IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BETH ANN McNELLIS, on behalf of the Estate of Theodore DeAngelis, Deceased, and IN HER OWN RIGHT, Plaintiffs, v. PFIZER, INC., et al., Defendants.	HONORABLE JEROME B. SIMANDLE Civil No. 05-1286 (JBS) **OPINION**

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SIMANDLE, District Judge:

This products liability case arises from the suicide death of Theodore DeAngelis on January 30, 2003. Plaintiffs, Beth Ann McNellis, on behalf of the estate of Theodore DeAngelis,

deceased, and in her own right, contend that Zoloft, an antidepressant drug manufactured by Defendant Pfizer, Inc., which Theodore DeAngelis began taking shortly before he died, was responsible for his suicide. Plaintiffs contend principally that Pfizer's warnings regarding suicide as a possible adverse reaction associated with Zoloft were inadequate. Presently before the Court is the motion for summary judgment of Defendant Pfizer, Inc., in which the issue presented is whether, in the circumstance of the ongoing regulation and scrutiny of Zoloft, the Food and Drug Administration's regulation of prescription drugs under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq. ("FDCA") and federal regulations preempts Plaintiffs' state law tort claims arising from the alleged failure to give sufficient warning of the possibility of an increased risk of suicide in depressed patients associated with this medication. For the reasons discussed below, this motion will be denied without prejudice to renewal upon completion of a limited period of discovery.

I. BACKGROUND

Plaintiff Beth Ann McNellis, suing individually and as executrix of the estate of her father, Theodore DeAngelis (collectively, "Plaintiffs"), claims that (1) Zoloft, a medication prescribed for Mr. DeAngelis, can and does "drive some people to their death" by suicide; (2) Pfizer, Inc. failed to

adequately warn Mr. DeAngelis's physician of that purported fact; and (3) the purported failure to warn caused Mr. DeAngelis to ingest Zoloft and become more prone to the suicide which ended his life. (Compl. at ¶¶ 10, 12, 16.)

Theodore DeAngelis ("Decedent") was a sixty-four year old retiree who, in late 2002, began to feel depressed and consulted his family doctor. Mr. DeAngelis was initially prescribed Lexapro, an anti-depressant, but disliked that medication and was prescribed Zoloft instead on January 22, 2003. Six days later, Mr. DeAngelis consulted a psychiatrist, who prescribed a higher dose of Zoloft. Two days later, on January 30, 2003, Mr. DeAngelis was found dead, having taken his own life. Mr. DeAngelis apparently had no prior history of depression or suicidal tendencies, and had not previously taken anti-depressant medications before Lexapro.

Plaintiffs filed suit in Atlantic County Superior Court and the case was removed to this Court on March 4, 2005. Plaintiffs' claims against Defendant Pfizer, Inc. ("Pfizer") include allegations of defective design, N.J.S.A. 2A:58C-2, et seq. (Count I), failure to warn (Count II), violations of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2, et seq. (Count III), and breach of express warranty (Count IV). Plaintiffs' primary contention is that Pfizer failed to adequately warn of the risk of suicidality associated with antidepressants such as Zoloft,

despite the presence of the warning label which FDA had authorized to be given verbatim. Pfizer filed the instant motion for summary judgment, arguing that Plaintiffs' state law tort claims are preempted by the federal Food, Drug and Cosmetic Act and its implementing regulations. Extensive oral argument was held and shortly thereafter Plaintiffs filed a motion for an extension of time to complete discovery pursuant to Fed. R. Civ. P. 56(f). Supplemental briefing was received from both parties as to the merits and the Rule 56(f) motion to extend discovery, which have been carefully considered.

II. DISCUSSION

A. Summary Judgment Standard of Review

Summary judgment is appropriate when the materials of record "show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the non-moving party." See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is "material" only if it might affect the outcome of the suit under the applicable rule of law. Id. Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment. Id.

In deciding whether there is a disputed issue of material fact, the court must view the evidence in favor of the non-moving

party by extending any reasonable favorable inference to that party; in other words, "[T]he nonmoving party's evidence 'is to be believed, and all justifiable inferences are to be drawn in [that party's] favor.'" Hunt v. Cromartie, 526 U.S. 541, 552 (1999) (quoting Liberty Lobby, 477 U.S. at 255). The threshold inquiry is whether there are "any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Liberty Lobby, 477 U.S. at 250; Brewer v. Quaker State Oil Refining Corp., 72 F.3d 326, 329-30 (3d Cir. 1995) (citation omitted).

