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*127 F. Supp. 2d 1085, *; 2000 U.S. Dist. LEXIS 18425, **;
CCH Prod. Liab. Rep. P15,976*

FLORA MOTUS, Plaintiff, v. PFIZER INC. (Roerig Division), et al., Defendants.

CASE NO. CV 00-00298 AHM (SHx)

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

127 F. Supp. 2d 1085; 2000 U.S. Dist. LEXIS 18425; CCH Prod. Liab. Rep. P15,976

December 12, 2000, Decided

December 12, 2000, Filed; December 13, 2000, Entered

DISPOSITION: [**1] Defendant's motion for partial summary judgment DENIED.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant drug manufacturer moved for partial summary judgment on plaintiff's claims of wrongful death/negligence, strict liability, and survival action for the pain, suffering and losses that her husband sustained while using Zoloft, a drug manufactured by defendant.

OVERVIEW: Plaintiff's husband began taking the drug Zoloft, which was manufactured by defendant. Zoloft was prescribed and supplied to plaintiff's husband by his internist, to whom defendant had provided a supply of Zoloft as a sample. For the one week that he took Zoloft, plaintiff's husband experienced agitation, confusion and suicidal thinking. Subsequently, plaintiff's husband took his life by shooting himself. Plaintiff filed suit against defendant, alleging claims of wrongful death/negligence, strict liability, and survival action for the pain, suffering and losses that her husband sustained while using Zoloft. Defendant moved for partial summary judgment, arguing that under both California law and federal "conflict" preemption doctrine, plaintiff's state law claims based on defendant's failure to include a suicide warning in Zoloft's labeling were barred because the Food and Drug Administration had already considered and rejected the inclusion of such a warning in Zoloft's labeling. The court held that defendant failed to establish that a plaintiff was barred from asserting state law tort claims based on failure to warn of a suicide risk. Thus, defendant's motion was denied.

OUTCOME: Defendant's motion for partial summary judgment denied; defendant failed to establish that a plaintiff was barred from asserting state law tort claims based on failure to warn of a suicide risk.

CORE TERMS: warning, labeling, state law, suicide, manufacturer, suicidal, regulation, patient, failure to warn, safe, preemption, antidepressant, depression, ideation, dicta, summary judgment, federal law, overdeterrence, suicidality, misleading, strengthened, doctor, scientific information, strict liability, sertraline, preempted, preempt, moving party, scientific, effective

CORE CONCEPTS -  [Hide Concepts](#)

Civil Procedure : Summary Judgment : Burdens of Production & Proof

Fed. R. Civ. P. 56(c) provides for summary judgment when 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 judgment as a matter of law. The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact for trial. A fact is material if it could affect the outcome of the suit under the governing substantive law. The burden then shifts to the nonmoving party to establish, beyond the pleadings, that there is a genuine issue for trial.

Civil Procedure : Summary Judgment : Burdens of Production & Proof

When the party moving for summary judgment would bear the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial. In such a case, the moving party has the initial burden of establishing the absence of a

genuine issue of fact on each issue material to its case. In contrast, when the non-moving party bears the burden of proving the claim or defense, the moving party can meet its burden by pointing out the absence of evidence from the non-moving party. The moving party need not disprove the other party's case. Thus, summary judgment for a defendant is appropriate when the plaintiff fails to make a showing sufficient to establish the existence of an element essential to his case, and on which he will bear the burden of proof at trial.

Civil Procedure : Summary Judgment : Burdens of Production & Proof

On a motion for summary judgment, when the moving party meets its burden, the adverse party may not rest upon the mere allegations or denials of the adverse party's pleadings, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e). Summary judgment will be entered against the non-moving party if that party does not present such specific facts. Only admissible evidence may be considered in deciding a motion for summary judgment.

Civil Procedure : Summary Judgment : Burdens of Production & Proof

In ruling on a motion for summary judgment, the nonmoving party's evidence is to be believed, and all justifiable inferences are to be drawn in that party's favor. But the non-moving party must come forward with more than the mere existence of a scintilla of evidence. Thus, where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial.

Civil Procedure : State & Federal Interrelationships : Federal Common Law

In the context of ways in which federal law will preempt a state law, Congress can define explicitly the extent to which its enactments pre-empt state law. Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. Such an intent may be inferred from a scheme of federal regulation so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, or where an Act of Congress touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. Finally, state law is pre-empted to the extent that it actually conflicts with federal law.

Civil Procedure : State & Federal Interrelationships : Federal Common Law

Evidence : Procedural Considerations : Burdens of Proof, Presumptions & Inferences

The party contending that a claim is preempted bears the burden of establishing preemption.

Healthcare Law : Treatment : Medical Devices

The Food and Drug Administration regulations as to design and warning standards are minimum standards which do not preempt state law defective design and failure to warn claims.

Healthcare Law : Treatment : Medical Devices

A change to labeling that adds or strengthens a contraindication, warning, precaution, or adverse reaction is within the category of changes that may be made before the Food and Drug Administration approval. [21 C.F.R. § 314.70\(c\)\(2\)\(i\)](#).

Healthcare Law : Treatment : Medical Devices

See [21 C.F.R. § 201.57\(e\)](#).

Healthcare Law : Treatment : Medical Devices

Prescription drug labeling may not be false or misleading in any particular. [21 U.S.C.S. § 355\(d\)](#).

Healthcare Law : Treatment : Medical Devices

Prescription drug labeling must be based on the essential scientific information needed for the safe and effective use of the drug. [21 C.F.R. § 201.56\(a\)](#).

Evidence : Procedural Considerations : Preliminary Questions

Healthcare Law : Treatment : Medical Devices

In appropriate cases, the Food and Drug Administration action or inaction, though not dispositive, may be admissible to show whether a risk was known.

COUNSEL: For FLORA MOTUS, plaintiff: George W Murgatroyd, III, Karen Ann Barth, Baum Hedlund Aristei Guilford & Downey, Los Angeles, CA.

For PFIZER INC, defendant: Pierce O'Donnell, Ann M Mortimer, Randy R Merritt, Daniel C Tepstein, O'Donnell & Shaeffer, Los Angeles, CA.

For PFIZER INC, defendant: Malcolm E Wheeler, Amy L Padden, James E Hooper, Michael L O'Donnell, Wheeler Trigg & Kennedy, Denver, CO.

JUDGES: A. Howard Matz, United States District Judge.

OPINIONBY: A. Howard Matz

OPINION: [*1086]

ORDER DENYING **Pfizer's** MOTION FOR PARTIAL SUMMARY JUDGMENT

INTRODUCTION

Victor **Motus** suffered from depression. To help deal with that illness, sometime in November 1998 he began taking the drug "Zoloft," which is manufactured by defendant **Pfizer** Inc. ("**Pfizer**"). Zoloft was prescribed and supplied to Victor **Motus** by his internist, to whom **Pfizer** had provided a supply of Zoloft as a sample. For the approximately one week that he took Zoloft, Victor **Motus** experienced agitation, confusion and suicidal thinking. On November 12, 1998, he took his life by shooting himself.

