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

GALE ZIKIS, Individually and as Administrator of the Estate of DONALD R. ZIKIS	)	
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 reconsideration of Defendant Pfizer Inc.'s federal pre-emption motion based on new evidence." For the reasons stated below, we deny the motion for reconsideration.

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, 2002, 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). On May 9, 2005, we denied Pfizer's motion for summary judgment, which was based upon an argument that the claims in the instant action were preempted by the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C . §§ 301 *et seq.* and its implementing regulations. Pfizer now asks the court to reconsider its denial based upon what Pfizer contends is new evidence.

LEGAL STANDARD

A motion for reconsideration may be brought "to correct manifest errors of law or fact or to present newly discovered evidence." *Caisse Nationale de Credit Agricole v. CBI Indus.*, 90 F.3d 1264, 1269-70 (7th Cir. 1996). Such motions cannot be used as a "vehicle to produce new evidence that could have been" produced earlier or as a vehicle to "rehash[]" the same arguments presented to the court on a prior occasion. *Id.*

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 in September 2005, in another similar case, the United States District Court for the District of Utah requested that the United States Department of Health and Human Services and the Food and Drug Administration ("FDA") submit an amicus brief ("Amicus Brief"). In light of this brief, Pfizer seeks a reconsideration of our denial of its motion for summary judgment. As we stated in our prior ruling, 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 v. National Foreign Trade Council*, 530 U.S. 363, 372-73 (2000); *see also Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)(stating that the Court has recognized a sufficient implied conflict).

Pfizer argues that the Amicus Brief and the regulatory documents identified in the brief "establish[] that in 2002 'the FDA did not believe that there was reasonable evidence of an association between Zoloft . . . and an increased risk of suicide or suicidality'. . . and that if Pfizer had included a warning of any such association at that time, the Zoloft label would have been 'false and misleading' under the applicable federal regulations." (Mot. 2)(quoting in part Govt. Br. 28-29). Pfizer also claims that the Amicus Brief provides evidence concerning the FDA's

interpretation of its regulations and evidence that the FDA's responsibilities and intended purpose would have been disrupted if Pfizer had put labels regarding suicide on the Zoloft packages. Pfizer argues that the Amicus Brief is compelling new evidence that warrants a finding that Zikis' claims are pre-empted by the FDCA.

Pfizer argued in its motion for summary judgment that if it had put the warnings sought by Zikis on the labels for Zoloft at the time in question, the FDA would have in fact rejected the warnings because the FDA would have deemed them to be inaccurate. Pfizer contended in its motion for summary judgment that the warnings would have disrupted the FDA in carrying out its official duties. In our prior ruling, we denied the motion for summary judgment in part because Pfizer failed to 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." (5/9/05 OP 7).

Even though Pfizer had pointed to a similar amicus brief in its motion for summary judgment, in our prior opinion we nonetheless concluded that the brief was not sufficient evidence to establish pre-emption. The Amicus Brief attached to the instant motion for reconsideration, unlike the prior brief presented by Pfizer, contains extensive citations and quotations from FDA documents and other exhibits to substantiate the statements in the Amicus Brief in question here. In the Amicus Brief, the government explains the FDA's regulation of labels and its duties in

addressing the meaning of the term "association" when utilized to show a connection between a medicine and a potential effect from the medicine. (AB 7). The Amicus Brief explains how the FDA engages in an extensive scientific analysis to address the likelihood that a medicine may cause an adverse effect such as a suicide. (AB 8). The government also expressly states in the Amicus Brief that in November 2002, "the FDA did not believe that there was reasonable evidence of an association between Zoloft (or similar SSRIs) and an increased risk of suicide." (AB 12). The Amicus Brief explains the FDA's findings and analysis prior to and after November 2002. The brief explains that in May 2003, the FDA received a report from GlaxoSmithKline indicating that there was a possible connection between Paxil and suicide. (AB 17). The FDA states that at that juncture it expanded its investigation to address whether there was a link between anti-depressant drugs and suicide in children. (AB 17). The FDA also explains that in July 2003, it was reevaluating certain data while awaiting requested information from certain drug manufacturers. (AB 18). The Amicus Brief indicates that the investigation process proceeded onward and in September 2003, the FDA approved a New Drug Application supplement for Zoloft to revisit the labeling and add safety information unrelated to suicide risks. The FDA claims that thereafter it received data from various drug manufacturers and "began its extensive analysis" of the data to determine whether there were any correlations between these drugs and suicide risks. (AB 19). The FDA claims that it retained experts to assist in the analysis.

The experts completed their assignments in June 2004, and after the FDA concluded its own analysis in October 2004, the FDA issued a Public Health Advisory announcing that it was directing manufacturers of all anti-depressants to expand warnings on labels to warn about an increased risk of suicide. (AB 22).