The moving party always bears the initial burden of showing that no genuine issue of material fact exists, regardless of which party ultimately would have the burden of persuasion at trial. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986); Country Floors v. Partnership of Gepner and Ford, 930 F.2d 1056, 1061-63 (3d Cir. 1991)(reviewing district court's grant of summary judgment in a trademark action); Lucent Info. Manage. v. Lucent Tech., 986 F. Supp. 253, 257 (D.N.J. 1997)(granting summary judgment in favor of telecommunications provider in trademark action), aff'd, 186 F.3d 311 (3d Cir. 1999); Jalil v. Avdel Corp., 873 F.2d 701, 706 (3d Cir. 1989), cert. denied, 493 U.S. 1023 (1990). However, where the nonmoving party bears the burden of persuasion at trial, as plaintiff does in the present case, "the burden on the moving party may be discharged by

'showing' -- that is, pointing out to the district court —- that there is an absence of evidence to support the nonmoving party's case." Celotex Corp., 477 U.S. at 325.

The non-moving party "may not rest upon the mere allegations or denials of" its pleading in order to show the existence of a genuine issue. Fed. R. Civ. P. 56(e). Plaintiff must do more than rely only "upon bare assertions, conclusory allegations or suspicions." Gans v. Mundy, 762 F.2d 338, 341 (3d Cir. 1985), cert. denied, 474 U.S. 1010 (1985) (citation omitted); see Liberty Lobby, 477 U.S. at 249-50. Thus, if the plaintiff's evidence is a mere scintilla or is "not significantly probative," the court may grant summary judgment. Liberty Lobby, 477 U.S. at 249-50; Country Floors, 930 F.2d at 1061-62.

B. 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. Fidelity 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). Defendant Pfizer argues that the third and final form of

preemption, namely conflict preemption, is implicated here, and that the complaint must be dismissed.

"[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 "under the circumstances of [a] particular case, [the challenged 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) (citing Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963), and Hines v. Davidowitz, 312 U.S. 52, 66-67 (1941)). Federal regulations "have no less pre-emptive effect than federal statutes." de la Cuesta, 458 U.S. at 153. The imposition of damages under state law is a form of state action subject to preemption. Geier v. American Honda Motor Co., 529 U.S. 861, 881 (2000). Where, as in the present circumstance, federal law does not directly preempt claims for inadequate warnings upon prescription drugs, the Supreme Court has cautioned that "a court should not find pre-emption too readily in the absence of clear evidence of a conflict." Id. at 885. The Supreme Court has

instructed that there is a presumption against conflict preemption, and that the court should presume "that the historic police power of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." New York Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995)(internal quotations omitted).

C. Plaintiffs' Failure to Warn Claim (Count II)

Defendant maintains that Plaintiffs' common law failure to warn claim is preempted by federal law because the Food and Drug Administration would consider any label suggesting that Zoloft "can and does cause suicide" "false and misleading," and therefore in direct contravention of the Food, Drug and Cosmetic Act.

1. FDA Prescription Drug Approval Process

By operation of federal law, the Food and Drug Administration ("FDA") occupies the field in determining the content of labeling on prescription pharmaceuticals such as Zoloft, as now discussed. The FDA's primary purpose is to protect consumers from dangerous prescription drugs and other products. United States v. Dotterweich, 320 U.S. 277 (1943). The FDA is charged with ensuring that "human and veterinary drugs are safe and effective" and approving prescription medicines as

such before they are sold in the United States. 21 U.S.C. § 393(b)(2)(B); § 355(d).

In order to obtain FDA approval for a prescription drug, the drug's manufacturer must file a New Drug Application ("NDA") with the FDA. 21 U.S.C. §§ 355(a), (b), (d). The FDCA requires the FDA to approve an application to market a prescription drug unless, inter alia, (a) the application does not include adequate tests to show whether the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling; (b) the results of clinical testing show that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in the proposed labeling; (c) there is insufficient information to determine whether the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling; (d) there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or (e) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular. 21 U.S.C. §§ 355(c), (d).

FDA regulations mandate the general format and content of all sections of labels for all prescription drugs as well as the risk information each section must contain. 21 C.F.R. §§ 201.56, 201.57. The FDA sets out the product-specific labeling

requirements in an "approvable" letter the FDA sends to the manufacturer. Id. at § 314.110(a) ("FDA will send the applicant an approval 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."). Final 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 label prior to marketing." Id. at § 314.105(b).

