showing of the contemporaneous observation of the injury of a close relative is required for a negligent infliction of emotional distress ("NIED") claim. *Brooks v. Decker*, 512 Pa. 365, 516 A.2d 1380, 1382 (1986) (father who came upon scene of accident after his son was struck by an automobile failed to state a claim for NIED because he did not witness the accident).

[19] Here, it is undisputed that Plaintiff came upon his wife's body after she had committed suicide. Whatever act or omission was allegedly undertaken by Defendants did not occur in Plaintiff's presence, which is required to establish the tort of infliction of emotion distress under either theory when it involves conduct directed at a third party. Plaintiff argues, however, that the *reasoning* articulated by Pennsylvania courts in requiring presence is that, in the absence of knowledge of the injury beforehand, the third party has no buffer against the full impact of observing the scene. Thus, he asserts that so long as the third party contemporaneously observes the *result* of the alleged intentionally outrageous or negligent conduct and has no warning of the incident before coming on the scene, the party sufficiently states a claim for infliction of emotional distress. Since he had no pre-warning of and thus no buffer against the full impact of observing the deceased Mrs. Colacicco after her suicide, Plaintiff therefore asserts both his IIED and NIED claims should survive this motion to dismiss. (Pl's Response to GSK at 14–17; Pl's Response to Apotex at 16–17).

Plaintiff misconstrues the caselaw, which clearly requires presence for both IIED and NIED. Both *Mazzagatti v. Everingham*, 512 Pa. 266, 516 A.2d 672 (1986), and *Bloom v. DuBois Regional Medical Center*, 409 Pa.Super. 83, 597 A.2d 671 (1991), although cited by Plaintiff, support Defendants' position. In fact, those courts dismissed the NIED counts for failure to plead the element of contemporaneous observance of traumatic infliction of injury by defendants. *See Mazzagatti*, 516 A.2d at 679 (mother who arrived at scene of accident after daughter was fatally injured by motorist not entitled to recover on theory of NIED); *Bloom*, 597 A.2d at 682–83 (husband who came upon wife who had attempted suicide at a psychiatric hospital had no cause of action for NIED because he did not witness defendants inflicting harm). Likewise, in *Taylor*, the parents of a patient who died during a catheterization procedure could not maintain an action for IIED because the mother was not present for the procedure and did not witness the physician's allegedly outrageous conduct. *Taylor*, 754 A.2d at 653. Accordingly, as with several of the individual claims above, even assuming *arguendo* that Plaintiff's complaint were not otherwise dismissed, the claims for intentional and negligent infliction of emotional distress (Counts V and VI) must still be dismissed.[35]

2. *Claims Sounding in Negligence*

Finally, we consider the individual causes of actions that sound in negligence. As discussed *supra* in Part VII.A.2, we hold that Apotex owed a duty of care to Plaintiff and Plaintiff's decedent, sufficient to give rise to liability against it. Therefore, while barred by preemption, Plaintiff's negligence-based claims against Apotex are unaffected by our conclusions: (1) as to the lack of a duty of care owed to GSK, and (2) as to both Defendants regarding *Hahn*, which explicitly allows a plaintiff to pursue inadequate warning

35. We also note the independent tort of IIED has never expressly been approved by the Pennsylvania Supreme Court. *Taylor*, 754 A.2d at 653.

claims under a theory of negligence. *Hahn*, 673 A.2d at 891. Therefore, if this Court's conclusion as to preemption were found improper, Apotex would have to respond to each individual claim sounding in negligence.

a. Negligence (Count VII)

[20] Under Pennsylvania law, the elements of negligence are: (1) a duty recognized by law, requiring the actor to conform to a certain standard of conduct for protection of others against unreasonable risks; (2) failure to conform to the standard required; (3) a causal connection between the conduct and resulting injury; and (4) actual loss or damage resulting to interests of another. *Griggs v. BIC Corp.*, 981 F.2d 1429 (3d Cir.1992) (citing *Morena v. South Hills Health Sys.*, 501 Pa. 634, 462 A.2d 680, 684 n. 5 (1983)).

There is no dispute that Plaintiff has adequately plead the second, third and fourth elements. However, Plaintiff cannot plead negligence without the existence of a duty, which Apotex urges is lacking in this case. (Def. GSK's Mem. at 6–8; Def. Apotex's Mem. at 23–24). However, as we previously held that Apotex owed a duty of care to Plaintiff and Plaintiff's decedent, if preemption did not bar Plaintiff's entire complaint, his negligence claim against Apotex would be adequate to survive this motion to dismiss.

b. Negligence per se (Count VIII)

Defendants also contend that the negligence *per se* claim is impliedly preempted, evidenced by the fact that there is no private right of action under the FDCA. (Def. GSK's Mem. at 9; Def. Apotex's Mem. at 25). *See In re Orthopedic Bone Screw Prods. Liability Litig.*, 159 F.3d 817, 824 (3d Cir.1998) ("Congress has not created an express or implied private cause of action for violations of the FDCA.").

[21] The doctrine of negligence *per se* liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, a standard of care appropriate to the underlying tort. Thus, if a plaintiff can show violation of a specific statute, this satisfies his or her burden of establishing duty and breach. Here, Plaintiff's negligence *per se* claim is premised on the alleged violation of the FDCA.

As discussed *supra* in Part VI, we hold all Plaintiff's claims, including that for negligence *per se*, are in fact barred by preemption.

c. Negligent Misrepresentation (Count IV)

Finally, Apotex urges that since it made no statements regarding efficacy and safety to the FDA, Plaintiff cannot show the required element of negligent misrepresentation that Apotex knew or should have known that certain representations were false. (Def. Apotex's Mem. at 19–20).

[22] The elements of negligent misrepresentation are as follows: (1) a misrepresentation of a material fact; (2) made under circumstances in which the party ought to have known its falsity; (3) with an intent to induce another to act on it, and; (4) which results in injury to a party acting in justifiable reliance on the misrepresentation. *Bortz*, 729 A.2d at 561; *Gibbs*, 647 A.2d at 890.

Accepting as true Plaintiff's averments that material submitted to the FDA and the labeling itself was intentionally false and misleading to the FDA, the general public, the decedent's physician, and decedent herself, and that decedent and her physician relied on this information, Compl. at 86–91, this claim must survive.

Also, it seems to this Court that even if Apotex did not make misrepresentations or material omissions to the FDA when it sought initial approval, Plaintiff's pleadings support the supposition that Apotex was also aware of an increased risk of suicide after approval and did not seek to strengthen its label. Compl. at 87–89. Accordingly, if Plaintiff's complaint were not otherwise dismissed, the Court would decline to dismiss the negligent misrepresentation claim.

d. Strict Liability (Count IX)

As discussed above, Defendants urge that *Hahn* holds that a manufacturer of drugs is not strictly liable for injury in connection with the use of prescription drugs. (Def. GSK's Mem. at 9–10; Def. GSK's Reply at 9). We need not re-visit Plaintiff's argument that *Hahn* does not apply at length; it suffices to say that as discussed *supra* in Part VII.C, we hold that *Hahn* clearly bars strict product liability claims against drug manufacturers, as well as any other failure-to-warn claim that does not sound in negligence. *Hahn*, 673 A.2d at 890.[36]

VIII. Conclusion

For the foregoing reasons, Defendants' Motions to Dismiss (Doc. Nos. 5 and 10) will be granted. An appropriate Order follows.

