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A legal update from Dechert's Mass Torts and Product Liability Group

Third Circuit Finds Preemption of Consumer Fraud Claims Challenging DTC Ads Based Upon FDA-Approved Labeling

State consumer fraud statutes play an increasingly important role in product liability litigation against pharmaceutical companies. Whether as a stand-alone claim in a class action lawsuit, or as an adjunct claim in a personal injury suit, plaintiffs are bringing such claims in ever greater numbers—undoubtedly because the substantive elements under such statutes are often easier to prove and both statutory multiple damages and attorneys' fees are available.

In a decision with potentially broad implications, however, the Third Circuit Court of Appeals has invoked preemption to limit such claims. In *Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.*, 2007 U.S. App. Lexis 19601 (3d Cir. Aug. 17, 2007), the court held that implied conflict preemption bars a large category of state-law consumer fraud claims against manufacturers of FDA-regulated prescription products.

Zeneca involved claims that direct-to-consumer ("DTC") advertisements that essentially repeated statements from the drug's FDA-approved label were false and misleading. Specifically, the advertisements were based upon one of the studies upon which the FDA relied in approving the drug. That study showed a "statistically significant healing rate," over a competing product. *Id.* at *4. The competing product, however, was less expensive because it had generic competition. *Id.* at *3, 5.

The plaintiffs, third-party payers, alleged that their expenses were increased because these comparative advertisements were false and misleading. *Id.* at *5. The Third Circuit held that such allegations were preempted by reason of "implied conflict preemption." *Id.* at *21. In a nutshell, the court held that where the FDA said "yes" to a statement in its labeling approval, state consumer fraud allegations cannot say "no" to the same statement when it appears in the manufacturer's advertising.

The key question, as the Third Circuit put it, was "whether state consumer fraud laws pose an obstacle to the FDA's congressionally-mandated regulation of prescription drug advertising." *Id.* at *22–23. "Critical" to this analysis was the FDA's regulation of drug "safety." *Id.* at *23. The FDA's safety regulations provide for review and analysis of clinical trials—including the study upon which the alleged misrepresentations were based.

Also essential to the analysis was the relationship between the Food, Drug & Cosmetic Act ("FDCA") and the Federal Trade Commission Act ("FTCA"). The FDCA specifically exempts advertisements that comply with FDA regulations from the false advertising provisions of the FTCA. *Id.* at *27–28. The court also reviewed FDA regulatory requirements applicable to DTC advertising: the specific categories of information that prescription drug advertising must include; the FDA's definition of a "true statement" in advertising; the twenty factors that the FDA considers in determining whether advertising violates the Act; and the range of FDA sanctions for false advertising. *Id.* at *24–26.

On this basis, the court determined that FDA supervision of prescription drug advertising was both "ongoing and extensive," and a matter within the Agency's considered discretion. "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. *Id.* at *27 (citations to various regulatory materials

omitted). This "ongoing and extensive" regulation of advertising for prescription medical products was a "shared [] vision" of both the FDA and Congress in enacting the FDCA. *Id.* at *27–28. It was sufficient to overcome any presumption against preemption. *Id.* at *30 n.11 ("While the protection of consumers from unfair practices is a traditional state police power function, federal laws and administrative regulations may operate in tandem with—or even preempt—state law under the Supremacy Clause") (citation and quotation marks omitted).

Nevertheless, "neither the language of the FDCA nor the regulations explicitly preempt state consumer fraud law." *Id.* at 28. Thus, only implied preemption was applicable. The Third Circuit held that allowing consumer fraud actions that challenged advertising permitted by the FDA would "frustrate" the FDA's superintendence of the administrative scheme:

> [A]llowing these claims to proceed would unnecessarily frustrate the FDCA's purpose and FDA regulations, as the extent of agency involvement in regulating prescription drug advertising is extensive and specific.

Id. It did not, however, rest its preemption decision solely upon general frustration of congressional purpose. The court went on to examine the particular nature of state-law consumer fraud claims and the impact of this sort of claim on FDA-regulated advertising and labeling:

> An even stronger case for preemption occurs when FDA approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising. The essential affinity between advertising and labeling is clear in the composition of the FDCA and its associated regulations. Although labeling is often directed at medical practitioners, the rules that govern labeling form the basis for the advertising regulations. *Accordingly, the purpose of protecting prescription drug users in the FDCA would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA.*

Id. at *34–35 (citations omitted; emphasis added). Thus, once a statement was approved by the FDA as labeling, that "affinity" carried over to "advertising" to bar state-law attacks on the same statement.

As further support for preemption the Third Circuit found the FDA's advertising requirements to be "specific" and observed that under the FDCA only the government has authority to pursue claims that regulated persons have violated the statute. Application of "general" state consumer protection statutes would be "irreconcilable" with this federal scheme:

> Implied conflict preemption of state consumer fraud laws is required in this setting because both the FDCA and FDA regulations provide specific requirements for prescription drug advertising. Congress specifically determined that all proceedings for the enforcement, or to restrain violations, of the FDCA shall be by and in the name of the United States. *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.* Accordingly, the plaintiffs' state consumer fraud claims are preempted.

Id. at *35–36 (citation and quotation marks omitted; emphasis added).

Zeneca is the first court of appeals case to find consumer fraud claims preempted by FDA approval of the statements in question. There is no way to predict whether *Zeneca*'s analysis will be adopted by other courts, although several courts have reached similar results, *see Prohias v. Pfizer, Inc.*, 490 F. Supp.2d 1228, 1234 (S.D. Fla. 2007); *In re Bextra & Celebrex Marketing Sales Practices & Product Liability Litigation*, 2006 WL 2374742, at *5-8 (N.D. Cal. Aug. 16, 2006); *Prohias v. AstraZeneca Pharmaceuticals, L.P.*, 958 So.2d 1054, 1056 (Fla. App. 2007).

Notably, *Zeneca* was a split decision with a strong dissent from Senior Judge Robert E. Cowen, and plaintiffs state they will seek *en banc* reconsideration. Nonetheless, it may become an important tool for defeating consumer fraud claims in pharmaceutical litigation.

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