Plaintiff Flora **Motus** ("**Motus**") was married to Victor **Motus**. She has brought **[**2]** this lawsuit, removed here from state court, seeking recovery on three claims: **[*1087]** (1) "wrongful death/negligence"; (2) strict liability; and (3) "survival action" for the pain, suffering and losses that Victor **Motus** sustained while using Zoloft. Her complaint alleges, among other things, that **Pfizer** "negligently ... failed to adequately warn the medical community, the general public and plaintiff's decedent, Victor **Motus** ... of the dangers, contraindications and side effects ... of Zoloft" **[Complaint, P 27]** and that in the United States "Zoloft was not properly labeled by defendants n1 ... and was not accompanied by proper warnings for safe, informed use ... The labeling ... did not warn physicians in general and Decedent in particular of the dangers inherent in its use, particularly that the drug can cause the user to become violent and suicidal." **Complaint, P 58.**

-----Footnotes-----

n1 Various "DOES" are sued along with **Pfizer**.

-----End Footnotes-----

Here is the suicide-related precaution that **Pfizer** gave:

Suicide - The possibility of a suicide **[**3]** 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.

DSUF, P 20.

Now **Pfizer** has moved for partial summary judgment dismissing plaintiff's "inadequate warning" claims. **Pfizer** seeks an order that as a matter of law it may not be held liable for its failure to include in the labeling for Zoloft a warning of the risk of suicide. **Pfizer** argues that under both California law and federal "conflict" preemption doctrine, plaintiff's state law claims based on **Pfizer's** failure to include a suicide warning in Zoloft's labeling are barred because the Food and Drug Administration ("FDA") has already considered and rejected the inclusion of such a warning in Zoloft's labeling. **Motus** responds that 1) although FDA did approve **Pfizer's** proposed labeling for Zoloft without the suicide warning, FDA did not prohibit **Pfizer** from adding such a warning and 2) Congress has not preempted state tort law claims for failure **[**4]** to warn just because FDA has approved a manufacturer's proposed warnings.

The Court DENIES defendant's motion for partial summary judgment. As set forth in more detail below, **Pfizer** has failed to establish that a plaintiff is barred from asserting state law tort claims based on failure to warn of a suicide risk.

FACTS n2

-----Footnotes-----

n2 All the facts recited in this Order are undisputed unless otherwise noted.

-----End Footnotes-----

A. Statutory Background

One aspect of the FDA's mission is to ensure that drugs sold in the United States are "safe and effective." 21 U.S.C. §§ 355(d) and 393(b)(2) (B). To obtain FDA approval of a drug, a manufacturer must submit a New Drug Application ("NDA"). 21 U.S.C. § 355(b). NDAs must include: "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use ... and specimens of the labeling proposed to be used for such drug." *Id.* The FDA will disapprove an NDA if: **[**5]**

(1) the investigations ... do not include adequate tests ... to show whether or not such drug is safe for use ... (2) the results of such tests show that such drug is unsafe for use ... or do not show that such drug is safe for use ... (4) ... [there is] insufficient information to determine whether such drug is safe for use ... or (7) based on a fair evaluation of all material facts, [the product's] labeling is false or misleading in any particular...

21 U.S.C. § 355(d).

If FDA approves an NDA, FDA will withdraw that approval if:

[*1088]

clinical or other experience, tests, or other scientific data show that such drug is unsafe ... [or] that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not ... safe for use ... or that the application contains any untrue statement of a material fact.

[21 U.S.C. § 355](#) [**6] (e).

B. The Zoloft New Drug Application

On April 13, 1988, **Pfizer** submitted an NDA to the FDA seeking approval to market Zoloft for treatment of depression. Defendant's Statement of Uncontroverted Facts ("DSUF"), P 11. Zoloft is the registered trademark and brand name in the United States for sertraline hydrochloride. DSUF, P 2. Sertraline hydrochloride is one of a class of medicines commonly referred to as "selective serotonin reuptake inhibitors," or "SSRIs." *Id.*

Pursuant to Title [21 U.S.C. § 355](#), the statute governing New Drug Applications, **Pfizer** submitted 117 volumes of safety and efficacy data on Zoloft that **Pfizer** had developed during the preceding seven years. DSUF, P 12; [21 U.S.C. § 355\(b\)](#). These submissions included information about suicidality in patients given Zoloft, placebos and other drugs, although plaintiff disputes the completeness and accuracy of the information. DSUF, P 13; Opposition, *passim*.

On November 19, 1990, FDA convened a committee of experts, the Psycho-pharmacological Drugs Advisory Committee ("PDAC"), to review the Zoloft NDA and to advise FDA regarding the medicine's safety and efficacy. [**7] DSUF, P 14. As part of his presentation of safety data, one of the PDAC experts, Dr. James Knudson, addressed suicide attempts in Zoloft, placebo and active-control treated patients during the clinical studies of Zoloft. DSUF, P 17. Dr. Knudson stated that:

Realizing the difficulty in interpreting data where analyses ignore differential exposure time, this table does show that disproportionate numbers of suicides do not occur among the three treatment groups. All suicide attempts appeared in depressed patients, none in the obese.

Id. At the conclusion of the meeting, the PDAC voted unanimously that the evidence **Pfizer** produced had shown that Zoloft "is safe when used in the treatment of depression." DSUF, P 18.

On September 30, 1991, FDA issued its "approvable" letter for the Zoloft NDA. DSUF, P 18. The letter stated that FDA has "proposed a number of changes to the draft labeling submitted in your July 24, 1990 amendment" and it proposed some different labeling. *Id.* The precaution section of the proposed labeling included this statement regarding suicide:

Suicide - The possibility of a suicide attempt is inherent in depression and may persist until [**8] 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.

DSUF, P 20. The FDA letter instructed **Pfizer** to "please use the proposed text verbatim." (As was shown above, **Pfizer** eventually did so.) DSUF, P 19. n3 In addition, FDA stated that final approval required **Pfizer's** responses to issues raised in the letter. Defendant's Motion for Partial Summary Judgment ("Defendant's Motion"), [*1089] Declaration of Martha Brumfield ("Brumfield Dec."), Exh.3.

-----Footnotes-----

n3 In addition to asserting that the data that **Pfizer** provided to FDA was incomplete and inaccurate, plaintiff contends that **Pfizer**, not FDA, drafted this language. Murgatroyd Dec., P 3, Exh. A, RFA # 144.

