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# The True Costs of Generic Drug Regulation

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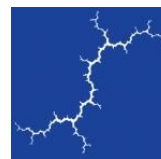
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# 1. INTRODUCTION

Are consumers being warned of the potential adverse health impacts of their prescription medications? Until recently there was a clear plan to provide such warnings: drug companies were responsible for informing their customers of any known hazards, through warnings included in the drug's labeling. However, a loophole in this standard opened up in 2011, exempting generic drug companies from a key part of their responsibility to inform their customers. In that year, the Supreme Court held in *Pliva v. Mensing* that Food and Drug Administration (FDA) regulations give generic manufacturers no control over drug labeling, requiring them to use the same label as the corresponding brand-name drug. Therefore, generic manufacturers cannot be held accountable for failing to warn their customers of potential harms, no matter how serious or well-known, if the brand-name label does not mention such risks.

In order for this decision to ensure adequate warnings to consumers, all brand-name labeling would have to be promptly and continually updated to include newly discovered hazards.<sup>1</sup> Yet that is not the case. Once low-priced generic drug production begins, brand-name producers typically lose most of their market share within months,<sup>2</sup> and may soon cease production – at which point they will cease to make labeling updates as well. In this common situation, a drug's labeling and its warnings are frozen in time: regardless of later research findings, no manufacturer is responsible for issuing any new health warnings, and no manufacturer is responsible for harm caused by adverse effects discovered after the brand-name producer leaves the market.

Label updates to brand-name drugs are often based on adverse event reports, posted online by the FDA and equally available to all manufacturers; but under current regulations, only brand-name producers are responsible for taking action in response to these posted reports. Adverse effects that have in some cases been associated with prescription drugs range from minor side effects, such as headaches and other temporary discomforts, to serious harms including elevated risks of birth defects, permanent disability, and death.<sup>3</sup>

In the majority opinion in *Mensing*, Justice Clarence Thomas wrote that from the perspective of patients harmed by a drug, differential liability for brand-name and generic drug companies

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<sup>1</sup> Adequate warnings could also result if the FDA required label updates – but this happens only rarely.

<sup>2</sup> Grabowski, Henry, Margaret Kyle, Richard Mortimer, Genia Long and Noam Kirson. 2011. "Evolving brand-name and generic drug competition may warrant a revision of the Hatch-Waxman Act." *Health Affairs* 30: 2157-2166; Grabowski, Henry, Genia Long and Richard Mortimer. 2014. "Recent trends in brand-name and generic drug competition." *Journal of Medical Economics* 17: 207-214.

<sup>3</sup> See the FDA's discussion of serious adverse effects at <http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm>.

...makes little sense. ... But “it is not this Court’s task to decide whether the statutory scheme established by Congress is unusual or even bizarre.” ... As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.<sup>4</sup>

The FDA now proposes to make such a change, allowing generic drug companies to update their own labels to reflect newly discovered health hazards. Under FDA’s proposal, generic producers would become responsible for warning their customers of all known hazards, just like brand-name drug companies. Could that impose ruinous economic costs on the generic drug industry and its customers?

The answer is clearly no, as this report will demonstrate. The generic drug industry, however, has claimed that FDA’s proposal would cause multi-billion-dollar increases in insurance costs and sharply reduced access to affordable prescriptions. A brief and barely documented cost-benefit analysis by Alex Brill, sponsored and circulated by the industry, makes the astonishing claim that the FDA proposal would impose annual costs of \$4 billion and might drive firms out of the industry.<sup>5</sup> This supposed economic devastation is the projected result of a 5.4 percent average increase in the price of generic drugs, which Brill anticipates would result from adoption of the FDA proposal.

This report addresses the concerns raised by the Brill report; whether the assumptions, data and cost-benefit analysis used in the report are accurate; and whether the FDA proposal will actually result in large costs to society. Our examination of the underlying basis for Brill’s claims reveals flaws so far-reaching as to render his cost estimate almost meaningless.

The Brill report relies on a sequence of three controversial claims. As summarized in Table 1 (next page), and presented in more detail in the following text, each of these claims is misleading and is refuted by an evidence-based, realistic analysis.

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<sup>4</sup> *Pliva, Inc. et al. v. Mensing*, 18-20. Available at <http://www.supremecourt.gov/opinions/10pdf/09-993.pdf>.

