

# **FDA's Proposed Generic Drug Labeling Rule: An Economic Assessment**

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## EXECUTIVE SUMMARY

On November 13, 2013, the Food and Drug Administration (FDA) released a Proposed Rule that would permit generic drug manufacturers to make changes to their products' labels. Lawmakers and policy experts have raised a number of concerns about the Proposed Rule, including its legality, cost, and impact on patient safety. This study investigates the cost of the Proposed Rule and estimates the impact on public and private generic drug spending should the rule be finalized.

The Proposed Rule would drastically alter the existing legal landscape by eliminating preemption and exposing generic manufacturers, who supply 84 percent of all prescriptions, to product liability lawsuits. This, in turn, would have substantial negative consequences for national health care spending due to the increase in generic drug prices that product liability would induce. Because the FDA fails to consider liability costs for generic manufacturers, the agency reaches the erroneous conclusion that the Proposed Rule would “generate little cost.”

In the highly competitive generic pharmaceutical market, additional costs can be expected to result in higher prices. A policy that eliminates preemption and introduces product liability for generic manufacturers would increase manufacturer costs—and generic prices—for the following reasons:

- **Generic manufacturers would face higher insurance premiums**, self-insurance costs, and reserve spending on product liability.
- **Generic manufacturers may exit or decline to enter the market for certain products** for which they perceive greater liability risk or uninsurable liability risks.
- **Insurance companies offering product liability insurance to generic manufacturers may leave the market** when faced with insuring against increased risk, resulting in higher premiums for generic manufacturers.
- **Generic manufacturers would bear the cost of duplicating brand companies' efforts** to monitor for safety-related issues.

Other negative consequences of exposing generic manufacturers to product liability include the incentive it creates for generic manufacturers to “overwarn.” The FDA has previously expressed concern about creating this dynamic because the agency is aware that overwarning dilutes the effectiveness of safety labeling and creates confusion for prescribers and patients.

This study offers a conservative estimate of one of the Proposed Rule's negative effects on generic drug manufacturers—and thus patients and payors—by modeling its impact on generic product liability spending. **In brief, the Proposed Rule could be expected to increase spending on generic drugs by \$4 billion per year (or 5.4 percent of generic retail prescription drug spending in 2012). Of this, government health programs would pay \$1.5 billion, and private health insurance, \$2.5 billion.**

Contrary to the FDA's assertion, this study finds that the Proposed Rule would result in an increase in expenditures far in excess of the \$141 million threshold for economic significance defined by the Unfunded Mandates Act of 1995. With pharmaceutical spending expected to rise substantially in the coming decade, the economic impact of the Proposed Rule will only increase over time.

## INTRODUCTION

On November 13, 2013, the Food and Drug Administration (FDA) released a Proposed Rule titled “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products.” If finalized, the rule would permit generic drug manufacturers to make changes to their products’ labels, which they currently are prohibited from doing unless the manufacturer of the reference listed drug (RLD) first changes its label. This rule would drastically alter the legal landscape that generic manufacturers face by exposing them to product liability lawsuits. Product liability exposure would in turn have substantial negative consequences for national health care spending. Both public (Medicare, Medicaid, and other programs) and private health insurance spending on generic drugs would increase due to the increase in prices that product liability would induce—a development that the FDA does not take into account in its economic impact assessment.

Lawmakers and policy experts have raised a number of concerns about the Proposed Rule, including its legality, cost, and impact on patient safety. To address the FDA’s failure to properly consider cost, this study investigates the economic impact of the Proposed Rule with regard to liability exposure and identifies a multitude of channels—direct and indirect—through which the cost of generic drugs could be affected if the Proposed Rule were finalized. The study then explores in greater detail one such channel and conservatively estimates the increased health care costs that could be expected.

The study is structured as follows. We begin in Section I by contrasting the FDA’s stated purpose for the Proposed Rule with the agency’s implicit purpose. In Section II, we contrast the FDA’s assessment of the Proposed Rule’s economic impact with an assessment that incorporates product liability exposure for generic drug manufacturers and the higher prices that would result. In Section III, we provide an overview of total drug spending and generic drug spending and savings in the United States to demonstrate the magnitude of even a small change in generic prices. Having laid this groundwork, we set forth in Section IV the data and methodology we use in our analysis before presenting the results.

In brief, we find that generic product liability would increase spending on generic drugs by \$4 billion per year (or 5.4 percent of generic retail prescription drug spending in 2012). Of this, government health programs would pay \$1.5 billion, and private health insurance would cover \$2.5 billion.