-----End Footnotes-----

FDA granted final approval of the Zoloft NDA on December 30, 1991. DSUF, P 21. Working from a draft submitted by **Pfizer**, FDA also prepared [**9] a final "Summary Basis of Approval" for Zoloft. DSUF, P 22; Plaintiff's Opposition to Defendant's Motion for Partial Summary Judgment ("Opposition"), Declaration of George Murgatroyd ("Murgatroyd Dec."), Exh. A, Response to Request for Admission Nos. 138, 139. Section 5.2.2.4.1 addressed the occurrence of suicide events in the database of tested sertraline users. DSUF, P 22. That section stated that with respect to suicidality in therapeutic depression trials "review of the rates of events defined by baseline to endpoint shifts in HAMD Item 3 scores [i.e., measurement of suicidal ideation] and baseline to endpoint changes in HAMD Item 3 scores showed results favoring [Zoloft] over placebo and supported the comparability of the [Zoloft] and active control groups." DSUF, P 22.

Following its approval of Zoloft for treatment of depression, FDA also approved Zoloft as safe and effective for treatment of obsessive compulsive disorder (October 25, 1996), pediatric obsessive compulsive disorder (October 10, 1997), panic disorder (July 8, 1997) and post-traumatic stress disorder (December 7, 1999). n4 DSUF, PP 45-48. (The latter approval was granted after Victor **Motus** took his life. [**10])

-----Footnotes-----

n4 The Court overrules plaintiff's FRE 402 and 403 objections to these facts. Further, at the hearing on this motion, counsel for **Pfizer** asserted that FDA reconsidered the issue of suicide and Zoloft on each occasion that it approved Zoloft for a new use. **Pfizer's** motion papers do not

specify what evidence proves such reconsiderations were undertaken. The Court has reviewed the Exhibits (5-9 in Brumfield's Declaration) related to FDA's subsequent approvals of Zoloft and found only one document regarding whether FDA reconsidered the suicide issue. That document is a report, apparently prepared by **Pfizer** at FDA's request, detailing **Pfizer's** findings concerning the relation between the use of Zoloft by adults and children for obsessive compulsive disorder and suicide related behavior. Brumfield Dec., Exh. 9. The report concluded, inter alia, that rate of suicidal behavior for adolescents treated with sertraline for obsessive-compulsive disorder was within the range described in normal population samples of adolescents.

-----End Footnotes----- [**11]

C. Other SSRI's and Labeling About Suicide n5

-----Footnotes-----

n5 The Court overrules plaintiff's FRE 402 and 403 objections to these facts. Plaintiff's own complaint refers to the risks posed by Prozac and to an article describing the risks of Prozac, and cites a quote from **Pfizer** that Zoloft works "just like Prozac" with the same side effects. Complaint, PP 16-18. The evidence is also relevant to establish how the FDA handled concerns about SSRI-induced suicidal ideations.

-----End Footnotes-----

Before and during FDA's consideration of the Zoloft NDA, FDA considered claims that other SSRIs, such as Prozac, cause suicide.

In early 1990, an article was published about Prozac that led to a much-publicized public debate about whether fluoxetine induced suicidal ideation in patients. On October 10, 1990, Sanford Block of the Church of Scientology's "Citizens Commission on Human Rights," ("CCHR") filed with FDA a petition claiming that Prozac caused suicidality and asking FDA to withdraw its approval of Prozac. DSUF, P 26. On May 23, 1991, Drs. [**12] Ida Hellander and Sidney M. Wolfe of "Public Citizen Health Research Group" ("PCHRA") filed a petition asking FDA to revise Prozac's labeling and "to include a box warning [] regarding its association with intense, violent suicidal preoccupation, agitation and impulsivity in a small minority of patients." DSUF, P 27.

On July 26, 1991, FDA denied the CCHR petition, stating that "the data and information available at this time do not indicate that Prozac causes suicidality or violent behavior..." DSUF, P 28.

On September 20, 1991, FDA convened the PDAC to further its "scientific investigation [*1090] into suicidal ideation, suicidal acts, and other violent behavior reported to occur in association with the pharmacological treatment of depression." DSUF, P 30. In his opening remarks to the committee meeting, Dr. Paul Leber, the then-Director of the FDA Division of Neuropharmacological Drug Products, stated that the "net effect" of "modifying antidepressant drug labeling" "might be a reduction in the use of antidepressants in the treatment of depression, and that the result might cause overall injury to the public health." DSUF, P 37. "Excerpted comments" of Dr. Leber also show that he stated [**13] that "if Prozac is not more likely to induce suicidal thoughts, acts and other violent behaviors, a labeling change of the sort contemplated by some, beyond being false and misleading, might well have a net adverse effect." *Id.* On the question whether "there is credible evidence to support a conclusion the antidepressant drugs cause the emergence and/or intensification of suicidality and/or other violent behaviors," the PDAC voted unanimously that there was no such evidence. DSUF, P 39. As to the question whether "there is evidence to indicate that a particular drug or drug class poses a greater risk for the emergence and/or intensification of suicidal thoughts and acts and/or violent behaviors," the PDAC also voted unanimously that there was not. DSUF, P 40.

On June 3, 1992, FDA denied the PCHRA petition because the evidence was "not sufficient to reasonably conclude that the use of Prozac is possibly associated with suicidal ideation and behavior..." DSUF, P 43.

Finally, on January 2, 1997, Ms. Rosellen Meysenburg petitioned FDA to require that Prozac's suicidality warning be expanded to indicate that "people who are considered at risk for suicide and who begin to take the [**14] antidepressant drug fluoxetine hydrochloride [sic] should be carefully observed and should consider taking a sedative as well." On June 25, 1997, FDA stated: "the agency has continued to monitor carefully reports of a possible connection between Prozac and increased suicidality. However, no credible scientific evidence has caused the agency to depart from its conclusion that the current Prozac labeling appropriately reflects the level of concern about Prozac and suicidality. Therefore, your petition requesting revision of the labeling for Prozac is denied." DSUF, P 56.

LEGAL STANDARDS FOR A MOTION FOR SUMMARY JUDGMENT

□ Federal Rule of Civil Procedure 56(c) provides for summary judgment when "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 judgment as a matter of law." The moving party bears the initial burden of demonstrating the absence of a "genuine issue of material fact for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256, 106 S. Ct. 2505, 2514, 91 L. Ed. 2d 202 (1986). A fact [**15] is material if it could affect the outcome of the suit under the governing substantive law. *Id.* at 248, 106 S. Ct. at 2510. The burden then shifts to the nonmoving party to establish, beyond the pleadings, that there is a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986).

