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VIA ELECTRONIC SUBMISSION
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Stephen Ostroff, M.D.
Acting Commissioner
Food and Drugs
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2013-N-0500 ((RIN) 0910-AG94) - Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

Dear Dr. Ostroff:

We are providing these comments in response to the reopening of the comment period for *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, Docket No. FDA-2013-N-0500 ((RIN) 0910-AG94)[1], published on November 13, 2013. As such, these comments and our public statement at the hearing held on March 27, 2015, should be considered supplements to our previous comments, on behalf of the U.S. Chamber Institute for Legal Reform ("ILR"). The U.S. Chamber of Commerce ("Chamber") is the world's largest business federation representing the interests of more than three million companies of every size, sector, and region. ILR is an affiliate of the Chamber, dedicated to making our nation's overall civil legal system simpler, fairer, and faster for all participants.

Summary of Previous Comments

As discussed in ILR's previous comments and at the public meeting, we believe that the FDA's proposed rule would impose new and unnecessarily burdensome compliance costs on prescription drug manufacturers and expose such manufacturers to additional litigation. Further, ILR believes the proposed rule violates the "sameness" requirements established under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, (commonly known as "Hatch-Waxman"). Since the passage of Hatch-Waxman, the FDA has maintained that brand and generic prescription drugs must carry labels that are materially identical. The proposed rule ignores both the plain language of the statute and the FDA's long-standing interpretation of the "sameness" requirement.

[1] Food and Drug Administration, *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 78 Fed. Reg. 67,985 (Nov. 13, 2013)

ILR is also concerned that the proposed change may increase healthcare costs for consumers and payers of prescription drug products. Cost increases are likely to result from the proposed rule's direct and indirect impacts, including (but not limited to) increased litigation, increased compliance costs, and decreased competition. The FDA did not address these costs in its Regulatory Impact Analysis as required by Executive Order 13563.[2] Nor did the Agency address the proposed rule's significant economic impact on small entities, as defined by the Regulatory Flexibility Act[3]. Independent experts have estimated that the proposed rule would increase drug spending by more than $4 billion per year, including an additional $2.5 billion in spending by consumers and private payers.[4] This amount greatly exceeds $141 million (with appropriate inflationary adjustments), the threshold set forth in the Unfunded Mandates Reform Act of 1995, Pub. L. No. 104-4, 2 U.S.C. § 1501, *et seq*.

For these reasons, rather than encouraging label disparities, ILR strongly urges the FDA to replace the current process for safety-related labeling changes [under 21 CFR § 314.70(c)(6)(iii)] with an Expedited Agency Review (EAR) process for the purpose of updating prescription drug labels when new safety information becomes available.

Expedited Agency Review

ILR supports the view of the Generic Pharmaceutical Association (GPhA) and the Pharmaceutical Research and Manufacturers of America (PhRMA), as contained in their joint letter of November 14, 2014, to then-Commissioner Hamburg. The EAR process is an alternative solution to the proposed rule that would still meet the goals of FDA: (1) assuring that all application holders meet their responsibility of reporting safety-related information; and (2) making newly evaluated safety information available to practitioners and the public as soon as possible. Furthermore, the EAR process is consistent with the "sameness" requirements of the Hatch-Waxman Act.

The EAR process could be initiated by NDA and ANDA holders ***or*** the FDA, and it would replace the current process for safety-related labeling changes. The EAR would require the FDA to provide NDA and ANDA holders with prompt notice of approval of a required label change, and would specify the timeframe for NDA and ANDA holders to make a corresponding label change. ILR recognizes the role NDA and ANDA holders play in the FDA process by their regular submissions of drug safety data to the FDA. However, not all individual NDA and ANDA may be in a position to determine whether the information they possess is "new" as they do not have access to all available data. Because the Agency does possess all necessary information, such as clinical trial data on a pharmaceutical product and adverse events and periodic reports from all manufacturers, the FDA is best situated to examine new safety information and make certain drug labeling determinations.

Once the EAR process is initiated, the FDA would have a set period of time to make a decision regarding the appropriateness of a label change. We would suggest that the FDA establish a process for soliciting, receiving and considering stakeholder feedback. NDA and ANDA holders would be required to update

[2] "Improving Regulation and Regulatory Review," Executive Order 13563, 76 Fed. Reg. 3821 (Jan. 2011), available at www.regulations.gov/docs/EO_13563.pdf. Executive Order 13563 requires agencies to ensure the rules are "supplemental and reaffirms the principles, structures, and definitions governing contemporary regulatory review… each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs…(2) tailor its regulations to impose the least burden on society…and to the extent practicable, the costs of cumulative regulations."

[3] Regulatory Flexibility Act, 5 U.S.C. § 601 et seq (1980).

[4] *See* Alex Brill, Matrix Global Advisors, FDA's Proposed Generic Drug Labeling Rule: An Economic Assessment 1 (2014).

their labels within 30 days of the FDA's labeling decision. Accordingly, the EAR process would ensure accurate, timely, and consistent labeling across all application holders. The EAR process accomplishes the goals the FDA intended with the proposed labeling rule, while minimizing the likelihood of market disruption and increased costs to consumers and payers. The result would be a reasonable process where data are reviewed and discussions are held among all parties that can result in changes, when necessary. This process will be better for consumers and healthcare providers.

Conclusion

The Hatch-Waxman Act, enacted over 30 years ago, and subsequent regulations contain a long-standing "sameness" requirement. ILR believes that the proposed regulatory changes violate the Hatch-Waxman law and would expose generic pharmaceutical manufacturers to a significant increase in litigation. The proposed changes are inconsistent with the text and underlying intent of the Hatch-Waxman Act, as well as the FDA's existing regulatory system. If finalized, the proposed rule would discourage generic pharmaceutical manufacturing and use. The proposed rule could increase costs throughout the healthcare system, and a thorough economic analysis would demonstrate its potential to negatively impact public and private healthcare spending.

By contrast, an EAR process, as proposed, would facilitate the swift update of prescription drug labels upon the availability of new safety information, while eliminating the potential for confusion created by simultaneous use of multiple labels for the same drug. The EAR process would also ensure that patients and healthcare professionals receive accurate and timely safety information. Lastly, this proposed process is consistent with the "sameness" requirements of the Hatch-Waxman Act.

For these reasons, ILR urges the FDA to adopt an Expedited Agency Review process.

Please do not hesitate to contact me at 202.331.3133 if we can provide additional clarification or be of any further assistance on this matter.

Thank you,

Nancy E. Taylor
Shareholder

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