### I. PURPOSE OF PROPOSED RULE

According to the FDA, as laid forth in the *Federal Register*, the stated purpose of the Proposed Rule is to “create parity among application holders with respect to these [CBE-0] safety-related labeling changes by permitting ANDA holders to distribute revised generic drug labeling.”<sup>1</sup>

However, in the “Preliminary Regulatory Impact Analysis” accompanying the Proposed Rule, the FDA reveals its underlying motivation of addressing a perceived inequity in the ability of consumers to bring suit against drug manufacturers:

#### B. Need for Regulation

Two recent Supreme Court cases (*Wyeth v. Levine* and *Pliva v. Mensing*) held that the difference between the NDA [new drug application] and ANDA [abbreviated new drug application] holders’

abilities to independently change their product labeling leads to different outcomes on whether federal labeling requirements preempt state law tort claims against drug manufacturers for “failure to warn.” As a result of these Supreme Court decisions, an individual can bring a product liability action for failure to warn against an NDA holder, but generally not an ANDA holder, and thus access to the courts is dependent on whether an individual is dispensed a “brand name” or generic drug.<sup>2</sup>

The legal authority and regulatory appropriateness of the agency’s using rulemaking to create access to the courts are beyond the scope of this study. However, as the next section details, the FDA’s own cost-benefit analysis would have differed greatly had the agency considered the economic impact of the true objective of this regulatory change and the associated consequences of the tort claims that would ensue against generic drug manufacturers.

## **II. IMPACT OF PROPOSED RULE**

We assert that the FDA’s assumptions about the Proposed Rule are incomplete and inaccurate, rendering their economic analysis moot. In this section, we identify and discuss the primary failings in the FDA’s assumptions before offering our own view of the Proposed Rule’s likely economic impact. Beyond the fact that the FDA does not consider the increased liability costs resulting from the Proposed Rule, the agency’s logic is riddled with inconsistencies and omissions.

### **FDA’s Assumptions about Proposed Rule’s Impact**

FDA estimates that the annual net social cost of the Proposed Rule is between \$4,237 and \$25,852 and further determines that the present discounted value over a 20-year horizon would be between \$44,890 and \$384,616.<sup>3</sup> This is based on the FDA’s estimate that the agency would receive 20 CBE-0 supplements each year from generic manufacturers.<sup>4</sup> More specifically, the FDA estimates a net social cost to ANDA holders between \$128 per year and \$6,683 per year and a net social cost to NDA holders between \$4,109 and \$19,169 annually.<sup>5</sup> As a result of the agency’s findings, the FDA concludes that the Proposed Rule 1) would not be an economically significant regulatory action, as defined by Executive Order 12866; 2) would not have a significant economic impact on small entities, as defined by the Regulatory Flexibility Act; and 3) would not result in an increase in expenditures of \$141 million or more, as set forth by Section 202(a) of the Unfunded Mandates Act of 1995, adjusted by the 2012 Implicit Price Deflator for the Gross Domestic Product.<sup>6</sup>

Among the FDA’s flawed and inconsistent assumptions about the Proposed Rule, the following are key to understanding why the agency’s economic impact assessment is grossly inadequate and generally incorrect:

#### ***1. FDA fails to consider liability costs***

As the FDA acknowledges in both the background section of the Proposed Rule and the Preliminary Regulatory Impact Analysis, generic manufacturers are currently protected from product liability suits because they are not allowed to make changes to their product labels. The FDA also acknowledges that the Proposed Rule “may eliminate the preemption of certain failure-to-warn claims with respect to generic drugs.”<sup>7</sup> However, the agency fails to consider that eliminating preemption of product liability claims would greatly increase liability risk for generic drug manufacturers, which in turn would lead to substantial price increases for generic drugs. Higher generic drug prices would have a measurable impact on states, the

federal government, private insurance, and consumers. Yet, according to the FDA, “The proposed rule is expected to generate little cost.”<sup>8</sup>

The FDA reaches this conclusion because it estimates the annual net social cost of the Proposed Rule based only on the paperwork and administrative burdens on ANDA and NDA holders and assumes “there will be no CBE-0 supplements in addition to the current level submitted by NDA holders each year as a result of the proposed rule.”<sup>9</sup> The agency does not estimate any impact from generic product liability and the accompanying price increases on physicians, pharmacists, hospitals, insurers, patients, or public payors such as Medicare or Medicaid. This is a gross oversight on the FDA’s part, as the Proposed Rule would, by the agency’s own admission, provide patients using generic drugs “access to the courts” to bring failure-to-warn suits against generic manufacturers. And, as explained in greater detail below, such tort liability will impose great cost—direct and indirect—on the generic drug industry, which will result in higher costs, greater risks, and reduced competition among generic drug manufacturers.

In its Preliminary Regulatory Impact Analysis, the FDA acknowledges that there are additional potential costs but excludes them because of “the large amount of uncertainty about how the proposed rule will alter consumer and industry behavior.”<sup>10</sup> However, the fact that a cost is uncertain does not justify excluding it or assuming it is zero. To the contrary, uncertainty is itself a burden, and the FDA’s inability to quantify certain consequences arising from the Proposed Rule should be considered a cost to stakeholders.

