IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**MDL No. 2:14-mn-02502-RMG** **CASE MANAGEMENT ORDER NO. 28** **This Order relates to:** **2:14-0589** **2:14-0922** **2:14-0966** **2:14-1338** **2:14-1712** **2:14-1847** **2:14-1945** **2:14-3087** **2:14-3249** **2:14-3483**

Pfizer's Motion for Judgment on the Pleadings (Dkt. No. 551)

For the reasons stated below, the Court DENIES Pfizer's Motion for Judgment on the Pleadings (Dkt. No. 551).

I. Background

The parties agree that Texas law applies to the Plaintiffs' claims at issue in this motion. (Dkt. No. 551 at 11-13; Dkt. No. 582 at 7). A Texas Statute creates an affirmative defense that a manufacturer of a pharmaceutical product is not liable in a failure-to-warn case if the FDA approved the warnings accompanied with the product. Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a). This affirmative defense may only be rebutted if the plaintiff establishes one of five exceptions delineated in the statute. *Id.* at § 82.007(b). The parties agree that the only such exception arguably applicable here is the first one: "the defendant, before or after pre-market approval or licensing of the product, 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." *Id.* at § 82.007(b)(1); (*see* Dkt. No. 582 at 10 ("The statute sets out four other means of rebutting the presumption, none of which is relevant here.")).

Pfizer contends that this state statutory exception is preempted by the Federal Food, Drug, and Cosmetic Act (FDCA), such that to succeed on a claim under this first exception, Plaintiffs must show that the FDA *itself* has determined that a fraud has been committed on the agency. Plaintiffs contend that no preemption exists under federal law and that they can prevail by convincing a jury that Pfizer withheld or misrepresented information to the FDA, regardless of whether the FDA has made such a finding. Both parties have authority on point in favor of their position, and there is a circuit split. The Fifth and Sixth Circuits have adopted Pfizer's position, and the Second Circuit has adopted Plaintiffs' position. *Compare Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372 (5th Cir. 2012) *and Garcia v. Wyeth-Ayerst Lab.*, 385 F.3d 961 (6th Cir. 2004) *with Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d. Cir. 2006). The Court finds the reasoning and analysis of *Desiano* more persuasive.

II. Presumption Against Preemption

As an initial matter, the Court finds that there is a presumption against preemption. The federal regulation of drug labeling does not preempt general failure-to-warn cases based on state tort law principles. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009). In reaching the conclusion that the FDCA did not preempt state tort claims, the Supreme Court started with "two cornerstones of our pre-emption jurisprudence": (1) "the purpose of Congress is the ultimate touchstone in every pre-emption case" and (2) that where Congress has legislated in a field traditionally occupied by the states, there is a presumption that Congress did not intend to pre-empt state law. *Id.* at 565 (internal quotes omitted). It also noted the Congress did not provide a federal remedy for

consumers harmed by unsafe drugs, and that Congress was well aware of the prevalence of such state tort litigation. *Id.* at 574, 575. Thus, the Court held that FDCA establishes a "floor" but not a "ceiling" on product labeling.

Pfizer first attempts to cast doubt on whether the presumption against preemption exists at all because the Supreme Court has not mentioned the presumption in two subsequent cases. (Dkt. No. 636 at 8). The Supreme Court clearly and unequivocally stated the presumption was a "cornerstone[] of our pre-emption jurisprudence" in 2009 in *Levine*. 555 U.S. at 565. That two subsequent cases simply failed to mention the presumption does not over rule *Wyeth* and years of jurisprudence reaffirming such a presumption.

Pfizer, relying on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), next argues that the presumption does not apply because policing fraud on federal agencies is not a field traditionally occupied by the states. In *Buckman*, the Supreme Court held that state law "fraud-on-the-FDA" claims were pre-empted by the FDCA, as amended by the Medial Device Amendments of 1976 (MDA). *Id.* at 343. In *Buckman*, the plaintiffs claimed that the defendant made fraudulent representations to the FDA in obtaining approval to market a medical device, that had the defendant not made such representations, the FDA would not have approved the device, and that, therefore, plaintiffs would not have been injured. *Id.* A traditional state negligence claim was not at issue in *Buckman*. The *Buckman* court held that the presumption against preemption did not apply because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 347 (internal quotes omitted).