□ "When the party moving for summary judgment would bear the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial. In such a case, the moving party has the initial burden of establishing the absence of a genuine issue of fact on each issue material to its case." *C.A.R. Transportation Brokerage Co., Inc. v. Darden Restaurants, Inc.*, 213 F.3d 474, 480 (9th Cir. 2000) (citations omitted). In contrast, when the non-moving party bears the burden of proving the claim or defense, the moving party can meet its burden by [*1091] pointing out the absence of evidence from the non-moving party. The moving party need not disprove the other party's case. See *Celotex*, 477 U.S. at 325, 106 S. Ct. at 2554. Thus, [**16] "summary judgment for a defendant is appropriate when the plaintiff 'fails to make a showing sufficient to establish the existence of an element essential to [his] case, and on which [he] will bear the burden of proof at trial.'" *Cleveland v. Policy Management Sys. Corp.*, 526 U.S. 795, 119 S. Ct. 1597, 1603, 143 L. Ed. 2d 966 (1999) (citing *Celotex*, 477 U.S. at 322, 106 S. Ct. at 2552).

□ When the moving party meets its burden, the "adverse party may not rest upon the mere allegations or denials of the adverse party's pleadings, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial." F.R.Civ.P. 56(e). Summary judgment will be entered against the non-moving party if that party does not present such specific facts. *Id.* Only admissible evidence may be considered in deciding a motion for summary judgment. *Id.*; *Beyene v. Coleman Sec. Serv., Inc.*, 854 F.2d 1179, 1181 (9th Cir.1988).

□ "In ruling on a motion for summary judgment, the nonmoving party's evidence 'is to be believed, and all justifiable inferences [**17] are to be drawn in [that party's] favor.'" *Hunt v. Cromartie*, 526 U.S. 541, 119 S. Ct. 1545, 1551-52, 143 L. Ed. 2d 731 (1999) (citing *Anderson*, 477 U.S. at 255, 106 S. Ct. at 2513). But the non-moving party must come forward with more than "the mere existence of a scintilla of evidence." *Anderson*, 477 U.S. at 252, 106 S. Ct. at 2512. Thus, "where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986) (citation omitted).

DISCUSSION

A. Federal Preemption

□ The Supreme Court has explained that there are three ways in which federal law will preempt a state law:

First, Congress can define explicitly the extent to which its enactments pre-empt state law. . . . Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. Such an intent may be inferred [**18] from a "scheme of federal regulation ... so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or where an Act of Congress "touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." Although this Court has not hesitated to draw an inference of field pre-emption where it is supported by the federal statutory and regulatory schemes, it has emphasized: "Where ... the field which Congress is said to have pre-empted" includes areas that have "been traditionally occupied by the States," congressional intent to supersede state laws must be "clear and manifest."

Finally, state law is pre-empted to the extent that it actually conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements, or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

English v. General Elec. Co., 496 U.S. 72, 78-79, 110 S. Ct. 2270, 2275, 110 L. Ed. 2d 65 (1990) (citations [**19] omitted) (holding that nuclear fuel production employee's state law claim for intentional infliction of emotional distress was not preempted by the Energy Reorganization Act). These categories are not "rigidly distinct;" in particular, "conflict" [**1092] and "field" preemption often overlap. *Id.* at 79 n. 5.

□ The party contending that a claim is preempted bears the burden of establishing preemption. *Jimeno v. Mobil Oil Corp.*, 66 F.3d 1514, 1526 n. 6 (9th Cir. 1995). n6

-----Footnotes-----

n6 The Court notes that several Supreme Court cases describe a presumption against finding preemption, especially where state or local regulation of matters related to health and safety are concerned. *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707, 715, 85 L. Ed. 2d 714, 105 S. Ct. 2371 (1985). **Pfizer** points out that cases like *Hillsborough* that employ the presumption do not address conflict preemption. The Court need not decide whether a presumption against preemption applies because the Court decides that **Pfizer** has not established preemption, even absent a presumption.

-----End Footnotes----- [**20]

Pfizer makes no express or field preemption argument. Instead, **Pfizer** argues that "plaintiff's attempt to use state tort law to require warnings that Zolofit causes suicide" conflicts with (1) FDA's various determinations regarding Zolofit's and SSRI's warnings and (2) the federal statutory and regulatory objective of ensuring that labeling effectively communicates the scientific information physicians need to make informed judgments. Defendant's Motion, p. 16-17.

1. Conflict Preemption

a. Impossibility of Compliance

In its opening motion papers, **Pfizer** asserts that federal law preempts plaintiff's claims based on failure to warn because "the state law advocated by plaintiff would make it impossible for **Pfizer** to comply both with plaintiff's demands for additional warnings and with FDA's requirement that **Pfizer** use the exact labeling approved by the agency. See *Hurley v. Lederle Labs.*, 863 F.2d 1173, 1179 (5th Cir.1988)." Defendant's Motion, p. 19.

Plaintiff responds that because FDA standards for labeling are minimum standards, FDA approval of **Pfizer's** proposed label does not mean that state law claims based on that labeling are preempted. Opposition, [**21] p.20, 22.

As plaintiff correctly argues, most courts have 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. See, e.g., [Hill v. Searle Labs](#), 884 F.2d 1064, 1068 (8th Cir.1989) ("FDA approval is not a shield to liability ... FDA regulations are generally minimum standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area."); [Kociemba v. Searle & Co.](#), 680 F. Supp.1293, 1299 (D.Minn.1988) ("The mere fact that the Cu-7 received FDA approval does not, by itself, indicate that Congress impliedly intended to preclude state tort actions against prescription drug manufacturers. This is especially true in light of the widely held view that FDA regulation of prescription drugs establishes minimum standards, both as to design and warning," citing [Graham v. Wyeth Labs](#), 666 F. Supp. 1483 (D.Kan. 1987), [Brochu v. Ortho Pharmaceutical Corp.](#), 642 F.2d 652 (1st Cir.1981) and [Salmon v. Parke Davis & Co.](#), 520 F.2d 1359 (4th Cir.1975)); [Mazur v. Merck & Co.](#), 742 F. Supp. [**22] 239, 247 (E.D.Pa. 1990) ("mere compliance with FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant...Compliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not necessarily absolve the manufacturer of all liability ... Manufacturers must meet state safety requirements, whether codified or embodied in the common law, in addition to satisfying initial FDA requirements"). Indeed, **Pfizer** cites not a single case holding that FDA prescription drug requirements preempted state law claims. n7

-----Footnotes-----

n7 **Pfizer** does however offer [Geier v. American Honda Motor Co.](#), 529 U.S. 861, 120 S. Ct.1913, 146 L. Ed. 2d 914 (2000), for the proposition that even minimum standards may preempt state law tort claims. Reply, p.5. But in [Geier](#), the Supreme Court expressly found that the Department of Transportation saw the disputed standard "not as a minimum standard, but as a way to provide a manufacturer with a range of choices among different passive restraint systems..." [Geier](#), 120 S. Ct. at 1915, 1922 ("This lawsuit actually conflicts with [the safety standard]. DOT saw [the safety standard] not as a minimum standard ... In petitioners' and the dissent's view, [the safety standard] sets a minimum airbag standard ... But that was not the Secretary's view."). In any case, even if standards deemed "minimum" could conflict with state law tort suits, the warning labeling standards here do not because, as explained shortly, **Pfizer** has not established that federal regulations or FDA meant to prohibit **Pfizer** from strengthening its warnings.