ORDER

AND NOW, this 26th day of May 2006, based on the foregoing memorandum and upon consideration of the pleadings and briefs, it is hereby ORDERED that:

1. Defendants' Motions to Dismiss (Nos. 5 and 10) will be GRANTED WITH PREJUDICE.

2. The Clerk shall close this case.

36. Even Plaintiff concedes that, on its face, *Hahn* appears to preclude his strict liability claim. (Pl's Supp. Mem. at 4).

Michael CARDELLO and Tracy Cardello, Plaintiffs,

v.

CRC INDUSTRIES, INC., et al., Defendants.

Civil Action No. 05–1773.

United States District Court, W.D. Pennsylvania.

May 31, 2006.

Background: Plaintiff brought products liability action against various defendants, in state court. One defendant removed.

Holding: The District Court, Lancaster, J., sua sponte, held that Federal Hazardous Substances Act (FHSA) did not completely preempt state law claims, precluding removal of case consisting exclusively of state claims.

Case remanded.

1. Removal of Cases ⇐25(1)

In order for state court suit to be removable, due to presence of federal question, that question must appear on the face of the complaint, unaided by the answer or petition for removal. 28 U.S.C.A. §§ 1331, 1441.

Briefs and Other Related Documents
McNellis ex rel DeAngelis v. Pfizer, Inc.D.N.J.,2006.Only the Westlaw citation is currently available.

United States District Court,D. 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.
No. Civ. 05-1286(JBS).

Sept. 29, 2006.

Gregory S. Spizer, Anapol, Schwartz, Weiss, Cohen, Feldman & Smalley, P.C., Cherry Hill, New Jersey, for Plaintiffs.
M. Karen Thompson, Steven A. Karg, Norris, McLaughlin & Marcus, P . A., Somerville, New Jersey, and Malcolm E. Wheeler, (pro hac vice), Wheeler, Trigg Kennedy, LLP, Denver, Colorado, for Defendant Pfizer, Inc.

OPINION

SIMANDLE, District Judge:

*1 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, bring this action contending that Zoloft, an antidepressant drug manufactured by Defendant Pfizer, Inc., ("Pfizer") 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, and that Pfizer is liable for failure to warn under New Jersey Product Liability Act. In 2005, Pfizer filed a motion for summary judgment arguing that Plaintiffs' state law tort claims are preempted by the Federal Food, Drug and Cosmetic Act (the "FDCA") and its implementing regulations. On December 29, 2005, this Court issued an Opinion (the "December 29 Opinion") and Order (the "December 29 Order") denying Pfizer's motion, without prejudice to renewal after a period of factual discovery. Presently before the Court is Pfizer's motion to vacate this Court's summary judgment order or, in the alternative, to certify under 28 U.S.C. § 1292(b) the December 29 Order for immediate interlocutory appeal. For the reasons expressed below, the Court will (1) deny Pfizer's motion to vacate this Court's December 29 Order but (2) will grant Pfizer's motion to certify the December 29 Order (as augmented by today's Order) for interlocutory appeal and, pursuant to 28 U.S.C. § 1292(b), stay the proceedings in this Court pending a determination by the Court of Appeals.

I. *BACKGROUND*

The Court will include only a brief summary of the relevant facts. Theodore DeAngelis ("DeAngelis") 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 antidepressant medications before Lexapro.

Plaintiff Beth Ann McNellis ("McNellis"), suing individually and as executrix of the estate of her father, DeAngelis,[FN1] claims that (1) Zoloft, a medication prescribed for Mr. DeAngelis, can and does "drive some people to their death" by suicide; (2) Pfizer failed to adequately warn Mr. DeAngelis's physician of risks of suicidality associated with Zoloft that had become apparent prior to his prescribing of Zoloft to Mr. DeAngelis; 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.)

FN1. McNellis and DeAngelis shall be referred to collectively as the "Plaintiffs."

*2 Plaintiffs' claims against Defendant Pfizer include allegations of (1) defective design, N.J.S.A. 2A:58C-2, *et seq.* (Count I), (2) failure-to-warn (Count II), (3) violations of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2, *et seq.* (Count III), and (4) 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 the FDA had authorized to be given verbatim. Pfizer filed a 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. On December 29, 2005, this Court denied Pfizer's motion. *See McNellis v. Pfizer, Inc.*, 2005 U.S. Dist. LEXIS 37505 (D.N.J. December 29, 2005).

This Court based its December 29, 2005 ruling in part on regulations of the Food and Drug Administration (FDA) at 21 C.F.R. § 314.70(c)(6) which, under certain circumstances, allows a pharmaceutical manufacturer to strengthen warnings while FDA approval is being sought for an enhanced warning. *See id.* Specifically, the Court held that "[i]f Plaintiffs can prove to the fact finder that Pfizer had, prior to January, 2003, 'reasonable evidence of an association of a serious hazard with a drug,' *see* 21 C.F.R. § 201.57(e), then the enhanced warning sought by Plaintiffs herein would not be preempted by the FDCA." *Id.* at *33.

Pfizer now brings this motion (1) to vacate this Court's December 29 Order or, (2) in the alternative, to certify the December 29 Order for interlocutory appeal, and (3) for an order staying discovery pending appeal. Pfizer moves to vacate the order on the basis that new evidence exists that establishes the actual meaning and intent of 21 C.F.R. § 314.70. Pfizer cites as new evidence a document published by the Food and Drug Administration ("FDA" or the "Agency") on January 24, 2006, about a month after this Court's December 29 Opinion, titled "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" (the "Final Rule"). The Final Rule, according to Pfizer, explicitly explained the agency's purposes, policies, and intent regarding Section 314.70, how the agency precludes any deviation in labeling notwithstanding the language of Section 314.70, and why preemption should apply in cases such as the present case. *See* 21 Fed.Reg. 3922, 3933-36, 3967-69 (Jan. 24, 2006). The FDA's new reading of its labeling regulations, the text of which is unchanged in relevant part, constitutes the new evidence that Pfizer posits in this motion to vacate.

II. *DISCUSSION*

A. *Pfizer's Motion to Vacate*

The district court has inherent power to vacate or revise its interlocutory orders before final judgment when justice so requires. *See Gallant v. Telebrands Corp.*, 35 F.Supp.2d 378, 394 (D.N.J.1998). An interlocutory order, such as the prior order herein denying summary judgment, may be vacated when there is newly discovered, non-cumulative evidence or in light of relevant changes in the facts or law of a case that would have altered earlier rulings by the Court. *See id.; see also Electric Mobility Corp. v. Bourns*, 87 F.Supp.2d 394, 401 (D.N.J.2000)("Reconsideration may be justified on the basis of an intervening change in law ... and is not necessarily barred by Local Civ. R. 7.1(g), requiring motions for reconsideration to be filed within ten days of an order.") Such a motion to vacate, however, is not intended as a vehicle to re-litigate issues that have already been decided. *See Gallant*, 35 F.Supp.2d at 394. Rather, "[i]n the absence of newly discovered, non-cumulative evidence, the parties should not be permitted to reargue previous rulings made in the case." *Id.*

1. The Preamble to the Final Rule is New Evidence

*3 In its submissions and at oral argument, Pfizer argues that there have been two significant developments since the December 29 Order which constitute new evidence and that this new evidence should cause the Court to reconsider its denial of Pfizer's earlier motion for summary judgment. The most significant development, Pfizer argues, is the issuance of the Final Rule on January of 2006. The preamble to the Final Rule (the "Preamble"), according to Pfizer, constitutes new, compelling evidence requiring vacation of this Court's December 29 Order because it

confirms the position the FDA had taken in amicus briefs in other cases that Pfizer had earlier submitted for consideration by this Court.[FN2] The second development is the recent decision of *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514 (E.D.Pa.2006), in which the court (1) gave deference to the FDA's interpretation (outlined in the Preamble) of its own regulations, and (2) held that the regulations to the FDCA preempt state failure-to-warn tort claims.
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> FN2. Specifically, Pfizer submitted amicus briefs from the *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir.2004) (the "*Motus* brief") and *Kallas v. Pfizer, Inc.*, No. 2:04-CV-0998 (Utah September 15, 2005)(the "*Kallas* brief"). Each of these briefs was considered herein previously and they are not "new."