<sup>5</sup> Brill, Alex. 2014. “FDA’s proposed generic drug labeling rule: An economic assessment.” *Matrix Global Advisors*. <http://www.matrixglobaladvisors.com/GenericLabelingRule.pdf> (hereafter, the “Brill report”).

**Table 1. Costs and Benefits of Generic Drug Regulation: Two Approaches Contrasted**

<i>The Brill report</i>	<i>The realistic analysis</i>
<p>Product liability insurance costs for generic drug companies are a new cost to society. Increases in these insurance costs are the principal social costs of the FDA proposal.</p>	<p>Product liability insurance is a transfer payment, transferring the cost of harms from the victims of unsafe drugs to the producers. It is also an incentive for safer production and prompt notification of known hazards, yielding a potential benefit to society of reduced overall harm.</p>
<p>The available evidence on product liability insurance costs implies that the regulation will cause a 5.4% increase in average retail prices of generic drugs, or \$1.16 per prescription.</p>	<p>The estimated 5.4%, or \$1.16, price increase is based on a single scrap of very old data, confusion about the scope of liability insurance, and an arbitrary, unsupported assumption about generic drug company insurance costs. Yet even if this unsubstantiated estimate were accurate, it would not have a major impact on the generic drug market.</p>
<p>A price increase of this magnitude would be devastating to generic drug producers, perhaps causing firms to leave the industry.</p>	<p>Changes in liability rules do not have a visible effect on drug prices. Generic drug companies do not mention changes in liability regulations when describing the factors affecting the profitability of their business.</p>

## 2. LIABILITY INSURANCE IS NOT A COST TO SOCIETY

The FDA proposal to allow generic drug manufacturers to initiate labeling updates has only minimal costs. FDA estimates that the regulation will cause a minor increase in reporting and paperwork requirements, costing the industry as a whole a projected annual total of only \$4,237 to \$25,852.<sup>6</sup> FDA did not quantify or monetize the benefits of the rule, but those benefits would easily exceed the costs: as the FDA explains, the rule would make drugs safer and thereby prevent serious harm to patients.

In contrast, the Brill report estimates an annual cost of \$4 billion, more than 100,000 times larger than the high-end FDA cost estimate. The wide gap between the two figures reflects Brill's fundamentally mistaken interpretation of the societal costs of regulation.

Some expenses are increases in total social costs; others are transfer payments, changing who pays the costs but not the extent of the costs. The damages done by a major storm are a cost to society. Changes in federal, state, or private insurance covering those damages are transfer payments, affecting who pays for the damages, but not the total amount of damage done by the storm. A cost-benefit analysis evaluating new storm preparedness measures would compare the cost of those measures to the storm damages they could avoid. The bottom-line result, determining whether the proposed measures are worthwhile to society, depends on the amount of avoidable storm damages but not on who pays for them.

The same is true for the costs of adverse effects of prescription drugs. Brill's first fundamental error is his failure to recognize this point. In the words of the Brill report, FDA expects minimal costs "because it estimates the annual net social cost of the Proposed Rule based only on the paperwork and administrative burdens... The agency does not estimate any impact from generic product liability and the accompanying price increases...".<sup>7</sup> Brill says that under the proposed rule "Generic manufacturers' costs would rise due to higher insurance premiums, self-insurance costs, and reserve spending on product liability." Brill goes on to suggest that generic manufacturers and their insurance companies might leave the market due to these higher liability costs, leaving the public with no alternative to higher-priced brand name drugs.<sup>8</sup>

Brill's approach misunderstands the logic of cost-benefit analysis of public policy. The costs that belong in such an analysis are the additional uses of society's resources caused by the policy, making those resources unavailable for other purposes. FDA's estimates of this category appropriately include only the relatively trivial administrative costs of the new proposal. When an injured person wins a product liability lawsuit and is awarded damages, the payment from the producer (or the producer's insurance company) to the injured customer is not a new cost to society. Rather, it is a transfer of cost associated with a harm that has already occurred.

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<sup>6</sup> 78 Federal Register 67996.

<sup>7</sup> Brill report, 4.

<sup>8</sup> Brill report, 6.

