Press Release

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In Victory for WLF, FDA Abandons Controversial Proposed Rule on Generic Drug Labeling

(*In re: Proposed Labeling Changes for Approved Drugs*)

"FDA's decision to abandon its controversial labeling rule is a major victory for American consumers. The rule's only purpose was to empower the plaintiffs' bar, and it posed major health and safety risks."
—Richard Samp, WLF Chief Counsel

WASHINGTON, DC—The Food and Drug Administration (FDA) announced today that it is abandoning a controversial proposed rule, first announced in 2013, that would have permitted generic drug companies to make unilateral changes to their product labeling. FDA's decision marked a major victory for Washington Legal Foundation (WLF), which repeatedly urged FDA to abandon the rule. In three separate formal comments submitted to the agency over the past five years, WLF argued that alternative procedures could ensure that new safety information about FDA-approved drugs reaches doctors and consumers much more quickly than under the labeling regulations proposed by FDA.

Under current law, generic drug companies must ensure that the labels of their products are identical to the labels of the brand-name drugs they emulate. In light of that "sameness" requirement, generic companies are not permitted to make unilateral changes in their product labels. If they discover new safety information that they believe should be brought to the attention of doctors, they are encouraged to submit that information to FDA but must await FDA approval before making changes. FDA's proposal would have permitted generic companies to revise their labels unilaterally while they awaited word on whether FDA approved the change.

WLF argued that the chief result of FDA's proposal would be consumer confusion, brought on because different versions of the same drug would bear conflicting safety warnings. WLF noted that the proposal included no mechanism for early resolution of the conflicts. WLF charged that the proposed rule's only purpose was to placate the plaintiffs' bar. Plaintiffs' lawyers supported the rule because it would have facilitated the filing of products-liability lawsuits against generic drug manufacturers. If manufacturers are permitted to change their labels unilaterally, they can be sued for failing to do so.

In announcing withdrawal of the 2013 proposed rule, FDA stated that it "is actively evaluating ways to facilitate the updating of generic drug labeling to help ensure that drug labeling reflects the most current information."

Celebrating its 41st year, WLF is America's premier public-interest law firm and policy center advocating for free-market principles, limited government, individual liberty, and the rule of law.

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