## ***2. FDA believes NDA holders would have more incentive than ANDA holders to initiate label changes***

The FDA asserts that “in our base case we expect the NDA holder to desire to be the firm on record for leading a safety-related labeling change.”<sup>11</sup> The FDA’s reason for this appears to be twofold. First, the agency thinks “the NDA holder [will perceive] its reputation as sufficiently important for it to be in its interest to maintain a reputation for dealing promptly and effectively with safety-related information.”<sup>12</sup> Second, the agency assumes that submitting a CBE-0 supplement will be costly enough to discourage ANDA holders from initiating a label change in most instances.

The FDA does note several instances in which an ANDA holder would initiate a label change, including “if, due to a larger market share, the expected economic benefit of moving first is larger [for the ANDA holder] than the expected cost of moving first, or if the expected economic risk of not moving first is larger than the expected cost savings of not moving first.”<sup>13</sup> In our opinion, this exception to the FDA’s base case should in fact be the base case, as the NDA holder on average has only 5 percent market share of any given multisource product.<sup>14</sup>

The FDA is correct in assuming that every firm can be expected to operate in its own interest. However, the agency fundamentally misrepresents the interests at stake. Drug manufacturers will be driven by their legal obligations and desire to minimize the risk of litigation arising from product liability suits. Potential failure-to-warn suits would provide a strong incentive for every generic manufacturer to be the first to submit a CBE-0 supplement. Therefore, the FDA’s assumption that “there will be no CBE-0 supplements in addition to the current level submitted by NDA holders” is implausible, and we should anticipate a far greater impact than the agency’s estimate of a shift of 20 CBE-0 supplements from NDA holders to ANDA holders.<sup>15</sup>

In the Preliminary Regulatory Impact Analysis, the FDA mentions in passing that the “likelihood of legal action against the firm for not updating product labeling” could “influence a firm’s decision to submit a

CBE-0 supplement,” but the agency offers no quantitative analysis.<sup>16</sup> In our opinion, this will be the dominant determining factor in a firm’s decision to submit a CBE-0 supplement.

### ***3. FDA asserts that generic insurance premiums will not increase and competition will not decline***

At the conclusion of the agency’s Preliminary Regulatory Impact Analysis, the FDA simply declares that “generic drug companies purchase insurance to cover a wide range of liabilities, and the cost of covering failure to warn claims will be, as it was in the past, part of an overall insurance cost. Accordingly, we do not anticipate that the proposed rule would result in higher costs to generic drug manufacturers.”<sup>17</sup> Because the FDA assumes that generic insurance costs will not increase, the agency also dismisses concerns that the Proposed Rule will induce generic manufacturers to leave or never enter the market.

However, it is illogical for the FDA to acknowledge that ANDA holders are currently exempt from failure-to-warn suits and in the same analysis insist that insurance premiums would not increase if preemption were removed. In addition, the FDA does not acknowledge the variety of ways generic manufacturers approach product liability, including self-insuring and purchasing insurance with very high deductibles. Not only are insurance premiums bound to increase should the Proposed Rule be finalized, but generic manufacturers’ direct spending on product liability, through reserve funds and self-insurance, would rise as well.

### ***4. FDA fails to estimate any social benefit from the Proposed Rule***

While the mere fact that a Proposed Rule imposes societal costs does not render the rule inappropriate, the premise of cost-benefit analysis for regulatory matters is to demonstrate that the expected benefits of a regulatory action exceed the expected costs. The FDA’s analysis fails even to attempt to quantify any expected benefit and instead makes only qualified, qualitative assertions while emphasizing the uncertainty of its predictions.

Specifically, the FDA states, “The public health benefits from adoption of the proposed rule are not quantified. By allowing all application holders to update labeling based on newly acquired information that meets the criteria for a CBE-0 supplement, communication of important drug safety information to prescribing health care providers and the public *could* be improved.”<sup>18</sup>

However, Executive Order 13563 expressly directs agencies “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible,”<sup>19</sup> and Executive Order 12866 indicates that an agency should “propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”<sup>20</sup> Given that the FDA does not attempt to quantify any public health benefit and does not even express confidence that such a benefit exists, the agency appears not to be acting in accordance with either governing Executive Orders.

### ***Likely Impact of Proposed Rule Considering Generic Drug Liability Exposure***

Contrary to the FDA’s assertions, we believe that the primary impact of the Proposed Rule would be the elimination of preemption for generic manufacturers and the introduction of the type of product liability that brand drug manufacturers currently face. This policy change would create a drastically altered landscape for generic drug manufacturers—one that would have significant consequences for both private and public U.S. health spending by increasing the prices of generic drugs.

