On the Legal Pulse

Timely Commentary from the *WLF Legal Pulse* blog

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Fifth Circuit Puts an End to Texas Pharma Plaintiff's California Dreamin'

June 6, 2014

By **Eric G. Lasker**, Hollingsworth LLP

Debates over whether—and in which circumstances—Food and Drug Administration (FDA) approval of prescription drugs and medical devices should preempt State law have been in the forefront of Supreme Court jurisprudence and Congressional action for over a decade. However, when a State itself concludes that FDA approval is the correct standard for state law liability, one would think that would end the debate, right? Well, yes, but not without a few tantrums along the way.

Texas's FDA Defense. In 2003, Texas enacted a tort reform statute which protects pharmaceutical products manufacturers (subject to specifically defined exceptions) from liability based upon a warning or other information that was approved by the FDA. Tex. Civ. Prac. & Rem. Code § 82.007(a). Texas took this step based upon the Legislature's informed view that the State was facing an environment of excessive litigation that had caused a crisis in access to healthcare. Of course, the plaintiffs' bar argued strenuously to the contrary. Many of their brethren appeared in hearings before the Texas Legislature; they accused the Legislature of caving to "Big Pharma" and argued that the FDA couldn't be trusted to review drug safety. But the Legislature disagreed, and FDA-approval was adopted as the presumptive standard of care in pharmaceutical products liability cases in Texas.

Plaintiffs' Bar's Efforts to Judicially Nullify § 82.007(a). What was the response? Predictable. The plaintiffs' bar turned to the courts to undo what the Legislature had done. They argued that § 82.007(a) should be read narrowly to apply only to expressly-labeled "failure to warn" claims, ignoring the fact that in pharmaceutical litigation, the adequacy of warnings is key regardless of the legal theory of liability. They argued that a jury should decide whether § 82.007(a) even applied, seeking a threshold whereby the jury could decide that the manufacturer secured regulatory approval through fraud on the FDA—despite clear U.S. Supreme Court authority that such a state law jury inquiry was preempted by federal law. They argued that the entire statute should be stricken if their interpretation of the fraud-on-the-FDA exception to § 82.007(a) was not accepted.

Thus far, each of these arguments has been rejected. As a result, one Texas plaintiff recently took a step that many Texans would consider a sacrilege: he asked the court to treat him as a Californian instead! The case is *McKay v. Novartis Pharmaceuticals Corp.*, and on May 27, 2014, the United States Court of Appeals for the Fifth Circuit rejected this desperate gambit as well. *McKay v. Novartis Pharm. Corp.*, __ F.3d __, No. 13-50404, 2014 WL 2198544 (5th Cir. May 27, 2014).

Fraud-on-the-FDA Suit Filed, 2006. Mr. McKay, a long-time Texas resident, filed suit in federal district court in Texas in 2006, asserting a products liability claim against Novartis Pharmaceuticals Corporation arising from his use of two FDA-approved prescription drugs, Aredia® and Zometa®, as treatment for prostate cancer. His case was transferred for pretrial coordination in a federal multi-district litigation (MDL) in Tennessee styled *In re Aredia and Zometa Products Liability Litigation*.In June 2008, Novartis filed a motion for summary judgment both as to Mr. McKay and a number of other Texas plaintiffs, arguing that their claims were barred by § 82.007(a).

Prior to Novartis' filing, the one Texas federal court to construe the fraud-on-the-FDA exception to § 82.007(a) had sided with the plaintiff and denied the defendant's argument for summary judgment based on the statute. *See* *Ackermann v. Wyeth Pharm.*, 471 F. Supp. 2d 739, 749-50 (E.D. Tex. 2006) (holding that § 82.007(a) creates nothing more than a presumption of adequacy to be considered by the jury), *summary judgment aff'd on other grounds*, 526 F.3d 203 (5th Cir. 2008). Mr. McKay decided to attack § 82.007(a) head on, (baselessly) alleging that Novartis had "withheld from or misrepresented to the [FDA] required information that was . . . causally related to the claimant's injury." Tex. Civ. Prac. & Rem. Code § 82.007(b)(1). FDA never had made any finding that it had been so defrauded. But Mr. McKay argued that he should nonetheless be able to make this claim before a jury. This argument, of course, should fail because it would eviscerate the protection provided by § 82.007(a). A creative plaintiffs' attorney (and are there any other kind?) will always be able to concoct an argument as to why a jury should believe—even if the FDA itself does not—that the FDA has been defrauded.