Plaintiffs counter-argue that Pfizer's motion to vacate rests on a faulty premise-that the Preamble to the FDA's newly issued Final Rule constitutes new evidence. According to Plaintiffs, the Preamble simply repeats the same position that was already argued to and rejected by this Court. Plaintiffs point out numerous examples of where both Pfizer and the Court have explained that the issue before the Court on Pfizer's motion for summary judgment was whether the FDCA and the FDA's regulations conflict with New Jersey's failure-to-warn law and whether the state law cause of action is preempted. Now, according to Plaintiffs, Pfizer seeks the "unusual" relief of a motion to vacate because the FDA's position on the preemptive effect of its regulations-which is identical to the FDA's position as articulated in the *Motus* and *Kallas* amicus briefs-is now articulated in "an advisory preamble" to the Final Rule. (Pl.'s Opp. Br. at 5.) Plaintiffs continue, contending that the format for this advisory opinion is meaningless because the Preamble and the *Motus* and *Kallas* amicus briefs carry the same weight-they are both advisory positions from the FDA, *see* 21 C.F.R. § 10.80, and, thus, there is no new evidence before the Court. *See Gallant*, 35 F.Supp.2d at 378.

This Court disagrees with Plaintiffs and finds that the Preamble to the Final Rule is new evidence that should be considered in a motion to vacate. The Preamble is an official agency statement purporting to establish preemption of conflicting state law claims. At minimum, the Final Rule is an advisory opinion representing the formal position of the FDA. As an advisory opinion, it "represents the formal position of FDA on a matter and except [under unusual situations involving an immediate or significant danger to health], obligates the agency to follow it until it is amended or revoked." 21 C.F.R. § 10.85(e). The Preamble is also distinguishable from an amicus brief. Amicus briefs, by their nature, are drafted in the context of specific ongoing litigation. The *Motus* and *Kallas* briefs, for example, represent the FDA's position on an issue that is tailored to those particular cases. In contrast, in the Preamble, the Agency (1) put forth its general position on the preemptive effect of its regulations (rather than a position tailored to a particular case) and (2) is obligated to follow it until amended or revoked. *See* 21 C.F.R. § 10.85(e).

2. Although the Issuance of the Preamble is "New Evidence," it does not Warrant Vacation of this Court's December 29 Order

a. Pfizer's Argument

***4** Next Pfizer argues that the issuance of the Final Rule articulating the FDA's interpretation of its regulations (specifically, that the regulations preempt state tort law) requires this Court to vacate its December 29 Order. According to Pfizer, because the Preamble represents an administrative agency interpreting its own regulations, the FDA's interpretation of regulations related to the FDCA are entitled to substantial deference. *See Auer v. Robbins*, 519 U.S. 452 (1997)(courts must give an administrative agency's interpretation of its own regulations substantial deference). Specifically, Pfizer argues that, in the Preamble, the FDA reaffirms that "under existing preemption principles, FDA approval of labeling ... preempts conflicting or contrary State law." 71 Fed.Reg. at 3934. The Preamble to the Final Rule also addresses the factual situation where the FDA has specifically considered and rejected the warning a plaintiff advocates, and explains why such an action by a plaintiff would, if allowed to proceed, impair the Agency's safety purposes and policies. *Id.* Specifically, the Preamble states:

FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.

Id. at 3935. Pfizer argues that this statement explains why two positions that served as the basis for this Court's December 29 Order misinterpret the agency's regulations. First, the FDA states that its labeling regulations are not "minimum standards" (as the Court's Opinion holds) but "establish both a 'floor' and 'ceiling.' " *Id.* Second, the FDA states that Section 314.70-the FDA regulation that explicitly permits drug manufacturers to unilaterally strengthen warning labels at any time without regulatory pre-approval-negates the preemptive effect of labeling requirements and "conflicts with the agency's own interpretations" of its own regulations. *Id.* Rather, the FDA explains that Section 314.70 does not preclude preemption because the FDA remains the final arbiter of the form and content of all labeling regardless of whether the manufacturer may temporarily alter a medication's label.

Next Pfizer argues that the Final Rule also addresses why preemption precludes a plaintiff from arguing to a jury or court that a manufacturer withheld information from the FDA. The Preamble to the Final Rule states that the FDA precludes:
[C]laims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which has been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn.)

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***5** 21 Fed.Reg. at 3936; *see Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 352-53 (2001) ("fraud on the FDA" theories are preempted by federal law); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir.2004) (affirming district court decision finding preemption because "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.")

b. Analysis

The FDCA contains no explicit preemption of state law as to labeling of pharmaceutical drugs, as Congress has historically declined to take this step. FN3 If the FDCA is seen as preempting state tort claims for failure to warn, it is only through conflict preemption that this can occur. Absent such language, this Court's inquiry 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) (internal quotations omitted).

> FN3. In contrast, the Medical Devices Amendment of 1976 to the FDCA contains an express preemption provision that is considerably broader than the limiting principle 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,' [a Medical Devices Amendment] requirement applicable to the medical device at issue." *McNellis*, 2005 U.S. Dist. LEXIS at *30 (citing 21 U.S.C. § 360k(a)).

This Court must be mindful that 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 superceded by the Federal Acts 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). With this in mind, this Court finds that, despite the issuance of the Preamble in January of 2006, vacation of the Court's December 29 Order is not warranted for two reasons. First, the text of the regulatory language upon which this Court seized in rejecting Pfizer's preemption argument (i.e.,

that a drug manufacturer is permitted to unilaterally strengthen the warnings on its labels under certain circumstances) was not changed in the Final Rule amendments. Indeed, the text of the relevant FDA regulations has been unchanged for years. As such, there can be no conflict preemption because the FDA's regulations do not conflict with New Jersey's failure-to-warn laws. Second, while the Court's deference to the agency's interpretation is substantial, it is not dispositive of the issue because (1) the FDA's position regarding the preemptive force of its regulations has not been consistent, requiring this Court to give it less deference, (2) the regulations at issue empower drug manufacturers to enhance the labeling warnings beyond the approved text when new risks emerge (otherwise, these regulations would have no meaning at all), and (3) as this Court explained in its December 29 Opinion, this Court finds certain of the cases Pfizer relies on in support of their argument unpersuasive, as they interpret medical device labeling regulations that contain an express preemption clause, while the Food, Drug and Cosmetic Act does not.

1. The FDA's Final Rule Does Not Conflict with New Jersey's Failure-to-Warn Law

*6 In its December 29 Opinion, this Court found that no conflict existed as a result of Pfizer's alleged inability to comply with both state and federal requirements. *McNellis,* 2006 U.S. Dist. LEXIS at *16-17. In making this conclusion, the Court noted that the FDA's regulations at issue "explicitly permit drug manufacturers to unilaterally strengthen warning labels at any time without regulatory pre-approval." *Id.* at *17 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)). Moreover, when discussing FDA regulations that permit a drug manufacturer to "add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage" or "add or strengthen an instruction about dosage or administration that is intended to increase the safe use of the drug product" without prior approval, *see* 21 C.F.R. § 314.70(c)(6)(iii)(B)-(C), this Court held that "[t]hese 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.' " *Id.* at *17 (citing 21 C.F.R. § 201.57(e)). The Court concluded that "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." *Id.* at *18.