## ***Product Liability and Prices***

In any competitive market, producers set their price equal to marginal cost. Therefore, the full burden of an additional cost must be passed forward in the price because the producer price cannot fall below marginal cost. The generic drug industry exhibits many characteristics indicative of a competitive marketplace. Bioequivalence, identical names, lack of advertising or branding, and relatively low cost of entry all indicate a commodity-type marketplace for generic drugs.<sup>21</sup> The FDA’s Preliminary Regulatory Impact Analysis affirms the competitiveness of the generic market—the analysis finds that among CBE-0 supplements for NDAs with an ANDA, the average number of approved generic competitors is 8.4.<sup>22</sup>

Given the nature of the generic industry, a policy that eliminates preemption and introduces product liability exposure would increase costs—and therefore generic prices—for the following reasons:

- Generic manufacturers’ costs would rise due to higher insurance premiums, self-insurance costs, and reserve spending on product liability.
- Generic manufacturers may exit the market for certain products for which they perceive greater liability risk or uninsurable liability risks. This can be expected to result in generic price increases. As the FDA’s own research concludes, “The appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower.”<sup>23</sup>
- Insurance companies offering product liability insurance to generic manufacturers may leave the market when faced with insuring against increased risk, resulting in higher premiums for generic manufacturers, which will in turn be passed on to payors.
- Generic manufacturers would also bear the cost of duplicating brand companies’ efforts to monitor for safety-related issues.

## ***Other Effects of Proposed Rule***

This study ultimately focuses on the Proposed Rule’s price impact, but it is worth noting two other negative consequences of product liability exposure for generic manufacturers. First, generic manufacturers would abstain from entering the market or entirely leave the market for certain products because of liability risk, leaving high-priced brand drugs as the only option. Second, the anticipation of liability claims could induce manufacturers to “overwarn,” an inclination that has previously concerned the FDA:

FDA noted that liability concerns were creating pressure on manufacturers to expand labeling warnings to include speculative risks and, thus, to limit physician appreciation of potentially far more significant contraindications and side effects. . . . Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health.<sup>24</sup>

In the case of one manufacturer’s incentive to overwarn, the primary effect would be to dilute the effectiveness of labeling warnings. However, with multiple manufacturers’ responding to this incentive,

the ensuing flurry of label changes for the same product would create confusion among providers and patients, to say the least.

Because the FDA does not incorporate the price effect or any of the other factors identified here in its assessment of the Proposed Rule, the agency does not attempt to quantify their impact. This study is intended to rectify that omission. Our analysis focuses on only one consequence of the Proposed Rule—the impact on generic prices as a direct result of increased liability costs—with the recognition that it is by no means the only negative impact. Indeed, the potential patient safety consequences are a very critical impact of the Proposed Rule, albeit outside the scope of this paper. Before we present our analysis, we offer an overview of current U.S. spending on generic drugs to establish a foundation for understanding the implications of the Proposed Rule’s price impact.

### **III. U.S. PHARMACEUTICAL SPENDING AND GENERIC DRUGS**

Generic drugs represent enormous savings for the U.S. health care system. In the last decade, generic drugs have reduced pharmaceutical spending by \$1.2 trillion in the United States.<sup>25</sup> In 2012 alone, generics were responsible for \$217 billion of savings. Retail prescription drug spending in the United States totaled \$263.3 billion in 2012,<sup>26</sup> meaning that without generics, retail prescription drug spending would have been over 82 percent higher.

Generic drugs provide this kind of savings because they constitute a huge share of total prescriptions but at a fraction of the cost of single-source brand products. In 2012, 84 percent of all retail prescriptions were filled with generics, accounting for only 28 percent of total drug spending.<sup>27</sup>

In 2012, government health insurance programs covered 36.8 percent (or \$96.9 billion) of all U.S. retail prescription drug spending.<sup>28</sup> Of this, more than 70 percent was borne by Medicare.<sup>29</sup> Because generics account for 28 percent of retail drug spending, government spending on retail prescription generic drugs can be assumed to total \$27.1 billion in 2012 alone.

Pharmaceutical spending is expected to increase significantly in the coming decade, as will the government’s share of spending. Retail prescription drug spending is projected to rise 73 percent to \$455 billion in 2022.<sup>30</sup> During this same period, Medicare spending on retail prescription drugs is projected to rise 115 percent; Medicaid spending, 86 percent; and total government spending, 107 percent. Given this forecast, government health insurance programs will cover 44 percent (or \$200.7 billion) of all U.S. retail prescription drug spending in 2022.<sup>31</sup> Assuming that the generic share of pharmaceutical spending remains constant (at 28 percent), total government spending on generics will exceed \$56 billion in 2022.

Given the level of government spending on generic drugs, even a small increase in generic prices would have a measurable impact on federal and state spending and thus be detrimental to the long-run viability of Medicare, Medicaid, and other government health care programs. As the preceding section established, liability costs in a competitive marketplace are passed on in the form of higher prices. Therefore, we can be sure that if the Proposed Rule is finalized, we will see an increase in public and private generic drug spending as generic manufacturers pass on new liability costs. In the next section, we estimate the spending increase that the Proposed Rule would induce as a result of this single factor.