MDL Court (2008) and Fifth Circuit (2012) Reject McKay's Suit. As the MDL court correctly held, however, plaintiffs' argument failed on an even more obvious ground: It was contrary to the United States Supreme Court's holding in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), that state law determinations that the FDA had been defrauded are preempted. *See In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2008 WL 2944910, at *5 (M.D. Tenn. July 25, 2008). Shortly after the MDL Court's ruling, Texas federal courts agreed, and in 2012, the U.S. Court of Appeals for the Fifth Circuit put any doubt to rest, concluding that the Aredia®/Zometa® MDL Court had gotten it right. *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 380 (5th Cir. 2012) (holding that "[i]n 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").

McKay Pulls Out the California Card, 2013. So where did this leave Mr. McKay? Due to the omnibus nature of the defendant's summary judgment motion in the MDL, the MDL court had not issued an immediate dismissal order as to the numerous plaintiffs at issue, but instead allowed each case to be remanded back to Texas federal district court for final disposition. By the time Mr. McKay's case landed back in Texas, however, *Lofton* had been

decided. Mr. McKay came up with some fashionably late legal arguments as to why § 82.007(a) shouldn't bar his claim, but the Texas federal court would have none of it, correctly holding that Mr. McKay had waived those arguments when he failed to assert them in the MDL. Still, Mr. McKay had what he thought was an ace in the hole: While he lived in Texas, had brought suit in Texas, and had suffered his alleged injury in Texas, Mr. McKay had traveled to California for some of his medical treatment and it was a California doctor who had prescribed him the drugs that allegedly caused his injury. The MDL court had held that Texas law applied, but the choice-of-law issue was properly positioned for appeal.

Novartis Has Superior Hand, Wins in Fifth Circuit, 2014. In the Fifth Circuit, Mr. McKay played his choice-of-law hole card with a flourish but in its May 27 opinion, the court concluded that Novartis still had the better hand. First, the Fifth Circuit roundly castigated Mr. McKay for his argument that the MDL court had erred in failing to grant his Rule 56(d) motion for additional discovery on choice-of-law. The court observed that Mr. McKay "did not need formal discovery to request his own medical records" and that he had had two years to gather this evidence prior to Novartis' 2008 summary judgment motion. *McKay*, 2014 WL 2198544, at *3. The Fifth Circuit then rejected Mr. McKay's argument that the MDL court should have reconsidered its choice of law ruling based upon subsequent discovery, finding that Mr. McKay had waited too long to seek reconsideration and had relied on the wrong federal rule section to boot. *Id.* at *4

Turning to the merits of the choice of law argument, the Fifth Circuit strongly proclaimed Texas's right to declare the law that governs its own citizens. While acknowledging Mr. McKay's argument that his drug treatment had been directed out of California by a California physician, the court held that those contacts "do not override his Texas connections." *See id*. at *5 ("Although McKay received some of his treatment in California, and [California oncologist] Dr. Leibowitz directed the progression of McKay's prescriptions there, it is undisputed that McKay resided in Texas and received treatment multiple times in Texas, and that his condition manifested itself in Texas."). The Fifth Circuit's holding strongly rebukes those who still seek to undermine the Texas tort reform statute: "Texas has a significant interest in remedying injury to Texas citizens through tort liability and also in defining the outer limits of tort liability." *Id.* (citation omitted)

After holding Mr. McKay to Texas law, the Fifth Circuit made short order of his remaining appellate arguments. The Fifth Circuit rejected Mr. McKay's attempt to construe § 82.007(a) narrowly to apply only to failure to warn claims. *Id.* at 5-6. The court held that Mr. McKay had waived his other statutory arguments by failing to properly raise them below. *Id.* at *6-7. And it concluded that Mr. McKay had failed to provide the pre-suit notice required under Texas law for his breach of warranty claim. *Id.* at *7-8.

California dreamin'? In Texas, "that dog don't hunt."

