Congress of the United States

Washington, DC 20510

June 25, 2014

The Honorable Howard A. Shelanski
Administrator of the Office of Information and Regulatory Affairs
The Office of Management and Budget
1725 17th Street Northwest
Washington, D.C. 20503

Dear Administrator Shelanski,

We are writing to inquire about the legal authority and cost-benefit analysis the Food and Drug Administration (FDA) included in its proposed rule ending the requirement that generic drugs have the same labeling as their brand-name counterparts.[1] By making generics independently responsible for the content of their labeling, the rule strikes at the heart of the federally mandated trade-off, embodied in the bipartisan Drug Price Competition and Patent Term Restoration Act of 1984, that keeps generic drug prices low.[2]

As the Supreme Court has described, Congress made the decision to "regulate . . . generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers incapable of modifying either the drugs' compositions or their warnings."[3] This trade-off has been ignored in FDA's cost-benefit analysis of the proposed rule. The consequences for the elderly and infirm, as well as government-sponsored plans like Medicare, could be severe if the rule is promulgated. We write with fresh cost data as well as analysis suggesting the benefits estimated by FDA are overstated. We also request a briefing to ensure that the Office of Information and Regulatory Affairs' (OIRA) final examination of the proposed rule will be more thorough.

Background

Executive Order 12866 requires OIRA to examine proposed rules that have "an annual effect on the economy of $100 million or more" or "raise novel legal or policy issues."[4] FDA's proposed rule does both.

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[1] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 (proposed Nov. 13, 2013).

[2] Pub. L. No. 98-417, 98 Stat. 1585.

[3] *Mutual Pharmaceutical Co., Inc. v. Bartlett,* 133 S. Ct. 2466, 2480 (2013).

[4] Exec. Order No. 12,866, 3 C.F.R. 638 (1994), *reprinted as amended in* 5 U.S.C. §601 (1994).

Legal Authority

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments, requires generic drug labels to be "the same as" the labels on their brand-name counterparts.[5] This requirement persists "throughout the lifecycle of the generic drug product."[6] As the Solicitor General told the Supreme Court in 2011, in the case of *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567, the "FDA has consistently taken the position that an ANDA holder [*i.e.*, generic manufacturer] may not unilaterally change its approved labeling."[7]

Notwithstanding the federal government's position before the Supreme Court, on November 13, 2013, FDA proposed a rule permitting generic drug companies to alter their drug labels unilaterally, without review by FDA or the pharmaceutical company whose product the generic brand copies. FDA claims it is authorized to promulgate the rule under the "same authority" that it has to regulate brand-name labeling. However, rulemaking for brand-name labels is different, because it is not limited by the statutory "same as" requirement that applies to generics labels. Tellingly, FDA does not address this. Instead, it merely asserts its own authority that "[n]othing in the Hatch-Waxman Amendments . . . limits the Agency's authority" to issue the rule.[8]

Cost-Benefit Analysis

Aside from these serious questions of legal authority, the agency's cost-benefit analysis is flawed and requires your scrutiny.

Benefits Assertions are Flawed

Supporters say the rule would allow new drug safety information to flow to consumers as quickly as possible. They argue that currently there is a "safety gap."

This argument, however, is contradicted by the Government's own brief in *Mensing*. The Solicitor General told the Court that even though generics cannot modify labeling, FDA "contemplated" this situation and provided methods for generics to "discharge their

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[5] 21 U.S.C. §355(j)(4)(G).
[6] 21 CFR 314.150(b)(10), *see also*, Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67,988 (proposed Nov. 13, 2013) ("FDA has generally taken the position that a generic drug must maintain the same labeling as the RLD throughout the lifecycle of the generic drug product").
[7] Brief for the United States as Amicus Curiae Supporting Respondents at 16, *PLIVA, Inc. v. Mensing*, No. 09-993 (2011).
[8] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67,995 (proposed Nov. 13, 2013).

duty to provide adequate warnings."[9] If a generic manufacturer "believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised."[10] In particular, FDA gives generic manufacturers "points of contact in FDA's Office of Generic Drugs . . . . [I]ntra-agency consultations regarding . . . 'possible serious safety concerns' are assigned the highest priority."[11]

Generics also currently have an obligation to report adverse events associated with their drugs to FDA and to conduct certain post-market surveillance regarding adverse events. This is another avenue in current law for FDA to determine whether a generic drug requires a change to its label. In a letter to Congress, FDA stated, "The proposed rule neither cites nor is based on evidence that generic drug manufacturers are not submitting to FDA required reports of spontaneous adverse event reports that they receive."[12]

FDA also argues that the decision in *Mensing* encourages generics to be lax, because the Court ruled that because generics must use the brand-name labeling, they cannot be sued for inadequate warnings on those labels.[13] This, FDA says, "alters the incentives for generic drug manufacturers to" keep drug safety information up to date.[14] Permitting generics to change their labels unilaterally would be intended to reinstate incentives rooted in exposure to tort liability.