In his in-depth treatment of the economics of pharmaceutical liability, RAND Corporation analyst Steven Garber says, “A payment or transfer of money has no direct consequences for economic efficiency because efficiency pertains to the aggregate material well-being in the United States regardless of its distribution among members of society.”<sup>9</sup>

The transfers of costs under current policies may have unfortunate effects on state governments, among others. In an *amici* brief in *Mensing*, 42 state governments and the District of Columbia argued against special treatment for generic drug makers:

Consumer protection, public health, and state budgets would be undermined if generic drug manufacturers were shielded from all state tort claims of this kind even when they sell drugs knowing that the label does not contain adequate warnings. [Such treatment of generic drug makers would]... eliminate a significant incentive for generic manufacturers to ensure the adequacy of warnings ... [and] leave uncompensated damages caused by generic drugs to be borne by state taxpayers who help finance Medicaid and other health-care programs...<sup>10</sup>

That is, holding a company liable for the cost of injury caused by its product does not change the cost to society; rather, it changes who pays that cost. Allowing drug companies to escape this liability transfers the costs of injuries from the companies to the patients, their private insurance providers, or public programs such as Medicaid.

Changes in product liability rules also have indirect incentive effects, both bad and good. But these effects are too uncertain for reliable measurement. On the negative side, Brill speculates that stronger product liability standards may discourage innovation, drive firms out of the industry, and incentivize “over-warning” that might scare patients from using beneficial drugs. It is extremely difficult to measure these effects (Brill does not even try to quantify them), and empirical research has not yielded a consensus on their likelihood, magnitude, or importance for the overall pharmaceutical industry.<sup>11</sup> Whatever the impact of product liability, the purported negative effects are far less important for generic firms than for brand-name firms. Generic firms engage in minimal innovation compared to the brand-name industry. Furthermore, the claim that firms will be driven from the industry is undermined by available data, as discussed below. And FDA officials have observed that over-warning is not a problem with brand-name drugs, where that incentive might be expected to be greatest (because greater liability risks attach to new and less proven medicines).<sup>12</sup>

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<sup>9</sup> Garber, Steven. 2013. “Economic effects of product liability and other litigation involving the safety and effectiveness of pharmaceuticals.” *RAND Corporation*. Available at <http://www.rand.org/pubs/monographs/MG1259.html>; quote from 13.

<sup>10</sup> *Amici curiae* brief of Minnesota, 41 other states and the District of Columbia in *Pliva v. Mensing*, 1. Available at [http://www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other\\_Brief\\_Updates/09-993\\_respondent\\_amcu\\_minnesota.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other_Brief_Updates/09-993_respondent_amcu_minnesota.authcheckdam.pdf).

<sup>11</sup> Garber, 2013.

<sup>12</sup> The FDA’s Associate Director for Policy, Center for Drug Evaluation and Research has stated: “We rarely find ourselves in situations where sponsors want to disclose more risk information than we think is necessary. To the contrary, we usually find ourselves dealing with situations where sponsors want to minimize the risk information.” She said that the FDA has not

On the positive side, making producers liable for the risks of their products creates an incentive for safer production and market surveillance, a vital safety tool since pharmaceuticals are generally tested on only hundreds or thousands of people before entering the marketplace. According to Richard Posner, a well-known federal judge and legal scholar:

Without tort liability, firms would have weak incentives to invest in safety measures... the aim of liability is to induce potential injurers to spend more on safety, and so the fact that they do spend more cannot be adjudged a failure to improve social welfare.<sup>13</sup>

In the words of the *New England Journal of Medicine* editors and authors:

Without the tort system, the FDA would be stripped of an essential source of information that the agency has consistently relied on when making its regulatory decisions, and the American public would be deprived of a vital deterrent against pharmaceutical company misconduct.<sup>14</sup>

Garber's lengthy and even-handed evaluation does not reach a conclusion about the balance of positive and negative incentive effects of pharmaceutical liability standards; he suggests specific modifications of selected details of regulations rather than sweeping changes. Even Brill did not attempt to put a dollar value on the incentive effects of regulations.

To summarize this section, Brill incorrectly describes product liability insurance costs as a new cost to society, rather than a transfer of responsibility for existing costs. As the next section will demonstrate, he is also wrong about the magnitude of those costs.

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experienced problems with over-warning. United States House of Representatives. October 2008. "FDA Career Staff Objected To Agency Preemption Policies." *Committee on Oversight and Government Reform, Majority Staff Report 3*.

<sup>13</sup> Posner, Richard. April 2007. *The Becker-Posner Blog*. Available at <http://www.becker-posner-blog.com/2007/04/index.html>.

<sup>14</sup> From their *amici* brief in *Wyeth v. Levine*, as quoted in Garber, 2013, 52.



### 3. CALCULATING THE COST OF PRODUCT LIABILITY INSURANCE

How much would generic drug company costs increase under the FDA proposal? An answer to this question is the core of the Brill report. And Brill's answer, as this section will show, is fundamentally mistaken.

