IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
February 22, 2012
Lyle W. Cayce
Clerk

No. 10-10956

CHRISTOPHER TYLER LOFTON, Individually and on behalf of the Estate of Christopher M. Lofton, deceased; TEGAN NICOLE LOFTON, individually and on behalf of the Estate of Christopher M. Lofton, deceased; LAUREN LOFTON,

Plaintiffs - Appellants

v.

MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a Division of McNeil-P.P.C. Incorporated; JOHNSON & JOHNSON,

Defendants - Appellees

Appeal from the United States District Court
for the Northern District of Texas

Before JONES, Chief Judge, and STEWART and SOUTHWICK, Circuit Judges.

EDITH H. JONES, Chief Judge:

Christopher M. Lofton tragically died from a rare disease called Toxic Epidermal Necrolysis ("TEN") after taking Motrin. Lofton's wife and children brought suit against the Appellees asserting that Motrin caused the disease and the Appellees had failed to warn consumers about the risk of these severe autoimmune allergic reactions. The district court entered summary judgment for the Appellees. The only issue on appeal is whether the district court correctly found that federal law preempts a Texas tort reform law that requires

plaintiffs to assert, in failure to warn cases, that a drug manufacturer withheld or misrepresented material information to the FDA. *See* TEX. CIV. PRAC. & REM. CODE § 82.007(b)(1). We agree with the district court and AFFIRM.

BACKGROUND

Christopher M. Lofton took over-the-counter Motrin between May 20 and May 22, 2000 to combat a fever. On May 24, after noticing a rash on his skin, Lofton went to the Plano Medical Center emergency room, where he reported both the fever and the rash. After his release, he resumed taking Motrin for pain. When his skin condition worsened, Loften saw a dermatologist on May 26. The dermatologist diagnosed him with Stevens-Johnson Syndrome ("SJS"), a less advanced form of TEN. The following day, Lofton returned to the emergency room and was soon admitted to the burn unit of Parkland Hospital for treatment of TEN. He died on June 3.

SJS and TEN are extremely rare maladies, occurring in only several people per million each year. One known cause of the diseases is an autoimmune reaction to medication. Whether ibuprofen is among the medications that can cause TEN is a contested issue. In a similar case, the Seventh Circuit noted that "[t]here is unquestionably an *association* between SJS/TEN and ibuprofen," but such association might arise only from patients' use of ibuprofen to combat the headaches and fevers associated with SJS/TEN. *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 868 (7th Cir. 2010).

The FDA is aware of the connection between ibuprofen and SJS/TEN and, starting in February of 2005, required that ibuprofen labels carry a warning about the symptoms of SJS/TEN. The warning listed skin reddening, rash, and blisters among the signs of an allergic reaction. Also during February 2005, a

group that Appellees describe as "experts retained by plaintiffs in Motrin litigation," filed a Citizen's Petition with the FDA. The petition sought additional labeling requirements, including an express reference to SJS/TEN, and alleged that McNeil and other manufacturers had withheld information from the FDA regarding the risk of severe skin disorders. The FDA rejected the petition, explaining that warnings beyond those already added would not be useful. Regarding the allegations that McNeil and other manufacturers withheld information, the agency stated: "[petitioners] provide no evidence to support this allegation. In addition, we have no evidence that there is additional undisclosed safety information that was withheld by the ibuprofen manufacturers."

Against this background, Lofton's family filed suit asserting common law negligence and strict products liability claims. Appellees moved for summary judgment on all claims, asserting in particular that the failure to warn claims, which are subject to a "fraud-on-the-FDA" proof requirement under Texas law, are preempted by *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 121 S. Ct. 1012 (2001). The district court delayed ruling on the motion until the Supreme Court decided *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009), which asked the Court whether FDA approval of drug labels preempted state failure to warn claims. Although *Levine* rejected a sweeping view of preemption, the district court in this case nevertheless granted the motion for summary judgment insofar as it related to the preemption of the Texas provision. *Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F. Supp. 2d 662, 676-78 (N.D. Tex. 2010). The Loftons' other claims have been dismissed.

