

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

TYLER DIVISION

MATTHEW D. CARTWRIGHT, §
Individually and as Administrator of the §
Estate of BETHANY J. CARTWRIGHT, §
and as Next Friend of BLAKE NICHOLAS §
CARTWRIGHT and KRISTAN ALLYSSA §
CARTWRIGHT §

Plaintiffs, §

v. §

PFIZER, INC. §

Defendant. §

6:04cv292

ORDER ON SUMMARY JUDGMENT

Came on this day for consideration the *Defendant Pfizer Inc's Motion for Summary Judgment (Federal Preemption) and Memorandum in Support* (Docket No. 13). After careful consideration, the Court is of the opinion that the following order should issue.

BACKGROUND AND PROCEDURAL HISTORY

This is a products liability case arising from the suicide death of Bethany Cartwright. According to the Plaintiffs' Complaint, two weeks prior to her death, Mrs. Cartwright was prescribed Zoloft by a local physician's assistant. She had taken Zoloft before, but was unable to remain on it consistently due to the side effects as well as the high cost of the drug. *Plaintiffs' Complaint*, ¶ 13. Zoloft is a member of the class of drugs referred to as "selective

serotonin reuptake inhibitors” (“SSRI”). SSRIs are used to treat major depressive disorder, from which Mrs. Cartwright suffered, as well as obsessive compulsive disorder, panic disorder, premenstrual dysphoric disorder, and social anxiety disorder.

After filling the prescription, her side effects became even more pronounced than before, including: “akathisia, insomnia, mania, agitation, emergent suicidality, emotional blunting and paradoxical worsening of depression.” *Id.*, ¶ 14. On May 30, 2002, Mrs. Cartwright, apparently while folding laundry, put the laundry aside, brought the family’s 22-caliber rifle into the bathroom, got into the bathtub, wrapped a towel around her head, placed the rifle in her mouth, and tragically, pulled the trigger.

The Plaintiffs, Mrs. Cartwright’s estate and heirs, argue that Zoloft, a drug manufactured by the Defendant Pfizer, Inc., which Mrs. Cartwright began taking before her death, was a cause of her suicide. The Plaintiffs further contend that Pfizer had sufficient knowledge of the association between Zoloft and acts of self-harm to warn of this association prior to Bethany Cartwright’s death and yet failed to warn of this association. The Defendant argues that the Plaintiffs’ state law tort claims are preempted by federal law and must, therefore, be dismissed.

The Court believes that analysis of the instant motion requires a summary of the federal Food and Drug Administration’s (“FDA”) drug approval process. The federal Food, Drug, and Cosmetic Act (“FDCA”) requires FDA approval of prescription medicines as “safe and effective” before they may be sold in this country. 21 U.S.C. §§ 355(d), 393(b)(2)(B).

To obtain approval, a manufacturer must submit a new drug application (“NDA”) containing test results, results of clinical studies, and other information. *Id.*, § 355(b), (d). The FDCA requires the FDA to disapprove an NDA if the agency finds that

(1) the investigations, reports of which are required to be submitted to the Secretary . . . , do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; . . . (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; . . . or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular[.]

Id., § 355(d).

After approving an NDA, the FDA continues to monitor the drug’s safety. The agency must withdraw its prior approval if at any time it finds that “clinical or other experience, tests, or other scientific data show that such drug is unsafe for use” or, “on the basis of new information,” that the labeling “is false or misleading in any particular.”

Id., § 355(e). An element the FDA considers crucial in determining whether a drug is safe is the labeling used to inform physicians about the drug’s uses and risks. 50 Fed. Reg. 7452-01, 7470 (Feb. 22, 1985) (“Drug labeling serves as the standard under which

FDA determines whether a product is safe and effective.”). The FDA regulates all such labeling, including “all written, printed, or graphic matter” used in marketing the drug. 21 C.F.R. § 1.3(a).

The FDA approves an NDA only if the agency “determines that the drug meets the statutory standards for safety ... and labeling.” *Id.*, § 314.105(c). The FDA refuses approval if test results “show that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in its proposed labeling or the results do not show that the drug product is safe for use under those conditions,” or if “[t]here is insufficient information about the drug to determine whether the product is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.” *Id.*, § 314.125(a), (b)(3)-(4).

