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15-SECOND
ADVERTISING LAW ALERT

REGULATORS' WARNINGS DO NOT ALWAYS MAKE CLAIMS ACTIONABLE

Suits by competitors to enjoin claims that regulators have found to be false or deceptive are not slam-dunks. In fact, courts frequently dismiss such suits on preemption grounds, as a recent case shows.*

BACKGROUND

Plaintiff markets a laxative as an over-the-counter drug. Defendants market generic versions of Plaintiff's OTC drug, but label the generics as being "Rx Only" or "Prescription Only."

The Director of the Office of Generic Drugs in the U.S. Food and Drug Administration sent Defendants warning letters stating that their "Rx Only" claims rendered their generics misbranded (false or deceptive labeling) and the products "may not be legally marketed" as labeled.

Another FDA employee granted Defendants' request for a time period within which to sell existing stocks of the misbranded generics. This was done expressly as a matter of "enforcement discretion" – FDA still considered the products to be unlawful. (There apparently was no safety issue.)

Plaintiff sued under Section 43(a) of the Lanham Act to enjoin the continued marketing of products under an "Rx Only" claim. It argued that the claim falsely stated that all such laxatives (including Plaintiff's) were available only by prescription

DECISION

The court dismissed Plaintiff's suit, concluding that "a ruling on the merits of [Plaintiff's] Lanham Act claim would require the court to usurp the FDA's responsibility for interpreting and enforcing the agency's regulations."

The court distinguished between "the opinions of the FDA officials who wrote the [warning] letters" and the agency, itself. It concluded that "FDA has not yet taken any official position concerning the labeling of defendants' products to which the court can defer."■

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* *Schering-Plough Healthcare Products, Inc. v. Schwarz Pharma, Inc., et al.*, E.D. Wis. No. 07-CV-642 (Feb. 29, 2008).