Brill deduces that there will be intolerably large costs from the FDA proposal based on one obsolete datapoint and a few simple, arbitrary assumptions:

- A 20-year-old academic study, relying on now 30-year-old data, reports the average cost of product liability insurance for industry – not the pharmaceutical industry, but all industry.
- Brand-name drug companies are assumed to pay exactly that percentage for liability insurance today.
- Under the FDA proposal, generic drug companies are assumed to charge customers the same dollar amount *per prescription* for insurance costs as brand-name companies do, amounting to 13 times as great a percentage of retail prescription costs.

#### 3.1. The Number from the 1980s

Brill's sequence of calculations starts with a single number, the average cost of product liability insurance. It was not an easy number to find: pharmaceutical (and other) companies do not usually release data on their product liability insurance costs. Brill used a statistic from a very old economics research article, showing that for U.S. industry as a whole, liability insurance premiums averaged 0.67% of sales. That number appeared in an article published in 1993, and is based on an apparently comprehensive database on liability insurance policies that were in effect from 1980 to 1984.<sup>15</sup> The article thus provides a snapshot of insurance policies carried by firms more than 30 years ago.

No obvious public source of comparable data exists for more recent years or for the pharmaceutical industry in particular. The 1993 article appears to be based on one-time access to privately held data, and provides less description of the underlying data than is typical in academic articles. It appears to use data on almost 200 industries; pharmaceuticals would have been one of these industries.<sup>16</sup> The industries with the highest liability insurance costs were producers of known industrial hazards and explosive risks.

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<sup>15</sup> Viscusi, W. Kip and Michael J. Moore. 1993. "Product liability, research and development, and innovation." *Journal of Political Economy* 101: 161-184.

<sup>16</sup> Viscusi and Moore (1993) used data on 3-digit industries, an intermediate level of detail in the Standard Industrial Classification (SIC) codes that were then in effect. Pharmaceuticals were a single 3-digit industry under the SIC codes. The main statistical result in Viscusi and Moore is based on 928 observations, including data for each of the five years from 1980 to 1984. This suggests there could have been almost 200 industries, if data were missing for some industries and years.

The goal of the 1993 article was to determine the effect of liability costs on research and development (R&D). It found that, at low levels, greater liability induced more R&D, perhaps to develop new, safer products. At high levels, greater liability led to less R&D, presumably because firms focused on older products that were already known to be safe rather than taking on new risks. The tipping point, where liability costs cease to encourage and start to discourage R&D, was estimated to occur when liability insurance premiums reached 5 percent of sales. Only 11 industries, not including pharmaceuticals, were beyond that point in the early 1980s. The article thus suggests that in the early 1980s, increased liability costs would have inspired pharmaceutical companies and all but 11 other industries to *increase* their research on safer products.

Such findings may be of historical interest, but they are not necessarily applicable today. Yet the number from the 1980s – liability insurance premiums equal to 0.67% of sales – is the fulcrum on which all of Brill’s calculations are balanced. Brill assumes that the number applies to brand-name drug producers today; due to retail markups at pharmacies, liability costs of 0.67% of corporate sales translate to 0.4% of retail prices. He then assumes that the same insurance cost, \$1.16 *per prescription* sold in 2012, applies to generic drug companies.<sup>17</sup> Because generic drug prices are much lower than brand-name prices, \$1.16 per prescription is a larger percentage of sales for generics. As it turns out, Brill’s estimates make it 13 times larger: he projects that liability insurance on generic drugs averages 5.4% of retail prices.<sup>18</sup>

### 3.2. Tracing Brill’s Errors

The errors in Brill’s cost calculation begin with the crucial number, 0.67% of sales. One mistake is the unsupported assumption that the same number applies today. Although there is no comprehensive source of contemporary data on liability insurance premiums paid by industry, at least one report suggests that the 0.67% cost is now too high. A 2013 blog post on an insurance company’s website mentions that “the average cost [of product liability insurance] is about 26 cents per each \$100 of retail costs.”<sup>19</sup> This estimate, 0.26% of retail prices, is less than half of the 1980s figure used by Brill.

A second error involves the scope of liability insurance. Brill has taken an estimate for the cost of *all* product liability insurance and assumed that it is the cost for the specific categories affected by the FDA proposal. Both the 0.67% value from the 1980s, quoted by Brill, and the 0.26% value recently suggested by an insurance company are estimates for insuring all types of product liability. Yet the *Mensing* decision removed, and the FDA proposal would have the effect of restoring, only certain specific forms of liability.