Here, vacation of this Court's December 29 Order is not warranted because the regulatory language seized upon by the Court in rejecting Pfizer's preemption arguments (*see* 21 C.F.R. § 201.57(e) and 314.70(c)(6)) is unaffected by the rule amendments articulated in the Final Rule. FDA regulations explicitly allow a manufacturer to add or strengthen warnings without prior FDA approval. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A). Indeed, the amended version of 21 C.F.R. § 201.57(e) (which will be recodified as 21 C.F.R. § 201.80(e)) will still place an affirmative responsibility upon drug manufacturers to revise a drug's label to "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." 21 C.F.R. § 201.57(e)). As such, the FDA's approved warnings will continue to reflect merely "minimum standards," to be enhanced as soon as new evidence of a serious hazard exists, whether or not a causal relationship is proved. To the extent that the Preamble purports to forbid a manufacturer from enhancing the warning when reasonable evidence of an association of a serious hazard emerges, the Preamble is squarely contradicted by the plain language of the regulations themselves, namely, 21 C.F.R. § 314.70(c)(6)(iii)(A) and 21 C.F.R. § 201.57(e).

The Preamble's words are in irreconcilable tension with the Final Rule itself. Specifically, the Final Rule states:

While a sponsor is permitted to add risk information to the [full prescribing information] without first obtaining FDA approval via a [change being effected] supplement, FDA reviews all such submission and may later deny approval of the supplement, and the labeling remains subject to enforcement action if the added information makes the labeling false or misleading under Section 502(a) of the Act.

*7 71 Fed.Reg. at 3934. Thus, despite the issuance of

the Final Rule and the language existing in the Preamble, the rationale of the Court's December 29 Opinion remains sound.

2. The Preamble Cannot be Enforced to Nullify the FDA's Own Regulations it Purports to Interpret.

As discussed previously, under the Final Rule, 21 C.F.R. § 314.70(c)(6)(iii) will still explicitly permit a drug manufacturer to change the labeling of a drug in order to "add or strengthen a contraindication, warning, precaution or adverse reaction...." Moreover, the amended version of 21 C.F.R. § 201.57(e) (now 21 C.F.R. § 201.80(e)) will still place an affirmative duty upon drug manufacturers to revise a drug's label to include a warning "as soon as there is reasonable evidence of an association of serious hazard with a drug...." If drug manufacturers were to follow the FDA's interpretation of these regulations as set out in the Preamble-which states that the FDA's labeling requirements are not "minimum standards" and that, instead, those regulations "establish both a 'floor' and a 'ceiling,' " *see* e 21 Fed.Reg. at 3934,-drug manufacturers would be precluded from enhancing a warning on their own. As such, the Preamble cannot be enforced as doing so would nullify Section 314.70(c)(6)(iii) and Section 201.57(e). An agency's interpretation of its own regulations which would nullify those regulations is not entitled to controlling weight.

3. The Interpretation Set Out in the Preamble is Not Entitled to Substantial Deference Because the FDA's Position Regarding Preemption has not been Consistent.

According to Pfizer, the FDA's interpretation of its own regulation (Section 314.70) is controlling unless that interpretation is "clearly erroneous" or "inconsistent" with FDA regulations; here, Pfizer continues, the FDA's conclusion that Section 314.70 does not preclude preemption is "neither plainly erroneous nor contrary to any FDA regulation." (Def.'s Br. at 7.) Pfizer also argues that the FDA's assessment of the preemptive effect of its actions is also entitled to substantial deference. In support of this position, Pfizer cites *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which the Supreme Court held that the FDA, in interpreting the express preemption provision of the Medical Devices Act (21 U.S.C. § 360(k)), "is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the ... execution of the full purpose of objective of Congress,' and therefore, whether it should be preempted." 518 U.S. at 496 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). This is because the FDA has a "special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether ... state requirements may interfere with federal objectives." *Id.* at 506 (Breyer, J., concurring). The Supreme Court has ruled similarly with respect to the deference a court must give to the Department of Transportation's interpretation of its regulations. *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 883 (2000) (holding that because the underlying "subject matter is technical" and the background into the issue "complex and extensive," the Department of Transportation was "uniquely qualified to comprehend the likely impact of state requirements.") Thus, according to Pfizer, the Court should vacate its December 29 Order and grant Pfizer summary judgment because Plaintiffs' claims are preempted by the FDCA.

***8** For the reasons next discussed, this Court, as it did in its December 29 Opinion with respect to legal positions taken by the FDA in amicus briefs, declines to give the Preamble preemptive force of law for two reasons. First, according to recent Supreme Court precedent, this Court is required to give less deference to an agency's interpretation of its own regulations if the agency's interpretation of those regulations has not been consistent. Second, this Court finds that the majority of cases cited by Pfizer in support of its argument that this Court should grant deference to the FDA's interpretation of its regulations involve the agency's interpretation of an express preemption clause. As such, these arguments carry little weight in this Court's determination of the present regulations.

(i) Inconsistency between the FDA's 2006 Preamble and the 2000 Proposed Rule

In determining the amount of deference to give to agency interpretations of their own regulations, this

Court must consider whether an agency's interpretation of its own regulations has been consistent. *See United State v. Mead Corp.*, 533 U.S. 218, 228 (2001) ("The fair deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to (1) the degree of the agency's care, (2) its *consistency*, formality and relative expertness ....") (emphasis added); *see also Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993) ("[T]he consistency of an agency's position is a factor in assessing the weight that position is due.") The Supreme Court has affirmed this stance towards deference to the FDA's interpretation of the Public Health Services Act, *see Hillsborough County v. Automated med. Labs, Inc.*, 471 U.S. 707, 714 (1985), [FN4] and more recently in the Environmental Protection Agency's interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act. *See Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005).[FN5]

> FN4. In *Hillsborough County*, when discussing the amount of deference to give to the FDA's interpretation of the FDA's blood plasma regulations, the Court stated "[t]he FDA's statement is dispositive on the question of implicit intent to pre-empt *unless* either the agency's position is *inconsistent* with clearly expressed congressional intent, or subsequent developments reveal a change in that position." *Hillsborough County*, 471 U.S. at 714 (emphasis added).
>
> FN5. In *Bates*, the Supreme Court rejected the Environmental Protection Agency's position supporting preemption, explaining that the agency's argument in favor of preemption was "particularly dubious given that just five years ago the United States advocated the interpretation [i.e., no preemption] that we adopt today." 544 U.S. at 449.

Here, the FDA's interpretation of regulations in 2006 (as expressed in the Preamble to the Final Rule) is in stark contrast to the FDA's position regarding the same regulations outlined in the FDA's 2000 Proposed Rules. As discussed previously, in the Preamble to Final Rule, which represents the finalized version of a proposal that was originally published in December 2000, the FDA fields comments submitted in response to the original proposal. In particular, the FDA addresses a number of comments expressing concern that the new labeling requirements "might have product liability implications" and requesting that the FDA "state in the final rule that FDA approval of labeling ... preempts conflicting and contrary State law, regulations, or decisions of a court of law...." 71 Fed.Reg. at 3933-34. In responding to those comments, the Final Rule discusses why, in its view, FDA regulations preempt State law tort claims.