## IV. ANALYSIS

As we have established, should the FDA Proposed Rule become final, it would expose generic manufacturers to product liability risks and associated legal costs, and these costs would be passed on to consumers and payors in the form of higher prices. In this section, we quantify the impact of increased generic prices on public, private, and out-of-pocket spending as a direct result of increased expected liability costs. To estimate the amount by which generic prices—and thus spending—could be expected to increase due to this new liability exposure, we use the following data and methodology.

In approaching our analysis, we first determine the degree to which the Proposed Rule would expose generic manufacturers to product liability to establish the validity of our hypothesis that it will result in higher costs. Having established this, we then construct a model to estimate the increase in generic spending on product liability.

### Generic Product Liability Exposure

To estimate the degree to which generics would face exposure to product liability under the Proposed Rule, we use as a proxy the share of all safety-related label changes that occur after generic entry. The Proposed Rule would expose generic manufacturers to product liability more broadly, but this proxy serves as a conservative measure of exposure.

In the Preliminary Regulatory Impact Analysis, the FDA analyzes CBE-0 supplements from 2009 and 2010 for boxed warnings and contraindications and finds that 39 of the 114 approved changes occurred for products that were available as generics at the time of the label change.<sup>32</sup> In a subsample of CBE-0 supplements including all types of label changes, not just boxed warnings and contraindications, the FDA finds that 27 out of 56 changes occurred for multisource products.<sup>33</sup> Using the following methodology, we conducted an analysis similar to the FDA's but incorporating more recent data and looking at all CBE-0 supplements.

The FDA makes publicly available all safety-related label changes for drugs.<sup>34</sup> We analyzed the most recently available twelve-month period (November 2012 to October 2013). Safety-related label changes are made either with a CBE-0 supplement or a prior approval supplement. Since CBE-0 supplements allow manufacturers to make unilateral changes to their labels and, as such, are the subject of the Proposed Rule, we analyzed only those supplements.

To distinguish between CBE-0 supplements and prior approval supplements, we located the corresponding approval letter, which states what type of supplement the manufacturer submitted, through the FDA's "Drugs@FDA" database.<sup>35</sup> Of the 541 safety-related label changes in the twelve-month period analyzed, 94 were CBE-0 supplements.<sup>36</sup>

To determine which products were available as generics when the label change was made, we cross-referenced the CBE-0 supplements with the Drugs@FDA database, which identifies whether a product has approved therapeutic equivalents. For those drugs with approved therapeutic equivalents, we determined whether a generic version had entered the market using the market date for the first generic manufacturer's participation in Medicaid.<sup>37</sup> An additional step in the analysis was to verify generic market entry with a secondary source, such as a manufacturer press release for the generic launch.

Of the 94 CBE-0 supplements, 40 products were multisource at the time the label change was made. Based on this proxy, we conclude that generic and brand manufacturers would face exposure to product liability to a similar degree.

### *Modeling Liability-Induced Costs for Generic Manufacturers*

Should the proposed FDA rule become final, the product liability and litigation costs to which it would expose generic manufacturers would result in dynamics in the generic drug industry similar to those already observed in the brand drug industry. To estimate the amount that generic manufacturer costs—and thus generic prices—could be expected to increase due to this new liability exposure, we construct a model based on the brand industry.

In a study on medical liability costs for physicians and hospitals, the Government Accountability Office outlines the various types of costs associated with pharmaceutical manufacturer liability and affirms that these costs are reflected in higher prices:

Manufacturers pass on their liability costs . . . in their products' prices. Their liability costs include insurance and liability-related production and marketing costs. Manufacturer insurance costs . . . can include periodic self-insurance payments, payments made for purchased insurance, and payments made from general revenues to cover uninsured losses. Liability-related production and marketing costs include expenses associated with actions taken primarily to protect the manufacturer from liability, such as multiple layers of packaging and repeated safety warnings.<sup>38</sup>

We conducted an extensive literature review in an effort to determine total product liability spending specific to the brand pharmaceutical industry but found no conclusive estimates. This is in keeping with the Office of Technology Assessment's (OTA) conclusion in 1993 that "the best source of information on the costs and implications of product liability law in this industry are drug companies themselves. The [OTA] found no published data summarizing industry experience."<sup>39</sup> Based on the OTA's direction, we analyzed brand pharmaceutical manufacturer financial statements but did not find consistent reports of product liability spending or product liability insurance premiums.<sup>40</sup>

Given the unfeasibility of quantifying brand drug manufacturers' total spending on product liability, we use average product liability insurance premiums across industries as a proxy. A study published in the *Journal of Political Economy* on the impact of product liability on innovation estimates that product liability insurance premiums for bodily injury represent 0.67 percent of firms' sales.<sup>41</sup>

It should be noted that for the purposes of our analysis, this is a conservative estimate for two reasons: 1) it does not include firms' self-insurance or spending on uninsured losses, and 2) the pharmaceutical industry bears a disproportionate liability burden relative to other industries.<sup>42</sup> Because brand manufacturers typically self-insure,<sup>43</sup> this is not a perfect proxy, but it does approximate product liability spending—and at a level lower than what brand drug companies likely spend on product liability.<sup>44</sup>

To relate drug company sales to drug spending, we use a report from the Bureau of Labor Statistics (BLS) to convert production value to consumption value.<sup>45</sup> According to BLS, U.S. pharmaceutical sales were \$300 billion in 2009 (the year reported in the BLS analysis), while U.S. production totaled \$177 billion (including

imports and excluding exports). The ratio of production value to consumption value is thus 0.59 (\$177 billion/\$300 billion). Drug companies' spending on product liability costs (0.67 percent of their revenue) is thus the equivalent of 0.4 percent of consumer spending (0.59 \* 0.0067).

