IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARION L. KNIPE, Individually and as Administratrix and Administratrix Ad Prosequendum of the Estate of HAROLD STANLEY JAKE GARRISON, Deceased, and HAROLD L. GARRISON, JR., Individually,	:	CIVIL ACTION
Plaintiffs,	:	
v.	:	
	:	NO. 06-3024
SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE,	:	
Defendant.	:	

MEMORANDUM

BUCKWALTER S. J. August 28 , 2008

Currently pending before the Court is (1) Defendant GlaxoSmithKline's ("GSK"'s) Motion for Summary Judgment on the Grounds of Federal Preemption (Docket No. 60), (2) the Response of Plaintiffs Harold L. Garrison, Jr., individually, and Marion Knipe, individually and as administratrix and administratrix *ad prosequendum* of the Estate of Harold Stanley Jake Garrison (Doc. No. 98), (3) Defendant's Reply Brief (Doc. No. 120), and (4) Plaintiff's Sur-reply Brief (Doc. No. 137). In addition, the Court jointly considers Plaintiffs' Motion to Strike Evidence Submitted by GSK in Support of Its Motion for Summary Judgment (Federal Preemption) (Doc. No. 107) and Defendant's Response thereto (Doc. No. 117).

This litigation commenced on July 10, 2006, when Plaintiffs sued Defendant for the wrongful death of sixteen-year old Harold Stanley Jake Garrison ("Jake"), who committed

suicide after taking Paxil, an antidepressant medication manufactured and sold by GSK. The core of Plaintiffs' claims alleges that GSK breached its state law duty to warn of the increased risk of suicide in pediatric patients as a result of taking the drug. Defendant now contends that Plaintiffs' state tort claims are preempted by federal law, *i.e.* the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* and its implementing regulations, due to a direct and actual conflict between state and federal law. For the following reasons, the Court denies the motion in its entirety.

I. BACKGROUND AND UNDISPUTED FACTS[1]

A. Jake Garrison's Suicide

In February 2001, deceased Plaintiff Jake Garrison ("Jake") was referred to dermatologist Booth Durham, M.D., for the treatment of acne. (Pls.' Ex. 153, Durham Dep. 11:8-17:8, Sep. 5, 2007.) Originally, Dr. Durham treated Jake with Accutane. Id. In light of the drug's labeling, the doctor informed Jake and his mother that the drug could cause suicidal behavior, and required them to sign a consent form. (Id.) The Accutane course of treatment was completed in August or September of 2001. (Id. at 21:13-22:2.)

On January 10, 2002, Jake, who was fifteen years old at the time, returned to Dr. Durham as a result of redness and irritation on his face. (Id. at 22:3-23:12.) Dr. Durham prescribed to

[1] The Court's summary of facts constitutes a ruling on the parties' various Objections to the evidence submitted in support of and in opposition to the Motion for Summary Judgment on preemption. Specifically, the parties repeatedly object on the basis of authenticity, lack of foundation and/or relevance. To the extent the Court has cited a particular piece of evidence, the Court overrules any objection thereto. To the extent a particular fact or piece of evidence is not cited, the Court has simply deemed that evidence irrelevant to a ruling on this motion.

Jake a fifteen-day supply of Paxil ten milligrams for treatment of his body dysmorphic disorder.[2] (Id. at 23:12-25:21.) The dosage was increased to twenty milligrams after two weeks. (Id. at 25:16-25:21.) At that time, the label for Paxil contained the following statement in the "PRECAUTIONS" section:

> Suicide: The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Precautions for Paxil should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

(Plaintiffs' Statement of Undisputed Facts ("PSUF") ¶ 23, Ex. 35 at 1610.) The 2002 label also included, in a section entitled "Other events Observed During the Premarketing Evaluation of Paxil" (under the sub-heading "Nervous System"), the adverse reaction of "emotional lability," which was identified as a "frequent event." (Id. ¶ 24, Ex. 35 at 1614.) Under the section entitled "Pediatric Use," the label stated, "Safety and effectiveness in the pediatric population have not been established." (Id. ¶ 25, Ex. 25 at 1611.)