-----End Footnotes----- [**23] [*1093]

So it is [Hurley](#) that **Pfizer** relies on for the proposition that an FDA determination of proper drug labeling can conflict with state law requiring additional or changed labeling. In [Hurley](#), the Fifth Circuit held that federal regulations *did not* preempt the plaintiff's state law product liability claims based on the allegedly unreasonable dangerousness and inadequate warnings of a whooping cough vaccine, [863 F.2d at 1176-1177](#). In dicta, however, the [Hurley](#) Court stated that:

The defendants propose that the question of adequacy of the warning is preempted by federal law since the warning used was FDA approved ... This is the one question in this case for which the defendants' arguments on preemption are compelling ... In the area of approving warnings ... the FDA ... accepts information given by manufacturers proposing the licensing of a particular vaccine, and determines a proper warning based upon the information provided ... A state law determination on this issue should not be interjected to overrule the decision of the FDA. Such a procedure would place vaccine manufacturers in a position where they could not comply with both obligations. The [**24] FDA extensively regulates the contents and wording of these product inserts ... A manufacturer must first provide all the relevant information to the FDA, which then determines a warning it deems appropriate. The manufacturer is required to print that precise warning in its product insert ... Most important, the manufacturers cannot change the language in the product insert without FDA approval. [21 C.F.R. § 601.12](#). It would be patently inconsistent for a state then to hold the manufacturer liable for including that precise warning when the manufacturer would otherwise be liable for not including it ... Such a case would fit one of the scenarios ... indicating preemption: the state statute actually and directly conflicts with federal law.

[Hurley](#), 863 F.2d at 1179.

[Hurley](#) dealt with and depended on federal regulations governing vaccines and other "biologics." The Court finds **Pfizer's** reliance on this language in [Hurley](#) misplaced. The dicta **Pfizer** relies on described one provision, [21 C.F.R. § 601.12](#), as "most important" to its statement of possible preemption. At the time [Hurley](#) was decided, [21 C.F.R. 601.12\(b\)](#) stated that "proposed changes in [**25] manufacturing methods and labeling may not become effective until notification of acceptance is received from the Director, Center for Biologics evaluation." n8 That provision formed the basis for the Fifth Circuit's decision that a "biologics" manufacturer could not simultaneously comply with FDA labeling requirements and a state law requiring different warnings. Neither party has indicated and nothing in the record indicates that the regulations governing "biologics" have any bearing on this case.

-----Footnotes-----

n8 [21 C.F.R. § 601.12](#) was subsequently amended to allow certain labeling changes prior to FDA approval. [21 C.F.R. § 601.12\(f\)\(2\)\(i\)](#).

-----End Footnotes-----

The regulations that do apply here, but that did not apply in [Hurley](#), militate strongly in favor of finding no conflict preemption, because they provide that **Pfizer** may strengthen Zoloff's warnings [**1094] without prior FDA approval. [21 C.F.R. § 314.70](#) is the federal regulation governing supplements to approved NDAs. It states that a change to labeling that "add[s] or strengthen[s] [**26] a contraindication, warning, precaution, or adverse reaction" is within the category of changes that "may be made before FDA approval." [21 C.F.R. § 314.70\(c\)\(2\)\(i\)](#). Therefore, unlike in [Hurley](#), here it is not true that "the manufacturers cannot change the language in the product insert without FDA approval" and is not true that a manufacturer "would otherwise be liable" for strengthening an FDA-approved warning. The FDA Commissioner's own comments support this view:

The commissioner also advises that these labeling requirements do not prohibit a manufacturer ... from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered. The addition to labeling ... of additional warnings ... is not prohibited by these regulations... In the case of an approved NDA, § 314.8(d) [now § 314.70(c)(2)(i)] permits the addition to the drug's labeling ... of information about a hazard without advance approval by the FDA ... At least one Court has held that an NDA holder may have a duty to add a warning before FDA approval of a supplemental application.

21 Federal Register 37447 (1979). There appears [**27] to be no inherent conflict between state law requiring a stronger warning for Zoloff and the FDA's approval of Zoloff's present warning.

In its Reply Memorandum, **Pfizer** supplements its argument from *Hurley* with additional "impossibility of compliance" arguments based on a federal statute and regulations:

Since FDA has expressly and repeatedly found that there is "no credible evidence" to support an association between SSRIs and suicide any inclusion in Zoloff's labeling of the warnings advocated by plaintiff would violate the statutory and regulatory prohibition against labeling that "is false or misleading in any particular." [21 U.S.C. § 355\(e\)](#); [21 C.F.R. § 201.56\(a\)-\(b\)](#). Inclusion of any such warning would violate the regulatory requirement that labeling must warn only of "known hazards and not theoretical possibilities" and must not include any "statement of differences of opinion." [21 C.F.R. § 201.57\(d\)](#), 1.21(c)(1). It would violate the limitation that labeling statements are permitted "only if they are supported by scientific evidence." 44 Fed. Reg. 37434, 37441 (June 26, 1979).

Reply, p. 14-15.

First, several of the [**28] regulations cited by **Pfizer** do not apply to its alleged failure to warn. n9 It is true that [21 C.F.R. § 1.21\(c\)\(1\)](#) states that § 1.21(a) does not "permit a statement of differences of opinion with respect to warnings..." but neither plaintiff nor defendant have asserted that plaintiff wishes to add such a statement. It is also true that [21 C.F.R. § 201.57\(d\)](#) states that "known hazards and not theoretical possibilities shall be listed, e.g., if hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication." But this language applies only to listing of "contraindications," or "those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit..." It does not apply to listings of "warnings" - which is what is at stake here and which is governed by a separate regulatory provision in § 201.57(e). Notably, **Pfizer** does not cite that regulation, which appears not to pose any conflict, in that it does not impose specific prohibitions. [*1095] Section 201.57 delineates the "specific requirements on content and format of labeling for human prescription drugs" and subsection (e) specifically governs "warnings." [**29] " In its entirety, subsection (e) states as follows:

□
Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning 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. A specific warning relating to a use not provided for under the "Indications and Usage" section of the labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location [**30] will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the "Adverse Reactions" section of the labeling.