Only one issue survives on appeal. 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. TEX. CIV. PRAC. & REM. CODE § 82.007(a)(1).[1] A plaintiff may rebut the presumption, *inter alia*,

> by establishing that . . . the defendant . . . 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.

§ 82.007(b)(1). As an affirmative defense, McNeil raised the § 82.007(a)(1) presumption, and the district court concluded that the conditions for invoking the provision were satisfied because McNeil complied with all FDA requirements governing the labels of over-the-counter ibuprofen. *Lofton*, 682 F. Supp. 2d at 673. The court went on to consider the plaintiffs' attempt to rebut that presumption based on § 82.007(b)(1). The court first concluded that "extending

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[1] Unredacted, this section states:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
> (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended; or
> (2) the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

the holding of *Buckman* to fraud-on-the-FDA exceptions is warranted." *Id.* at 675. In addition, after noting that the FDA rejected the 2005 Citizen's Petition, the court held that "section 82.007(b)(1) is preempted in some circumstances, including as here, where Plaintiffs ask the court to reach the conclusion opposite of that reached by the FDA, that Defendants did not withhold information or mislead it." *Id.* As a result, the district court granted the Appellees' motion for summary judgement. *Id.* at 681. This appeal followed.

STANDARD OF REVIEW

This court reviews a district court's grant of summary judgment *de novo* applying the same standard as the district court. *Onoh v. Northwest Airlines, Inc.*, 613 F.3d 596, 599 (5th Cir. 2010). The court views all evidence in the light most favorable to the nonmoving party and grants summary judgment if there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. *Id.* Questions of law regarding preemption are reviewed *de novo*. *Tex. Midstream Gas Servs., LLC v. City of Grand Prairie*, 608 F.3d 200, 206 (5th Cir. 2010).

DISCUSSION

Provisions similar to § 82.007(a)(1) and (b)(1) have been subject to conflicting treatment in the courts of appeals. The Sixth Circuit held that a Michigan statute similar to the contested Texas provision is preempted in some applications. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). The Second Circuit, however, held the same Michigan statute not preempted. *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). Both cases interpreted *Buckman,* which held that state

law fraud-on-the-FDA claims are preempted because they "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 350, 121 S. Ct. at 1018.

Following *Buckman*, the Supreme Court held that state common law failure to warn claims are not preempted by FDA approval of drug labels. *Wyeth* 555 U.S. 555, 129 S. Ct. 1187. Consequently, the Loftons' appeal hinges on the characterization of their case as presenting a failure to warn claim analogous to *Levine*, which is not preempted, or a fraud-on-the-FDA claim analogous to *Buckman,* which is. If *Buckman* is more analogous, we must determine whether to follow the Second or Sixth Circuit concerning *Buckman's* applicability to provisions like § 82.007(b)(1).

1. *Buckman* or *Levine*

Buckman held that federal law preempts state-law causes of action claiming that a medical device manufacturer made fraudulent representations to the FDA. 531 U.S. at 353, 121 S. Ct. at 1020. The case involved orthopedic bone screws that the FDA approved in an expedited process as "substantially equivalent" to devices already on the market. 531 U.S. at 346, 121 S. Ct. at 1016. Plaintiffs who suffered injuries after implantation of the screws brought suit alleging that the manufacturer misled the FDA. They further alleged that the misrepresentations were a "but for" cause of their injuries because, absent the misrepresentations, the product would never have reached the market. 531 U.S. at 343, 121 S. Ct. at 1015.