FDA regulations mandate the format and content of all the labeling sections – “Contraindications,” “Warnings,” “Precautions,” and “Adverse Reactions” – and the risk information each section must contain. *Id.*, §§ 201.56, 201.57. The FDA states its product-specific labeling requirements in an “approvable” letter to the manufacturer. *Id.*, § 314.110(a) (“FDA will send the applicant an approvable letter if the application ... substantially meets the requirements of this part and the agency believes that it can approve the application ... if ... specific conditions (for example, certain changes in labeling) are agreed to by the applicant. The approvable letter will describe ... the conditions the applicant is asked to meet.”). Approval of the NDA is “conditioned upon the applicant

incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.” *Id.*, § 314.105(b).

On April 13, 1988, Pfizer submitted to the FDA an NDA seeking approval to market Zoloft to treat depression in adults. The NDA comprised 117 volumes of safety and efficacy data. The information in it and in supplemental submissions included detailed information about suicidality in patients given placebo, Zoloft, and active control drugs during clinical studies. *See Defendant’s Motion for Summary Judgment*, Exhibit C.

On November 19, 1990, the FDA convened its Psychopharmacological Drugs Advisory Committee (“PDAC”) to review the NDA and advise the FDA regarding the medicine’s safety and efficacy. The PDAC consisted of psychiatrists, statisticians, and other experts chosen by the FDA from academic and research institutions throughout the nation. The PDAC voted unanimously that the evidence had shown that Zoloft “is safe when used in the treatment of depression.” *Defendant’s Motion for Summary Judgment*, Exhibit E.

The FDA issued its “approvable” letter on September 30, 1991. *See Defendant’s Motion for Summary Judgment*, Exhibit F. Attaching proposed required labeling, the FDA stated, “We believe it presents a fair summary of the information available on the benefits and risks of [Zoloft],” and directed Pfizer to “use the proposed text verbatim.” *Id.* at 1. The “Precautions” section of the labeling stated:

Suicide – The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high

risk patients should accompany initial drug therapy. Prescriptions for Zoloft (sertraline) should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

Id. at 5-6.

In addition, the “Adverse Reactions” section of the FDA’s proposed required labeling listed “suicide attempt” as an “Infrequent” occurrence, explained that “infrequent adverse events are those occurring in 1/100 to 1/1000 patients,” and stated, “It is important to emphasize that although the events reported occurred during treatment with Zoloft (sertraline), they were not necessarily caused by it.” *Id.* at 14-15.

The FDA granted final approval on December 30, 1991. *See Defendant’s Motion for Summary Judgment*, Exhibit G. It also prepared a final report summarizing the bases for its conclusion that Zoloft, with the required labeling, was safe and effective for treating depression. *See Defendant’s Motion for Summary Judgment*, Exhibit H.

FDA’s ongoing study of Zoloft and other SSRIs during the ensuing decade continued to find no causal relationship to suicide. Indeed, the FDA made six more explicit determinations that Zoloft was “safe and effective” with the FDA-required labeling. In 1996, the FDA approved Zoloft, as labeled, as safe and effective for treatment of adult obsessive compulsive disorder (“OCD”). *See Defendant’s Motion for Summary Judgment*, Exhibit P. In 1997, FDA approved Zoloft, as labeled, as safe and effective for treatment of panic disorder and of pediatric OCD. *See Defendant’s Motion for Summary Judgment*, Exhibits Q and R. In 1999, FDA approved Zoloft, as labeled, as safe

and effective for treatment of post-traumatic stress disorder (“PTSD”). *See Defendant’s Motion for Summary Judgment*, Exhibit S. On May 16, 2002, only two weeks before Decedent’s death, FDA approved Zoloft, as labeled, as safe and effective for treatment of premenstrual dysphoric disorder. *See Defendant’s Motion for Summary Judgment*, Exhibit T. Most recently, on February 7, 2003, nine months after Decedent’s death, FDA approved Zoloft, as labeled, as safe and effective for social anxiety disorder. *See Defendant’s Motion for Summary Judgment*, Exhibit U.

