Press Release

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

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Media Contact: Alex Booze | abooze@wlf.org | 202-588-0302

WLF Urges FDA to Adopt "Expedited Agency Review" In Lieu of Allowing Unilateral Generic Label Changes

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WASHINGTON, DC—Washington Legal Foundation yesterday urged the Food and Drug Administration (FDA) to adopt the Expedited Agency Review ("EAR") proposal submitted by several pharmaceutical industry trade groups, in lieu of FDA's own proposal to permit generic drug companies to make unilateral changes to their product labels. In formal comments submitted with the agency, WLF argued that the EAR proposal ensures that new safety information about FDA-approved drugs would reach 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 to their product labels. If they discover new safety information that they believe should be brought to the attention of doctors, their only recourse is to call that information to the attention of FDA and suggest that the labeling be updated. FDA's proposal would permit generic companies to revise their labels unilaterally while they await word regarding whether FDA approves the revisions.

WLF argues that the principal result of FDA's proposal would be consumer confusion, brought on by a situation in which different versions of the same drug would bear conflicting safety warnings. WLF notes that the FDA proposal includes no mechanism for early resolution of such conflicts.

WLF praises the inclusion of such a mechanism as the principal virtue of the EAR proposal. Under that proposal, any submission of "new safety information" by either FDA or a drug manufacturer would trigger a safety review proceeding that would result in a final decision within a specified number of days regarding whether to change product labeling. Upon filing its comments, WLF issued the following statement by Chief Counsel Richard Samp:

"FDA claims that its proposal will ensure that patients and doctors get early access to new safety information about drugs—that claim is inaccurate. The FDA proposal is simply a cynical effort to cater to the plaintiffs' bar by increasing the potential tort liability of generic drug companies. If generics were legally permitted to change their labels, they could be sued for failing to do so."

WLF is a public-interest law firm and policy center that regularly litigates in defense of free enterprise.