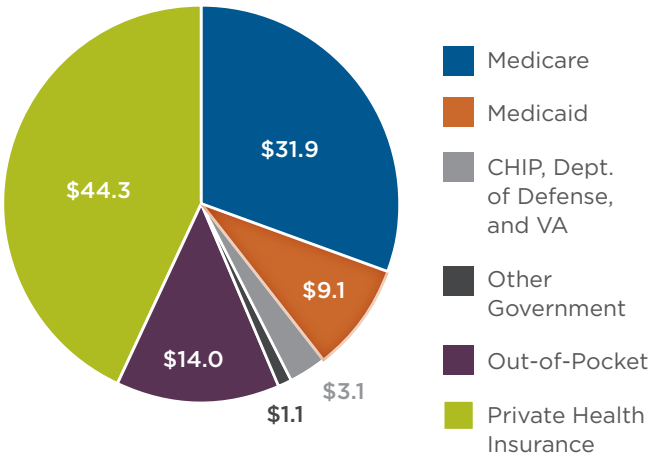
Lawmakers and policy experts have raised a number of concerns about the FDA's Proposed Rule, including its legality, cost, and impact on patient safety. A policy that eliminates preemption and introduces product liability for generic manufacturers would increase generic prices for multiple reasons, including higher insurance premiums, self-insurance costs, and reserve spending on product liability; fewer generic competitors; and the added cost to generic manufacturers of duplicating brand companies' efforts to monitor for safety-related issues. The analysis of the Proposed Rule in Brill (2014) focused exclusively on the increase in generic prices—and thus national health care spending—that would be induced by generic manufacturers' exposure to failure-to-warn claims.

Based in part on 2012 sales data, Brill (2014) estimated that the Proposed Rule would increase spending on generic drugs by $4 billion per year because of new product liability. Of this, government would pay $1.5 billion, and private health insurance would pay $2.5 billion. The analysis below updates this estimate with new data and forecasts the annual increase in spending through 2024.

NEW ANALYSIS

Employing new National Health Expenditures (NHE) forecasts from the Centers for Medicare & Medicaid Services (CMS) for prescription drug spending by payer,[2] this analysis estimates the additional generic drug spending between 2017 and 2024 that would arise because of the FDA's Proposed Rule. The analysis divides spending between government (Medicare, Medicaid, CHIP, Department of Defense, Veteran's Affairs, and other government health programs) and nongovernment (private insurers and patients' out-of-pocket expenses).

CHART 1. GENERIC DRUG SPENDING BY PAYER, 2017 ($ BILLIONS)



Source: *CMS Office of the Actuary, National Health Expenditure Accounts.*

The NHE forecast for total retail prescription drug spending in 2017 is $364.4 billion, of which 43.6 percent will be government and 56.4 percent will be nongovernment. IMS Health reports that generic spending is 28.4 percent of total prescription drug spending,[3] so we infer that government spending on generics in 2017 will be $45.1 billion and nongovernment spending will be $58.4 billion. See **Chart 1** for estimated generic drug spending by payer in 2017.

By estimating the cost of failure-to-warn liability per brand prescription and extrapolating that to generic drugs, Brill (2014) estimated that the Proposed Rule would increase generic drug spending by 5.4 percent annually. Utilizing the new NHE estimates of expected prescription drug spending, our new analysis estimates that the total U.S. impact of the Proposed Rule in 2017 would be $5.6 billion—$2.4 billion for government, and $3.2 billion for private insurers and out-of-pocket. Using this same methodology, we project costs for each year through 2024, at which point the increase in spending will reach $8.6 billion. See **Table 1** for the full breakdown of results.

DISCUSSION

The generic drug industry is a competitive marketplace characterized by multiple manufacturers selling indistinguishable products. As in any highly competitive market, producers must price their products close to or at marginal cost. Therefore, higher costs, such as the cost of additional liability imposed by the FDA's

TABLE 1. INCREASE IN SPENDING FROM FDA'S PROPOSED GENERIC DRUG LABELING RULE ($ BILLIONS)

	2017	2018	2019	2020	2021	2022	2023	2024
Government	$2.4	$2.6	$2.8	$3.0	$3.2	$3.5	$3.7	$4.0
Private insurance and out-of-pocket	$3.2	$3.3	$3.5	$3.7	$3.9	$4.1	$4.4	$4.6
Total impact	**$5.6**	**$5.9**	**$6.3**	**$6.7**	**$7.1**	**$7.6**	**$8.1**	**$8.6**

Proposed Rule, must necessarily lead to higher prices for generic drugs. This analysis assumes that the cost will be passed forward uniformly across all payers. But recent legislation will effectively impose a tax on generic manufacturers in Medicaid for price increases above inflation. As a result, the additional costs imposed by FDA's Proposed Rule may disproportionately affect the Medicare program and private insurers.

In addition to the direct impact of FDA's Proposed Rule on the cost of generic drugs, other effects are worth noting. For example, as described in Brill, Gottlieb, and Pollock (2014), the Proposed Rule will induce generic manufacturers to "load their drug labels with as many warnings as possible."[4] Such over-warning is not costless, and the FDA has repeatedly cautioned that too many warnings on a drug label can deter the use of beneficial products.

CONCLUSION

Brill (2014) cautioned that with pharmaceutical spending expected to rise substantially in the coming decade, the economic impact of the Proposed Rule would only increase over time. By incorporating new prescription drug expenditure projections, this updated analysis offers specific estimates of this increase in spending, which can be expected to reach $8.6 billion in 2024.

NOTES

1 Alex Brill, "FDA's Proposed Generic Drug Labeling Rule: An Economic Assessment," February 5, 2014, available at www.matrixglobaladvisors.com/GenericLabelingRule.pdf.

2 CMS Office of the Actuary, National Health Expenditure Accounts, "Table 11: Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2008–2024," updated July 2015.

3 IMS Institute for Healthcare Informatics, "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014," April 2015.

4 Alex Brill, Scott Gottlieb, and Robert W. Pollock, "Proposed FDA Generic Drug Regulation: Higher Prices, No Public Health Benefit," *AEI Health Policy Outlook*, March 2014, available at www.aei.org/wp-content/uploads/2014/03/-health-policy-outlook-march-2014_135106617382.pdf.

ABOUT THE AUTHOR

Alex Brill is the CEO of Matrix Global Advisors. He is also a research fellow at the American Enterprise Institute. Previously, he was chief economist and policy director to the House Ways and Means Committee and also served on the staff of the President's Council of Economic Advisers.

ABOUT MGA

Matrix Global Advisors (MGA) is a Washington, DC-based economic policy consulting firm founded in 2007 by Alex Brill. MGA engages in economic and policy consulting on a range of fiscal, economic, tax, and health policy matters. Through insights and knowledge of the political process and the application of analytical tools, MGA has helped health care providers, taxpayers, commercial banks, investment banks, and others understand and navigate legislative and regulatory processes.

MATRIX GLOBAL ADVISORS

1350 Connecticut Avenue, NW Suite 610 Washington, DC 20036 | 202-558-7159 | info@matrixglobaladvisors.com
www.matrixglobaladvisors.com