## Results

In 2012, U.S. retail prescription drug spending totaled \$263.3 billion,<sup>46</sup> of which brand drugs represented 72 percent, or \$189.6 billion.<sup>47</sup> If the cost of product liability for brand companies equals 0.4 percent of consumer spending, product liability costs in 2012 totaled \$758.3 million. Prescriptions in 2012 totaled 4.1 billion, and brand drugs accounted for 16 percent of these, or 652.5 million prescriptions.<sup>48</sup> Therefore, brand product liability spending was roughly \$1.16 per prescription in 2012.

Since generics account for 84 percent of all prescriptions (or roughly 3.4 billion prescriptions), generic product liability spending could be expected to total \$4 billion (or 5.4 percent of generic retail prescription drug spending in 2012), based on our model. It is worth noting again that our model estimates just one negative economic impact of the Proposed Rule.

### ***Increase in government spending***

As mentioned above, government spending on retail prescription generic drugs was \$27.1 billion in 2012. With the introduction of product liability, we could expect government spending to increase \$1.5 billion (or 5.4 percent), given that government spending accounts for 36.8 percent of all retail prescription drug spending. The impact on government spending would be higher with the inclusion of Medicare Part B spending (which is excluded here because of the data lag for Part B).

### ***Increase in private and out-of-pocket spending***

Private and out-of-pocket spending on generic drugs totaled \$46.6 billion in 2012. With the introduction of product liability, we could expect generic spending to increase \$2.5 billion, or 5.4 percent, given that private and out-of-pocket spending represents 63.2 percent of all retail prescription drug spending.

As mentioned above, these estimates should be considered conservative given that we use a proxy for product liability insurance premiums that is likely low, do not account for self-insurance and reserve spending, exclude certain drug spending, and do not model the effect of fewer or no generics in a given market. Therefore, while it is difficult to quantify future product liability because of the unpredictability of this type of lawsuit, our results are certainly an underestimate of product liability costs. To depict a far larger but perfectly plausible economic impact on the generic drug industry, we present before concluding a case study of the well-known product liability lawsuits over the brand drug Vioxx.

### **Results in Brief**

- Total increase in generic drug spending by consumers due to product liability:  
**\$4 billion (5.4 percent)**
  - Increase in government spending:  
**\$1.5 billion (5.4 percent)**
  - Increase in private and out-of-pocket spending:  
**\$2.5 billion (5.4 percent)**

### Case Study: Vioxx

Vioxx was an anti-inflammatory drug that entered the market in mid-1999 and was pulled by Merck & Co., Inc. in September 2004 because of the health risks it posed. During its time on the market, Vioxx recorded more than \$11 billion in sales and was used by roughly 20 million Americans.

By 2007, Merck was facing 28,000 Vioxx-related lawsuits and set up a settlement fund of \$4.85 billion for qualifying product liability claims. The Vioxx settlement fund was concluded in 2010, with 33,075 plaintiffs receiving compensation.

Had generic versions of Vioxx been available, they could have been expected to comprise 95 percent of the market—and thus 95 percent of the liability. It could thus be assumed that generic manufacturers would have been responsible for \$4.6 billion of the \$4.85 billion in settlements. Given that generic drugs on average are 80 percent cheaper than brands, settlement costs would have dwarfed sales.

While Vioxx was on the market, it generated annual sales of \$2.5 billion, but annual generic sales would have been 20 percent of that, or about \$500 million. Over the period that Vioxx was marketed, generic manufacturers' revenue would have been roughly \$2 billion, versus Merck's \$11 billion.

Since settlement payments depended on the severity of injuries and length of time consumers took Vioxx, a similar settlement agreement would have been necessary for generic manufacturers to settle the same number of claims. Although the revenue generated by brands and generics differs substantially, personal injury claims would have been the same. Thus, generics would have been responsible for \$4.6 billion in settlements for a product that generated only \$2 billion in revenue.

## V. CONCLUSION

In this study, we provide a conservative estimate of just one of many negative economic impacts that the FDA's Proposed Rule would have on generic drug manufacturers and thus patients and payors. According to our analysis, we estimate that imposing liability risk on generic manufacturers would increase generic drug spending by 5.4 percent. For the government, this means an increase in annual generic drug spending of \$1.5 billion, and for private payors an increase of \$2.5 billion.