If the manufacturer desires to make changes to the labeling after a drug is approved, it must generally submit a Supplemental NDA to the FDA pursuant to 21 C.F.R. § 314.70(b)(2)(v)(A). Although most labeling changes require a Supplemental NDA, a number of exceptions have been enumerated in 21 C.F.R. § 314.70(c)(6)(iii), which provides in pertinent part:

> (6) 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;
>
> (B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;
>
> (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;
>
> (D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or
>
> (E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

21 C.F.R. § 314.70(c)(6)(iii). Thus, it is apparent that prior FDA approval need not be obtained, nor will a product be deemed mislabeled, if the manufacturer voluntarily or even unilaterally strengthens the approved warnings, precautions or potential adverse reactions upon the label pursuant to 21 C.F.R. § 314.70(c)(6)(iii)(A). The FDA's approved label as part of the NDA process can therefore be said to set the minimum labeling

requirement, and not necessarily the ultimate label where a manufacturer improves the label to promote greater safety.

2. The FDA's Approval of Zoloft

On April 13, 1988, Pfizer submitted an NDA to the FDA seeking approval to market their drug, Zoloft, for the treatment of depression in adults. (Def.'s Ex. C, App. 49-52.) The FDA issued its approvable letter on September 30, 1991. (Def.'s Ex. F, App. 267-88.) The approvable letter contained "the Agency's proposal for the labeling of Zoloft," and requested that Pfizer "please use the proposed text verbatim." (Id. at App. 267.) The FDA-proposed labeling mentioned suicide in two locations. First, the FDA required that Pfizer include in the "Precautions" section the following language:

> 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 App. 276.) Second, in the "Adverse Reactions" section of the labeling, the FDA required that Pfizer include a "Psychiatric Disorders" subsection that listed "suicide attempt" as an "Infrequent" occurrence, and explained that "infrequent adverse events are those occurring in 1/100 to 1/1000 patients," and that "[i]t is important to emphasize that although the events reported

occurred during treatment with Zoloft (sertraline), they were not necessarily caused by it." (Id. at App. 284-85.) Pfizer followed the FDA's instructions and included the proposed labeling verbatim. Therefore, the FDA granted Pfizer final approval on December 30, 1991. (Def.'s Ex. G, App. 289-306.) Moreover, the FDA approved Zoloft for treatment of other ailments on five subsequent occasions and required the exact language with respect to suicide that has been required for initial approval.[1]

3. Preemption Analysis

Defendant argues that Plaintiffs' inadequate warning claim, based on the notion that Pfizer should have provided a different, presumably stronger, warning before Decedent committed suicide on January 30, 2003, directly conflicts with the FDA's requirement that Pfizer provide "verbatim" the language regarding suicide in the "Precautions" and "Adverse Reactions" sections of Zoloft's

[1]In 1996, the FDA found Zoloft, as labeled, safe and effective for treatment of adult obsessive compulsive disorder ("OCD"). (Def.'s Ex. P, App. 800-25.) In 1997, the FDA found Zoloft, as labeled, safe and effective for treatment of panic disorder and of pediatric OCD. (Def.'s Ex. Q, App. 826-54; Def.'s Ex. R, App. 855-85.) In 1999, the FDA found Zoloft, as labeled, safe and effective for treatment of post-traumatic stress disorder ("PTSD"). (Def.'s Ex. S, App. 886-914.) On May 16, 2002, the FDA found Zoloft, as labeled, safe and effective for treatment of premenstrual dysphoric disorder. (Def.'s Ex. T, App. 915-949.) Finally, on February 7, 2003, the FDA found Zoloft, as labeled, safe and effective for treatment of social anxiety disorder. (Def.'s Ex. U, App. 950-87.) Notably, this most recent approval occurred shortly after Decedent committed suicide. The label's precaution concerning suicide remained the same throughout each successive approval.

labeling at that time and, therefore, is preempted. In addition, Pfizer maintains that any label suggesting that Zoloft causes suicide would be considered by the FDA to be "false and misleading," and thus it would be in direct conflict with the FDCA. See 21 U.S.C. § 355(d) (an NDA must be refused if the Secretary finds that a label is "false and misleading in any particular"). Plaintiffs allege that Pfizer was not preempted from strengthening the label regarding suicidality before the time of Mr. DeAngelis' death because Pfizer allegedly knew of an increased incidence requiring a stronger warning than the original FDA-approved version.

This Court finds no conflict to exist as a result of Pfizer's alleged inability to comply with both state and federal requirements. Defendant argues that if it had more strongly warned of an association between Zoloft and suicidality, it would have violated the FDA's order to use the FDA approved warning label language "verbatim." It should be noted that the word "verbatim" appears only in the FDA approvable letter to Pfizer, however, and not in any of the misbranding statutes or regulations. Moreover, as discussed above, the FDA's regulations at issue explicitly permit drug manufacturers to unilaterally strengthen warning labels at any time without regulatory pre-approval. See 21 C.F.R. § 314.70(c)(6)(iii)(A). Indeed, this particular regulation was promulgated precisely to allow drug

manufacturers to quickly strengthen label warnings when evidence of new side effects are discovered. See 30 Fed. Reg. 993 (Jan. 30, 1965).