The motion is now ripe for determination.

STANDARD OF REVIEW

A party is entitled to summary judgment on all or any part of a claim “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986). The moving party must show initially that there is no genuine issue of any material fact. *Anderson*, 477 U.S. at 256, 106 S.Ct. at 2514. The movant may meet this burden by pointing out the absence of evidence supporting any essential element of the non-moving party’s claim. *Celotex Corp. v. Catrett*, 477 U.S. 317, 23-25, 106 S.Ct. 2548, 553, 91 L.Ed.2d 265 (1986).

In deciding whether to grant a motion for summary judgment, the Court “review[s] the evidence and inferences to be drawn therefrom in the light most favorable to the nonmoving party.” *Duplantis v. Shell Offshore, Inc.*, 948 F.2d 187, 189 (5th Cir. 1991) (citing

Duvall v. The Ritz Carlton Hotel Co., 946 F.2d 418, 420 (5th Cir. 1991), and quoting Fed. R. Civ. P. 56(c)). An issue is "genuine" only if the evidence could lead a reasonable jury to return a verdict for the nonmoving party. *Thomas v. Price*, 975 F.2d 231, 235 (5th Cir. 1992) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. at 255, 106 S.Ct. at 2513).

The opposing party may not rest on the mere allegations or denials of artful pleading, but must set forth affirmative facts that show a genuine issue for trial. *Anderson*, 477 U.S. at 256, 106 S.Ct. at 2514. This requires that the non-moving party make a showing sufficient to establish the existence of any element essential to that party's case, and on which that party will bear the burden at trial. *Nowlin v. R.T.C.*, 33 F.3d 498, 501 (5th Cir. 1994) (citing *Celotex*, 477 U.S. at 322-23, 106 S.Ct. at 2552-553).

ANALYSIS

Federal Preemption

This case presents a difficult and very close question of conflict preemption. The Supremacy Clause, article VI, clause 2, of the United States Constitution, preempts any state law that conflicts with the exercise of federal power. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1982). "Federal law will override state law under the Supremacy Clause when (1) Congress expressly preempts state law; (2) Congressional intent to preempt may be inferred from the existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes. *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990).... '[T]he purpose of Congress is the ultimate touchstone in every preemption

case.” *Frank v. Delta Airlines, Inc.*, 314 F.3d 195, 197 (5th Cir. 2002) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

The Defendant argues solely for the third option, conflict preemption. “[I]f a state common-law claim directly conflicted with a federal regulation ..., or if it were impossible to comply with any such regulation without incurring liability under state common law, [conflict] pre-emption would occur.” *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002). Conflict preemption occurs either “where it is impossible for a private party to comply with both state and federal law” or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000) (citation omitted). Federal regulations “have no less pre-emptive effect than federal statutes.” *de la Cuesta*, 458 U.S. at 153. And the imposition of damages under state tort law is a form of state action subject to preemption. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000); *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 327 (1981).

Here, the Defendant argues that Plaintiff’s attempt to use state tort law to require warnings that Zolof causes suicide conflicts with (i) the FDCA and its implementing federal regulations, including FDA’s specification of the suicide precautions required to be given with Zolof, and (ii) FDA’s determination that the suicide warnings advocated by Plaintiff are inappropriate and, if given, could be false, misleading, and harmful to patients. The Defendant further argues that the FDA has made clear that any such use of state tort law would impermissibly interfere with the agency’s regulation of drug labeling

and impair the federal objective of ensuring that labeling of prescription medicines effectively communicates scientific information physicians need to make informed medical judgments. The Court disagrees.

State-law tort claims are preempted if they “stand as an obstacle to the accomplishment and execution of the full purposes and objectives” of federal law. *Geier*, 529 U.S. at 873. Even when state and federal laws have the same goal, a state tort claim is preempted if it would interfere with a method by which the federal law promotes that goal. *Int’l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (“[I]t is not enough to say that the ultimate goal of both federal and state law is [the same]. A state law also is preempted if it interferes with the methods by which the federal statute was designed to reach this goal.”); *Perez v. Campbell*, 402 U.S. 637, 650-52 (1971) (whether conflict exists between state and federal law depends not on state law’s purpose, but on state law’s effect on federal regulatory plan). The state law tort claims in the instant case do not fall into any of these categories. Thus, they are not preempted by federal law.