The Court rejected the novel cause of action because the state law claim would conflict with the FDA's authority to punish fraud on the agency. The Court stated "that the federal statutory scheme amply empowers the FDA to

punish and deter fraud against the Administration."[2] 531 U.S. at 348, 121 S. Ct. at 1017. Not only does federal law provide administrative tools to punish and deter fraud, but the agency's decision to employ those tools implicates its discretion and special competence. Among the factors that make FDA enforcement "a somewhat delicate balance of statutory objectives," *id.*, are the need for administrative efficiency and the possibility that tort liability based on inadequate disclosures would create "an incentive to submit a deluge of information," 531 U.S. at 351, 121 S. Ct. at 1019. The Court concluded that authorizing tort liability for failure to comply with FDA disclosure requirements "would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." 531 U.S. at 353, 121 S. Ct. at 1020.

In *Levine*, the plaintiff brought a traditional failure to warn claim under state common law for injuries accruing from the administration of Phenergan. The defendant responded that because the FDA approved the drug labels, state law claims were preempted. 555 U.S. at 559-60, 129 S. Ct. at 1191-92. The Court rejected the preemption argument as an "overbroad view of an agency's power to pre-empt state law." 555 U.S. at 574, 129 S. Ct. at 1199. Among other reasons, the Court noted that the Food, Drug and Cosmetic Act ("FDCA") contains no express preemption provision regarding prescription drugs, and federal law provides no remedy for consumers harmed by unsafe drugs. 555 U.S. at 573-74, 129 S. Ct. at 1199. The Court was unpersuaded by the argument for conflict preemption, which asserted that Wyeth could not simultaneously comply with FDA labeling regulations and additional requirements imposed by state

[2] The FDA has authority to investigate fraud, 21 U.S.C. § 372, consider citizen petitions, 21 C.F.R. § 10.30, and seek criminal and civil penalties particular to fraud-on-the-FDA, 21 U.S.C. § 332-33. *Buckman*, 531 U.S. at 349, 121 S. Ct. at 1017-18.

common law. *Id.* *Levine* is not the Court's first holding that state tort actions can complement rather than conflict with FDA safety regulations. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495, 116 S. Ct. 2240, 2255 (1996), the Court held that a finding of equivalency by the FDA, which led to approval of a medical device, did not "den[y] Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Accord Buckman*, 531 U.S. at 353, 121 S. Ct. at 1020 ("*Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements.").

At first glance, the case at bar bears some resemblance to both *Levine* and *Buckman*. Texas adopted § 82.007 as a tort reform measure, intentionally restricting certain common law claims concerning FDA-approved drugs except where such claims closely parallel the procedures and results required by the agency itself. Thus, Section 82.007(a)(1) creates a statutory presumption that drug manufacturers and related parties are not liable for failure to warn claims if the FDA approved the label. Under § 82.007(b)(1), the relevant exception here, the presumption against liability can be rebutted if the plaintiff can "establish" that the drug manufacturer "withheld" from the agency or "misrepresented" "material" information "required" by the FDA. As in *Buckman*, the plaintiffs must show fraud-on-the-FDA for their claims to survive, but as in *Levine*, the tort covered by the statute is a failure to warn products liability claim. This hybrid appearance dissolves, however, when one focuses on § 82.007(b)(1), the contested statutory provision.

Buckman's fraud-on-the-FDA analysis is more factually and legally apposite to the interpretation of § 82.007(b)(1). 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. The question then becomes whether to subscribe to the Sixth Circuit's or Second Circuit's interpretation of *Buckman*.

2. Competing Interpretations of *Buckman*

As noted above, the courts of appeals split on whether *Buckman* requires preemption of a Michigan provision similar to § 82.007.[3] In *Garcia*, the Sixth

[3] Although neither party mentions it, the presumption accorded defendants under the Michigan law is broader than that in Texas law. The Michigan presumption covers several products liability claims if a defendant's product complies with FDA regulations, while the Texas presumption only applies to failure to warn claims. The statute reads, in relevant part:

> (5) In a product liability action against a manufacturer or a seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . . This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would