The position of the FDA as outlined in the Final Rule is opposite to the position of the FDA as stated in its December 2000 proposal of the same amendments (the "2000 Proposal.") *See* 65 Fed.Reg. 81082 (Dec. 22, 2000). The 2000 Proposal explicitly stated that its regulations *do not* have preemptive effect. *See id.* Rather, the preamble to the 2000 Proposal explained that the FDA did not want its regulations to preempt state tort law, stating that "there should be little, if any, impact from this rule, if finalized, on the States" and that the "FDA has determined that this proposed rule *does not* contain policies that have federalism implications or that *preempt State law.*" *Id.* [FN6] (emphasis added).

> FN6. The Court notes too that the position taken by the FDA in the 2000 Proposal was entirely consistent with the position the Agency took in 1998 in the Preamble to the new regulations regarding consumer medications guides. *See* 63 Fed.Reg. 66378 (Dec. 1, 1998.) Specifically, the comments stated that:
>
> FDA's regulations establish the minimum standards necessary, but were not intended to preclude the states from imposing additional labeling requirements. States may authorize additional labeling....
>
> *Id.*

***9** Also contained in the 2000 Proposal is a discussion of "Executive Order 13132: Federalism." *Id.* at 81103. In the 2000 Proposal, the FDA states that it has "analyzed this proposed rule in accordance with Executive Order 13132: Federalism ... [which] requires Federal agencies to carefully examine actions

to determine if they contain policies that have federalism implications or that preempt State law" and concluded that:
Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule, if finalized, on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of Government. In addition, *this proposed rule does not preempt State law.* Accordingly, FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.

Id. (emphasis added). However, in the Preamble to the Final Rule in 2006, the FDA has changed its position on the preemptive effect of the very same regulations while still maintaining that the FDA complied with Executive Order 13132:[The FDA has] analyzed this final rule in accordance with the principles set forth in Executive Order 13132[and][h]ere, FDA has determined that the exercise of State authority conflicts with the exercise of Federal authority under the act.

In conclusion, the agency believes that it has complied with all of the applicable requirements under Executive Order 13132 and has determined that this final rule is consistent with the Executive order.

71 Fed.Reg. at 3967-68.

Because of the unexplained change in position, under the rule in *Bates* and *Hillsborough,* this Court must give less deference to the FDA's interpretation of its regulations.

Further, the 2006 Preamble was a novation, not subjected to prior public notice or comment while inverting the agency philosophy standing behind the regulations when proposed in 2000. While an agency's explanatory statement, composed after receiving comment upon the duly-published proposed regulations, is admittedly not itself subject to notice and comment before final publication, the abrupt rejection of the agency's own prior interpretation (while the regulations themselves are unchanged) suggests a degree of informality yielding an interpretation unhinged from the text and original intent of the regulations themselves.

(ii) The case law cited by Pfizer does not support its position that the FDA's interpretation should be given deference

Finally, as noted in the December 29 Opinion, the case law cited by Pfizer does not support its argument that the FDA's most recent opinion on preemption (i.e., the Preamble) is entitled to deference. Specifically, Pfizer cites *Medtronic, Inc. v. Lohr,* in which the Supreme Court held, in the context of medical devices, that the FDA "is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the ... execution of the full purpose of objective of Congress,' and therefore, whether it should be pre-empted." 518 U.S. at 496 (quoting *Hines,* 312 U.S. at 67); *see also Horn,* 376 F.3d at 171 (holding that, while the FDA's interpretation of statutes it has been charged by Congress with enforcing is not fully dispositive of the issues in the case, "the Supreme Court has instructed us that the FDA's preemption determinations are significant and should inform our interpretation" of the preemption clause of the Medical Device Amendments to the FDCA.)

***10** As noted in the December 29 Opinion, "the issue before this Court is not one of express preemption, as presented in those cases [i.e., *Medtronic* and *Horn*] addressing the language set forth explicitly by Congress in the Medical Device Amendments ("MDA") of 1976 to the FDCA." *McNellis,* 2005 U.S. Dist. at *30. In *Medtronic,* the Supreme Court afforded deference to the FDA's determination of the preemptive effect of the medical device labeling regulations because it found that Congress had included an express preemption clause in the statute that explicitly authorized the FDA to preempt state law. *Medtronic,* 518 U.S. at 496. Congress, however, "did not extend such preemptive force to the regulation of pharmaceutical drugs in the FDCA." *McNellis,* 2005 U.S. Dist. at *30.

Thus, the reasoning in *McNellis* remains sound and this Court will not vacate its December 29 Order. The Preamble, without more, does not signal to this Court Congressional intent to obviate state law. The issu-

ance of the Preamble does not change the fact that Congress has not expressed an intent to preempt state failure-to-warn laws with respect to pharmaceutical drugs. *See e.g.*, Bates, 544 U.S. at 449 ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.") Thus, this Court remains "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 clear and compelling Congressional statement." *McNellis*, 2005 U.S. Dist. at *31.

3. The Recent Decision in *Colacicco v. Apotex, Inc.* does not Warrant Vacation of this Court's December 29 Order

In its supplemental submissions to this Court and at oral argument, Pfizer urges this Court to follow the recent decision of *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514 (2006) in which a district court in the Eastern District of Pennsylvania granted summary judgment in favor of a defendant-pharmaceutical company on grounds that the FDA's regulations preempt state failure-to-warn laws. Specifically, in *Colacicco*, the district court gave substantial deference to the FDA's interpretation of its own regulations-as outlined in the Preamble-including the FDA's interpretation that Section 314.70 preempts state tort law. *See id.*

Having considered the holding in *Colacicco*, this Court will not depart from its holding that the Preamble should not be afforded the force of law. First, it is fundamental, but bears repeating, that *Colacicco* is not binding on this Court. Thus, while the *Colacicco* opinion is persuasive authority on this Court, the holding is not controlling. Second, for the reasons discussed *supra*, this Court respectfully disagrees with *Colacicco* that the "principles of deference do not allow [the Court] to question the FDA's interpretation of its own regulations ..." or that the Court must defer to the FDA's interpretation of its own regulations. *Id.* at 528. This overstates the deference due to an agency's interpretation under the present circumstances. Under well-settled precedent, where Congress has given no implicit empowerment to the FDA to preempt state law when the FDA deems it appropriate, this Court can not conclude that a high degree of deference is warranted where (1) the agency's interpretation has been inconsistent and (2) where there is no ambiguity in the federal regulations in question here. As such, the Court concludes that the recent decision in *Colacicco* does not warrant vacation of this Court's December 29 Order.

B. *Pfizer's Motion for Interlocutory Appeal*

***11** As an alternative to vacating this Court's December 29 Order, Pfizer advocates that the Court certify the Order for immediate interlocutory appeal. Under 28 U.S.C. § 1292(b), interlocutory review is appropriate if the appeal (1) involves a controlling question of law; (2) there is a "substantial ground for difference of opinion" about that question of law; (3) and where immediate appeal may materially advance the ultimate termination of the litigation.[FN7] *See Katz v. Carte Blanche Corp.*, 496 F.2d 747, 754 (3d Cir.1974). Interlocutory appeal under § 1292(b), however, is to be "used sparingly" and only in "exceptional" cases. *Holmes v. Honda Motor Co.*, 936 F.Supp. 195, 208 (D.N.J.1996) (citing 16 Charles A. Wright, et al., *Federal Practice and Procedure*, § 3929 at 132 (1977)); *see Gardner v. Westinghouse Broadcasting Co.*, 437 U.S. 478, 480 (1977). As such, even if Pfizer meets all three requirements, this Court may still deny certification as the decision to deny certification is entirely within the Court's discretion. *See Bachowski v. Usery*, 545 F.2d 363 (3d Cir.1976). According to Pfizer, the preemption issue presented satisfies all three prongs of the interlocutory appeal test, while Plaintiffs oppose interlocutory appeal.