FDA-Approved Labeling

The Defendant asserts that the state-law requirement advocated by Plaintiff would conflict with the FDA’s requirement that Pfizer use “verbatim” the labeling specified by the agency, and as such, Plaintiffs’ claims are preempted. The Court is not persuaded. The FDCA and FDA’s regulations do not conflict with Texas failure to warn law because they merely set minimum standards with which manufacturers must comply; they *expressly* do not prohibit a manufacturer from “add[ing to] or strengthen[ing] a

contraindication, warning, precaution, or adverse reaction. 21 C.F.R. § 314.70(c)(6)(iii)(A). This is consistent with Congress' primary goal in enacting the FDCA, which is "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696, 68 S. Ct. 331, 335, 92 L. Ed. 297 (1948). The minimum standards approach is also consistent with Congress' stated intent that the FDCA "'must not weaken the existing laws', but on the contrary 'it must strengthen and extend that law's protection of the consumer.'" *United States v. Dotterweich*, 320 U.S. 277, 282, 64 S. Ct. 134, 137, 88 L. Ed. 48 (1943). With little exception, courts that have considered this exact issue have concluded that state failure to warn claims are not preempted by the FDCA and its attendant regulations.

Numerous courts over the years have recognized that the FDCA and its associated regulations set out minimum requirements that drug manufacturers must follow which may be supplemented by state tort laws which are stronger. "FDA regulations are generally minimal standards of conduct" *Hill v. Searle Laboratories, Inc.*, 884 F.2d 1064, 1068 (8th Cir. 1989). "An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes." *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 746 (11th Cir. 1986).

At one time, the FDA did not view its standards regarding drug warnings as the minimum requirement. Prior to 1965, "the FDA regulations applicable to drugs prohibited companies from adding warnings or other information without prior approval." *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018, 1034 (S.D. Ill. 2001)

(citing 25 Fed. Reg. 12,592, 12,595 (1960)). In 1965, however, the FDA changed its regulations to allow “labeling changes related to safety to be ‘placed into effect at the earliest possible time,’ the goal of which was ‘to enable prompt adoption of such changes.’” *Id.* (citing 30 Fed. Reg. 993 (1965)).

Since 1965, the FDA’s regulations permit a manufacturer “[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction,” without prior approval by the FDA. 21 C.F.R. § 314.70(c)(6)(iii)(A); *In re Tetracycline Case*, 747 F. Supp. 543, 549-50 (W.D. Mo. 1989). In addition, a drug manufacturer may “add or strengthen a statement about drug abuse, dependence, psychological effect, or overdose,” without prior approval (21 C.F.R. § 314.70(c)(6)(iii)(B)), and “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,” without prior approval. 21 C.F.R. § 314.70(c)(6)(iii)(C). Thus, FDA’s position regarding stronger warnings by drug manufacturers, as expressed through *its own regulations*, is that a manufacturer could, and should, provide stronger warnings as soon as such a warning is warranted.

Further, the regulations require a manufacturer to issue a warning whenever there is “reasonable evidence of an association of a serious hazard with a drug; *a causal relationship need not have been proved.*” 21 C.F.R. § 201.57(e) (emphasis added). In fact, this same regulation requires that “black box” warnings be used for drugs which have problems “that may lead to death or serious injury,” the very same black box

warnings that the FDA's pharmoneurological drug advisory committee ("PDAC") recommended be placed on all SSRI drugs, including Zoloft, regarding *suicidality in children and adolescents*. See *Plaintiffs' Opposition to Defendant's Motion for Summary Judgment*, Exhibit 80. Thus, it is clear to this Court that manufacturers must act quickly to warn regarding possibly deadly side effect associated with a drug because the FDA only sets forth minimum standards for labeling and safety of drugs.

