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FALSE ADVERTISING GROUP

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Broad Preemption Ruling by Third Circuit Seemingly Sounds Death-Knell for State Consumer Fraud Claims Arising from Prescription Drug Advertising

In a far-reaching decision that stands as a virtual bar to pleading consumer fraud claims arising from prescription drug advertising, the Third Circuit has held that state consumer fraud laws are preempted by the Federal Food Drug and Cosmetic Act ("FDCA") and regulations adopted thereunder because they "pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users." *Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc.*, 2007 U.S. App. LEXIS 19601 (3d Cir. Aug. 17, 2007). Moreover, in affirming denial of plaintiffs' motion for leave to amend, the Court stated that its preemption holding applies, even if a consumer could allege that the FDA expressly refused to approve the types of advertising claims at issue. The panel's decision was accompanied by a strong dissenting opinion expressing that judge's view that, because the challenged advertising's representations of comparative superiority were not reviewed or approved by the FDA, the plaintiffs' claims were not preempted.

At issue were advertisements by AstraZeneca ("Zeneca") for its acid reflux disease and heartburn medication, Nexium, which was manufactured by Zeneca and approved by the FDA shortly before Zeneca lost patent protection on Priolsec – Zeneca's highly-successful drug for similar acid reflux and heartburn conditions. Zeneca undertook a physician-directed and consumer advertising campaign for Nexium that represented that Nexium was superior to Prilosec. Thereafter, plaintiffs commenced a putative class action against Zeneca, alleging that Zeneca's Nexium marketing campaigns misleadingly stated that Nexium was superior in efficacy to Prilosec. Plaintiffs brought claims against Zeneca under Delaware's Consumer Fraud Act ("Delaware Act"), as well as the other 49 states' consumer protection statutes, and related common law claims of unjust enrichment and negligent misrepresentation.

The district court dismissed plaintiffs' claims on two grounds. First, the court held that the Delaware Act did not apply to Zeneca's advertisements because that statute excludes from liability any advertisement that is "subject to and complies with" FTC rules and regulations. The Court reasoned that Zeneca's advertisements were consistent with the FDA-approved labeling for Nexium and, therefore, were entitled to immunity under the Delaware Act's exemption. Second, the court applied principles of "implied conflict preemption" and held that plaintiffs' claims were preempted by the FDCA. On appeal, plaintiffs argued that the Delaware Act's exemption is limited to conduct expressly approved by the FTC, and that because the challenged Nexium advertisements were not approved by the FDA and went beyond the label approved by the FDA, the Delaware Act did exempt Zeneca's conduct. Secondly, plaintiffs maintained that their state consumer protection claims were not preempted by federal law.

The Third Circuit agreed with plaintiffs' argument that the district court erroneously applied the Delaware Act's exemption provision, but affirmed dismissal of plaintiffs' claims on the ground that they were preempted by the FDCA. The Court acknowledged that nothing in the FDCA explicitly preempted state consumer fraud claims based on prescription drug advertisements. Relying on the Supreme Court's litany of well-established preemption decisions (*Medtronic, Inc. v. Lohr, Geier v. Am. Honda Motor Co.*, and *Buckman Co. v. Plaintiffs' Legal Committee*), the Court noted that even if not expressly preempted, the doctrine of implied conflict preemption

could bar plaintiffs' state consumer fraud claims if the state statute at issue "pose[d] an obstacle to the FDA's congressionally-mandated regulation of prescription drug advertising." The Court reviewed the numerous provisions of the FDCA, regulations adopted thereunder, and statements by the FDA addressing advertising and misbranding, and concluded that the "degree of discretion inherent in the regulations demonstrates that the FDA envisioned itself occupying an ongoing and extensive role in the supervision of prescription drug advertising." The Court stated that the Supreme Court has "suggest[ed] that state laws are preempted when they frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority," and that an "even stronger case for preemption occurs when FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising." The Court held that the "high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising."

Before the district court, plaintiffs had sought leave to amend on the ground that they could allege that the FDA expressly declined to approve any representation by Zeneca that Nexium was more effective than Prilosec. The Court of Appeals affirmed denial of leave to amend, holding that any such allegation would not overcome its preemption holding.

The dissenting judge invoked the "presumption against a finding of preemption," which applies where the subject matter alleged to be federally preempted is an area traditionally regulated by the states (such as consumer protection), and parted company with the majority opinion on a number of grounds. First, the dissenter quoted Supreme Court authority holding that a preemption inquiry cannot be based on broad statements of "comprehensive" federal regulation, and thereby concluded that the majority's reliance on the supposedly "high level of specificity" in the FDA regulatory scheme was improper as a matter of law. Second, the dissenting judge reasoned that because the FDA never considered or approved the allegedly false comparative claims in Zeneca's Nexium advertising, there was no conflict with an FDA ruling, and, thus, no preemption. At the same time, however, the dissent recognized that conflict preemption may exist where, for example, a consumer fraud claim was based on advertising claims that were consistent with FDA-approved labeling, but nevertheless alleged to be inadequate. Third, the dissenting judge rejected the majority's reasoning that the existence of state law standards for false and misleading advertisements, as well as remedies parallel to those provided for under the FDCA, necessarily create a conflict required a finding of preemption.

The panel majority's conclusion that state law claims based on an advertisement, neither approved nor disapproved by the FDA, conflict with the FDA's ability to review and approve prescription drug advertisements and labeling is purportedly based on notions of implied conflict preemption. However, the panel's reasoning aligns more closely with principles of "field preemption." Given the exceedingly broad scope and implications of the panel majority's opinion, as it relates to consumer fraud claims based on prescription drug advertising, it would be surprising if plaintiffs did not file a petition for rehearing and rehearing en banc.

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