Jake refilled a thirty-day prescription for Paxil twenty milligrams, on January 27, 2002, and another thirty-day supply for Paxil twenty milligrams on April 8, 2002. (Pls' Resp., Objections and Evid. in Response to GSK's "Statement of Undisputed Facts" in Support of Mot. Summ. J. on Fed. Preemp. ("Plaintiffs' Objections") ¶ 1, Exs. 146, 147.) Thereafter, for

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[2] "Body Dysmorphic Disorder ("BDD") is a type of somatoform disorder, a mental illness in which a person has symptoms of a medic"al illness, but the symptoms cannot be fully explained by an actual physical disorder. People with BDD are preoccupied with an imagined physical defect or a minor defect that others often cannot see. As a result, people with this disorder see themselves as 'ugly' and often avoid social exposure to others or turn to plastic surgery to try to improve their appearance." http://www.webmd.com/mental-health/mental-health-body-dysmorphic-disorder.

unknown reasons, Jake stopped taking Paxil. (Id.) On September 11, 2002, Jake refilled another Paxil twenty milligram prescription and took the medication for three days. (Id.) On September 14, 2002, Jake committed suicide by gunshot. (PSUF ¶ 27, Ex. 38.)

B. FDA Regulation of New Drugs and Drug Labeling Generally

In the FDCA, Congress charged the Food and Drug Administration ("FDA") with the duty to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products" and to "protect the public health by ensuring that . . . drugs are safe and effective." 21 U.S.C. § 393(b)(1), (b)(2)(B) (1997). To satisfy its regulatory mission, the FDA engages in a thorough review of any proposed new drugs prior to their entry in the market. See 21 U.S.C. § 355. Under this procedure, a person or company that wishes to market a new drug[3] must initially file a new drug application ("NDA") with the FDA. Id. at § 355(b). This NDA requires, among many other things, (a) full

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[3] The term "new drug" means–

> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
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> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C.A. § 321(p).

reports of investigations which have been made into the safety and effectiveness of the drug; (b) a list of all articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a complete description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (e) samples of such drug and of the articles used as components thereof as the Secretary may require; and (f) specimens of the labeling proposed to be used for such drug. 21 U.S.C. § 355(b)(1); see also 21 C.F.R. § 314.50 (setting forth a complete list of requirements for an NDA).

The "labeling" requirement for a drug refers not simply to the label attached to the drug, but rather "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). By regulation, "[t]he labeling shall contain a summary of the essential scientific information needed for the safe and effective use of the drug." 21 C.F.R. § 201.56(a).[4] Drug labeling must include specific information under prescribed section headings, including, *inter alia*, contraindications, warnings and precautions, adverse reactions and use in particular populations, including pediatrics. Id. § 201.56(d)(1). Under the "Warnings" section, "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." 21 C.F.R. § 201.57(e). In addition,

> 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

[4] Many of the regulations pertinent to this litigation were revised and/or relocated in January 2006, and effective June 30, 2006, subsequent to Jake Garrison's suicide. To the extent that the regulations have changed substantively, the Court will rely on those in effect during the relevant events in this lawsuit between 1999 and the end of 2002. Where the Court references a new regulation not in effect at the relevant time, it will be designated with the appropriate year.

> 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 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.

Id. Notably, "[t]he 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." Id.

The FDA must disapprove an NDA if, among other reasons, it finds that (1) the investigations submitted to the FDA "do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;" (2) "the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;" (3) the FDA has insufficient information to determine the drug is safe for use under such conditions; (4) "there is a lack of substantial evidence 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;" or (5) "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." 21 U.S.C. § 355(d); 21 C.F.R. § 314.125. Further, the FDA "will approve an application and send the applicant an approval letter if none of the[se] reasons . . . for refusing to approve the application applies." 21 C.F.R. § 314.105(a). The FDA "will approve an application and issue the applicant an approval letter . . . on the basis of draft labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft labeling." Id. § 314.105(b). "Such approval will be

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 labeling prior to marketing." Id.

A drug may be deemed "misbranded" if its labeling is "false or misleading," 21 U.S.C. § 352(a), fails to bear "adequate directions for use" or fails to bear "such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." 21 U.S.C. § 352(f). Failure to include a scientifically valid warning the FDA believes is necessary, or the inclusion of warning information not based on reliable scientific evidence, causes the labeling of the drug to be deemed "false and misleading," and renders the drug misbranded. (Def. Mot. Summ J. Fed. Preemp., Ex. A ("Arning Decl."), ¶ 15 (citing 21 U.S.C. §§ 331(a), 331(b), 331(k), 352(a) and 352(f)).) Again, the labeling must be identical, in every material respect, to the labeling that accompanies the approval letter. 21 C.F.R. § 314.105(b). Distribution of a misbranded drug that fails to comply with the FDA-approved labeling is prohibited and may result in withdrawn approval of the NDA, *in rem* forfeiture, injunction, and/or criminal prosecution against the responsible person. 21 U.S.C. §§ 332(a), 333, 334(a), 337(a); 21 C.F.R. § 314.150(b).