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<sup>17</sup> Brill report, 9-10.

<sup>18</sup> Brill estimates the average retail price per prescription to be about 13 times higher for brand name drugs than for generics, \$290 versus \$22, which leads directly to the 13-fold differential in liability costs as a share of retail prices.

<sup>19</sup> Diversified Insurance Service. *Divinsurance.com*. Last accessed February 2015. Available at <http://www.divinsurance.com/commercial-insurance-blog/bid/292757/Product-Liability-Insurance-Costs-and-Coverage>.

There are three major categories of product liability, involving defects in design, manufacturing, and marketing. Design defects can cause adverse effects even when a product is made according to plans; manufacturing defects occur when impurities or other flaws are introduced in production; and marketing defects arise when companies fail to warn customers of known adverse effects. Each of these categories has been the subject of litigation, including major cases filed against pharmaceutical companies.

The *Mensing* decision only released generic drug companies from some forms of marketing, or failure to warn, liability.<sup>20</sup> That is, even under *Mensing*, generic companies need insurance (or self-insurance) against many other forms of product liability. Hence their liability insurance costs cannot be zero at present.

The FDA proposal, which would effectively reverse *Mensing*, likewise only affects some forms of failure to warn liability. Thus the new insurance costs associated with the FDA proposal must be only a fraction of the industry total. Brill has fudged this distinction, inappropriately using an estimate for the cost of *all* forms of product liability insurance, but applying it as if it were the cost of just the failure to warn liability affected by the FDA proposal.

A third mistake in the calculations is the strange assumption that branded drug companies pay the nationwide average cost, while generics pay 13 times as much per dollar of sales. This assumption is defended only in passing by Brill's statement that it is the level of insurance costs that "could be expected ... based on our model".<sup>21</sup> But the Brill report never describes the model or presents evidence to show either that pharmaceutical company insurance premiums are set on a per-prescription basis, or that they are 13 times as much of a burden on generic companies as on brand-name producers.

On this topic, contradictory factors point in opposite directions. On the one hand, if liability per consumer were effectively the same for branded and generic producers, then liability costs per prescription would be higher for generic companies. On the other hand, generic companies are selling older medicines, for which the adverse effects should be better known than for newer, brand-name products. This suggests that liability costs per consumer should be considerably lower for generic drugs.

Each of the assumptions underlying Brill's calculation results in arbitrary errors or overestimation of the cost of a change in FDA labeling rules:

- There is no reason to think that an estimate of product liability insurance for all of American industry in the early 1980s applies to brand-name pharmaceutical companies today.
- The 2011 Supreme Court ruling and the recent FDA proposal affect only one of several forms of product liability. A cost estimate for all forms of product liability insurance is sure to be an overestimate for the specific form of liability affected by the FDA proposal.

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<sup>20</sup> Even after *Mensing* generic companies may be subject to failure to warn liability, if they fail to conform their labeling to updated brand-name labeling.

<sup>21</sup> Brill report, 10.

- There is no evidence that generic companies have exactly the same liability insurance costs per prescription as brand-name companies, as Brill assumes.

As a result of this cascade of errors, there is no reason to take seriously Brill’s estimate of a 5.4 percent, or \$1.16 per prescription, increase in the cost of generic drugs under the FDA proposal.

### 3.3. How Much Does a \$1.16 Price Increase Matter?

Suppose that a change in regulations did cause a 5.4 percent increase in the price of generic drugs, or equivalently, imposed a new charge of \$1.16 per prescription. We saw in the last section that these numbers are suspect and unsubstantiated, but now assume that for whatever reason, they turn out to be true. The final step in Brill’s analysis is the assertion that these are ruinous increases, enough to drive drug companies and insurers out of the market and to reduce consumer access to valuable prescription drugs.

Imagine that, as you are picking up a prescription drug, the pharmacist tells you that there is a new \$1.16 fee in addition to the price you had expected to pay. Moreover, the same fee now applies to every generic drug on the market, with only the much more expensive branded drugs escaping the fee. Of course it would not be welcome news – but would an extra \$1.16 change your decision to fill a needed prescription? If consumers or their health insurance providers grumble but pay the fee, then profits will not fall and drug companies will not stop selling drugs. The sky is falling, according to the Brill report, only because a \$1.16 across-the-board price increase on generic drugs would cause people across the country to cut back on purchases of prescriptions in such large numbers that drug companies would be forced to leave the industry.

