Alerts and Updates

Fifth Circuit Concludes That U.S. Supreme Court's "Fraud-on-the-FDA" Federal Preemption Precedent Has Broad Application

March 2, 2012

The *Lofton* decision deepens the split among the U.S. circuit courts on whether or not the U.S. Supreme Court's "fraud-on-the-FDA" preemption decision in *Buckman* applies broadly and forcefully to all claims that, either explicitly or implicitly, include an allegation that a drug or medical device manufacturer did not appropriately satisfy its disclosure obligations vis-à-vis the FDA.

On February 22, 2012, the U.S. Court of Appeals for the Fifth Circuit unanimously affirmed the U.S. District Court for the Northern District of Texas' granting of a defendant drug manufacturer's motion for summary judgment on all claims, including the plaintiffs' failure-to-warn claims, in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, No. 10-10956, *slip op.* (5th Cir. Feb. 22, 2012). At issue was whether, under Texas law, "a drug manufacturer enjoys a rebuttable presumption that it is not liable for failure to warn if the FDA has approved 'the warnings or information' accompanying the product alleged to have harmed the plaintiff."

The defendant drug manufacturer asserted as an affirmative defense the rebuttable presumption that it had complied with all U.S. Food and Drug Administration (FDA) requirements governing its product's labeling. Under Texas law, a defendant drug manufacturer is afforded a rebuttable presumption defense against failure-to-warn claims if "the FDA has approved 'the warnings or information' accompanying the product alleged to have harmed the plaintiff." Pursuant to Texas law, the affirmative defense may be rebutted if the plaintiff can establish the defendant drug manufacturer "withheld from or misrepresented to the United States Food and Drug Administration 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(a)(1).*

The *Lofton* decision was rendered in the context of the U.S. Court of Appeals for the Sixth Circuit holding in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), in which the Sixth Circuit held that a Michigan statute akin to Texas' adequacy presumption statute was preempted in some applications. The Fifth Circuit also issued its opinion in *Lofton* in the wake of the U.S. Court of Appeals for the Second Circuit decision in *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). In *Desiano*, the Second Circuit addressed whether Michigan's adequacy presumption statute, the same statute at issue in *Garcia*, was federally preempted, and the court held that the statute was not preempted.

The Fifth Circuit found that the plaintiffs' claims were tantamount to a fraud-on-the-FDA claim analogous to the plaintiffs' allegation in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 121 S. Ct. 1012 (2001). In *Buckman*, the U.S. Supreme Court held that state law fraud-on-the-FDA claims are preempted insofar as they "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 1018.

In *Lofton*, the Fifth Circuit reasoned that section 82.007(b)(1) of the Texas statute in question required the plaintiff to prove fraud-on-the-FDA in order to establish a failure-to-warn claim. Such a requirement in the Fifth Circuit's judgment invokes federal preemption analysis pursuant to the U.S. Supreme Court's *Buckman* decision. Specifically, the *Lofton* court emphasized that the Texas statute "requires a plaintiff to establish that a drug maker 'withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury.'" The Fifth Circuit stressed that the term "required information" "refers to federal requirements under the FDCA; what is 'material' and 'relevant' must be determined by FDA itself, not by state court juries." Because the Fifth Circuit determined that the Texas presumption of adequacy statute required the plaintiff to "establish" a violation of FDA disclosure requirements, "the plaintiff necessarily re-treads the FDA's administrative ground both to conduct discovery and to persuade a jury." Furthermore, the *Lofton* court held that in cases 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." Accordingly, the Fifth Circuit concluded that the Texas presumption of adequacy statute was federally preempted, unless the factual record revealed that the FDA had found fraud.

Analysis

The Fifth Circuit's decision in *Lofton* deepens the split among the U.S. circuit courts on whether or not the U.S. Supreme Court's "fraud-on-the-FDA" preemption decision in *Buckman* applies broadly and forcefully to all claims that, either explicitly or implicitly, include an allegation that a drug or medical device manufacturer did not appropriately satisfy its disclosure obligations vis-à-vis the FDA. Similar to the presumption of adequacy statute in question in the *Lofton* case, several other states have analogous statutes that will likely be the focus of decisions by other circuit courts. Thus, it is

probable that the U.S. Supreme Court will have to provide further clarification with reference to the scope of the application of *Buckman*. In the interim, both drug and medical device manufacturers can rely on the Fifth Circuit's *Lofton* opinion in trying to defeat state law-based failure-to-warn claims that implicate the manufacturers' dealings with the FDA.

For Further Information

If you have any questions about this *Alert* or would like more information, please contact Sharon L. Caffrey, Paul M. da Costa, any member of the Products Liability and Toxic Torts Practice Group or the attorney in the firm with whom you are regularly in contact.