Once a drug is approved, it is included in the FDA's published list of approved drugs. 21 U.S.C. § 355(j)(7). Even after approval of the NDA, however, the FDA maintains substantial control over a prescription drug's safety and the content of its labeling. The FDA can move to withdraw approval of a drug on a showing that the drug is unsafe or ineffective. Id. § 355(e). Further, the FDA can withdraw approval if, among other reasons, "on the basis of new

information before [the FDA], evaluated together with the evidence before [the FDA] when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the [FDA] specifying the matter complained of." Id.

Drug manufacturers also maintain continuing obligations to report to the FDA adverse drug experiences, 21 C.F.R. § 314.80(c), as well as any "significant new information . . . that might affect the safety, effectiveness, or labeling of the drug product." 21 C.F.R. § 314.81(b)(2)(i). Per the regulations in effect at the time relevant to this litigation, an applicant is required to notify the FDA of any changes to an approved drug, including its labeling, by one of three methods. 21 C.F.R. § 314.70(a)-(d). Subsection (b) governs "changes requiring supplemental submission and approval prior to distribution of the product made using the change (major changes)," including any change in labeling, other than one described in later subsections. Id. at § 314.70(b)(2)(v). Subsection (d) references minor changes that could be submitted with the drug manufacturer's annual report, but does not allow any changes in labeling. Id. at § 314.70(d). Finally, subsection (c), concerns "moderate changes" that may be made before FDA approval pursuant to a Changes Being Effected ("CBE") supplement. 21 C.F.R. § 314.70(c)(3), (6); (Arning Decl. ¶ 17.) Changes under this section do not require prior approval, but do require supplemental submission to the FDA for review and final approval.[5] 21 C.F.R. § 314.70(c)(6). Among the alterations that may be unilaterally made by a manufacturer under this section are

[5] The regulations effective 2006 still allow the manufacturer to strengthen a warning, but require that the manufacturer inform the FDA thirty days prior to distributing the new warning. 21 C.F.R. § 314.70(c)(6)(iii)(A) (2006).

changes to "add or strengthen a contraindication, warning, precaution or adverse reaction."[6] 21 C.F.R. § 314.70(c)(6)(iii)(A). Like other warnings, changes to warnings may only be added when there is "reasonable evidence of an association of a serious hazard with a drug; a causal connection need not have been proved." 21 C.F.R. § 201.57(c). Although "in practice, manufacturers typically consult with FDA prior to adding risk information to labeling," Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 FR 3922-01, 3934 (Jan. 24, 2006), such prior consultation is not required in the regulations. 21 C.F.R. §314.70(c)(6)(i). If the FDA disapproves of the revised label, it may order the manufacturer to cease distribution of the drug products made with the change. 21 C.F.R. § 314.70(c)(7).

C. The Regulatory History of Paxil[7]

Paxil is generally classified as a selective serotonin reuptake inhibitor ("SSRI"), currently approved on a prescription basis only for the treatment of depression, obsessive compulsive disorder, panic disorder, social anxiety disorder, generalized anxiety disorder, post-traumatic stress disorder and premenstrual dysphoric disorder in adult patients. (Arning Decl. ¶ 5.) On November 20, 1989, SmithKline Beecham Pharmaceuticals ("SB")[8] filed an NDA for paroxetine

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[6] Prior to 1965, FDA regulations prohibited drug companies from strengthening their warnings without prior regulatory approval. See Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1018, 1034-35 (S.D. Ill. 2001) (citing 25 Fed.Reg. 12,592, 12,595 (Dec. 9, 1960)).

[7] The parties have compiled an extensive regulatory history for Paxil in their briefs and "Statements of Undisputed Facts." Although the Court finds that a discussion of this history is pertinent to the pending litigation, we limit that discussion to a description of the more salient points.

[8] SB merged with GlaxoWellcome in December 2000 to form GlaxoSmithKline PLC. (Arning Decl. ¶ 1 n.1.)

