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Greenberg Traurig's Nancy Taylor Testifies at FDA Public Meeting on Supplemental Drug Labeling Changes

On March 27, 2015, Greenberg Traurig Shareholder Nancy Taylor presented testimony at a public meeting of the U.S. Food & Drug Administration (FDA) on behalf of the Institute for Legal Reform, U.S. Chamber of Commerce. The FDA convened the meeting to discuss:

- The proposed rule on *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, Docket No. FDA-2013-N-0500 ((RIN) 0910-AG94) published in the Federal Register on November 13, 2013, and
- Alternatives offered to this proposed rule.

Background

In November 2013, the FDA proposed a rule to change the way generic pharmaceutical labels are updated to reflect newly acquired safety information. The rule change was proposed against the backdrop of two recent U.S. Supreme Court Cases, which considered whether state law tort claims against pharmaceutical manufacturers for "failure to warn" are preempted by Federal law. The Court reached different conclusions depending on whether the drug in question is a brand name drug or a generic drug.

In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Court held that state law claims against brand name application holders are not preempted by Federal law. Conversely, in *Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), the Court held that Federal law preempts similar claims against generic drug application holders. The Court reasoned that under Federal law generic pharmaceutical labels are required to be materially identical those of their brand name equivalent. Therefore, a generic drug application holder cannot simultaneously meet its Federal law duty to maintain the same label as a brand name drug and its state law duty to provide adequate labeling (131 S.Ct. at 2578).

Under the proposed rule, a generic drug maker would be required to revise a drug's label and send a "Changes Being Effected" (CBE-0) supplement to the FDA for certain types of newly acquired information related to drug safety. The generic manufacturer would also be required to transmit the information prompting the change to the relevant brand name drug application holder. If the FDA finds that the new information submitted by the generic manufacturer is sufficient to require a change to the label of the corresponding brand name drug, the FDA will provide a 30-day window for all other generic application holders for the drug in question to update their labels. In testimony before the Committee on Energy and Commerce of the United States House of Representatives in April 2014, Dr. Janet Woodcock, Director for the FDA's Center for Drug Evaluation and Research, acknowledged that the new rule, "may eliminate the preemption of certain failure-to-warn claims, with respect to generic drugs."[1]

[1] http://www.fda.gov/NewsEvents/Testimony/ucm389606.htm

Opposition to the Proposed Rule

The Institute for Legal Reform at the U.S. Chamber of Commerce, with the assistance of Greenberg Traurig's Health & FDA Practice Group, filed comments to the FDA on March 13, 2014 urging the agency to consider alternative approaches to those contained in the proposed rule. The proposed rule would impose new and unnecessarily burdensome compliance costs on drug manufacturers and expose them to additional litigation. This result would increase health care costs for millions of Americans who rely on generic medications for the treatment or prevention of disease. In addition, the new requirements would promote inconsistency in labels for the same drug that will create consumer confusion at a time when Federal Government is working to educate consumers about the appropriate use of health care services and how to assess the costs and value of their care.

The new rule would also violate the requirements of the long-standing interpretation of the "sameness" requirements contained in the *Drug Price Competition and Patent Term Restoration Act* (Public Law 98-417), commonly referred to as the "Hatch-Waxman Act." This law requires that generic drugs must carry labels that are materially identical to their corresponding brand name drug.

The U.S. Chamber of Commerce joined others, including the Pharmaceutical Research and Manufacturers Associations (PhRMA) and the Generic Pharmaceutical Association (GPhA), in advocating the FDA's adoption of an Expedited Agency Review (EAR) process instead of the new rule. An EAR process would create a mechanism for generic manufacturers to share safety information with the FDA where none currently exists. It would also require a shortened, defined timeframe for the FDA to determine whether a label change is necessary and to notify all application holders of this change.