IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

GALE C. ZIKIS, individually and as administrator of the Estate of Donald R. Zikis, deceased,	)	
Plaintiff,	)	
v.	)	**No. 04 C 8104**
PFIZER, INC., a Delaware corporation,	)	
Defendant.	)	

MEMORANDUM OPINION

SAMUEL DER-YEGHIAYAN, District Judge

This matter is before the court on Defendant Pfizer, Inc.'s ("Pfizer") motion for summary judgment. For the reasons stated below, we deny the motion for summary judgment.

BACKGROUND

Plaintiff Gale C. Zikis ("Zikis") brought the instant action on behalf of herself and on behalf of the estate of her deceased husband Donald R. Zikis ("D. Zikis"). Zikis alleges that on December 16, 2005, D. Zikis died as a result of taking the prescription drug Zoloft. Zikis alleges that Pfizer has known about serious side effects associated with Zoloft for a long time, but has only recently begun to inform

physicians and consumers about the side effects. Zikis brought the instant action and includes in the complaint a negligence claim (Count I), a strict liability claim (Count II), a breach of implied warranty claim (Count III), a breach of express warranty claim (Count IV), and a fraud claim (Count V). Pfizer has now moved for summary judgment prior to discovery.

LEGAL STANDARD

Summary judgment is appropriate when the record, viewed in the light most favorable to the non-moving party, reveals that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In seeking a grant of summary judgment the moving party must identify "those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (quoting Fed. R. Civ. P. 56(c)). This initial burden may be satisfied by presenting specific evidence on a particular issue or by pointing out "an absence of evidence to support the non-moving party's case." *Id.* at 325. Once the movant has met this burden, the non-moving party cannot simply rest on the allegations in the pleadings, but, "by affidavits or as otherwise provided for in [Rule 56], must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e). A "genuine issue" in the context of a motion for

summary judgment is not simply a "metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rather, a genuine issue of material fact exists when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Insolia v. Philip Morris, Inc.*, 216 F.3d 596, 599 (7th Cir. 2000). The court must consider the record as a whole, in a light most favorable to the non-moving party, and draw all reasonable inferences that favor the non-moving party. *Anderson*, 477 U.S. at 255; *Bay v. Cassens Transport Co.*, 212 F.3d 969, 972 (7th Cir. 2000).

DISCUSSION

Pfizer argues that the instant action is preempted by federal law. The Constitution of the United States provides in part the following: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. Art. VI cl. 2. Unless there is reason to believe that Congress intended otherwise, a federal law can preempt a state common law cause of action brought by private citizens. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 520-21 (1992). The Supreme Court of the United States has recognized

doctrines of express preemption and implied preemption. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000). Field preemption is a type of implied preemption, *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372 (2000), and "conflict preemption" is a type of implied preemption." *Geier*, 529 U.S. at 869. Conflict preemption is distinguishable from express preemption in that it requires "the identification of 'actual conflict,' and not on an express statement of pre-emptive intent." *Id.*

Under the implied preemption doctrines, "a federal statute implicitly overrides state law either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively, . . .or when state law is in actual conflict with federal law." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). *Geier*, 529 U.S. at 869(stating that one type of implied federal preemption recognized by the Supreme Court of the United States is preemption that is implied when there is a conflict with federal law).

Although Congress may not have impliedly "occupied the field" in a certain area, "state law is naturally preempted to the extent of any conflict with a federal statute" that either: 1) makes it "impossible for a private party to comply with both state and federal law," or 2) makes the state law "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372-73; *see also Freightliner Corp.*, 514 U.S. at 287 (stating that the Court has recognized a sufficient implied conflict where: 1) "it is 'impossible for a private

party to comply with both state and federal requirements,'" or 2) "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"); *Geier*, 529 U.S. at 884 (stating that "conflict pre-emption is different in that it turns on the identification of 'actual conflict'"). Under the implied preemption doctrine, "[f]ederal regulations have no less pre-emptive effect than federal statutes." *Fidelity Federal Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). The Supreme Court of the United States has cautioned that "a court should not find pre-emption too readily in the absence of clear evidence of a conflict." *Geier*, 529 U.S. at 885.