Contrary to the FDA's assertion, we find that the Proposed Rule would both be an economically significant regulatory action as defined by Executive Order 12866 and would result in an increase in expenditures far in excess of the \$141 million threshold set forth by Section 202(a) of the Unfunded Mandates Act of 1995. Given that pharmaceutical spending is expected to rise, the economic impact of the Proposed Rule will only increase in significance.

## **ABOUT THE AUTHOR**

Alex Brill is the CEO of Matrix Global Advisors, an economic policy consulting firm. He is also a research fellow at the American Enterprise Institute and in 2010 served as an advisor to the Simpson-Bowles Commission. Previously, he was chief economist and policy director to the House Ways and Means Committee. Prior to his time on the Hill, he served on the staff of the President's Council of Economic Advisers.

This report was sponsored by the Generic Pharmaceutical Association. The author is solely responsible for the content. Any views expressed here represent only the views of the author.

## NOTES

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<sup>1</sup> Food and Drug Administration (FDA), “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” *Federal Register* 78, no. 219 (November 13, 2013), 67985, available at [www.gpo.gov/fdsys/pkg/FR-2013-11-13/pdf/2013-26799.pdf](http://www.gpo.gov/fdsys/pkg/FR-2013-11-13/pdf/2013-26799.pdf).

<sup>2</sup> FDA, “Preliminary Regulatory Impact Analysis: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products” (November 13, 2013), 5, available at [www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM375128.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM375128.pdf). While the Proposed Rule does include similar language, it is buried in the background section (see pp. 67988–9), whereas the Preliminary Regulatory Impact Analysis presents the rationale in its description of the “Need for Regulation.”

<sup>3</sup> FDA, “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” 67986.

<sup>4</sup> *Ibid.*, 67996.

<sup>5</sup> FDA, “Preliminary Regulatory Impact Analysis: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” Table 4.

<sup>6</sup> FDA, “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” 67995.

<sup>7</sup> *Ibid.*, 67989.

<sup>8</sup> *Ibid.*, 67996.

<sup>9</sup> FDA, “Preliminary Regulatory Impact Analysis: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” 16.

<sup>10</sup> *Ibid.*, 18.

<sup>11</sup> *Ibid.*, 11.

<sup>12</sup> *Ibid.*

<sup>13</sup> *Ibid.*, 11–12.

<sup>14</sup> IMS Institute for Healthcare Informatics, “Declining Medicine Use and Costs: For Better or Worse? A Review of the Use of Medicines in the United States in 2012,” May 2013.

<sup>15</sup> FDA, “Preliminary Regulatory Impact Analysis: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” 13.

<sup>16</sup> *Ibid.*, 12.

<sup>17</sup> *Ibid.*, 19.

<sup>18</sup> FDA, “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” 67986. (Emphasis added.)

<sup>19</sup> Barack Obama, “Improving Regulation and Regulatory Review,” Executive Order 13563 (January 18, 2011), 3821, available at [www.regulations.gov/docs/EO\\_13563.pdf](http://www.regulations.gov/docs/EO_13563.pdf).

<sup>20</sup> Bill Clinton, “Regulatory Planning and Review,” Executive Order 12866 (September 30, 1993), available at [www.regulations.gov/docs/EO\\_12866.pdf](http://www.regulations.gov/docs/EO_12866.pdf).

<sup>21</sup> If there are cases within the generic drug industry in which pricing power exists (as may be the case for small generic markets), then prices may rise by more than the increased cost of liability. As economists Don Fullerton and Gilbert Metcalf describe in a paper on the incidence of taxes, “This indirect price effect arises because the decrease in the equilibrium number of firms yields increased market power for the remaining firms.” (Don Fullerton and Gilbert Metcalf, “Tax Incidence,” in *Handbook of Public Economics, Volume 4*, 1st edition, ed. Alan Auerbach and Martin Feldstein (Amsterdam: Elsevier Science B.V., 2002), 1827.)

<sup>22</sup> FDA, “Preliminary Regulatory Impact Analysis: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” Table 3.

<sup>23</sup> FDA, “Generic Competition and Drug Prices,” available at [www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm).

<sup>24</sup> FDA, “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,” *Federal Register* 71, no. 15 (January 24, 2006), 3935, available at [www.gpo.gov/fdsys/pkg/FR-2006-01-24/pdf/FR-2006-01-24.pdf](http://www.gpo.gov/fdsys/pkg/FR-2006-01-24/pdf/FR-2006-01-24.pdf).

<sup>25</sup> Generic Pharmaceutical Association, “Generic Drug Savings in the U.S.: Fifth Annual Edition,” 2013, available at [www.gphaonline.org/media/cms/2013\\_Savings\\_Study\\_12.19.2013\\_FINAL.pdf](http://www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf).

