# Fifth Circuit Breaks Buckman Tie

**Friday, February 24, 2012**

Does Buckman v. Plaintiff's Legal Commmittee, 531 U.S. 341 (2001), apply any time that a plaintiff raises a fraud on the FDA allegation in litigation, or is it limited to causes of action denominated "fraud on the FDA? Most courts have agreed with the Sixth Circuit that Buckman applies across the board. See , 385 F.3d 961 (6th Cir. 2004). A persistent minority, however, has limited Buckman to complete "fraud on the FDA" causes of action. See Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2006). The Supreme Court attempted, but failed, to close the split in Desiano, but failed - splitting 4-4. See Warner Lambert LLC v. Kent, 552 U.S. 440 (2008). Garcia v. Wyeth-Ayerst Laboratories

Both Garcia and Desiano involved the "fraud on the FDA" exception to a Michigan tort reform statute that imposes a presumption of adequacy on warnings that are FDA approved - that is, just about every warning. The Michigan statute was essentially dispositive.

Then Texas passed a similar presumption statute that is almost as dispositive in the ordinary case as Michigan's. It was only a matter of time before the Fifth Circuit would be called upon to decide the same question as in Garcia/Desiano.

Also in the mix is the Supreme Court's later, extremely anti-preemption, decision in Wyeth v. Levine, 555 U.S 555 (2008).

We're pleased to be able to report that, unanimously, the Fifth Circuit has agreed with Garcia and given Buckman a broad reading that can't be avoided by simple pleading strategems. The rationale of Buckman applies anytime fraud on the FDA is asserted by a civil litigant:

> *"Buckman's fraud-on-the-FDA analysis is more factually and legally apposite to the interpretation of §82.007(b)(1) [the Texas statute]. Moreover, Levine preserves common law state tort claims that parallel or reinforce the agency's efforts but do not involve the relationship between the federal regulator and the regulated entity, the dispositive factor for federal preemption in Buckman. In fact, neither the majority nor dissent in Levine cut back on Buckman or, indeed, found a state law fraud-on-the-agency theory viable in this broader context. Only by denying that the Texas statute is what it is - a requirement to prove fraud on the FDA - can Levine prevail or Buckman be distinguished. Lofton v. McNeil Consumer & Specialty Pharmaceuticals, No. 10-10956, slip op. (5th Cir. Feb. 22, 2012).*

Nor does the "presumption against preemption" (assuming it survived PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011)) apply where fraud on the FDA is being alleged:

> *"Even with the benefit of Levine and PLIVA, this court is unable to assess the current scope or existence of the presumption against preemption. We take refuge in the conclusion that because §82.007(b)(1) requires a Texas plaintiff to prove fraud-on-the-FDA to recover for failure to warn, this requirement invokes federal law supremacy according to Buckman.*

Lofton, slip op. at 13.

Buckman, of course, found the presumption inapplicable because federal agency fraud is a "uniquely federal" area of the law. 531 U.S. at 347-48.

Thus, Lofton aligned itself with Garcia. We repeat the Fifth Circuit's excellent analysis in full:

> *"Desiano's and [plaintiffs'] focus on "traditional" tort duties is unpersuasive when the statute at issue conditions recovery on "establishing" what amounts to fraud on the agency.*
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> *Also unpersuasive is the idea that it makes a difference for preemption purposes whether fraud-on-the-FDA has become an "element" of traditional tort claims because of the state statutes, or an item of rebuttal to a defendant's affirmative defense. We reject [plaintiffs'] specific argument that §82.007(b)(1) "is merely a legislative means to produce some evidence" of fraud on the FDA to counter the insulation from liability otherwise afforded by §82.007(a)(1). Either way, under the Texas provision, a plaintiff must "establish" a violation of FDA's required disclosures. In so doing, the plaintiff necessarily re-treads the FDA's administrative ground both to conduct discovery and to persuade a jury. [Plaintiffs'] artful reasoning overlooks the reality of trial practice and the precise statutory language.*
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> *We also disagree with the Second Circuit that statutes like §82.007(b)(1) and the Michigan statute do not pose the same over-disclosure problems that Buckman contemplated. The Supreme Court was concerned that "disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." Buckman, 531 U.S. at 351. When the FDA has not found fraud, two sorts of interference arise from these claims. First, §82.007(b)(1) allows the state court to interject varying views on what disclosures are sufficient. The resulting uncertainty compels manufacturers to flood the FDA with information to ensure that they retain the §82.007(a)(1) presumption of non-liability. FDA in turn loses control over its ability, based on scientific expertise, to prescribe – and intelligently limit – the scope of disclosures necessary for its work. Second, the statutory requirement of proving fraud-on-the-FDA may directly invade the agency's processes when close questions of "withholding" or "misrepresentation" arise. These dangers are inherent in Buckman's concern to preserve the agency's discretion to police the conduct of regulated entities.*
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> *While Desiano strains to evoke distinctions between the claim in Buckman and the Michigan statute, the Sixth Circuit's approach is more faithful to Buckman. 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. Under such circumstances Buckman found a violation of the Supremacy Clause. Thus, §82.007(b)(1), is preempted unless the FDA itself has found fraud.*

Lofton, slip op. at 14-16.

Obviously, we agree with with Lofton. In fact, we said pretty much the same thing way back when when Desiano was first before the Supreme Court in Kent.

Labels: Fraud On The FDA, Implied Preemption, Presumption Against Preemption