FN7. Section 1292(b) ("Interlocutory decisions") states, in pertinent part:
When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such or-

> der. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order....
> 28 U.S.C. § 1292(b).

1. Controlling Question of Law

The Third Circuit Court of Appeals has held that a "controlling question of law" is one in which, either: (1) if decided erroneously, would lead to reversal on appeal; or (2) is "serious to the conduct of the litigation either practically or legally." *See* Katz, 496 F.2d at 755 (citations omitted); *see* Public Interest Research Group of N.J., Inc. v. Hercules, Inc., 830 F.Supp. 1549, 1554 (D.N.J.1993). The Third Circuit has held that the preemptive scope of federal law is a "controlling question of law" for interlocutory appeal purposes. *See* Cipollone v. Liggett Group, Inc., 789 F.2d 181, 183 (3d Cir.1986) (finding that question of whether Federal Cigarette Labeling and Advertising Act preempts state common law claims granted review under Section 1292(b)); *see also* C.E.R.1988, Inc. v. Aetna Casualty and Surety Co., 386 F.3d 263 (3d Cir.2004) (accepting for interlocutory appeal the question whether National Flood Insurance Program preempted state tort claims).

Here, there is little question that the preemption issue would be dispositive if decided in Pfizer's favor and therefore is "controlling" under either definition advanced by the Third Circuit in *Katz*. In addition, Plaintiffs concede that the summary judgment decision is a controlling question of law. (Pl.'s Opp. Br. at 15.) As such, this Court finds Pfizer has satisfied the first requirement of the three-prong test.

2. Substantial grounds for a difference of opinion

The second requirement for an interlocutory appeal is that the question of law at issue present "substantial grounds for a difference of opinion." 28 U.S.C. § 1292(b). Here, there is sufficient grounds for a difference of opinion for two reasons.

*12 First, numerous conflicting decisions can constitute a sufficient basis for the finding that substantial differences of opinion exist. *See* White v. Nix, 43 F.3d 374, 378 (8th Cir.1994) (conflicting and contradictory opinions provide substantial grounds for a difference of opinion); *see also* Oyster v. Johns-Manville Corp., 568 F.Supp. 83, 88 (E.D.Pa.1983) (identification of "a sufficient number of conflicting and contradictory opinions" would provide substantial ground for disagreement). Here, the district courts throughout the country have come to different conclusions when addressing the same issue of law addressed by this Court in its December 29 Opinion. Specifically, the cases of *Colacicco, Dusek v. Pfizer, Inc.* and *Needleman v. Pfizer, Inc.* have held that state failure-to-warn claims were preempted by the FDCA and the FDA regulations. *See* Colacicco, 432 F.Supp.2d at 536; *Dusek v. Pfizer, Inc.*, No. 02-3559, 2004 U.S. Dist. LEXIS 28056 (S.D.Tex. Feb. 20, 2004) and *Needleman v. Pfizer, Inc.*, No. 03-3074, 2004 U.S. Dist. LEXIS 15495 (N.D.Tex. Aug. 6, 2004). In contrast, a number of recent decisions addressing the same issue have held, consistent with this Court's December 29 Opinion, that the FDA regulations establish minimum requirements such that they do not preempt state laws. *See* Jackson v. Pfizer, Inc., 432 F.Supp.2d 964 (2006); *Madden v. Wyeth*, No. 03-0167, 2005 U.S. Dist. LEXIS 19989 (N.D.Tex.2005); Witczak v. Pfizer, 377 F.Supp.2d 726 (D.Minn.2005); *Sybinski v. Pfizer*, No. YC047439 (Cal.Super. Ct., County of Los Angeles, July 12, 2005); *Zikis v. Pfizer*, No. 04-8104, 2005 U.S. Dist. LEXIS 27253 (N.D.Ill. Nov. 8, 2005); *Miles v. Pfizer*, 03-731C (M.D.La. Mar. 30, 2005); and Cartwright v. Pfizer, Inc., 369 F.Supp.2d 876 (E.D.Tex.2005). Such a split in authority certainly constitutes a "sufficient number of conflicting and contradictory opinions."

Second, this Court can rest its conclusion that a substantial difference of opinion exists on the fact that the FDA's position-as established in the Preamble to the Final Rule-that Section 314 .70 requires a finding of preemption, is in contrast to this Court's conclusions in its December 29 Opinion and today. Thus, Pfizer has satisfied the second prong of the analysis.

3. Resolution of Issues Will Materially Advance the Termination of Litigation

Third, Pfizer must prove that resolution of the issue to be appealed will materially advance the termination of the litigation. *See* 28 U.S.C. 1292(b). This presents a closer issue. One "critical requirement [is] that [an interlocutory appeal] have the potential for substantially accelerating the disposition of the litigation." *In re Duplan Corp.*, 591 F.2d 139, 148 n. 11 (2d Cir.1988). According to Pfizer, because none of Plaintiffs' claims can survive the dismissal of their failure-to-warn claim, the resolution of this issue may terminate this litigation at the summary judgment stage. Plaintiffs disagree. According to Plaintiffs, any grant of interlocutory review would have the opposite effect as it would halt this litigation as the Third Circuit reviewed the issue.[FN8]

> FN8. Plaintiffs also contend that, "because the Court's finding is so clearly supported by case law ... the Third Circuit would in all likelihood affirm the District Court's finding and trial would proceed as intended originally." (Pl.'s Opp. Br. at 17.)

*13 In the December 29 Opinion and Order, this Court provides a roadmap by which a limited period of discovery will be undertaken during which Plaintiffs may acquire essential information and provide an expert's report, to determine whether Pfizer had "knowledge of a heightened risk of suicidality, which should have resulted in enhanced labeling beyond the FDA-approved warning." *McNellis*, 2005 U.S. Dist. LEXIS 37505 at *33. Specifically, the Court stated:

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.

Id. at *33. If Plaintiffs then have no evidence, then their case cannot withstand summary judgment and the case will be over soon. If Plaintiffs survive summary judgment, then they will have demonstrated a reasonable basis upon which Pfizer shall have enhanced its warning of suicidality consistent with the governing regulations, 21 C.F.R. § 314.70(c)(6)(iii) and 201.57(e), and there is no conflict between the FDCA and the New Jersey Product Liability Act, and hence no conflict preemption. It is tempting to let this case go forward to this phase of renewal of the Defendant's summary judgment motion to test whether Plaintiffs can meet this standard, consistent with the FDA's regulations.

On balance, however, given the dispositive nature of the preemption issue, immediate appellate review will prevent the needless expenditure of resources on further discovery and renewed summary judgment motion practice, in the event Defendant were to succeed on appeal.

III. *CONCLUSION*

For the reasons discussed above, Pfizer's motion to vacate this Court's December 29 Order will be denied. The Court finds that the FDCA does not preempt a plaintiff from claiming that an FDA-approved warning was inadequate under State law if the plaintiff is able to demonstrate that the manufacturer knew of "reasonable evidence of an association of a serious hazard with a drug" and thus had a duty to supplement its warning under 21 C.F.R. § 201.57(e). While Pfizer has demonstrated that new evidence (in the form of the Preamble) exists, this Court is not persuaded that the Preamble should be given the force of law under the circumstances explained above, nor should it persuade this Court to vacate its December 29 Order. However, this case is appropriate for interlocutory review as the appeal meets all three criteria under 28 U.S.C. § 1292(b). As such, this Court will grant Pfizer's motion to certify the Order for immediate interlocutory appeal.[FN9] Finally, because this Court is certifying the Order for immediate interlocutory appeal, it is appropriate for this Court to stay the proceedings pending a determination by the Court of Appeals.