Circuit concluded that the Michigan provision is preempted unless the FDA itself finds that fraud has been committed during the approval process. 385 F.3d at 966. The court observed that under *Buckman*, state fraud-on-the-FDA claims are impliedly preempted by the FDCA because the state provisions "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives." *Id.* at 965 (quoting *Buckman*, 531 U.S. at 350, 121 S. Ct. at 1018). While the court recognized that the Michigan provision, which requires evidence of fraud-on-the-FDA to rebut a presumption of non-liability, is not a direct fraud-on-the-FDA cause of action, the court did not find the difference from *Buckman* significant. *Id.* at 965-66. Because the provision ultimately requires the plaintiff to provide proof that the drug manufacturer defrauded the FDA, it conflicts with the FDA's duties and is preempted. *Id.* at 966. Where the FDA itself finds fraud, however, the Sixth Circuit would allow the state claim to proceed because the state tort remedy does not intrude upon the FDA's responsibility or authority. *Id.*

Analyzing the same Michigan statute, the Second Circuit disagreed with *Garcia* and distinguished the Michigan statute from *Buckman* in three ways. *Desiano,* 467 F.3d at 93. First, the traditional "presumption against preemption" applied to the Michigan statute because it embodies a state's regulation of health and safety where the presumption "stands at its strongest." *Id.* at 94. The court did not view the statute as an attempt to police fraud-on-the-FDA but instead

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> have not been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

MICH. COMP. LAWS § 600.2946(5).

a prerequisite to allowing victims to recover under existing state product liability laws. *Id.* Second, the underlying claims were traditional product liability claims not involving a "newly-concocted duty" between the manufacturer and the federal agency. *Id.* at 94-95. Pairing the Michigan provision with the common law claims distinguished the case from *Buckman*, in which the only claim alleged was fraud-on-the-FDA. *Id.* at 95. Moreover, the Second Circuit posited that the Michigan statute in its entirety creates an affirmative defense available to drug manufacturers but does not render fraud-on-the-FDA, asserted on rebuttal by a plaintiff, an "element" of the plaintiff's claims. Finally, the court discounted the likelihood that this provision—unlike a stand-alone fraud-on-the-FDA claim—would engender practical conflict with FDA's approval process and would inflict a deluge of unnecessary information on the agency, as the Supreme Court feared in *Buckman*.

3. *Buckman* applied to TEXAS CIV. PRAC. & REM. CODE § 82.007(b)(1)

a. Presumption Against Preemption

The Supreme Court has occasionally stated that a preemption inquiry "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715, 105 S. Ct. 2371, 2376 (1985) (internal citations omitted). Among the traditional police powers, the Court has also occasionally recognized "the historic primacy of state regulation on matters of health and safety." *Medtronic,* 518 U.S. at 485, 116 S. Ct. at 2250. *See also Wyeth*, 555 U.S. at 565, 129 S. Ct. 1194-95 (repeating these "presumptions"). *But see Wyeth*, 555 U.S. 624 & n.14, 129 S. Ct. 1228-29 & n.14 (Alito, J., dissenting) ("But the

Geier Court specifically rejected the argument . . . that the 'presumption against preemption' is relevant to the conflict-preemption analysis."). Most recently the Court cast doubt on a presumption against preemption in *PLIVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567 (2011). The five-member majority opinion in *PLIVA* made no reference to the "presumption" in the course of upholding implied conflict preemption over state law claims for failure to maintain adequate warning labels for FDA-approved generic drugs. *Id.* Thus, whatever value or relevance a presumption against preemption of state tort law should play is uncertain.

What we can conclude with confidence, though, is that the primacy of the state's police powers is not universal: "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Buckman*, 531 U.S. at 347, 121 S. Ct. at 1017. *Buckman* squarely declined to apply a presumption against preemption of a state law claim for fraud-on-the-FDA, as the Court reasoned that federal law dictates which information the manufacturer is obliged to disclose and imposes penalties for omissions and misrepresentations. 531 U.S. at 347-48, 121 S. Ct. at 1017. As a result, disclosures to the FDA are "uniquely federal" and thus beyond the states' traditional police power. *Id.* State laws that depend on such disclosures are not entitled to a presumption against preemption. *Id.*