In more formal economic terms, the price elasticity of demand (the percent change in sales volume caused by a one percent change in price) is quite small for pharmaceuticals. A recent study found price elasticities of less than -0.16 for all eight categories of medications in the study.<sup>22</sup> With elasticities this small, Brill’s projected and feared 5.4 percent price increase would imply a decrease in sales volume of less than one percent.<sup>23</sup>

Price increases much bigger than 5.4 percent or \$1.16 per prescription are sadly familiar to patients. Manufacturers of brand-name drugs that are under patent protection – typically a period of 7-12 years after the drug comes on the market – can raise their prices with relative impunity. From 2000 to 2008,

<sup>22</sup> Gatwood, Justin, Teresa B. Giobson, Michael E. Chernew, Amanda M. Farr, Emily Vogtmann and A. Mark Fendrick. 2014. “Price elasticity and medication use: Cost sharing across multiple clinical conditions.” *Journal of Managed Care & Specialty Pharmacy* 20: 1102-1107a.

<sup>23</sup> For example, 5.4% price increase \* (-0.16 elasticity) = -0.86% change in sales.

there was a 100 percent or greater price increase on a brand-name prescription drug product once every eight days.<sup>24</sup>

Big price increases are likewise not unknown for generic drugs.<sup>25</sup> Although the overall trend in generic prices has been downward over the last several years, recent and abrupt price increases for some generic drugs prompted a Congressional hearing and a Justice Department investigation in 2014.<sup>26</sup> In the Congressional hearing, Senator Bernie Sanders observed that the prices of more than 1,200 generic medications had increased by an average of 448 percent between July 2013 and July 2014.<sup>27</sup>

Several theories about these price increases have been suggested. One theory is that manufacturing problems and shortages of raw materials have led to shortages and price spikes for some generics.<sup>28</sup> One observer, William Comanor, head of pharmaceutical economics and policy studies at the University of California, Los Angeles, thinks that many generic drugs are priced so low that manufacturers cannot invest in long-term stocks of raw materials, resulting in price fluctuations as inventories rise and fall.<sup>29</sup> Many have blamed the consolidation of market power through mergers and acquisitions, which has sharply reduced competition among generic drug makers.<sup>30</sup> Since 2011, generic drug company mergers have cut the number of manufacturers of each drug down to only a few, and in some cases just one, allowing big price increases.<sup>31</sup>

Whatever the explanation, the facts are clear: prices of both brand-name and generic drugs have frequently changed by much more than 5.4 percent without destroying the industry or ending patients' access to needed medicines.

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<sup>24</sup> U.S. Government Accountability Office. 2009. "Brand-name prescription drug pricing: Lack of therapeutically equivalent drugs and limited competition may contribute to extraordinary price increases." Available at <http://www.gao.gov/new.items/d10201.pdf>.

<sup>25</sup> Alpern, Jonathan D., William M. Stauffer, and Aaron S. Kesselheim. 2014. "High-cost generic drugs – Implications for patients and policymakers." *New England Journal of Medicine* 371: 1859-1862.

<sup>26</sup> Silverman, Ed. 2014. "Justice Department Probes Generic Companies after Price Hike Reports." *The Wall Street Journal*, November 10. Available at <http://blogs.wsj.com/pharmalot/2014/11/10/justice-department-probes-generic-competition-after-price-hike-reports/>.

<sup>27</sup> Mohney, Gillian. 2014. "Generic Drug Price Sticker Shock Prompts Probe by Congress." *ABC News*. November 21. Available at <http://abcnews.go.com/Health/generic-drug-prices-skyrocketing-lawmakers-warn/story?id=27060992>.

<sup>28</sup> Bliss, Susan, J. 2014. "Shortages of Prescription Drugs Reported Nationwide." *Healthline.com*. Available at <http://www.healthline.com/health-news/shortages-of-prescription-drugs-reported-072114#1>.

<sup>29</sup> Lazarus, David. 2014. "What's behind the huge price jump for some generic drugs?" *Los Angeles Times*, October 21. Available at <http://www.latimes.com/business/la-fi-lazarus-20141021-column.html>.

<sup>30</sup> Rosenthal, Elisabeth. 2014. "Rapid Price Increases from Some Generic Drugs Catch Users by Surprise." *New York Times*, July 9. Available at [http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html?\\_r=0](http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html?_r=0).