It is important to note that there is a strong presumption against implied conflict preemption in matters dealing with the FDA given the FDA's ability to promulgate regulations which can have preemptive effect. *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 721 (1985). Recently, the Supreme Court clarified the application of the conflict preemption doctrine in the *Geier v. Am. Honda Motor Co.* case. In that case, the Court held that a federal statute which gave automobile manufacturers the choice between two different passive restraint systems (airbags and automatic shoulder belts) preempted any state tort law requirement that an automobile be manufactured with airbags. *Id.*, 529 U.S. at 886. The Court held that state tort law requirements would pose an "obstacle" to the accomplishment of a complex federal regulatory scheme because the regulation in question set forth a specific balance regarding the deployment of airbags and, thus, any additional state law requirements would upset this balance. *Id.* at 885-86. However, the court limited its conflict preemption holding to the language of the federal regulation at question and stated that "the language of [the regulation] and the contemporaneous [agency] explanation is clear

enough - even without giving [the agency's] own view special weight." *Id.* at 886. Importantly, the Court found that the federal regulation did not impose a minimum standard, but rather, provided the manufacturer with a "range of choices." *Id.* at 874-75.

Consistently, courts have held that state law failure to warn cases are not preempted by the FDCA or its associated regulations. In *Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908, 912-913 (5th Cir. 1987), the Fifth Circuit held that preemption was not appropriate in a failure to warn case under Texas law because the FDA regulations "specifically permitted [the manufacturer] to add additional warnings to a previously approved label as soon as it became aware of the necessity to do so - without any need to first obtain FDA approval of the supplemental warning."¹ The Court concluded that the "FDA regulations [] did not prevent [the manufacturer] from adding to its label warnings ...," and, thus, "federal law neither made it practically (nor legally) impossible, nor would it have posed an obstacle to accomplishing the objectives of the FDCA." *Id.*

In *Hurley v. Lederle Laboratories*, 863 F.2d 1173 (5th Cir. 1988), the Fifth Circuit, again, found that the FDCA and its regulations did not preempt a state law failure to warn claim against a vaccine manufacturer. The Court canvassed previous preemption decisions and stated that "the great majority of United States district courts which have addressed this issue have ruled against preemption." *Id.* at 1176. Indeed, the Court cited *seventeen* previous decisions which ruled against preemption. The Court stated that in a situation where there is no express preemption clause, "[c]ourts should be reluctant to

¹ In *Osburn*, the Court was interpreting FDA regulations applicable to veterinary drugs. However, the FDA regulations regarding prescription drugs for humans are virtually identical in this regard. See 21 C.F.R. § 314.70(c)(6)(iii)(A).

find that federal law *implicitly* preempts state law.” *Id.* (emphasis in original). With regard to the FDCA, the Court stated that “FDA regulation does not generally preempt stricter state law standards for medical products.” *Id.* at 1177; *see also Tobin v. Astra Pharmaceutical Prods., Inc.*, 993 F.2d 528 (6th Cir. 1993) (no preemption for state law design defect claim against prescription drug manufacturer).

Recently, a number of courts who have considered this exact issue have ruled in favor of no preemption. In *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), a district court in California ruled against Pfizer’s Motion for Summary Judgment regarding preemption stating that, “[a]lthough certain suicide warnings could violate federal law because they were false or misleading or were not based on the ‘essential scientific information needed’ for safe use, the Court does not think that any and every suicide-related warning that might be required under state law is necessarily false or misleading” *Id.* at 1095. On appeal, the United States filed an *amicus* brief in favor of the Defendant’s position. In the *amicus* brief, the United States urged that any warning of a causal relation between Zolofit and suicide would have “misbranded” the drug. *See Defendant’s Motion for Summary Judgment*, Exhibit B, p. 17. The United States further stated that when the plaintiff in *Motus* was prescribed Zolofit, “any warning, no matter how worded, that could reasonably have been read as describing or alluding to such a relation would have been false or misleading, and therefore in conflict with federal law because there was no (and still is not) scientific support for such a warning.” *Id.* at 21. Here, on numerous occasions, the Defendant refers to the *amicus* brief for support of its

arguments. The main flaw in Defendant's argument now is that the Plaintiffs have produced evidence to the contrary. There *is* support for such a warning.