Writing prior to *Levine*'s or *PLIVA*'s discussion, or omission, of the "presumption against preemption," both *Garcia* and *Desiano* cited the presumption, but then diverged in their analyses. *Garcia* characterized the Michigan Statute as preserving claims against drug manufacturers for

"circumstances involving, *inter alia*, fraud on the FDA." 385 F.3d at 965. The court felt bound by *Buckman*'s analysis. *Id.* at 966. *Desiano*, however, viewed the Michigan law at a higher level of generality as just another state-law harmful drug remedy, albeit a remedy limited by proof of fraud on the FDA "submitted to neutralize a drugmaker's use of an affirmative defense available under state law." 467 F.3d at 96. The presumption, in other words, might be said to be tied to the courts' ultimate preemption decision.

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*.

b. Section 82.007(b)(1) is a Fraud-on-the-FDA Provision

Section 82.007 is not, like the tort in *Levine*, an expression of traditional state common law. The Texas statute presumptively insulates from liability, for failure to warn, defendants who made, prescribe, or sell drugs in accord with FDA standards. TEXAS CIV. PRAC. & REM. CODE § 82.007(a)(1). Section 82.007(b)(1) eliminates their protection only in cases where a defendant committed the same fraud that federal law "amply empowers the FDA to punish and deter." *Buckman*, 531 U.S. at 348, 121 S. Ct. at 1017. Although the Supreme Court has interpreted the Supremacy Clause to permit some parallel state law tort suits, the current case does not raise that issue. State tort claims are impermissible if they "exist solely by virtue of the FDCA disclosure requirements." *Buckman*, 531 U.S. at 353, 121 S. Ct. at 1020. To repeat, 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." § 82.007(b)(1). 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. This language inevitably relies on FDCA disclosure requirements. Thus, this exception is "premised principally . . . on a drug maker's failure to comply with federal disclosure requirements." *Desiano*, 467 F.3d at 95.

The Second Circuit attached significance to its characterization of the underlying claims in *Desiano* as traditional tort claims not based on a duty between a federal agency and drug manufacturer. Likewise, the Loftons' attempt to distinguish their claim from *Buckman* as a traditional failure to warn tort claim. Parenthetically, the principal question briefed here is not whether a traditional failure to warn claim is preempted, but whether § 82.007(b)(1), the Texas fraud-on-the-FDA exception to a presumption, is preempted. But in any event, *Desiano*'s and Appellants' focus on "traditional" tort duties is unpersuasive when the statute at issue conditions recovery on "establishing" what amounts to fraud on the agency.

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 the Loftons' 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. The Appellants' artful reasoning overlooks the reality of trial practice and the precise statutory language.

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, 121 S. Ct. at 1019. 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.

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.[4]

4. Severability

Appellants argue for the first time on appeal that § 82.007(b)(1) is not severable from § 82.007(a). The district court, while concluding that federal law preempts § 82.007(b)(1), did not discuss the presumption of adequate warning in § 82.007(a). Appellants concede the severability argument is newly raised. "[A]rguments not raised before the district court are waived and will not be considered on appeal unless the party can demonstrate extraordinary circumstances." *French v. Allstate Indem. Co.*, 637 F.3d 571, 582-83 (5th Cir. 2011). The Fifth Circuit has a "virtually universal practice of refusing to address matters raised for the first time on appeal." *Karl Rove & Co. v. Thornburgh*, 39 F.3d 1273, 1280 (5th Cir. 1994). There is no reason to deviate from longstanding practice here.

CONCLUSION

Because we conclude that § 82.007(b)(1) is a fraud-on-the-FDA provision analogous to the claim considered in *Buckman*, we hold that it is preempted by the FDCA unless the FDA itself finds fraud. The judgment of the district court is **AFFIRMED**.

[4] Having decided that § 82.007(b)(1) is preempted, we need not review the district court's factual determination that because FDA rejected the 2005 Citizen's Petition, the agency necessarily found that the Appellees neither withheld information nor misled it.