Since 1965, the FDA's regulations have permitted 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 addition, a drug manufacturer may "add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage," 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). These 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). Thus, FDA's position regarding stronger warnings by drug manufacturers, as expressed through its own regulations, is that a manufacturer could, and should if warranted, provide stronger warnings as soon as it is evident that such a warning is appropriate.

As such, the FDCA and the FDA's regulations do not conflict with New Jersey's failure to warn law because those federal regulations merely set minimum standards with which manufacturers

must comply. Indeed, this minimum standards approach is fully 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 (1948), as well as 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 (1943).

Pfizer maintains, however, that § 314.70 gives manufacturers only temporary authority to strengthen the warning language on their labels. While the FDA's regulations do grant it the power to later disapprove a label strengthened pursuant to § 314.70, nothing in the regulation requires that the FDA take any action when a manufacturer makes a change pursuant to § 314.70(c). See 56 Fed. Reg. 59290 (Nov. 25, 1991). If the FDA does nothing, the change remains in effect. Moreover, the FDA's ultimate power to disapprove the change does not render the manufacturer's unilateral strengthening of the label language a violation of any federal law. Instead, if the FDA exercises its power to disapprove the strengthened warning, the manufacturer simply ceases the use and distribution of the new label. 21 C.F.R. § 314.70(c)(7).

Pfizer also asserts that the FDA would have regarded any unilateral label change to be "false and misleading" and thus in

direct conflict with 21 U.S.C. § 355(e) by pointing to the FDA's frequent reapproval of Zoloft without any changes to its warnings or its labels both before and after Decedent committed suicide. The record reflects that the FDA comprehensively evaluated Zoloft clinical-trial data before it first found the medication safe and effective as labeled and approved it for marketing in 1991. (Def.'s Ex. C, App. 49-52; Def.'s Ex. D, App. 53-135; Def.'s Ex. G, App. 289-306; Def.'s Ex H., App. 307-65.) In addition, the FDA found Zoloft safe and effective as labeled six more times before and after January 2003. (Def.'s Ex. P., App. 800-25; Def.'s Ex. Q, App. 826-54; Def.'s Ex. R, App. 855-85; Def.'s Ex. S, App. 886-914; Def.'s Ex. T, App. 915-49; Def.'s Ex. U, App. 950-87.) In 1996, Thomas P. Laughren, M.D. of the FDA's Center for Drug Evaluation and Research submitted a detailed memo, concluding that the data presented in response to a concern about the possibility of a signal of emergent suicidality associated with sertraline use in adult and pediatric patients did not "represent a signal of risk for suicidality for either adults or children." (Def.'s Ex. X, App. 1054.) In June 2003, the FDA completed an analysis of Zoloft adverse event reports under the Best Pharmaceuticals for Children Act, including reports of suicidal ideation or behavior temporally associated with the use of Zoloft, (Def.'s Ex. KK, App. 1180-1202), and concluded that the data "do not provide any safety signals that indicate that

the agency needs to do anything except continue to actively assess the evolving benefit-risk profile of these products." (Def.'s Ex. LL, App. 1203.) It was not until October of 2004, more than a year after Decedent's death, however, that the FDA "directed manufacturers of all antidepressant drugs to revise the labeling for their products to include a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents . . . ." (Def.'s Ex. EE, App. 1091.) No such expanded warning statements were required by FDA for the adult users of antidepressants.

This record evidence, however, at this early stage of the case, cannot suffice to satisfy Defendant's burden on the instant motion for summary judgment. Pfizer's assertion here fails to recognize that "FDA regulations are generally minimum standards of conduct" unless Congress has expressed clear intent to preempt state common law, which it has not done here. Hill v. Searle Laboratories, 884 F.2d 1064, 1068 (8th Cir. 1989). Rather than acting as an absolute edict on the appropriate label language, the reapprovals merely confirmed the minimum labeling required and do not prove that a label strengthened pursuant to § 314.70(c)(6)(iii)(A) would be considered "false and misleading," rendering it in conflict with 21 U.S.C. § 355(e).

