"Fraud-on-the-FDA" Failure to Warn Claims Are Preempted by Federal Law

Pharmaceutical Law Update

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The extent to which federal law preempts state law claims is an issue that has been in the forefront of drug and medical device litigation throughout the past few years. In the context of medical device litigation, the U.S. Supreme Court rendered its seminal *Buckman v. Plaintiffs' Legal Comm*., 531 U.S. 341 (2001), decision determining that federal law preempts state law causes of action based on a medical device manufacturer's alleged fraudulent representations to the Food and Drug Administration (FDA). Since that decision, federal courts have been considering whether the *Buckman* analysis applies more broadly to all claims asserting allegations of "fraud-on-the-FDA," or simply just to causes of action titled "fraud-on-the-FDA." Compare *Garcia v. Wyeth-Ayerst Labs*., 385 F.3d 961 (6th Cir. 2004), with *Desiano v. Warner-Lambert & Co*., 467 F.3d 85 (2d Cir. 2006), *aff'd by an equally divided court sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440, 128 S. Ct. 1168 (2008). The Fifth Circuit Court of Appeals is the most recent court to weigh in on this issue in *Lofton v. McNeil Consumer & Specialty Pharm*., *et al*, 2012 WL 579772 (5th Cir. Feb. 22, 2012).

In 2000, shortly after taking over-the-counter Motrin for a fever, Christopher Lofton died from a rare disease known as Toxic Epidural Necrolysis (TEN). Around the time when labeling changes were implemented requiring that ibuprofen labels contain a warning regarding the symptoms of TEN, and a citizen's petition was filed seeking additional labeling requirements on ibuprofen products, Lofton's family filed suit against McNeil asserting claims of common law negligence and strict products liability. McNeil moved for summary judgment.

At issue in *Lofton* was a Texas law that presumptively insulates a drug manufacturer from liability for failure to warn claims when it has complied with FDA standards. Specifically, TEX. CIV. PRAC. & REM. CODE § 82.007(a)(1) provides a drug manufacturer with a rebuttable presumption that it is not liable for failure to warn claims if the FDA has approved the "warnings or information" accompanying the allegedly defective product. A plaintiff can, however, rebut this presumption by establishing that

the manufacturer "withheld" from or "misrepresented" to the FDA "required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." TEX. CIV. PRAC. & REM. CODE § 82.007(b)(1). McNeil argued that the plaintiffs' failure to warn claim was preempted by the Food, Drug & Cosmetic Act (FDCA) because the exception to CIV. PRAC. & REM. CODE § 82.007(a)(1) required the plaintiffs to demonstrate a fraud on FDA.

The District Court for the Northern District of Texas granted summary judgment in favor of McNeil. The District Court first determined that "extending the holding of *Buckman* to fraud-on-the-FDA exceptions is warranted." Moreover, in light of FDA's rejection of the citizen's petition based on a decision that there was no evidence supporting an allegation that McNeil withheld information, the District Court further determined that "section 82.007(b)(1) is preempted in some circumstances, including as here, where the plaintiffs ask the court to reach the conclusion opposite of that reached by FDA, that the defendants did not withhold information or mislead it." The plaintiffs appealed, and, in a unanimous decision, the Fifth Circuit affirmed the District Court's decision finding that federal law preempts Texas' tort reform law that requires a plaintiff to assert, in failure to warn claims, that a drug manufacturer withheld or misrepresented material information to the FDA.

The Fifth Circuit looked to the Supreme Court's decision in *Buckman*, finding that federal law preempts state law causes of action in the context of fraudulent representations to FDA relating to medical device manufacturers, and *Wyeth v. Levine*, 555 U.S. 555 (2009), finding that state common law failure to warn claims are not preempted by FDA's approval of drug labels, to determine whether the claims at issue were preempted. The Fifth Circuit determined that the Loftons' claim presented more of a fraud-on-the-FDA claim analogous to Buckman, rather than a failure to warn claim analogous to Levine. This is because the narrow exception to section 82.007 requires a plaintiff to "establish" that the drug manufacturer "withheld" or "misrepresented...material" information "required" by FDA, which is tantamount to requiring a plaintiff to prove fraud-on-the-FDA to establish a failure to warn claims.

In interpreting Buckman, the Fifth Circuit came to a similar conclusion as the Sixth Circuit Court of Appeals did in *Garcia v. Wyeth-Ayerst Labs*, regarding a Michigan law much like Texas' section 82.007. The Fifth Circuit agreed with the Sixth Circuit that *Buckman* should be read broadly. It

explained that, "in cases like this, where the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities" and violates the Supremacy Clause. Thus, section 82.007(b)(1) is preempted unless the FDA itself has found fraud.

While there is still a split among the courts, the *Lofton* decision provides additional support for drug and medical device manufacturers seeking a broad application of the Supreme Court's *Buckman* "fraud-on-the-FDA" preemption decision to all claims that a manufacturer fraudulently withheld information from FDA. To the extent a state law requires elements of proof tantamount to demonstrating a fraud on the FDA, or a plaintiff asserts claims alleging that a pharmaceutical manufacturer withheld or misrepresented information to FDA, the *Lofton* case will help bolster any preemption argument in support of dismissal.

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