> FN9. The precise question to be certified for interlocutory appeal is stated:
> Whether that the United States Food and Drug Administration's requirements for the form and content of the labeling for the prescription antidepressant Zoloft preempted New Jersey's failure-to-warn law, under the

> doctrine of conflict preemption, where the FDA's regulations at 21 C.F.R. 201.57(e) and 314.70(c)(6)(iii) permit a manufacturer to unilaterally enhance its warning when the manufacturer has reasonable evidence of an association of a serious hazard with a drug.

The accompanying Order is entered.

D.N.J.,2006.
McNellis ex rel DeAngelis v. Pfizer, Inc.
Slip Copy, 2006 WL 2819046 (D.N.J.)

Briefs and Other Related Documents (Back to top)

- 2006 WL 1042666 (Trial Motion, Memorandum and Affidavit) Defendant Pfizer Inc's Reply in Support of its Motion to Vacate, or in the Alternative for Certification of Interlocutory Appeal and for A Stay Order (Mar. 9, 2006) Original Image of this Document (PDF)
- 2006 WL 1042664 (Trial Motion, Memorandum and Affidavit) Plaintiff's Response in Opposition to Defendant's Motion to Vacate the Court's Order of December 29, 2005 and to Enter Summary Judgment in Favor of Pfizer Inc. or, in the Alternative, for an Order 1) Certifying the Court's December 29, 2005 Order for Interlocutory Appeal Under 28 U.S.C. 1292(B), 2) Certifying the Court's Order Denying Pfizer's Motion to Vacate the Court's December 29, 2005 Order for Interlocutory Appeal Under 28 U.S.C. 1292(B), and 3) Staying Discovery Pending Appeal. (Mar. 2, 2006) Original Image of this Document (PDF)
- 2006 WL 1042665 (Trial Motion, Memorandum and Affidavit) Plaintiff's Response in Opposition to Defendant's Motion to Vacate the Court's Order of December 29, 2005 and to Enter Summary Judgment in Favor of Pfizer Inc. or, in the Alternative, for an Order 1) Certifying the Court's December 29, 2005 Order for Interlocutory Appeal Under 28 U.S.C. 1292(B), 2) Certifying the Court's Order Denying Pfizer's Motion to Vacate the Court's December 29, 2005 Order for Interlocutory Appeal Under 28 U.S.C. 1292(B), and 3) Staying Discovery Pending Appeal. (Mar. 2, 2006) Original Image of this Document (PDF)
- 2006 WL 379411 (Trial Motion, Memorandum and Affidavit) Defendant Pfizer Inc's Memorandum of Law in Support of its Motion to Vacate, or in the Alternative for Certification of Interlocutory Appeal and for A Stay Order (Jan. 30, 2006)
- 2005 WL 923702 (Trial Pleading) Answer, Separate Defenses, Request for Exemption from Compulsory Arbitration Under L.CIV.R. 201.1, Certification Under L.CIV.r. 11.2, and Certification of Service, on Behalf of Pfizer INC. (Mar. 24, 2005)
- 1:05cv01286 (Docket) (Mar. 4, 2005)

END OF DOCUMENT

Briefs and Other Related Documents

Levine v. WyethVt.,2006.

Supreme Court of Vermont.

Diana LEVINE

v.

WYETH.

No. 2004-384.

Oct. 27, 2006.

On Appeal from Washington Superior Court, Geoffrey W. Crawford, J.

Richard I. Rubin and Kerry B. DeWolfe of Rubin, Kidney, Myer & DeWolfe, Barre, for Plaintiff-Appellee.

Allan R. Keyes and R. Joseph O'Rourke of Ryan, Smith & Carbine, Ltd., Rutland, and Bert W. Rein, Karyn K. Ablin and Sarah E. Botha of Wiley Rein & Fielding LLP, and Daniel S. Pariser of Arnold & Porter LLP, Washington, D.C., for Defendant-Appellant.

Present: REIBER, C.J., DOOLEY and JOHNSON, JJ., and MORRIS, D.J., and ALLEN, C.J. (Ret.), Specially Assigned.

¶ 1. JOHNSON, J.

Defendant Wyeth, a drug manufacturer, appeals from a jury verdict in favor of plaintiff Diana Levine, who suffered severe injury and the amputation of her arm as a result of being injected with defendant's drug Phenergan. Plaintiff claimed at trial that defendant was negligent and failed to provide adequate warnings of the known dangers of injecting Phenergan directly into a patient's vein. Defendant argues that the trial court should not have allowed the jury to consider plaintiff's claims because the claims conflict with defendant's obligations under federal law regulating prescription drug labels. We hold that there is no conflict between state and federal law that requires preemption of plaintiff's claim. Defendant also raises two claims of error relating to the jury instructions on damages. We hold that the court's rulings on these jury instructions were correct, and we affirm.

¶ 2. In April 2000, plaintiff was injected with defendant's drug Phenergan at Northeast Washington County Community Health, Inc. ("the Health Center"). The drug was administered to treat plaintiff's nausea resulting from a migraine headache. Plaintiff received two injections. The drug was first administered by intramuscular injection. Later the same day, when plaintiff's nausea continued, she received a second dose by a direct intravenous injection into her arm, using a procedure known as "IV push." The second injection resulted in an inadvertent injection of Phenergan into an artery. As a result, the artery was severely damaged, causing gangrene. After several weeks of deterioration, plaintiff's hand and forearm were amputated.

¶ 3. Plaintiff brought a superior court action for negligence and failure-to-warn product liability, alleging that defendant's inadequate warning of the known dangers of direct intravenous injection of Phenergan caused her injuries. During a five-day jury trial, both parties presented expert testimony regarding the adequacy of the warnings defendant placed on Phenergan's label. Plaintiff's experts testified that the label should not have allowed IV push as a means of administration, as it was safer to use other available options, such as intramuscular injection or administration through the tubing of a hanging IV bag. Defendant's expert testified that allowing IV push with instructions cautioning against inadvertent arterial injection was sufficient. The court instructed the jurors that they could consider the FDA's approval of the label in use at the time of plaintiff's injury, but that the label's compliance with FDA requirements did not establish the adequacy of the warning or prevent defendant from adding to or strengthening the warning on the label. At the conclusion of the trial, the jury found in favor of plaintiff on both the negligence and product-liability claims and awarded her $2.4 million in economic damages and $5 million in non-economic damages. Pursuant to the parties' stipulation, this award was reduced to a total of $6,774,000 to account for pre-judgment interest and plaintiff's recovery in a settlement of a separate action she had filed against the Health Center.

¶ 4. In a summary judgment motion prior to trial, as

well as in its timely motion for judgment as a matter of law following trial, both of which the superior court denied, defendant argued that federal law preempted plaintiff's claim. These arguments rested in part on defendant's contention that it had submitted an adequate warning to the FDA, but that the FDA rejectedthe change because it did not favor strengthening the warning.[FN1] Plaintiff contended that neither warning would have been adequate. The trial court stated, in its decision on defendant's motion for judgment as a matter of law, that although the FDA had rejected a new warning, the agency's "brief comment" failed to explain its reasoning or demonstrate that it "gave more than passing attention to the issue of whether to use an IV infusion to administer the drug. The proposed labeling change did not address the use of a free-flowing IV bag." The court concluded that there was "no basis for federal preemption" and upheld the jury's verdict.