In further support of its argument that Plaintiffs' state law claims are preempted by federal law, Defendant offers the amicus brief filed by the United States in support of Defendant's position in Motus v. Pfizer, 358 F.3d 659 (9th Cir. 2004).[2] (See Def.'s Ex. B, App. 17-48.) In Motus v. Pfizer, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), the plaintiff claimed that Zoloft caused her husband to commit suicide. Defendant Pfizer moved for summary judgment on the grounds that the plaintiff's failure to warn claims were preempted by federal law. On appeal, the United States, through its amicus brief, urged that the warning of a causal relation between Zoloft and suicide would have "misbranded" the drug. (Def.'s Ex. B, App. 38-43.) The United States specifically stated that

> 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. This is not just because FDA had rejected any link between Zoloft and suicide when, in 1991, the agency approved the drug as a treatment for depression. Subsequently, in response to petitions making

[2]The district court in Motus granted summary judgment in favor of Defendant Pfizer on the grounds that the plaintiff there had no evidence of causation. Motus v. Pfizer, Inc., 196 F. Supp. 2d 984 (2001). That decision was affirmed by the Ninth Circuit, but the court did "not reach the pre-emption issues raised by Pfizer on cross-appeal." Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004). Thus, the Ninth Circuit did not actually rely upon the amicus brief in deciding the appeal on other grounds.

> similar allegations as to the related drug, Prozac, FDA found no link between antidepressants and suicide.

(Id. at App. 42-43) (emphasis in original) (internal citations omitted).

After oral argument, the Defendant submitted for this Court's consideration, the amicus brief field by the United States on September 15, 2005, in Kallas v. Pfizer, Inc., No. 2:04-CV-0998 (PGC), in the U.S. District Court for the District of Utah. The amicus brief in Kallas was submitted to the Utah court at the request of Judge Paul G. Cassell, and it was followed by a corrected amicus brief on September 30, 2005. The brief asserted the Government's position that "the state tort law claims in this case - under which plaintiffs argue that defendant Pfizer should be liable for using only the labeling for Zoloft approved by FDA - are preempted because they would punish Pfizer for not using a label that, as of November 2002, would have misbranded the drug." (Kallas Amicus Br. at 2.) The brief recited in detail why, in FDA's judgment, there was not reasonable evidence of an association between Zoloft and an increased risk of suicide or suicidality as of November, 2002. Id. at 2-3, 12-23. The brief noted that especially intensive evaluations of the data were undertaken by FDA and manufacturers of the SSRI class of antidepressants to which Zoloft belongs, focusing on the impacts of antidepressants on pediatric and adolescent patients,

beginning with the FDA's July 2003 data requests, resulting in the requirement on March 22, 2004, that Zoloft and the other SSRI medications include an enhanced warning statement recommending "close observation of adult and pediatric patients treated with those drugs for worsening of depression or the emergence of suicidality." (Id. at 21, quoting FDA Public Health Advisory "Worsening Depression and Suicidality in Patients being Treated with Antidepressant Medications," dated March 22, 2004.) The amicus brief summarized the FDA's conclusions in 2002, 2003 and early 2004 that there was not reasonable evidence of an association between Zoloft (or SSRI's generally) and an increased risk of suicidality, and that suicidality had not emerged as a matter of concern based on those reviews. (Id. at 35-37.)

Plaintiff responded that material facts are in dispute whether, prior to Decedent's death in January, 2003, there was "reasonable evidence of an association of a serious hazard with a drug [for which] a causal relationship need not have been proved," within the meaning of 21 C.F.R. § 201.57(e), supra. Plaintiffs posit that the data requested by FDA from manufactures on July 22, 2003, collected over the course of years, and supports the notion that there was a link between Zoloft and suicidality prior to January, 2003, at least among the pediatric patients studied. Plaintiffs also cite to a 2000 study published by the British Journal of Psychiatry by Stuart Donovan, et al.,

titled "Deliberate Self-harm and Antidepressant Drugs," pointing to a significantly elevated risk of self-harm among SSRI patients (including Zoloft users) compared with the tricyclic class of antidepressants (TCA). The enhanced incidence of suicidality in clinical trials of SSRIs associated with patients treated for anxiety and depression was also reported, according to Plaintiffs, in August 2002's "Clinical Psychiatry News," in which Dr. Arif Khan was reported to conclude that from 1985 until 2000, the rate of suicides in trials for antidepressant drugs was 718/100,000 compared to 11/100,000 in the general population. Plaintiffs also presented the Declaration of Dr. Arvin Shroff, who retired in 2002 from the FDA, most recently as Deputy Director in the Office of Enforcement. (Pl.'s Letter Br. dated 10/21/2005 at Ex. H.) Dr. Shroff stated that in his FDA experience he does "not know of any case where FDA has considered a product to be 'misbranded' because if had a stricter warning on the label than FDA had originally approved.... Normally FDA has considered a drug 'misbranded' when a manufacturer promotes the drug for indications that are outside of the labeling." (Id. at ¶ 14.) Dr. Shroff's testimony is consistent with Judge Rosenbaum's opinion in Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 729 (D. Minn. 2005), regarding the FDA's permissiveness toward voluntary strengthening of warning labels:

> The FDA's regulations do grant it the power to later disapprove a label strengthened pursuant to §314.70. 21

> C.F.R. § 314.70(c)(7). But the regulation "does not require that FDA take any action when a manufacturer" makes a change pursuant to [§314.70(c)]; if the FDA does nothing, the change remains in effect. See 56 Fed. Reg. 59290 (Nov. 25, 1991). Further, even if exercised, the power to disapprove does not retroactively make the manufacturer's strengthened label a violation of any law. Rather, if the FDA exercises its power to disapprove, the manufacturer simply stops distributing the new label. 21 C.F.R. § 314.70(c)(7).

Under certain situations, the FDA's position is entitled, under Supreme Court precedent, to some deference. In Geier v. American Honda Motor Co., for example, the Supreme Court placed considerable weight upon the Department of Transportation's interpretation of the regulation at issue's objectives and its conclusion that tort suits such as the one presented would stand as an obstacle to the accomplishment and execution of those objectives. 529 U.S. at 883. The Court acknowledged that "[t]he agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." Id. (quoting Medtronic, 518 U.S. at 496). See also Sprietsma, 537 U.S. at 67-68 (affording deference to the agency's position on preemption). That deference may be particularly appropriate when the regulatory scheme is silent as to preemption. "[W]hen a statute speaks clearly to the issue at hand, courts 'must give effect to the unambiguously expressed intent of Congress,' but when the statute 'is silent or ambiguous,' courts must defer to a

reasonable construction by the agency charged with its implementation." Barnhard v. Thomas, 540 U.S. 20, 26 (2003) (quoting Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843 (1984)).

This Court, however, declines to treat statements from the amicus legal briefs as declarations to be afforded the preemptive force of law. Notably, the propositions Pfizer cites from the Motus brief were not even addressed by the Motus court itself. See Motus, 358 F.3d at 661. The FDA was not a party nor did the Court adopt its legal position. Moreover, the premise of the brief's argument that Pfizer should be insulated from liability because the FDA rejected suicide warnings on the Zoloft label previously is no longer valid. In recommending labeling changes that reflect concerns about the association between SSRIs and suicidality, neither the FDA nor Pfizer can now claim, as they had in Motus, that no scientific basis exists for a suicide warning.

It must be noted that the issue before this Court is not one of express preemption, as presented in those cases addressing the language set forth explicitly by Congress in the Medical Device Amendments ("MDA") of 1976 to the FDCA. See, e.g., Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996). Indeed, the MDA's express preemption provision is considerably broader than the limiting principles of the conflict preemption doctrine in that it

preempts not only when a state law actually conflicts with federal law, but even when a state law is merely "different from, or in addition to," an MDA requirement applicable to the medical device at issue. 21 U.S.C. § 360k(a). Congress did not extend such preemptive force to the regulation of pharmaceutical drugs in the FDCA.

The express preemption language of the MDA thus demonstrates that where Congress means to explicitly preempt the laws of the various states, it knows how to do so. Absent such language in the FDCA with respect to the labeling of prescription drugs, this Court's inquiry is a far narrower one, as it is limited to whether Plaintiffs' claim "would 'stand as an obstacle to the accomplishment and execution of' the objective of the safety and effectiveness" of the drug specifically and "would conflict with the federal requirements imposed" by the FDCA. Horn v. Thoratec Corp., 376 F.3d 163, 179 (3d Cir. 2004) (quoting Geier, 529 U.S. at 873). This Court is unwilling to find, as Pfizer would have it, that Congress intended to obviate the very state laws that provide remedies to consumers harmed by dangerous products and deceptive marketing in the absence of a clear and compelling Congressional statement. See Bates v. Dow Agrosciences LLC, 125 S. Ct. 1788, 1802 (2005) ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.").