One premise of the proposed rule is that the absence of tort liability for inadequate labeling reduces the incentives for generics to report new safety information to the FDA to keep warning labels up-to-date. If that is true, one would expect that the number of black box warnings would fall after 2011, when, in *Mensing*, the Supreme Court announced that generics were immune from tort liability for failure to warn. In fact, Public Citizen's data on black box warnings from 2008-2012 exhibits the opposite trend. From 2008 to 2011, the number of updates, respectively, were 10, 10, 4 and 10.[15] The Supreme Court decision came in June 2011. During the following year, 2012, there were 22 updates.[16] FDA's data show that in 2013 there

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[9] Brief of United States, *supra* note 6, at 20.
[10] *Id.*
[11] *Id.* at 21.
[12] Howard, Sally, Deputy Commissioner, Food and Drug Administration. Letter to Senator Lamar Alexander (February 26, 2014).
[13] *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011).
[14] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 at 67988-89 (proposed Nov. 13, 2013).
[15] Public Citizen, Generic Drug Labeling: A report on serious warnings added to approved drugs and on generic drugs marketed without a brand-name equivalent (June 2013) *available at* http://www.citizen.org/documents/2138.pdf at pages 7-10.
[16] *Id.*

were another 19 black box warnings added to generic drug labels.[17] Thus, the preliminary trend has been the opposite of what would be expected by the rule's proponents, even after liability was removed. This data could suggest that the public safety benefits of the rule may be overstated.

Costs Assertions are Flawed

Weighed against the unproven benefits of the proposed rule are its costs, which new data suggest are significant. FDA originally estimated the rule's net annual social costs to be between $4,237 and $25,852.[18] These figures derive from the costs of "submitting and reviewing" the paperwork associated with labeling changes. Oddly, FDA did not consider litigation-associated costs, even though reinstating tort liability for generic manufacturers was a stated intent of the rule. According to a February 2014 economic analysis from Matrix Global Advisors, when these litigation related costs are included, the costs of the proposed rule jump to $4 billion annually.[19] The author of the analysis, moreover, terms this figure a "conservative estimate," and the estimate includes $1.5 billion in annual higher drug costs for government health care plans like Medicaid.[20]

Such significant estimates of cost increases are realistic, given that Congress purposely exempted generics from independent and extensive safety testing requirements in order to lower medication costs for the public. As the Supreme Court explained:

> In 1984 . . . Congress passed the . . . Hatch-Waxman Amendments. Under this law, "generic drugs" can gain FDA approval simply by showing equivalence to [an] . . . approved [drug]. This allows manufacturers to develop generic drugs in-expensively, without duplicating the clinical trials already performed on the equivalent brand-name drug.[21]

Justice Sotomayor agreed that the law was "wildly successful."[22] Today, 90% of prescriptions for which generics are available are filled with those generics. Ending the generic industry's ability to rely on brand-name manufacturers for safety information extinguishes the very advantage that keeps generic prices low.

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[17] Public Citizen's data was only current through March 2013. The 2013 data is from the FDA's Drug Safety Labeling Changes website, available at http://www.fda.gov/Safety/MedWatch/SafetyInformation/Safety-RelatedDrugLabelingChanges/default.htm.
[18] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67,996 (proposed Nov. 13, 2013).
[19] Alex Brill, *FDA's Proposed Generic Drug Labeling Rule: An Economic Assessment*, Matrix Global Advisors, Feb. 5, 2014.
[20] *Id.*
[21] *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011).
[22] *Id.* at 2584.

Public interest comments submitted by the Mercatus Center in response to the proposed rule identify additional problems with FDA's cost analysis.[23] FDA assumes generics will change their behavior in response to the rule, but fails to account for the cost of those changes in behavior. For example, FDA does not estimate any costs associated with increased monitoring or researching, developing, and writing label changes. FDA also acknowledges in the proposed rule that costs may be higher if generics submit multiple proposed label changes for the same adverse event, but FDA does not quantify that cost due to the uncertainty of how the rule will impact industry behavior. "That costs are uncertain is not an excuse for not including estimates of it in the analysis and biasing the estimated costs downward in the process."[24] Additionally, Mercatus notes that the cost to FDA of maintaining the proposed public website are not included in the estimates for the proposed rule.

Accordingly, in keeping with our oversight responsibilities, we respectfully request the following:

(1) A commitment from you to review FDA's proposed rule and supporting documentation, particularly the cost-benefit analysis submitted by FDA, independently and with specific attention to potential litigation-related costs;

(2) Details of OIRA's consultations, if any, with the Justice Department regarding the legality of the proposed rule in light of the statutory sameness requirement and the Solicitor General's recent statements of the Executive Branch's interpretation of the law in *Mensing*;

(3) A briefing provided by OIRA to address the issues raised in this letter.

We look forward to your prompt reply.

Sincerely,

Rep. Bob Goodlatte
Chairman
Judiciary Committee
U.S. House of Representatives

Senator Lamar Alexander
Ranking Member
Committee on Health, Education, Labor & Pensions
U.S. Senate

[23] Todd M. Nesbit, *Public Interest Comment on Docket No. FDA-2013-N-0500*, Mercatus Center George Mason University, March 4, 2014. *Available at:* http://mercatus.org/sites/default/files/Nesbit_Generic-Drug_PIC_022714.pdf

[24] *Id.*