Likewise, in *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001), the district court ruled against preemption because the manufacturer was explicitly authorized by the FDA's regulations to add or strengthen its warnings without prior FDA approval. *Id.* at 1033-34. The *Caraker* court cited to the FDA commissioner's statement that "labeling regulations do not prohibit a manufacturer, packer, relabeler, or distributor from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered." *Id.* at 1034 (citing 44 Fed. Reg. 37,434, 37,447 (1979)).

Thus, numerous federal courts who have considered this issue have determined that preemption is not appropriate. On the other hand, Pfizer cites to a number of cases which hold that preemption is appropriate in this case. However, Pfizer's citations are misleading because these cases are express preemption cases. Express preemption caselaw has no application to this case because there is no provision in the FDCA or its regulations regarding prescription drugs which purport to preempt state law.

In *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001), the Court held that the plaintiff's state law failure to warn claims against a medical device manufacturer were preempted because of an express preemption clause in the Medical Device Amendments ("MDA") to the FDCA, codified at 21 U.S.C. § 360k. Importantly, the Court stated that preemption was appropriate under the preemption clause because the manufacturer had gone through the rigorous approval requirements required for new medical devices.

Brooks, supra, 273 F.3d at 794-95. Although the approval process for Zolofit may have been equally rigorous, Congress and the FDA has chosen not to include an express preemption clause in the statutes and regulations for prescription drugs. Clearly, Congress knows how to enact FDA legislation that contains a preemption clause. Thus, the absence of any such clause with respect to prescription drugs demonstrates an implied intent not to preempt cases, such as this.

Similarly, in *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) and *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), the courts considered the same preemption issue pursuant to the express preemption clause in the MDA. Both courts held that the plaintiffs' failure to warn claims were preempted because both of the medical products in question had been subjected to the rigorous approval process for new medical devices. 254 F.3d at 584-85; 231 F.3d at 236-37. However, these cases, just like *Brooks*, are inapplicable to the situation presented here because there is no express preemption clause regarding prescription drugs. Thus, Pfizer's reliance on these cases is misplaced.

Finally, Pfizer cites to the newly published case of *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), for the proposition that conflict preemption should apply in this case. In *Horn*, the Court stated that the state tort law claims were in "severe tension" with the federal requirement regarding medical devices. *Id.* at 177. However, *Horn*, just like the courts in *Brooks*, *Martin*, and *Kemp*, was interpreting the *express* preemption clause of the MDA. Importantly, this clause reads "[n]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement - (1) which is different from, or in addition to, any requirement applicable

to this chapter to the device.” 21 U.S.C. § 360k(a) (emphasis added); *Horn, supra*, 376 F.3d at 166. Thus, by this provision, Congress has clearly expressed an intent that stricter state law requirements should not be allowed. The exact *opposite* is true with prescription drugs as has been discussed previously.

Thus, the cases cited by Pfizer are, by and large, completely inapplicable to the question before this Court. The sole question this Court must decide is whether plaintiffs’ state law failure to warn claims conflict with the federal requirements regarding prescription drugs such that the state claims should be preempted. As stated above, the federal labeling requirements for prescription drugs are minimum standards; states can impose stricter requirements regarding labeling and warnings if they so choose. The only limiting regulation is that the warnings must not be false or misleading. Given the hearings by both Congress and the FDA regarding suicidality, the FDA’s PDAC’s recent decision to recommend black box warnings regarding suicidality in children and adolescents, and the numerous experts who have concluded that there is a link between SSRIs, like Zoloft, and suicidality, it would be inconceivable to this Court to argue that an additional warning regarding suicidality would be false or misleading.