In its argument that conflict preemption applies in this case, Pfizer places significant weight on the Third Circuit's decision in Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004). In Horn, the Third Circuit stated that the state tort law claims were in "severe tension" with the federal requirement regarding medical devices. Id. at 177. The court in Horn, however, was interpreting the express preemption clause of the MDA, which commands: "No 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, 376 F.3d at 166. Thus, by this provision, Congress has clearly expressed its intent that stricter state law requirements should not be permitted in the case of medical devices. The opposite, however, is true with prescription drugs, as discussed above. In the realm of prescription drugs regulated by the FDA under the FDCA, this Court finds that the federal labeling requirements are minimum standards; states can impose stricter requirements regarding labeling and warnings if they so choose by operation of customary tort law. The only limiting regulation is that the warnings must not be false or misleading, as that would lead ultimately to the FDA's rejection of Pfizer's labeling, and that any requirement for stricter labeling be based upon at least

reasonable evidence of the association of a serious hazard with the drug, even if a causal relationship has not been proved, consistent with 21 C.F.R. §201.57(e). Here, the question of whether the FDA would have so acted can only be answered when it is clear what Pfizer knew about the link between Zoloft and suicidality, whether (as Plaintiffs allege) the company withheld crucial information on that issue from the FDA in seeking approval and reapproval of the drug, and how, if at all, its withholding of any relevant information matters.

Thus, stated differently, if Plaintiffs can demonstrate that Pfizer had knowledge of a heightened risk of suicidality, which should have resulted in enhanced labeling beyond the FDA-approved warning, then the FDCA does not preempt Plaintiffs' claim. If Plaintiffs can prove to the factfinder that Pfizer had, prior to January 2003, "reasonable evidence of an association of a serious hazard [suicidality] with a drug [Zoloft or the SSRI class generally,]" see 21 C.F.R. § 201.57(e), then the enhanced warning sought by Plaintiffs herein would not be preempted by the FDCA. There remains, at this early stage, the need for Plaintiffs to have the opportunity to obtain discovery upon this material issue before Plaintiffs can fairly be called upon to rebut Pfizer's showing on summary judgment, as requested by Plaintiffs in their Rule 56(f) motion. At this stage, therefore, summary judgment will be denied without prejudice.

D. Plaintiffs' Defective Design, Warranty and Consumer-Fraud Claims

In addition to their failure to warn claim, Plaintiffs assert claims for defective design under N.J.S.A. 2A:58C-2, et seq. (Count I); violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2, et seq. (Count III); and breach of express warranty (Count IV). At oral argument, Plaintiffs' counsel clarified that the Complaint does not allege that the product was defective or adulterated when consumed by Mr. DeAngelis, as the essential basis of liability was the content of labeling and warnings. These additional claims are also not preempted for the reasons set forth above because they, like Plaintiffs' inadequate warning claim, present no conflict between federal and state law arising solely from the approved labeling of this pharmaceutical. While these claims may present Plaintiffs with an especially steep burden in the context of this case, this Court cannot agree with Pfizer that Congress implied that preemption of such claims without a more specific indication of congressional intent.

E. Plaintiffs' Rule 56(f) Motion

By agreement of the parties, no discovery has been exchanged in this case. After oral argument was heard in this case, Plaintiffs filed a motion for an extension of time to complete discovery pursuant to Rule 56(f), Fed. R. Civ. P. Rule 56(f) provides in pertinent part that

> Should it appear from the affidavits of a party opposing the motion that the party cannot for reasons stated present by affidavit facts essential to justify the party's opposition, the court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just.

Defendant's summary judgment motion and extensive affidavits and appendices in support were filed on May 10, 2005. Thereafter, Plaintiffs agreed by Consent Order filed May 27, 2005 to Defendant Pfizer's request for a stay of discovery while the legal issue of conflict preemption was decided. Now, however, Plaintiffs argue that while it was anticipated that the law, and not the factual record, would be the deciding factor in this Court's determination of the conflict preemption issue, it is clear that the factual record may have more relevance. (Rule 56(f) Affidavit of Gregory Spizer at ¶ 7.) What Pfizer knew and when it knew it, Plaintiffs maintain, can only be obtained through the Defendant during discovery. (Id. at ¶ 8.)

"[W]here the facts are in possession of the moving party a continuance of a motion for summary judgment for purposes of discovery should be granted almost as a matter of course." Miller v. Beneficial Mgmt. Corp., 977 F.2d 834, 846 (3d Cir. 1992) (holding in certain circumstances the incomplete state of discovery itself warrants preclusion of summary judgment on the merits) (quoting Sames v. Gable, 732 F.2d 49, 51 (3d Cir. 1984)).

Here, Defendant alone is in possession of all relevant information. The studies Pfizer performed on Zoloft, the risks inherent from use of the drug, including suicidal ideation, adverse event reports related to Zoloft use, the manner in which Zoloft was sold and marketed to physicians and patients, and the communications it had with the FDA about all of these topics are all relevant to Plaintiffs' arguments.