Unlike the provision on "contraindications," which does seem to point out one type of statement that *may not* be included in the "contraindication" section of drug labeling, the provision on "warnings" very clearly lists only those statements that must be included, not statements that may *not* be included.

-----Footnotes-----

n9 **Pfizer** also cites to several comments of the FDA commissioner, which are now memorialized in the federal register, that come under the heading not of "warnings," but of "adverse reactions," a different part of prescription drug labeling that is subject to its own separate requirements. Reply, p.15, Fed. Reg. 37453; [21 U.S.C. § 201.57\(e\)](#) (governing warning labeling); [21 U.S.C. § 201.57\(g\)](#) (governing adverse reaction labeling).

-----End Footnotes----- [**31]

Although some of the federal statutory and regulatory law **Pfizer** cites does appear to apply to Zoloff's warning label, that law does not establish conflict preemption because **Pfizer** has not established that plaintiff's theory of liability would require warnings that would violate federal law. It is true that □ prescription drug labeling may not be "false or misleading in any particular." [21 U.S.C. § 355\(d\)](#); [21 C.F.R. § 201.56\(b\)](#). It is also true that, as described in the federal register commentary and codified in section 201.56(a), □ labeling must be based on "the essential scientific information needed for the safe and effective use of the drug." [21 C.F.R. § 201.56\(a\)](#); Fed Reg. 37441. But **Pfizer** has not attacked any specific warning as "false or misleading" or not based on "the essential scientific information needed" for safe use. Instead, **Pfizer** attacks plaintiff's general allegation of failure to warn. Defendant's Motion, p.3-4. n10

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n10 In fairness to **Pfizer**, plaintiff evidently has not yet identified the precise warning that she thinks **Pfizer** should have provided. As the Court stated at the hearing on this motion, this has proven vexing to the Court, too, because it would be much easier to analyze whether a supposedly necessary warning conflicted with the federal requirement if one knew what the warning said.

-----End Footnotes----- [**32]

The Court finds **Pfizer's** attack overbroad. Although 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, or not based on "the essential scientific information needed" for safe use. For example, in her opposition, plaintiff discussed the SSRI warning recommended by the Medicines Control Agency, the British equivalent of the FDA: "occasionally, [*1096] thoughts of suicide or self harm may occur or increase in the first few weeks of treatment with sertraline, until the antidepressant effect becomes apparent. Tell your doctor immediately if you have any distressing thoughts or experiences." Opposition, p.23. In its Reply Memorandum, **Pfizer** did not refer to or attack this example of a warning. The Court has no basis to find that a restrained warning like this one is necessarily false or misleading, or not based on "the essential scientific information needed" for safe use. Therefore, the Court is not persuaded that to the extent that plaintiff's [**33] claims are based on failure to warn, they necessarily would violate federal law, regulations or policies.

Moreover, and perhaps most importantly, although FDA did not require **Pfizer** to include suicide-related warnings in Zolof's label, FDA has not prohibited **Pfizer** from doing so. On the occasions cited by **Pfizer** that FDA considered links between suicide and SSRIs, FDA did find that the evidence did not support requiring manufacturers to include additional suicide-related warnings. But FDA never stated that it would be impermissible to include additional warnings. This is consistent with the regulatory provision governing warning labels, 21 C.F.R. § 201.57(e), which indicates only those warnings that must be included in drug labeling, but does not prohibit any warnings.

Pfizer suggests that FDA *impliedly* prohibited additional suicide-related warnings, based on a comment of Dr. Paul Leber, the former Director of Neuropharmacological Drug Products, that "a labeling change of the sort contemplated by some" could be "false and misleading." Defendant's Motion, p.10; Gaul, Dec., Exh.15. But **Pfizer** has not established that the labeling change "contemplated" by plaintiff's law suit [**34] is "a labeling change of the sort contemplated by some"; it is not clear just what "sort" of labeling change Leber is referring to; and, as discussed above, plaintiff has not limited herself to advocating any particular warning. Further, the Court does not agree that an excerpted comment of an FDA doctor, phrased as a hypothetical, made in ostensibly informal introductory comments to a meeting of the PDAC, and presented here only in a footnote constitutes formal FDA prohibition of any and every strengthened suicide-related warning.

To summarize, several other courts have determined that FDA requirements are minimum standards and that FDA approval is not a shield to liability; 21 C.F.R. § 314.70(c)(2)(i) permits manufacturers to strengthen warning labels without prior FDA approval; **Pfizer** has not limited its attack to any specific warnings; and finally the FDA has not made any statement that **Pfizer** could not include a strengthened suicide warning. In light of these factors, the Court finds that **Pfizer** has not established that it would be impossible to comply simultaneously with FDA requirements and with a state law or decision requiring a strengthened warning.

b. Frustration of [**35] Congressional Purpose

Pfizer asserts that permitting plaintiff's state law claims for failure to warn would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress:

Plaintiff seeks to require warnings that FDA has determined are not only unnecessary and unsupported by scientific data and information, but false, misleading and potentially harmful to the public. Such warnings would overdeter use of the medicine, reduce the labeling's effectiveness in communicating necessary information to doctors, and impair the value of federally mandated labeling by undermining physicians' ability to rely on the labeling as scientifically based and accurate.

Defendant's Motion, p.21.

Pfizer relies on many of the same regulations for its "frustration of purpose" argument that it relied on for its "impossibility of compliance" argument. Defendant's [*1097] Motion, p.21-22. **Pfizer** essentially argues that permitting a strengthened suicide warning in Zolof's labeling would violate the federal purpose - embodied in the regulations - of ensuring that doctors act on accurate, scientifically established information. But the Court has already found [**36] that plaintiff's state law failure to warn claims do not conflict with federal statutory prohibitions and requirements because those claims do not necessarily call for false and misleading labeling or labeling not based on scientific information. The Court therefore also finds that plaintiff's state law "failure to warn" claims for relief do not necessarily conflict with the regulations' straightforward purpose of ensuring that doctors receive accurate, scientifically based information.

Pfizer also argues that permitting plaintiff to proceed with these claims would conflict with congressional purposes, because it would "overdeter" use of Zolof. Defendant's Motion, p.21-23. According to **Pfizer**, "adding warnings that FDA has determined to be unsupported would give physicians a false impression of the risks entailed in prescribing the drug, thereby deterring its use ... [and] ... would inhibit physicians from using the drug to provide their patients the available benefit..." *Id.* at 22.

At the hearing on this motion, counsel for **Pfizer** indicated that three sources, independent of FDA, supported this assertion. The first is "A Report of the Surgeon General on Mental Health." Declaration [**37] of Dr. Roger Lane ("Lane Dec."), Exh. 2. The Court has read the excerpt of this report that **Pfizer** submitted. Although it states that SSRIs are "a first-choice medication in treating depressed suicidal children and adolescents" and that "the incidence of treatment related suicidal thoughts for the SSRIs is low and comparable to the rate observed for other antidepressants" it nowhere expressly addresses the issue of overdeterrence. Exh.2, p.58,61.