<sup>31</sup> Katz, Alan. 2013. "Surprise! Generic-Drug Prices Spike." *Bloomberg Businessweek*, December 12. Available at <http://www.businessweek.com/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise>.

## 4. AN IMMATERIAL IMPACT?

There is no public information bearing directly on the magnitude of product liability insurance or self-insurance costs for generic drug companies. If, however, a rule that will result in potential liability for generic manufacturers would have significant negative impacts on the industry, then one would expect that the June 2011 Supreme Court ruling that those manufacturers could not be held liable should have had a significant positive impact. At the time, no leading generic drug firms made this assertion.

Every year, generic drug companies, like other publicly traded companies, submit 10-K forms (for domestic firms) or 20-F forms (for foreign firms) to the Securities and Exchange Commission (SEC). These forms require companies to disclose a range of information to current and potential investors, including any potential policies or changes in the market that might materially impact future profits over the coming year(s).

A review of 10-K's and 20-F's from six of the largest generic drug firms between 2011 and 2013 revealed that only one, Teva, even mentioned the Supreme Court's *Mensing* ruling. Teva's brief mention of the subject in 2013 said that the 2011 *Mensing* decision was "likely to reduce [Teva's] aggregate exposure in currently pending product liability lawsuits, including those described below, although the extent of such reduction is uncertain at this time."<sup>32</sup> Teva also reported that "[t]he Company and its subsidiaries are involved in various patent, product liability, commercial, government investigations, environmental claims and other legal proceedings that arise from time to time in the ordinary course of business."<sup>33</sup>

Although they do not otherwise mention the impact of the *Mensing* ruling, the 10-K's and 20-F's of the six companies have numerous mentions of product liability issues that arise in generic drug production. For example, in 2013 Actavis noted:

The design, development, manufacture and sale of our products involve an inherent risk of product liability claims and the associated adverse publicity. Insurance coverage is expensive and may be difficult to obtain... If the coverage limits for product liability insurance policies are not adequate or if certain of our products are excluded from coverage, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.<sup>34</sup>

Hospira acknowledged similar concerns:

Hospira's business is subject to potential product liability risks that are inherent in the design, development, manufacture and marketing of drugs, medical devices and other

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<sup>32</sup> Teva Pharmaceutical Industries. 2013. Teva Form 20-F: F-35. Available at <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-reportsAnnual>.

<sup>33</sup> Teva Pharmaceutical Industries. 2013. Teva Form 20-F: 86. Available at <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-reportsAnnual>.

<sup>34</sup> Actavis Plc. 2013. Actavis Form 10-K: 39-40. Available at <http://ir.actavis.com/phoenix.zhtml?c=65778&p=irol-reportsAnnual>.

products. In the ordinary course of business, Hospira is the subject of product liability claims and lawsuits alleging that its products have resulted or could result in an unsafe condition or injury to patients. Product liability claims and lawsuits, safety alerts, recalls or corrective actions, regardless of their ultimate outcome, could have a material adverse effect on Hospira's business and reputation and on its ability to attract and retain customers.<sup>35</sup>

Sanofi saw reasons for concern in general about product liability:

Substantial damage awards and/or settlements have been handed down — notably in the United States and other common law jurisdictions — against pharmaceutical companies based on claims for injuries allegedly caused by the use of their products ...

We are currently defending a number of product liability claims ... and there can be no assurance that the Group will be successful in defending against each of these claims or will not face additional claims in the future.<sup>36</sup>

Annual reports provide a similar, sometimes more expansive account of major issues facing companies, and tell a similar story to the 10-K/20-F forms. We reviewed annual reports for eight of the top generic drug companies from 2011 through 2013, as shown in Table 2.<sup>37</sup> Teva was again the only firm to mention *Mensing*, with the same single comment. In contrast, seven of the eight highlighted product liability issues in their annual reports, and six mentioned product liability lawsuits in which the company was engaged.

**Table 2. Product liability issues in top generic drug company annual reports, 2011-2013**

Company	Mentions Product Liability?	Mentions Lawsuits?	Mentions <i>Mensing</i> ?
Teva	✓	✓	✓
Mylan	✓	✓	
Abbott	✓		
Sanofi	✓	✓	
Sun Pharma	✓	✓	
Actavis	✓	✓	
Hospira	✓	✓	
Aspen			

Source: Assembled by authors from annual reports

<sup>35</sup> Hospira, Inc. 2013. Hospira Form 10-K: 25. Available at <http://www.hospirainvestor.com/phoenix.zhtml?c=175550&p=irol-sec>.