However, unlike the claim in *Buckman,* the claims at issue here rely "on traditional state tort law which [] predate[] the federal enactments in question." *Id.* at 353. They arise "from the manufacturer's alleged failure to use reasonable care . . ., not solely from the violation of FDCA

requirements." *Id.* at 352. The objective of the statute at issue was "to regulate and restrict when victims could continue to recover under preexisting state products liability law," which "falls squarely within its prerogative to regulate matters of health and safety." *Desiano*, 467 F.3d at 94 (internal quotes omitted); *see also* Tex. S. Journal 78-2003, 2003 Reg. Sess. No. 84 (Tex. June 1, 2003) (stating that the legislature wanted to "provide manufacturers some protection" in general tort suits "where they comply with mandatory federal standards"). Thus, the Court agrees with *Desiano*, that "the cause of action . . . cannot reasonably be characterized as a state's attempt to police fraud against the FDA." 467 F.3d at 94. Rather, these claims are traditional tort claims, which implicate "'federalism concerns and the historic primacy of state regulation of matters of health and safety'"; thus, the presumption against preemption applies. *Buckman* 531 U.S. at 348 (quoting *Medtronic, Inc. v. Lahor*, 518 U.S. 485 (1996)).

III. Texas statute is not preempted by the FDCA.

As explained above, the Court begins its analysis with the presumption that Congress did not intend to preempt Texas product liability claims. The Court is even more hesitant to find preemption where the withholding or misrepresentation of information to the FDA is not an element of the state claim but instead "may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law." *Desiano*, 467 F.3d at 96.

Pfizer argues preemption is necessary to prevent a "deluge" of information on the FDA that hinders its ability to efficiently process applications. The Supreme Court did raise this concern in *Buckman*: "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the [FDA], will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the [FDA] neither wants nor needs, resulting in additional burdens on the FDA's

evaluation of an application." *Buckman* 531 U.S. at 351. However, as explained above, the claims at issue here are not fraud-on the-FDA claims but traditional tort claims where misrepresentation or withholding from the FDA can negate an affirmative defense. As the Second Circuit explained, there is little difference between the claims at issue here and claims like those in *Silkwood*[1] where evidence of fraud against a federal agency is permitted but not conclusive. *Desiano*, 467 F.3d at 97. The incentive to supply additional information to the FDA remains as long as such evidence is admissible in state tort cases. *Id.*

At oral argument, Pfizer was not able to point to any indication that the FDA has suffered a deluge of information since the Second Circuit's decision in *Desiano*. The lack of a post-*Desiano* deluge on the FDA suggests *Desiano* was correct in its conclusion that these claims provide no greater incentive to supply information than traditional claims where evidence of fraud on the FDA is permitted. Perhaps the incentive is increased where a state allows a cause of action based ***solely*** on a drug manufacturer's obligation to provide information to the FDA, as was the case in *Buckman*. However, the Court does not believe the concern is sufficient to warrant a finding of preemption here.

Pfizer also argues that without preemption the parties will have to litigate whether the FDA would have changed its position given the new information and engage in obtrusive discovery of the FDA. However, the Texas statute does not require that Plaintiffs prove that the FDA would have required a label change or taken other action. It only requires that the Plaintiffs show that "the defendant, before or after pre-market approval or licensing of the product, 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."

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[1] *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984).

Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(1). How this information would have affected the FDA's decision is irrelevant.

In sum, the Court finds no reason to suggest that Congress intended to preempt the claims at issue here or to override the presumption against preemption in "a sphere in which the presumption . . . stands at its strongest." *Desiano*, 467 F.3d at 94. As the Supreme Court has repeatedly noted, Congress did not provide a federal remedy for consumers harmed by unsafe drugs, and that Congress is well aware of the prevalence of such state tort litigation. *Levine* 555 U.S. at 574, 575. The Court finds no reason to believe Congress intended to preempt Texas products liability claims simply because the Texas legislature has allowed a plaintiff to negate a statutory affirmative defense by showing that the defendant withheld or misrepresented information to the FDA. Therefore, the Court finds that the Texas statute is not preempted by federal law.

IV. Pleading Requirement

Pfizer claims that Plaintiffs have not adequately pled the exception in Section 82.007(b)(1). However, as explained above, this exception negates a statutory affirmative defense. As such it need not be pled in the complaint. Indeed, it is not even at issue until Pfizer pleads the affirmative defense in its Answer. Therefore, the Court finds that Plaintiffs have adequately pled a failure-to-warn claim in the Complaints at issue.

V. Conclusion

For the reasons stated above, Pfizer's Motion for Judgment on the Pleadings (Dkt. No. 551) is DENIED.

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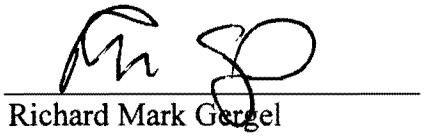
AND IT IS SO ORDERED.



Richard Mark Gergel
United States District Court Judge

February 2, 2015
Charleston, South Carolina