Counsel's Advisory

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FDA PREEMPTS "FAILURE-TO-WARN" PHARMACEUTICAL LIABILITY CLAIMS

by
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Law students in 2016 may be astounded to hear the torts professor recall that as recently as 2006 plaintiffs routinely sued pharmaceutical companies on failure-to-warn theories under state law. "That doesn't make sense," the students may say. "Didn't FDA approve the warnings? How could a plaintiff sue under state law?"

This utopian prediction might well come true, because on January 18, FDA, in adopting its long-awaited rule on prescription drug labeling, emphatically stated that "[i]f State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs . . ., the federal system for regulation of drugs would be disrupted."[1] FDA supported this statement with extensive explanation of the deleterious effects product liability lawsuits under state law have on FDA's statutory responsibilities under federal law.

The Washington Legal Foundation has long advocated the concept of FDA issuing such a statement preempting pharmaceutical product liability cases where the plaintiff challenges the adequacy of the warnings given by the drug's manufacturer — even though FDA approved those warnings as "adequate" under the Food Drug & Cosmetic Act. *E.g.*, James Dabney Miller, *FDA Should Propose Rule on Federal Preemption of Failure-to-Warn Lawsuits,* LEGAL BACKGROUNDER (Wash. Lgl. Found), Sept. 19, 2003. Better late than never.

FDA's statement applies to all prescription drugs approved by FDA, not just those drugs sold with the new labeling: "FDA approval of labeling under the [Food Drug & Cosmetic Act], *whether it be in the old or new format*, preempts conflicting or contrary State law. FDA Final Rule, at 38. Also, FDA explicitly extended preemption to claims against physicians "for claims related to dissemination of risk information beyond what is included in the [FDA-approved] labeling." *Id*. at 47.

The courts that have rejected preemption in drug product liability cases were persuaded by the arguments that the drug manufacturer could have strengthened the warnings accompanying the drug, or that FDA applied merely "minimum standards" in establishing warnings, precautions, and counterindications. FDA dynamites both these arguments. Whether labeling revisions are necessary "is,

[1]FDA, Final Rule, Requirements on Content & Format of Labeling for Human Prescription Drug & Biologic Products, 175 (Jan. 18, 2006) (to be published in the Federal Register on Jan. 24, 2006), *hyperlink at* http://www.fda.gov/bbs/topics/news/2005/NEW01272.html.

in the end, *squarely and solely* FDA's under the [Food Drug & Cosmetic Act]," *id*. at 41, so whether the manufacturer might have initiated a label change is irrelevant. With respect to the 'minimum standards' argument, FDA establishes "both a 'floor' and a 'ceiling'" for prescription drug labeling. *Id*. at 42.

The key issue now is to take maximum advantage of FDA's preemption statement. FDA's position on preemption should be brought to the attention of the courts in these cases as forcefully as possible. *See* 44 U.S.C. § 1507 ("[T]he contents of the Federal Register shall be judicially noticed . . . ."). The goal should be to see that law students in 2016, when they hear about past pharmaceutical product liability cases, chuckle to themselves over this curious historical anomaly.

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