FN1. The warning on the label that was in use in 2000 read in relevant part:
INADVERTENT INTRA-ARTERIAL INJECTION: Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of [Phenergan], usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs....
When used intravenously [Phenergan] should be given in a concentration no greater than 25 mg per ml and at a rate not to exceed 25 mg per minute. WHEN ADMINISTERING ANY IRRITANT DRUG INTRAVENOUSLY IT IS USUALLY PREFERABLE TO INJECT IT THROUGH THE TUBING OF AN INTRAVENOUS INFUSION SET THAT IS KNOWN TO BE FUNCTIONING SATISFACTORILY.
(Emphasis added.) The revised warning the FDA failed to adopt read in relevant part:
INADVERTENT INTRA-ARTERIAL INJECTION: There are reports of necrosis leading to gangrene, requiring amputation, following injection of [Phenergan], usually in conjunction with other drugs; the intravenous route was intended in these cases, but arterial or partial arterial placement of the needle is now suspect....
There is no established treatment other than prevention:
1. Beware of the close proximity of arteries and veins at commonly used injection sites and consider the possibility of aberrant arteries.
2. When used intravenously, [Phenergan] should be given in a concentration no greater than 25 mg/ml and a rate not to exceed 25 mg/minute. INJECTION THROUGH A PROPERLY RUNNING INTRAVENOUS INFUSION MAY ENHANCE THE POSSIBILITY OF DETECTING ARTERIAL PLACEMENT. IN ADDITION, THIS RESULTS IN DELIVERY OF A LOWER CONCENTRATION OF ANY ARTERIOLAR IRRITANT.
(Emphasis added.)

¶ 5. Defendant claims the superior court erred by: (1) failing to dismiss plaintiff's claim on the basis that the Food and Drug Administration's approval of the Phenergan label preempted state common law claims that the label was inadequate; (2) failing to instruct the jury to reduce plaintiff's damages by the amount of fault attributable to the Health Center; and (3) failing to instruct the jury to calculate the present value of plaintiff's damages for future non-economic losses. We reject these claims of error, and we affirm.

I. Federal Preemption

¶ 6. Defendant's principal argument on appeal is that the court should have dismissed plaintiff's claim be-

cause it was preempted by federal law. Defendant asserts that any state common law duty to provide a stronger warning about the dangers of administering Phenergan by IV push conflicts with the FDA's approval of the drug's label. As preemption is a question of law, we review the trial court's decision de novo. *Office of Child Support v. Sholan*, 172 Vt. 619, 620, 782 A.2d 1199, 1202 (2001) (mem.). We hold that the jury's verdict against defendant did not conflict with the FDA's labeling requirements for Phenergan because defendant could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor, not a ceiling, for state regulation.

¶ 7. The United States Constitution provides that federal law is the supreme law of the land. U.S. Const. art. VI, cl. 2. The Supremacy Clause is the basis for the doctrine of preemption, according to which "state law that conflicts with federal law is 'without effect.' " *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). In Cipollone, the Court described the relevant analysis for determining whether Congress intended a federal statute to preempt state law:

> Congress' intent may be explicitly stated in the statute's language or implicitly contained in its structure and purpose. In the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.

Id. (quotations and citations omitted). Absent clear congressional intent to supersede state law, including state common law duties, there is a presumption against preemption. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action."); Cipollone, 505 U.S. at 516 ("Consideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by ... Federal Act unless that [is] the clear and manifest purpose of Congress.' " (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))). This presumption has "add[ed] force" when there has been a "long history of tort litigation" in the area of state common law at issue. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

¶ 8. Defendant concedes that Congress has not expressly preempted state tort actions through the Food, Drug and Cosmetics Act (FDCA), 21 U.S.C. ¶¶ 301-399, and that Congress did not intend the FDCA to occupy the entire field of prescription drug regulation. Rather, it asserts that plaintiff's action "actually conflicts with federal law." Cipollone, 505 U.S. at 516. This requires defendant to show either that "it is impossible for a private party to comply with both state and federal requirements," or that Vermont's common law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quotations and citations omitted).

¶ 9. Defendant presents two alternative baes for its assertion of conflict preemption: (1) in the specific context of the Phenergan label, the FDA was aware of the dangers of IV-push administration and specifically ordered defendant to use the warning it used, making it impossible for defendant to comply with both its state common-law duty and the requirements of federal law; and (2) by penalizing drug companies for using FDA-approved wording on drug labels, state tort claims like plaintiff's present an obstacle to the purpose of the FDA's labeling regulations. Before reaching these issues, we briefly examine the FDA's role in regulating prescription drug labels and the general approach courts have taken to the preemptive effect of federal labeling requirements.

A. Regulatory Background

¶ 10. Prior to distributing a prescription drug such as Phenergan, the manufacturer must submit a New Drug Application (NDA) for FDA approval. 21 U.S.C. ¶ 355(a). The FDA must approve the application unless it fails to meet certain criteria, including whether test results and other information establish that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," whether there is "substantial evid-

ence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," and whether, "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." Id. ¶ 355(d).

¶ 11. "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," and "[f]inal 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.' " *McNellis v. Pfizer, Inc.*, 2005 WL 3752269, at *4 (D.N.J.) (citing 21 C.F.R. ¶¶ 201.56, 201.57, and quoting 21 C.F.R. ¶ 314.105(b)). Once a drug and its label have been approved, any changes to the label ordinarily require submission and FDA approval of a "Supplemental NDA." Id.; 21 C.F.R. ¶ 314.70(b)(2)(v)(A).

¶ 12. If the NDA process and the submission of changes for FDA approval were the exclusive means of creating and altering prescription drug labels, this might be a very different case. A key FDA regulation, however, allows a drug's manufacturer to alter the drug's label without prior FDA approval when necessary. The regulation provides in relevant 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 an instruction about dosage and administration that is intended to increase the safe use of the drug product[.]

21 C.F.R. ¶ 314.70(c).

¶ 13. Section 314.70(c) creates a specific procedure allowing drug manufacturers to change labels that are insufficient to protect consumers, despite their approval by the FDA. "The FDA's approved label ... 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." McNellis, 2005 WL 3752269, at *5. While specific federal labeling requirements and state common-law duties might otherwise leave drug manufacturers with conflicting obligations, ¶ 314.70(c) allows manufacturers to avoid state failure-to-warn claims without violating federal law. Id. ("[I]t 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)."). There is thus no conflict between federal labeling requirements and state failure-to-warn claims. Section 314.70(c) allows, and arguably encourages, manufacturers to add and strengthen warnings that, despite FDA approval, are insufficient to protect consumers. State tort claims simply give these manufacturers a concrete incentive to take this action as quickly as possible.

B. Conflict Preemption in Other Jurisdictions

¶ 14. In light of the leeway created by ¶ 314.70(c) for drug manufacturers to add warnings, courts have been nearly unanimous in holding that state failure-to-warn tort claims do not conflict with federal law. See, e.g., McNellis, 2005 WL 3752269, at *7 ("[T]he 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."). McNellis is the latest in a series of recent cases addressing this issue as it relates to the anti-depressant Zoloft, which allegedly increases the risk of suicide in some patients. See id., at *7-8 (denying summary judgment and rejecting conflict preemption in Zoloft case); accord *Zikis v. Pfizer, Inc.*, 2005 WL 1126909, at *2-3 (N.D.Ill.); *Witczak v. Pfizer, Inc.*, 377 F.Supp.2d 726, 729-30 (D.Minn.2005); *Motus v. Pfizer, Inc.*, 127 F.Supp.2d 1085, 1096-1100 (C.D.Cal.2000); see also *Cartwright v. Pfizer, Inc.*, 369 F.Supp.2d 876, 882