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May 20, 2016

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In Victory for WLF, FDA Again Postpones Adopting Proposed Rule on Generic Drug Labeling

(In re: Proposed Labeling Changes for Approved Drugs)

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—Richard Samp, WLF Chief Counsel

WASHINGTON, DC—The Food and Drug Administration (FDA) announced this week, without further explanation, that it has postponed (until at least April 2017) its controversial proposed rule that would permit generic drug companies to unilaterally change their product labeling. FDA’s decision to postpone final action on the rule until after the presidential election marks a victory for Washington Legal Foundation, which has repeatedly urged FDA to abandon the rule.

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 may submit that information to FDA but must await FDA approval before making changes. FDA’s proposal would permit generic companies to revise their labels unilaterally while they await word regarding whether FDA approves the change.

WLF has called on FDA to adopt the Expedited Agency Review (“EAR”) proposal, submitted by several pharmaceutical industry trade groups, in lieu of FDA’s own labeling proposal. In three separate formal comments submitted to the agency over the past two years, WLF has argued that the EAR proposal ensures that new safety information about FDA-approved drugs reaches doctors and consumers much more quickly than under the labeling regulations proposed by FDA. WLF argues that the chief result of FDA’s proposal would be consumer confusion, because different versions of the same drug would bear conflicting safety warnings (and the proposal includes no mechanism for early resolution of such conflicts).

Upon learning of FDA’s decision to postpone final action a third time, WLF issued the following statement by Chief Counsel Richard Samp: “This week’s decision marks the third time FDA has delayed finalizing its controversial labeling rule and may signal that FDA is considering abandoning the rule altogether. That would be good news for consumers, whose safety could be jeopardized by a proposed rule whose only purpose is to assist the plaintiffs’ bar. The rule would make it much easier for lawyers to file products liability lawsuits against drug manufacturers. If generics are permitted to change their labels unilaterally, they can be sued for failing to do so.”

WLF is a public interest law firm and policy center that seeks to ensure that economic liberty is not impeded by excessive litigation.