Next, **Pfizer's** counsel referred to a statement of the American Psychiatric Association ("APA"). The Court found one exhibit in Dr. Lane's

Declaration that the APA published but this document merely listed the "criteria for major depressive episode[s]" and has no relation to overdeterrence. Lane Dec., Exh.3. However, on November 28, 2000, the day after the hearing on this motion, **Pfizer** filed an APA "news release" to which **Pfizer's** counsel had referred. The "news release" concerns the FDA's denial of CCHR's petition to ban Prozac outright. It does indeed state that "our members have reported to us that the CCHR media campaign to discredit Prozac frightened many people with depression into discontinuing their medicine without first discussing [*38] it with their physicians, and discouraged others from seeking needed treatment." But the mere fact that a negative media campaign may have overdeterred prospective SSRI users does not mean that a modest warning label that Doctors could evaluate would do the same thing. Indeed, the "news release" itself states that psychiatrists routinely warn patients that antidepressants may contribute to suicidal action: "many patients, however, are so depressed that they don't have the energy to act on [suicidal] thoughts," "antidepressants ... may lead to an increase in energy before it eliminates suicidal thoughts" and "psychiatrists routinely alert patients and their families to this possibility...").

Third, **Pfizer's** counsel directed the Court's attention to the American College of Neuropsychopharmacology's Consensus Statement on Suicidal Behavior and Psychotropic Medication. Lane Dec., Exh.6. The Statement does assert that "there is no evidence that antidepressants such as ... fluoxetine trigger emergent suicidal ideation over and above rates that may be associated with depression and other antidepressants." Exh.6, p.112. However, the Statement does not explicitly address the overdeterrence [**39] issue. Moreover, it indicates that "case reports suggest that a small minority of patients may experience [*1098] emergent suicidal thoughts or evince such behavior during the pharmacological treatment of depression" and that "patients should be warned that suicidal ideation may occasionally worsen in the course of treatment ... and that such an event would be a reason for immediately contacting their doctor. Applying this standard clinical practice to all patients would constitute a reasonable safeguard in the event that there are, indeed, a small minority of vulnerable patients who are at risk for emergent suicidal ideation." *Id.* at 112, 114.

In sum, the Court finds an absence of persuasive evidence establishing a threat of overdeterrence from strengthening suicide warning labeling for SSRIs. Indeed, several of the sources suggest that overdeterrence is not a concern because they recommend providing modest warnings that antidepressants may contribute to suicidal thoughts or action.

Pfizer also asserts that FDA's own rationale for rejecting strengthened suicide warnings for SSRIs was concern about overdeterrence. In support, **Pfizer** cites to the opening remarks to a PDAC committee meeting [**40] of Dr. Paul Leber, the then-Director of the FDA Division of Neuropharmacological Drug Products. Leber stated that:

It is very difficult for us to be Solomon-like in situations as complex and vexing as this ... We have to recognize that the net effect" of "modifying antidepressant drug labeling" "might be a reduction in the use of antidepressants in the treatment of depression, and that the result might cause overall injury to the public health ... many letters we receive ... emphasize this point. Whether they are correct or not, I am not going to speak to that, but certainly it is a concern.

DSUF, P 37; Gaul Dec., Exh.14, p.662-3. Further, the "Excerpted Comments" of Dr. Leber's remarks state that "if Prozac is not more likely to induce suicidal thoughts, acts and other violent behaviors, a labeling change of the sort contemplated by some, beyond being false and misleading, might well have a net adverse effect." *Id.*

The Court is not persuaded that FDA has found or has relied on a finding that strengthened suicide warnings would overdeter SSRI use. First, Leber's comments state only that strengthened suicide warnings "*might*" overdeter SSRI use. Leber himself [**41] states that:

it is easy enough for me to understand why someone could conclude it would be constructive and in the interest of public health to inform individuals using the drug, and the practitioners, about the high rate of reporting ... It is not difficult to appreciate the arguments of those who advocate what have you got to lose? Why not at least point out that some people believe there is a special linkage between Prozac and suicidal ideation.

Exh.14, p.663. Leber's introductory comments set out different positions on SSRI labeling and do not discuss "whether they are correct or not." *Id.* at 662. Second, **Pfizer** has not established that Leber's ostensibly informal introductory comments to a committee meeting represent the formal position of the FDA.

The evidence **Pfizer** cites does not establish a threat of overdeterrence or a congressional purpose of preventing overdeterrence. n11 Thus, **Pfizer** has not presented surveys, statistical data or other facts. **Pfizer** may be correct in its assertion ... but it may not be. Potential users of Zoloft might continue to ingest it but simply be more vigilant about noticing the emergence of or an increase in suicidal ideation [**42] and more likely to call their doctor in the event of an adverse reaction.

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n11 **Pfizer** presents no legislative history or other evidence suggesting that in creating the FDA and enacting drug laws Congress intended to prevent or even considered overdeterrence of drug use.

-----End Footnotes----- [*1099]

Pfizer also argues, based on *Chicago and North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 101 S. Ct. 1124, 67 L. Ed. 2d 258 (1981), that preemption is appropriate because FDA's approval of **Pfizer's** labeling for Zoloft and determination that **Pfizer** was not required to add to the label should be "entitled to considerable deference." Defendant's Motion, p.25. In *Kalo Brick*, a shipper brought an action against a railroad to recover under state law for failure to provide adequate rail service. The railroad had abandoned a railroad line and, pursuant to the Interstate Commerce Act ("ICA"), the Interstate Commerce Commission ("ICC") had approved that abandonment. The Supreme Court held that the ICA preempted the shipper's state law claims. *Id.* at 327. [**43] **Pfizer** argues that *Kalo Brick* is instructive because in both that case and here an agency was empowered to approve defendant's challenged conduct, balanced the relevant interests

and then approved the conduct. Defendant's Motion, p.24-5.

Kalo Brick is inapposite. In that case, the Supreme Court specifically held that the "findings by the Commission, made pursuant to the authority delegated by Congress, simply leave no room for further litigation over the matters respondent seeks to raise in state court," *Id.* at 327. In accordance with that holding, the Court repeatedly emphasized the pervasive and exclusive nature of the ICA:

The [ICA] is among the most pervasive and comprehensive of federal regulatory schemes...The authority of the [ICC] to regulate abandonments is exclusive ... The breadth of the Commission's statutory discretion suggests a congressional intent to limit judicial interference ... The Act in fact spells out with considerable precision the remedies of a shipper ... Congress intended that an aggrieved shipper should seek relief in the first instance from the Commission ... It would vitiate the overarching congressional intent of creating [**44] an efficient an nationally integrated railroad system ... to permit the State of Iowa to use the threat of damages to do exactly what the Commission is empowered to excuse. A system under which each State could, through its own courts, impose on railroad carriers its own version of reasonable service requirements could hardly be more at odds with the uniformity contemplated by Congress in enacting the [ICA].