This Court will therefore grant Plaintiffs' Rule 56(f) motion and permit a 120 day period of discovery, at the conclusion of which, Plaintiffs should be prepared to submit a competent expert report[3] to support its argument that there exists a prima facie basis for believing that Pfizer possessed sufficient information before January, 2003 from which it is reasonable to conclude there existed a link between Zoloft and enhanced suicidality which rendered the product warning

[3] In matters of epidemiology such as the evaluation of adverse reactions to prescription medication, such an association can only be shown through the testimony of a competent expert using reliable methodology as required by Rule 702, Fed. R. Evid. See, e.g., DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.3d 941, 954 (3d Cir. 1990). Here, of course, the scope of the expert's task is two-fold; first, to identify whether evidence supports a statistically significant elevation of the risk of suicidality in Zoloft (or SSRI class drugs) in depressed patients, and second, whether it is probable, to a reasonable medical probability, that ingestion of Zoloft was a proximate cause of Mr. DeAgelis' suicide. In the Third Circuit, the latter aspect may also be demonstrated by a "thorough differential diagnosis" by a medical expert who is able to reliably rule out other causes of plaintiff's death, see, e.g., Heller v. Shaw Indus., Inc., 167 F.3d 146, 154 (3d Cir. 1999).

inadequate. This period enables Plaintiffs, through prompt efforts, to seek and obtain relevant discovery within the scope of this motion, focusing on the evidence of suicidality prior to the Decedent's death in January, 2003. The period is not so lengthy, however, that Plaintiffs can embark upon a fishing expedition in hopes of obtaining something of interest.[4] Until Plaintiffs have this opportunity to obtain relevant discovery, the present summary judgment motion is premature.

III. CONCLUSION

For the reasons discussed above, Defendant's motion for summary judgment will be denied without prejudice and Plaintiffs' motion pursuant to Fed. R. Civ. P. 56(f) will be granted, and relevant discovery within the scope of this summary judgment motion may be exchanged promptly; Plaintiffs, as the parties opposing this summary judgment motion, must serve a competent expert's report within 120 days demonstrating a basis for prevailing upon its claims on all counts, alleging deficient warnings and causation and especially with regard to an analysis of data showing that the risk of suicidality as of January, 2003, associated with Zoloft was not adequately reflected on the FDA-approved label. If Plaintiffs are unable to do so, Pfizer may

[4] The Court is cognizant that at oral argument Plaintiffs' counsel admitted he was in possession of no facts demonstrating that Pfizer actually understated the risk of suicidality, but counsel believes such information will be developed in discovery.

renew this summary judgment motion. The accompanying Order is entered.

December 29, 2005	**s/ Jerome B. Simandle**
DATE	JEROME B. SIMANDLE United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BETH ANN McNELLIS, on behalf of the Estate of Theodore DeAngelis, Deceased, and IN HER OWN RIGHT, Plaintiffs, v. PFIZER, INC., et al., Defendants.	HONORABLE JEROME B. SIMANDLE Civil No. 05-1286 (JBS) **ORDER**

This matter having come before the Court upon the motion of Defendant Pfizer, Inc. for summary judgment as well as the motion of Plaintiffs Beth Ann McNellis, on behalf of the Estate of Theodore DeAngelis, deceased, and in her own right, for an extension of time to complete discovery pursuant to Fed. R. Civ. P. 56(f); and the Court having considered the submissions of the parties in support thereof and in opposition thereto; and the Court having heard oral argument on July 6, 2005; and for the reasons set forth in the Opinion of today's date; and for good cause shown;

IT IS this **29th** day of December, 2005 hereby

ORDERED that Defendant Pfizer, Inc.'s motion for summary judgment [Docket Item No. 12-1] shall be, and it hereby is,

DENIED WITHOUT PREJUDICE;

IT IS FURTHER ORDERED that Plaintiffs' motion for an extension of time to complete discovery pursuant to Fed. R. Civ. P. 56(f) [Docket Item No. 24-1] shall be, and it hereby is, **GRANTED**; and

IT IS FURTHER ORDERED that Plaintiffs may seek relevant discovery within the scope of this motion, to be concluded within the next 120 days, at which time Plaintiffs shall be required to serve a competent expert's report analyzing the data regarding suicidality and demonstrating prima facie why the Defendant's failure to supplement the FDA-approved label for Zoloft, as of January, 2003, is actionable in this case and how such conduct by Defendant resulted in an inadequate warning that was more likely than not a probable cause of Decedent's suicide.

s/ Jerome B. Simandle
JEROME B. SIMANDLE
United States District Judge