<sup>36</sup> Sanofi S.A. 2013. Sanofi Form 20-F: 5. Available at [http://en.sanofi.com/investors/news/financial\\_publications/financial\\_publications.aspx](http://en.sanofi.com/investors/news/financial_publications/financial_publications.aspx)

<sup>37</sup> Annual reports to investors, but not SEC 10-K or 20-F forms, were available for Sun Pharma and Aspen.

Product liability is a much-discussed part of business as usual for the generic drug industry. Yet the reduction in that cost after June 2011 barely warranted mention in the industry's SEC filings (either 10-K's or 20-F's) and annual reports to investors.





## 5. CONCLUSION

Branded and generic drug companies are becoming harder to distinguish from one another. Both industries are dominated by multi-billion-dollar multinational companies that have consolidated market power in recent years. It is not uncommon for the same companies to operate in both markets. As generic drug companies themselves note in their annual reports, they are well aware of the legal risks they face when entering the market and consider those risks to be part of the costs associated with the industry.

The FDA's proposed change in prescription drug regulation would have the effect of reversing an unusual exemption from corporate responsibility that generic drug companies have enjoyed only since 2011. Like brand-name drug makers and other corporations, the generic producers would become responsible for warning their customers of known hazards associated with their products. Failure to warn their customers could expose the generic companies to liability for damages caused by known hazards, just as it does for brand-name drug producers and other manufactures of all other types of products, and just as was the case for generic firms before 2011.

The generic drug companies have claimed, based largely on the Brill report, that ending their recently created idiosyncratic exemption from liability would cause multi-billion dollar losses and would reduce public access to valuable pharmaceuticals. As seen above, the wildly overestimated value of losses presented in the Brill report is a consequence of three major missteps:

1. It counts liability insurance payments as a cost to society, rather than as a transfer payment that transfers costs from victims to those responsible for harming them.
2. It assumes that brand-name drug companies are paying for liability insurance at a rate that was prevalent in the 1980s, and that generic companies would have to pay 13 times as much – rather than noticing that generic companies are multi-billion dollar multinational corporations that already manage significant product liability risks, frequently through self-insurance.
3. Projecting, on flimsy grounds, a 5.4 percent or \$1.16 per prescription retail price increase for generic drugs, it asserts that the FDA proposed regulation would be a game-changing economic disaster – ignoring the fact that generic drug companies frequently impose much larger price increases on their customers without apparent losses.

In the world according to Brill, generic drug companies are frightened of disastrous cost increases from a proposed regulatory change. Yet when they report on their financial prospects, providing information to current and potential investors on 10-K forms and annual reports, those same generic companies have not flagged the issue.

Finally, companies that remain frightened of the economic consequences of the FDA proposal should note that failure to warn customers of known hazards is an avoidable error. As the pharmaceutical industry itself has suggested, in an article on PharmaManufacturing.com,

... loss control aims to reduce both the frequency and severity of loss. In the context of pharmaceutical product liability, four specific steps are:

- Safe design of drugs
- Good manufacturing practices
- Effective warnings and labels
- FDA regulatory compliance

View these as the four pillars of effective product liability loss control. If pharmaceutical firms have these components buttoned down, they have a good chance of either preventing product liability claims or successfully defending any claims and lawsuits that surface.<sup>38</sup>

For a concluding perspective on the issue, consider the views of Richard Levick, a corporate communications consultant writing for *Forbes*:

Until now...the generic companies have been cast in an appealing hero's role, the plucky underdogs who offer the public financially critical alternatives to Big Pharma.

As healthcare industry growth patterns persist, it will be hard for the generics to maintain that role. Now they *are* Big Pharma...

At the end of the day, every business is responsible for the goods and services it sells, and the FDA has signaled its intent to impose just such responsibility on the generic companies.

They do sell drugs, after all.<sup>39</sup>

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<sup>38</sup> Quinley, Kevin M. 2011. "Building an Effective Pharmaceutical Product Liability Risk Management System." *Pharmamanufacturing.com*. January 25. Available at <http://www.pharmamanufacturing.com/articles/2011/009/>.

<sup>39</sup> Levick, Richard. 2013. "Generic Drug Makers Will Soon Face The Regulatory Music." *Forbes*, July 15. Available at <http://www.forbes.com/sites/richardlevick/2013/07/15/generic-drug-makers-will-soon-face-the-regulatory-music/>.