The Amicus Brief, however, is insufficient to tip the balance in favor of Pfizer. Many issues regarding Zikis' claims are left unresolved even after considering the content of the Amicus Brief. As is indicated above, there can be conflict preemption "where local law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Hoagland*, 415 F.3d at 696(quoting *Freightliner Corp.*, 514 U.S. at 287). Pfizer argued in its motion for summary judgment that the "state-law requirement advocated by Plaintiff would conflict with FDA's requirement that Pfizer use 'verbatim' the labeling specified by the agency." (SJ Mem. 3). However, Pfizer has yet to point to any tangible conflicts between the claims in the instant action and the FDCA. For instance, Zikis alleges that prior to December 2002, Pfizer had sufficient information to determine that there was an association between Zoloft and an increased risk of suicide. Zikis argues that Pfizer could have provided the FDA with the information and such information would have caused the FDA to alter its position sooner. Zikis argues that it was Pfizer's obligation to notify the FDA about the data showing an increased risk of suicide. Pfizer has not pointed to any statutory authority or regulation that would have prevented Pfizer from disclosing the data to the FDA

prior to December 2002, and thus has not shown any conflict in this regard. The Amicus Brief provides nothing more than a historical summary of the FDA's position in the absence of the information that Pfizer was allegedly withholding in order to further the sales of its product. We note that we are not making any finding at this juncture concerning the information that Pfizer allegedly possessed or Pfizer's alleged concealment of such information. Pfizer's motion for summary judgment was filed in the initial pleadings stage and thus did not encompass analysis of any of the evidence in this case.

Zikis also argues that, despite the FDA's control over label warnings, Pfizer has authority to make a unilateral change to the labels. Pfizer is provided with authority to make corrections to labels under 21 C.F.R. § 314.70, which provides the following:

> The 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. These 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, a drug manufacturer is expressly provided with the authority to unilaterally, without prior approval by the FDA, add warnings that "add or strengthen a contraindication, warning, precaution, or adverse reaction." *Id.*; *Witczak v. Pfizer, Inc.*, 377 F.Supp.2d 726, 727-32 (D. Minn. 2005). The FDCA

was designed primarily "to protect consumers from dangerous products." *Cartwright v. Pfizer, Inc.*, 369 F.Supp.2d 876, 882 (E.D.Tex. 2005)(quoting *United States v. Sullivan*, 332 U.S. 689, 696 (1948)). That purpose is clearly served by the provision in 21 C.F.R. § 314.70(c)(6)(iii)(A), which allows for an amendment to a label without extended delay when a drug manufacturer learns of new dangerous side effects of a drug.

Pfizer contends that the FDA is also concerned with added warnings to a label that might mislead physicians about the risks entailed in prescribing a drug, "thereby overdeterring its use." (Reply 15). Pursuant to 21 CFR § 314.70(c)(7), if the FDA "disapproves the supplemental application, it may order the manufacturer to cease distribution of the drug product(s) made with the manufacturing change." 21 C.F.R. § 314.70(c)(7). Thus, the FDA can stop a label that contained warnings that are excessive in addition to warnings that are incomplete. However, it is not relevant in this case as to whether or not the FDA could have ordered corrections to the labels of Zoloft after Pfizer had supplemented the labels to include warnings about an increased risk of suicide. Zikis argues that Pfizer possessed information regarding a danger associated with its product and Zikis argues that Pfizer should have unilaterally sought to supplement the Zoloft label in order to notify the public of that danger. Such an action would have been the type of rapid dissemination to the public of dangers associated with a drug that is entirely consistent with the regulatory scheme mentioned above. Zikis argues that such a supplement would

have warned D. Zikis and his loved ones of the increased risk of suicide and therefore his death could have been avoided. Nothing advocated in Zikis' claims conflicts with the federal statutes or regulations at issue.

Pfizer might contend that even if it had supplemented the label, the FDA may have revoked it by December 2002, and D. Zikis would still have not had the benefit of such a warning. However, there is no indication by Zikis that if such a sequence of events had occurred, Zikis would have proceeded with the instant claims against Pfizer. The fact is that Pfizer did not seek to supplement its label, which it could have done in accordance with the regulations. Also, Zikis contends in the pleadings that the information being withheld by Pfizer, if disclosed at the time of the supplement, would have negated any possibility of the FDA revoking the label supplement. Therefore, Pfizer has not shown that the claims in the instant action are preempted by the FDCA and we deny Pfizer's motion for reconsideration.

We note that Pfizer's motion for summary judgment that is the subject of the instant motion for reconsideration was filed by Pfizer in the initial pleading stages. Discovery has since been completed in the instant action and dispositive motions are currently due on November 10, 2005. Pfizer filed the instant motion for reconsideration in the midst of the briefing of the dispositive motions and since the parties may have been awaiting the ruling on the instant motion before proceeding to work on their dispositive motions, we shall extend the deadlines for the filing of dispositive motions. This extension will give the parties an opportunity to take into

consideration the instant ruling when preparing their dispostive motions. The prior dispositive motion dates are therefore stricken and dispositive motions will now be due on December 1, 2005. Answers will be due on December 15, 2005, and replies will be due on January 6, 2006. The status date set for December 20, 2005, is stricken and the next status date is set for February 15, 2006, at 9:00 a.m.

CONCLUSION

Based on the foregoing analysis, we deny Pfizer's motion for reconsideration.

Samuel Der-Yeghiayan
United States District Court Judge

Dated: November 8, 2005