American Association for Justice Misses on 'The True Costs of Generic Drug Regulation'

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On March 26, 2015, energy economist Frank Ackerman released a report[1] prepared for the American Association for Justice. This report alleged fault in a 2014 Matrix Global Advisors (MGA) study[2] authored by Alex Brill on the economic impact of the Food and Drug Administration's (FDA) Proposed Rule on generic drug labeling.[3] The MGA study estimates that the Proposed Rule would increase U.S. health care spending by $4 billion annually. Here, we respond to the myriad false claims that Ackerman makes about the MGA analysis and the consequences of the Proposed Rule.

Ackerman makes both unfounded criticisms of the MGA analysis and false assertions about the impact of the Proposed Rule. We first address the former before discussing two of the most problematic examples of the latter.

I. Responding to Ackerman's Erroneous Criticisms

Ackerman criticism:

"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" (p. 4).

MGA response:

Ackerman does not understand the type of impact analysis required by law. As the FDA notes in its analysis of the Proposed Rule:

> [T]he Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year."[4]

The FDA asserts that the Proposed Rule does not reach the inflation-adjusted threshold for one-year expenditures ($141 million at the time the Proposed Rule was released). But the agency fails to account for the liability exposure that generic drug manufacturers would face as a result of the Proposed Rule. We estimate that this would increase public and private health care expenditures by $4 billion annually—far in excess of the threshold established in the Unfunded Mandates Reform Act.

Ackerman criticism:

"Brill incorrectly describes product liability insurance costs as a new cost to society, rather than a transfer of responsibility for existing costs" (p. 6).

MGA response:

We do not contend in our study or elsewhere that product liability costs are a new cost to society. We argue that costs associated with failure-to-warn lawsuits would be a new cost to generic drug companies and that these costs would be borne by payors.

Ackerman criticism:

"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" (p. 9).

MGA response:

On the contrary, there is no reason to think that product liability costs have declined in the last several decades. And, as noted in the MGA study, the pharmaceutical industry bears a disproportionate liability burden relative to other industries.

Ackerman criticism:

"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" (p. 9).

MGA response:

We look at product liability insurance premiums for bodily injury, not all forms of product liability insurance. We also note that we do not include self-insurance costs (including deductibles), which in the drug industry is a very common and significant manner of insurance.

Ackerman criticism:

"There is no evidence that generic companies have exactly the same liability insurance costs per prescription as brand-name companies, as Brill assumes" (p. 10).

MGA response:

It should be intuitive that the liability risk for a generic prescription is not different than for a brand prescription, and the evidence is clear, as we discuss in the MGA study, that label changes occur for new and old drugs with similar frequency. Therefore, it is logical to assume that generic drugs would have the same per-prescription liability costs as brand drugs.

Ackerman criticism:

"With elasticities this small [–0.16], Brill's projected and feared 5.4 percent price increase would imply a decrease in sales volume of less than one percent" (p. 10).

MGA response:

This criticism displays a fundamental misunderstanding of our analysis. It is precisely because the demand for

pharmaceuticals is so inelastic that the Proposed Rule would increase health care spending by $4 billion.

Ackerman criticism:

"*[P]rices 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" (p. 11).*

MGA response:

We do not claim that the increase in drug spending would destroy the industry or affect patient access. We note in our analysis that generic drug firms may decide to leave the market because of product liability risk, but this is entirely separate from the cost estimate of $4 billion.

II. RESPONDING TO ACKERMAN'S ERRONEOUS ASSERTIONS

Ackerman assertion:

"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" (p. 9).

MGA response:

Our analysis of label changes for older drugs, described in our study, disproves Ackerman's assumption. We, like the FDA, find that label changes often occur after generic entry.

We are interested in knowing why Ackerman asserts that "if liability per consumer were effectively the same for branded and generic producers, then liability costs per prescription would be higher for generic companies." Because generic drugs fill more than five times the prescriptions that brand drugs fill, it stands to reason that generic manufacturers' product liability exposure would be far greater than brand companies' exposure. But Ackerman's assertion contradicts the intuition that liability costs per prescription would be similar for brand and generic firms.

Ackerman assertion:

"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" (p. 14).

MGA response:

Ackerman assumes there was a reduction in generic drug firms' product liability costs following the Supreme Court's *Mensing* decision, yet he offers no support for this assumption. It behooves him to determine the liability risk faced by generic firms before 2011 from failure-to-warn claims.

III. CONCLUSION

We note in conclusion that Ackerman offers an alternative to the proxy for product liability cost that we use in our analysis. He prefers an alternative estimate of the average cost of product liability insurance of 0.26 percent of retail costs.[5] This corresponds to an estimate of 0.67 percent in the MGA analysis.

The estimate we use was published in a peer-reviewed academic journal in the early 1990s.[6] As we note above, there is no reason to believe that this number needs to be updated. And, while not a perfect proxy, it is a conservative estimate of product liability costs for drug manufacturers, as we explain in the MGA study. Ackerman's preferred estimate is more recent but is derived from an insurance company's blog post that includes no attribution. Yet, even using this assumption yields an estimate of approximately $1.5 billion annually in increased expenditures by public and private payors. This is still far above the Unfunded Mandates Reform Act threshold that, as discussed above, should guide the FDA's analysis.

It is important that economists maintain high professional standards when engaging in public policy debate. Reasonable experts can certainly disagree about assumptions and models, but neither the public nor the FDA is well served by misinformation or baseless attacks.

Estimating the full economic impact of the Proposed Rule poses some legitimate challenges. In our study, we present a systematic analysis of the product liability costs that the Proposed Rule would induce. But other effects could also materially impact public and private expenditures. These include dynamic responses by manufacturers who may exit certain product lines or consolidate with larger firms. Ackerman's efforts would have been better directed toward contributing to a thorough understanding of these impacts rather than confusing policymakers, stakeholders, and consumers with false claims.

NOTES

[1] Frank Ackerman and Joseph Daniel, "The True Costs of Generic Drug Regulation," Synapse Energy Economics, March 2015, available at www.synapse-energy.com/sites/default/files/Synapse-Generic-Drug-Report-14-137.pdf.
[2] Alex Brill, "FDA's Proposed Generic Drug Labeling Rule: An Economic Assessment," Matrix Global Advisors, February 2014, available at www.matrixglobaladvisors.com/GenericLabelingRule.pdf. This report was sponsored by the Generic Pharmaceutical Association.
[3] 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.
[4] FDA, "Preliminary Regulatory Impact Analysis: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products" (November 13, 2013), 3, available at www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM375128.pdf.
[5] Zach Emly, "Product Liability Insurance Costs and Coverage," Diversified Insurance Service Blog, May 20, 2013, available at www.divinsurance.com/commercial-insurance-blog/bid/292757/Product-Liability-Insurance-Costs-and-Coverage.
[6] 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.