FDAs Objective

Pfizer argues that preemption is appropriate in this case because the Plaintiffs’ state law failure to warn claims will “interfere” with the FDA’s objective “of ensuring that all warnings are supported by scientific evidence sufficient to demonstrate that the warnings are accurate and not misleading.” *Defendant’s Motion for Summary Judgment*, pp. 24-25. Additionally, inclusion of scientifically unsupported warnings also would

interfere with the FDA's goal of providing patients with the benefit of appropriate medications. According to Pfizer, "scientifically unsupported warnings" in drug labeling "deafen doctors to the labeling's important, scientifically based information." *Id.*, p. 25. However, Pfizer ignores the FDA's *primary* objective, which is to protect consumers. *United States v. Dotterweich*, 320 U.S. 277, 282, 64 S. Ct. 134, 137, 88 L. Ed. 48 (1943).

Clearly, the FDA, through its regulations, recognizes its important dual purpose – to provide scientifically accurate information and to protect consumers – because it allows, and even encourages, manufacturers to be proactive when learning of new safety information related to their drug. As previously stated, the FDA's regulations allow a manufacturer to add to or strengthen warnings *without prior FDA approval*. 21 C.F.R. § 314.70(c)(6)(iii)(A). In fact, the manufacturer must do this "as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."² 21 C.F.R. 201.57(e). Thus, the FDA has made clear, through its regulations, that manufacturers, not the FDA, are tasked with the responsibility of taking proactive steps once a manufacturer learns of "reasonable evidence of an association of a serious hazard with a drug." *Id.*

Likewise, Texas products liability law requires manufacturers to provide consumers (or doctors in the case of products, such as drugs, where the learned intermediary doctrine applies) with warnings regarding "reasonably foreseeable or

² It is important to note that although Pfizer has characterized the Plaintiffs' failure to warn claim as requiring Pfizer to issue a "drug-causes-suicide-warning" (*Defendant's Motion for Summary Judgment*, p. 26), in fact, the Plaintiffs are simply seeking a warning regarding the association between suicidality and Zoloft - an association that Pfizer has known about for many years.

scientifically discoverable” dangers at that time the product is sold. *See Wood v. Phillips Petroleum Co.*, 119 S.W.3d 870, 873 (Tex. 2003) (citing *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1088 (5th Cir. 1973)). This duty to warn requires manufacturers to “test and inspect its product” to determine whether warnings are necessary or appropriate. *Id.* at 873-74. This state law duty regarding warnings is directly parallel with the FDA’s requirements that manufacturers provide safety warnings to consumers as soon as there is “reasonable evidence.” It is clear that Texas state law does not require manufacturers to issue warnings that are “scientifically unsupported.” Instead, Texas, just like the FDA, requires warnings when there is safety information that is scientifically discoverable. *Wood*, 119 S.W.3d at 873. Thus, Texas law compliments and is parallel to the FDA’s regulations regarding safety warnings and, thus, does not interfere with the objectives of the FDA.

Ultimately, it is clear that Pfizer’s arguments regarding the supposed thwarting of the FDA’s objectives in this case are misguided. The evidence unequivocally proves that the FDA’s objective, as expressed through its regulations, demonstrate that manufacturers should provide consumers with all the safety information about their drugs as soon as the information is known, which is exactly what Texas law requires. Thus, there is no FDA objective that is being subverted or thwarted.

CONCLUSION

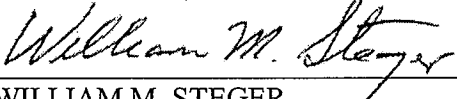
After a thorough review of the pleadings, the briefs, and the exhibits submitted as summary judgment evidence, the Court holds that summary judgment should be denied and this case should proceed. This case presents a difficult and very close question of

conflict preemption. However, when viewing all of the evidence in the light most favorable to the Plaintiff, the Court finds that the Plaintiff has provided evidence to establish a genuine issue as to a material fact regarding the Defendant's federal preemption defense. As such, the Plaintiffs' state law tort claims are not preempted by federal law and must, therefore, not be dismissed.

It is therefore

ORDERED that the *Defendant Pfizer Inc's Motion for Summary Judgment (Federal Preemption) and Memorandum in Support* (Docket No. 13) is hereby **DENIED**.

SIGNED this 31st day of March, 2005.


WILLIAM M. STEGER
UNITED STATES DISTRICT JUDGE