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Paper Assesses Judicial Reaction to FDA "Failure-to-Warn" Preemption Policy

A year ago as part of a new regulation intended to simplify drug labels, the Food and Drug Administration (FDA) issued a formal statement of the its position on federal policy and state "failure-to-warn" liability suits. In a new Washington Legal Foundation (WLF) WORKING PAPER, a leading pharmaceutical liability defense attorney examines how judges have reacted to FDA's pronouncement that federal drug law preempts this category of state tort suits, and finds that courts have been regretfully inconsistent on how they apply the policy.

The publication, **COURTS GIVE MIXED REVIEWS TO PREEMPTION POLICY IN 2006 FDA LABELING RULE**, was authored for WLF by **James M. Wood**, a partner in the Oakland, California office of the law firm Reed Smith LLP, with the assistance of University of California at Hastings third-year law student **Claire Hass**. Mr. Wood is also the Chairman of the Food and Drug Law Institute.

As the paper notes in its introduction, for many years FDA had taken the perspective in friend-of-the-court (i.e. *amicus* briefs) that federal drug labeling law preempts state failure-to-warn liability claims because a judge or jury would impose conditions on the labeling which were inconsistent with or in addition to what federal law required. Warnings above and beyond what federal regulators required, FDA reasoned, could deter use of the product, sew confusion among consumers, and result in a product being misbranded and subject to federal recall or seizure actions. FDA formalized this preemption theory into the preamble to the Final Rule "Requirements on the Content & Format of Labeling for Human Prescription Drug and Biological Products."

After summarizing the content of this preamble, Mr. Wood and Ms. Hass provides an instructive primer on the law of federal preemption. FDA's legal theory falls under the rubric of "implied" preemption, since Congress did not explicitly provide the agency with preemptive authority in the Federal Food, Drug & Cosmetic Act. Within this area of preemption, they then describe the case law which has developed around the FDA 2006 preemption pronouncement. The opinions assess FDA's main preemption arguments: first, that state failure to warn suits make it impossible for drug makers to comply with both federal and state requirements; and second that such lawsuits are a direct impediment to FDA's ability to fully achieve its objectives and purposes. The authors critically

analyze the reasoning of judges who have rejected preemption in drug cases, and find critical flaws in their application of the FDA policy.

The WORKING PAPER concludes with a discussion of a case which Mr. Wood and Ms. Hass call the "most comprehensive analysis of the effect of the Final Rule to date," *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 2006 WL 2374742 (N.D. Cal., 2006). The authors urge other judges to look upon Judge Charles Breyer's *Bextra and Celebrex* ruling as a roadmap on how to properly apply the FDA preemption policy.

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Copies of this educational paper, WLF WORKING PAPER, Number 143 (January 2007), can be obtained by forwarding a request to: Publications Department, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, D.C. 20036, or calling (202) 588-0302.

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