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Two Important Issues, One Ruling: Consumer Fraud Class Actions and Federal Preemption

The U.S. District Court for the District of Delaware recently granted defendant manufacturers' motion to dismiss in *Pennsylvania Employee Benefit Trust Fund v. Zeneca, Inc.*, 2005 U.S. Dist. LEXIS 27444 (D. Del. Nov. 8, 2005), a consumer fraud class action, concluding that, by approving a drug's labeling, the FDA also supported statements made in advertisements. Therefore, the allegedly misleading statements were not actionable under the Delaware Consumer Fraud Act.

A New Type of Class Action Suit

Pennsylvania Employee Benefit Trust Fund is illustrative of a new breed of consumer fraud class action suit whereby plaintiffs claim only an economic injury. Because these lawsuits do not allege personal injuries, they include not only individual plaintiffs, but also employee benefit funds, as was the case here, as well as private health insurers and healthcare advocacy organizations. (The question whether such organizations may bring such actions will be addressed at a later time.) Further, plaintiffs will rely on clinical trials and epidemiological studies that allegedly conclude that the product (whether it be a prescription drug or over-the-counter medication) is not as effective as marketed, regardless of FDA approval.

Plaintiffs, a putative nationwide class, alleged that the manufacturer violated the Delaware Consumer Fraud Act (DCFA) by using misleading information to convince consumers that Nexium® was significantly better for treating heartburn than the company's older proton pump inhibitor (PPI), Prilosec®. Plaintiffs claimed that the marketing campaign was designed solely to transfer patients from Prilosec® (which was set to go off patent in 2001) to Nexium®, to preserve the manufacturer's presence in the prescription PPI market. In doing



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so, plaintiffs argued, the manufacturer suppressed or omitted information in its advertising, that demonstrated that the drugs were equally effective at equivalent doses.

Plaintiffs' 74-page complaint alleged that the manufacturer "either implicitly or expressly represented" that Nexium® was superior to Prilosec® and described the manufacturer's \$500 million "advertising blitz" in exhausting detail. Plaintiffs asserted claims for violation of the DCFA, violation of the "consumer protection statutes of the 50 states," restitution, and negligent misrepresentation.

Moreover, plaintiffs cited data from clinical trials and other studies, which, according to plaintiffs, supported a finding that, while Nexium® provided greater therapeutic relief than placebo, there was no statistically significant evidence that Nexium® performed better than Prilosec®. Plaintiffs further claimed that the manufacturer designed its clinical trials such that the reported data was skewed.

Delaware CFA Safe Harbor Provision

The *Pennsylvania Employee Benefit Trust Fund* court explained that the DCFA does not apply "[t]o any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission." 6 Del. C. § 2513(b)(2). Under this provision, the court concluded that plaintiffs' claims were not actionable. "The Federal Trade Commission and the FDA share exclusive jurisdiction over regulation of drug marketing; the FDA is given primary authority to regulate prescription drugs." Where a manufacturer complies with FDA rules and regulations and receives FDA-approval regarding its labeling, the court found that a drug's labeling cannot be construed as false or misleading. *Pennsylvania Employee Benefit Trust Fund*, at *8-9.

While the court did not address the issue of class certification or the propriety of plaintiffs' claim for violations of the consumer protection statutes of the fifty states, these issues are certainly ones to watch for in other similar lawsuits because many consumer protection statutes have "safe harbors."

Preemption Exists Where Plaintiffs' Ad Claims Were Within the Bounds of FDA-Approved Labeling

After thoroughly reviewing the Nexium® advertisements, the court found that the advertisements complied with the FDA-approved product labeling. Further, the court found that the manufacturer did not make any "explicit statements that Nexium® was 'superior' to Prilosec®." Even if the manufacturer implicitly claimed that Nexium® was superior to Prilosec®, the plaintiffs would still have had to prove that the approved dosage of Nexium® was not superior to the approved dosage of Prilosec®. The court explained, "[t]he issue of whether one drug is more effective than another drug is clearly within the expertise of the FDA and should not be resolved in a court of law through the adversarial system." The court

concluded that the DCFA does not apply to pharmaceutical advertising if the ad claims are within the bounds of the drug's FDA-approved labeling.

The information included in the labeling of a new drug reflects a determination by the FDA that the information is not “false or misleading.” By approving information to be included in the drug labeling, the FDA has determined that the information complies with its rules and regulations. Therefore, if the FDA labeling supports the statements made in advertising for an FDA-approved drug, the statements are not actionable under [the Delaware statute].

Pennsylvania Employee Benefit Trust Fund, at *8-9.

Because the “information included in the labeling of a new drug reflects a determination by the FDA that the information is not ‘false or misleading,’” (citing 21 C.F.R. § 314.125(b)(6)) “any statements made that comply with the FDA-approved labeling would not be actionable under a state consumer fraud act because they are preempted by federal law.” *Id.* at * 15. This conclusion is reached without any explicit analysis supporting the determination. Whether this ruling stands will be followed with great interest.

Conclusion

This case is an important decision for the pharmaceutical industry. It not only facilitates a discussion regarding the successful use of the preemption defense in prescription drug cases, it may foster ongoing debate pertaining to plaintiffs' use of consumer protection class action suits targeting prescription drugs and over-the-counter products.

We welcome your questions and comments. For more information, please contact:

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