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- <sup>26</sup> National Health Expenditure Accounts, historical data, Table 2, updated January 7, 2014, available at [www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables). IMS Health reports that nominal pharmaceutical spending totaled \$325.8 billion in 2012. We use National Health Expenditure Accounts data here for consistency in the government’s share of spending.
- <sup>27</sup> IMS Institute for Healthcare Informatics, “Declining Medicine Use and Costs: For Better or Worse? A Review of the Use of Medicines in the United States in 2012.”
- <sup>28</sup> National Health Expenditure Accounts, historical data, Table 16. These programs include Medicare, Medicaid, the Children’s Health Insurance Program (Titles XIX and XXI), the Department of Defense, and the Department of Veterans Affairs. Other smaller programs such as the Substance Abuse and Mental Health Services Administration and Indian Health Services are not included.
- <sup>29</sup> *Ibid.* This does not include drugs reimbursed through Medicare Part B, which totaled \$19.5 billion in 2010 (latest data available). See James Cosgrove, “Medicare: Information on Highest-Expenditure Part B Drugs,” testimony before the House Subcommittee on Health, June 28, 2013, available at [www.gao.gov/assets/660/655608.pdf](http://www.gao.gov/assets/660/655608.pdf).
- <sup>30</sup> *Ibid.*, “National Health Expenditure Projections 2012–2022,” Table 11, available at [www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf).
- <sup>31</sup> *Ibid.*
- <sup>32</sup> FDA, “Preliminary Regulatory Impact Analysis: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products,” 13.
- <sup>33</sup> *Ibid.*, 7.
- <sup>34</sup> FDA, “Drug Safety Labeling Changes,” available at [www.fda.gov/Safety/MedWatch/SafetyInformation/Safety-RelatedDrugLabelingChanges](http://www.fda.gov/Safety/MedWatch/SafetyInformation/Safety-RelatedDrugLabelingChanges).
- <sup>35</sup> FDA, “Drugs@FDA: FDA Approved Drug Products,” available at [www.accessdata.fda.gov/scripts/cder/drugsatfda](http://www.accessdata.fda.gov/scripts/cder/drugsatfda).
- <sup>36</sup> We excluded 24 label changes from the analysis because we were unable to determine whether the source was a CBE-0 supplement or a prior approval supplement, despite consultation with the Division of Drug Information within FDA’s Center for Drug Evaluation and Research.
- <sup>37</sup> We used the drug product data file for the third quarter of 2013, available at [www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html](http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html).
- <sup>38</sup> Government Accountability Office (GAO), “Medical Liability: Impact on Hospital and Physician Costs Extends Beyond Insurance” (September 1995), 16, available at [www.gao.gov/assets/230/221826.pdf](http://www.gao.gov/assets/230/221826.pdf).
- <sup>39</sup> U.S. Congress, Office of Technology Assessment, “Product Liability and the Pharmaceutical Industry,” in *Pharmaceutical R&D: Costs, Risks and Rewards* (Washington, DC: U.S. Government Printing Office, 1993), 170.
- <sup>40</sup> According to GAO, “[Drug and medical device] industry and insurance company officials stated that . . . manufacturers are reluctant to disclose settlement terms for fear of encouraging new suits or inflating future claims. Manufacturers are also reluctant to disclose their pricing strategies because of competition.” (GAO, “Medical Liability: Impact on Hospital and Physician Costs Extends Beyond Insurance,” 16.)
- <sup>41</sup> W. Kip Viscusi and Michael J. Moore, “Product Liability, Research and Development, and Innovation,” *Journal of Political Economy* 101, no. 1 (February 1993): 161–84.
- <sup>42</sup> W. Kip Viscusi, “Regulatory Reform and Liability for Pharmaceuticals and Medical Devices,” in *Advancing Medical Innovation: Health, Safety and the Role of Government in the 21st Century* (Washington, DC: Progress & Freedom Foundation, February 7, 1996), 79–115.
- <sup>43</sup> Brief for PhRMA and BIO as Amici Curiae Supporting Petitioner, p. 14, *Wyeth v. Diana Levine*, 555 US 555 (2009).
- <sup>44</sup> While the proxy is not perfect, a model based on the brand drug industry is the most appropriate given the unique risks pharmaceutical firms face. According to PhRMA and BIO’s brief in *Wyeth v. Levine*, “Insurance experts have observed that ‘the pharmaceutical industry presents one of the most volatile risk management challenges in the world of business today’” (p. 14).
- <sup>45</sup> Bureau of Labor Statistics, “The Pharmaceutical Industry: An Overview of CPI, PPI, and IPP Methodology,” October 2011, available at [www.bls.gov/ppi/pharmpricescomparison.pdf](http://www.bls.gov/ppi/pharmpricescomparison.pdf).
- <sup>46</sup> National Health Expenditure Accounts, “National Health Expenditure Projections 2012–2022,” Table 2.
- <sup>47</sup> IMS Institute for Healthcare Informatics, “Declining Medicine Use and Costs: For Better or Worse? A Review of the Use of Medicines in the United States in 2012.”
- <sup>48</sup> *Ibid.*