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Federal Preemption of State Pharmaceutical Product Liability Tort Law: The FDA Speaks Out

By Glenn M. Farnet

The U.S. Food and Drug Administration (FDA) announced on January 18, 2006 that it is issuing final regulations making a "major revision" to the format of prescription drug information. Among other things, the rule revises the current regulations to require that the prescribing information of new and recently approved products includes "Highlights" of the prescribing information and a table of contents for the full prescribing information.1 This new "Highlight" procedure is designed to make the product warnings and package inserts easier to read and understand, both by prescribing physicians and by patients.

Of particular importance for pharmaceutical companies faced with increasing product liability litigation, the FDA included in the comments to the new rule a detailed discussion of FDA's views on the preemptive effect of its labeling decisions in the context of state product liability tort law. The FDA states that "… under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." The comment proceeds to give a thorough and detailed explanation of the reason behind this interpretation. (The full discussion can be found at the following link, under section "D" entitled "Comments on Product Liability Implications of the Proposed Rule," at p. 37).
http://www.fda.gov/OHRMS/DOCKETS/98fr/00n-1269-nfr0001-01.pdf

The FDA explains that "… the agency makes approval decisions based not on an abstract estimation of [the product's] safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of the use prescribed, recommended, or suggested in the labeling." The FDA expresses concern that, in the past, there have "… several instances in which product liability lawsuits have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the act." It explains that state court rulings often misconstrue the agency's labeling requirements as a "minimum safety

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1 http://www.fda.gov/bbs/topics/NEWS/2005/NEW01272.html.

standard" rather than both a "floor and a ceiling." This inappropriate interpretation can have the dangerous effect of making companies engage in "defensive labeling" – that is, including speculative risks in their product inserts to avoid possible tort liability. As explained by the FDA in its comments, "exaggeration of risk could discourage appropriate use of a beneficial drug …, [and] labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to 'lose its significance.'"

These comments are the most recent and forceful statement by the FDA of the preemptive effect of its labeling decisions. They will certainly provide a new impetus for asserting the federal preemption defense to many types of pharmaceutical product liability lawsuits.

About the Author:

Glenn Farnet is a partner in the Baton Rouge office of Kean Miller. He joined the firm in 1991 and practices in the commercial litigation, class action and toxic tort defense groups. Glenn has more than 14 years of experience in product liability defense litigation, toxic tort defense litigation, class action defense litigation, and commercial litigation. He advises clients on litigation strategy and class action litigation management. Glenn has particular experience in class action litigation involving consumer products, computers and software, chemical exposures, mass torts arising from releases or catastrophic accidents, as well as pharmaceutical product liability litigation. He can be reached at 225.382.3431 or glenn.farnet@keanmiller.com