Pfizer argues that since Zikis' action is based upon insufficient warnings regarding Zoloft, an ultimate finding in this action regarding the appropriateness of the warnings or the type of warning that was required would overlap the Federal Drug Administration's ("FDA") duties and regulations. Pfizer cites *Geier* in support of its preemption position and argues that there is an implied preemption by the FDA due to actual conflicts between the FDA and state law. However, as Zikis points out, Pfizer must do more than point to hypothetical potential conflicts with FDA regulations and overlapping areas in this action and the FDA's responsibilities. Pfizer argues that it is required to include the FDA approved language on its labels. However, pursuant to 21 C.F.R. § 314.70(c)(6)(iii)(A), "[t]he agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of

the drug product involved upon receipt by the agency of a supplement for the change. . .[and] [t]hese changes include, but are not limited to: . . .(iii) Changes in the labeling to accomplish any of the following: (A) To add or strengthen a contraindication, warning, precaution, or adverse reaction. . . ." 21 C.F.R. § 314.70(c)(6)(iii)(A). Thus, nothing prevented Pfizer from seeking to amend the language in the labels to include the known additional side effects.

Pfizer criticizes Zikis' contention that Pfizer should have included a warning on the label stating that Zoloft causes suicide. Pfizer argues that such a warning would not be based on scientific information. Pfizer also argues that such a dire warning would scare off all potential users and prescribing physicians regardless of the potential benefits. However, nowhere in the complaint does Zikis make such an allegation. Zikis further states in her answer to the motion for summary judgment that she is "not seeking to require Pfizer to include within its labeling information which is not scientifically accurate" and "is not seeking to hold Pfizer liable for failing to provide scientifically inaccurate warnings." (Ans. 2, 10). She merely contends that the wanting should have included a warning about "the association between Zoloft and acts of self-harm." (Ans. 2). Zikis points as an example to a warning provided by Pfizer to patients in Canada that reads the following: "potential association with the occurrence of behavioral and emotional changes including self-harm." (R SF 2). Zikis emphasizes that it is not, as Pfizer contends, seeking a "drug-causes-suicide-warning" (Ans. 9 n.8). It is Zikis, not Pfizer that determines

the claim that Zikis is pursuing and Zikis states quite plainly that "Plaintiff is simply alleging that Pfizer should have included the same type of warning to Donald Zikis' doctor that it currently provides to doctors in Canada." (Ans. 10).

Pfizer also argues that the same warnings that Pfizer claims that Zikis advocates were previously rejected by the FDA. Pfizer points to another case in which it claims that similar warnings were rejected. In support, Pfizer improperly relies upon an *Amicus* brief filed by the United States Government in another case that contains nothing more that legal argument by counsel. Pfizer also points to what it perceives as indications by the FDA in the past that it would not accept such warnings. However, Pfizer fails to point to evidence that shows any tangible conflict. Neither does Pfizer point to evidence that shows that Pfizer's belief that the FDA would reject such warnings is the result of anything other than Pfizer's own speculation and imagination. Pfizer also argues that the warning that Pfizer contends is advocated by Zikis would interfere with the FDA's "objective of providing only scientifically accurate information in drug labeling." (SJ Mot. 8). However, again Pfizer does not provide sufficient evidence of any "actual conflicts" with this objective of the FDA. Pfizer attempts, through speculation, to artificially construct conflicts where none actually exist. In addition, the FDA does not prohibit a manufacturer such as Pfizer from providing additional warnings along with those required by the FDA. *Geier*, 529 U.S. at 884 *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F.Supp.2d 1018, 1033 (S.D.Ill. 2001); *Eve v. Sandoz Pharmaceutical*

Corp., 2002 WL 181972, at *3 (S.D. Ind. 2002)(stating that "[c]ourts have generally found that 'FDA regulations as to design and warning standards are minimum standards which do not preempt state law defective design and failure to warn claims' and FDA approval does not shield a manufacturer from liability."). Pfizer has failed to point to sufficient evidence that it would be impossible to comply with both the FDA and Illinois common law, and Pfizer has failed to show that allowing Zikis to proceed with his Illinois common law claims would be "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372-73. Therefore, based upon the above analysis and the undisputed facts as determined by the requirements of Local Rule 56.1, we cannot find that the claims brought by Zikis are preempted as a matter of law and we deny Pfizer's motion for summary judgment.

CONCLUSION

Based on the foregoing analysis, we deny Pfizer's motion for summary judgment. We deny Zikis' motion to strike Pfizer's Exhibit B as moot since it does not alter the outcome of our decision even when considered.

Samuel Der-Yeghiayan
United States District Court Judge

Dated: May 9, 2005