Chicago & North Western Trans. Co. v. Kalo Brick, 450 U.S. 311 at 318, 321-2, 323, 325-6, 67 L. Ed. 2d 258, 101 S. Ct. 1124. In contrast, several courts have held that food and drug regulation and FDA determinations regarding labeling standards are not so broad or exclusive as to preempt state law claims. See *supra* at p. 10-11. Because *Kalo Brick* was based largely on the pervasive and exclusive nature of the ICA, it does not require preemption here.

In sum, the Court finds that **Pfizer** has failed to establish that plaintiff's state law failure to warn claims conflict with congressional purposes.

In fact, the Court notes that permitting plaintiff's state law "failure to warn" claims may complement the congressional purposes of FDA regulations. **Pfizer** does not dispute that the FDA and its governing statute and regulations [**45] serve the purpose of enhancing drug safety. Defendant's Motion, p.20-21; 21 U.S.C. §§ 355(d) and 393(b)(2)(B). As plaintiff asserts, state law suits against drug manufacturers for defective drug design or failure to warn can serve the same public safety purpose as federal regulations by punishing perpetrators and thus preventing future harm. n12 *Bansemmer v. Smith* [*1100] *Labs*, 1988 U.S. Dist. LEXIS 16208, 1990 WL 132579, *3 (E.D. Wis. 1988). Indeed, state suits may complement the regulatory methods of promoting safety by directly flushing out more information about the risks of drugs and indirectly encouraging manufacturers to make complete risk disclosures to the FDA. *Id.* 1988 U.S. Dist. LEXIS 16208, at *10, *Id.* at *4 (quoting *Ferebee v. Chevron Chemical Co.*, 237 U.S. App. D.C. 164, 736 F.2d 1529, 1541-42 (D.C.Cir.1984). n13

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n12 The Court acknowledges that just because federal law and state law serve the same general purpose does not mean that no conflict can exist. Defendant's Motion, p.20 (citing *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913, 1923-25, 146 L. Ed. 2d 914 (2000)). However, the Court has examined **Pfizer's** asserted bases for a conflict and has rejected them. [**46]

n13 Plaintiff asserts that the FDA has itself acknowledged "the importance of jury verdicts and the fact that they can help the FDA learn about the dangers of drugs." Opposition, p.24. Plaintiff cites the following language from the FDA's denial of the CCHR petition to withdraw approval of Prozac: "On the other hand, an actual court finding of a causal relationship between Prozac and violent behavior would be relevant. In that event, the agency would be able to evaluate the scientific basis for the court's conclusion and consider whether the court's conclusion warranted a modification of its own position," Gaul Dec., Exh. 12, p.513. FDA made this comment in response to CCHR's assertion that several lawsuits had been filed against Lilly based on Prozac's alleged causation of tardive dyskinesia. FDA's response was that mere filings are irrelevant but that actual court findings could be. Although the factual context of the comment is different from the circumstances here (e.g., different drug, different alleged adverse effect), the comment nonetheless does indicate that judicial findings based on scientific evidence may play a role in FDA determinations and could affect FDA's position on the issue of health risks.

-----End Footnotes----- [**47]

B. Bar under California Law

Pfizer argues that plaintiff's California state law strict liability inadequate warning claims are barred under the California Supreme Court case of *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1115, 920 P.2d 1347 (1996). In *Carlin*, a prescription drug user brought a products liability action against a drug manufacturer for failure to warn about known or reasonably scientifically knowable dangerous propensities of a drug. Despite the defendant's argument that permitting plaintiff's strict liability claims to proceed would create a conflict with FDA labeling regulations, the Court held that plaintiff successfully stated a cause of action for strict liability premised on failure to warn. *Carlin*, 13 Cal. 4th at 1113, 1118. **Pfizer** nevertheless relies on the following dicta from *Carlin*:

In the case of an alleged "known" risk, if state-of-the art scientific data was fully disclosed to the FDA and it determined, after review, that the pharmaceutical manufacturer was not permitted to warn -- e.g., because the data was inconclusive or the risk was too speculative to justify a warning -- the manufacturer [**48] could present such evidence to show that strict liability cannot apply; the FDA's conclusion that there was, in effect, no "known risk" is controlling.

Carlin, 13 Cal. 4th at 1114-1115. Based on this dicta, **Pfizer** argues that because FDA has not found that SSRIs cause suicide, plaintiff cannot establish that **Pfizer** knew that SSRIs and Zolofit cause suicide and therefore cannot make out a strict liability claim. Defendant's Motion, p.15.

The Court rejects this argument. First, the language **Pfizer** relies on is only dicta and did not affect the Court's ultimate holding that plaintiff's claims *could* proceed. Second, the dicta refers only to the effect on FDA determinations on the issue of "known risks"; it does not say anything about the other possible basis that a plaintiff may, and that **Motus** did, assert for strict liability failure to warn claims - namely, that a manufacturer reasonably *should have known* about certain risks. Complaint, P 33 ("defendants knew or should have known that their product was unsafe."). Third, the dicta does not state that an FDA determination is wholly preemptive; it instead states merely that "the manufacturer could present [**49] such evidence [of FDA's determination] to show that strict liability cannot apply," which is consistent with the California

Supreme Court's statement that: "[i]n appropriate cases, FDA action or inaction, *though not* [*1101] *dispositive*, may be admissible ... to show whether a risk was known ..." [Carlin, 13 Cal. 4th at 1114, 1115](#) (emphasis added). Fourth, the dicta expressly states that it applies only to those situations in which FDA "determined, after review, that the pharmaceutical manufacturer was not permitted to warn ..." The Court has already found that FDA has never determined that **Pfizer** was not *permitted* to strengthen the Zoloft suicide warning, but instead determined only that **Pfizer** was not *required* to include strengthened warnings. For these reasons, *Carlin* is inapposite. n14

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n14 Plaintiff attacks *Carlin's* dicta because it requires that "state-of-the-art scientific data concerning the alleged risk was fully disclosed to the FDA..." and plaintiff asserts that **Pfizer** did not disclose all risk-related data to FDA. Opposition, p.10. It is not clear that this issue may be or need be evaluated by the Court and the Court does not reach it on this motion.

-----End Footnotes----- [**50]

CONCLUSION

For the foregoing reasons and good cause appearing therefor, the Court DENIES defendant's motion for partial summary judgment.

IT IS SO ORDERED.

DATE: December 12, 2000

A. Howard Matz

United States District Judge

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