(Paxil) seeking FDA approval for the treatment of depression in adults. (Id. ¶ 19.) In support of ths application, SB submitted data to the FDA, including toxicology data, animal studies and clinical studies in humans, as well as data on suicides, suicide attempts and suicidal behavior. (Id. ¶ 21.) [9]

In 1990, prior to the completion of the FDA's review, press reports of a possible linkage between increased suicidality and Prozac, another SSRI, began to surface.[10] As a result, in 1990 and 1991, two groups filed "Citizen Petitions," seeking either the withdrawal of NDA approval for Prozac, which was the only approved SSRI at the time, or alternatively, a warning statement in labeling regarding an increased risk of suicide. (Def. Mot. Summ. J. Fed. Preemp., Ex. B ("Howard Decl."), Exs. 4 and 5.) Dr. Martin Brecher, the lead FDA safety reviewer on the Paxil NDA, contacted SB and requested a report discussing the relationship between Paxil and "violence-ideation and suicide-ideation." (Arning Decl. ¶ 22, Ex. 1.) The following May, SB submitted a report stating that, "data from prospective clinical trials in depressed patients clearly demonstrates that patients randomized to paroxetine therapy were at no greater risk for suicidal

[9] Plaintiffs argue that when GSK submitted its data to the FDA, it obscured the elevated adult suicidal behavior rates for Paxil over placebo by improperly including run-in events as if they were post-baseline events. Further, they claim that GSK failed to include in the NDA the actual placebo suicide and suicide attempt rates. Defendant disputes such allegations and argues that, in any event, they are preempted under Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S. Ct. 1012 (2001). As the Court does not rely on any of these facts to resolve the motion, but merely cites them for background purposes, we decline to resolve the parties' dispute.

[10] Plaintiffs filed a Motion to Strike documents submitted by Defendant regarding the FDA's consideration of a possible association between Prozac and suicidality in the early 1990's. The Court does not give any weight to these documents when ruling on this motion, since they relate to adult, not pediatric use of Paxil. We do, however, take note of their relevance in understanding the background of the dispute at bar. Accordingly, this portion of the Motion to Strike is denied.

ideation or behavior than patients who were randomized to placebo or other active medication." (Id. ¶ 23, Ex. 2.) Given this information, Dr. Brecher issued his Safety Review report, which concluded that, "Although the instruments available may not be ideal to capture the elusive clinical events reported by Teicher in 6 patients, there is no signal in this large data base that paroxetine exposes a subset of depressed patients to additional risk for suicide, suicide attempts or suicidal ideation."[11] (Id. ¶ 24, Ex. 3 at 25.)

In September of 1991, the FDA held a Psychopharmacological Drugs Advisory Committee ("PDAC") meeting to consider further whether there was an association between SSRIs and suicide. (Howard Decl., Ex. 6.) The study was based primarily on information received on Prozac, with no information given on Paxil. (PSUF ¶ 155, Ex. 135.) The FDA did not dismiss the possibility of a connection and suggested that further study on this issue was encouraged. (Pls. Exs. 135 at 126, 137.) Nonetheless, the unanimous conclusion that resulted from the PDAC was that no credible evidence existed to conclude that "antidepressant drugs cause the emergence and/or intensification of suicidality and/or other violent behaviors." (Howard Decl, Ex. 6 at 294.) As a result, the FDA denied the pending citizen petitions in 1991 and 1992 respectively, concluding that "[t]here is no reasonable evidence of an association between the use of Prozac and suicidality." (Id. Ex. 7 at 15.)

The FDA asked the PDAC to independently evaluate the data on Paxil. (Arning Decl. ¶ 25.) On October 5, 1992, the PDAC held its panel meeting and FDA officials presented their

[11] Plaintiffs again argue that SK obscured the relevant information showing that patients on Paxil had a statistically significant greater than eight-fold increase in suicidal behavior, and thus, Dr. Brecher's findings are not relevant. As indicated *infra* footnote 9, however, the Court need not resolve this factual dispute.

analysis of the Paxil NDA, including clinical trial data on safety and efficacy. (Id. ¶¶ 25-27.) Dr. Thomas Laughren, an FDA official, reported that "there was no suggestion here of emergence of suicidality with paroxetine." (Id. ¶ 26, Ex. 4 at 29-30.) Ultimately, the PDAC deemed Paxil safe and effective for use in the treatment of adult depression and voted unanimously in favor of approval. (Id. ¶ 27, Ex. 4 at 153-54.)

The FDA issued an approval letter for Paxil on December 29, 1992, but made clear that the approval was conditioned on the use of the FDA-approved prescribing information accompanying the letter. (Id. ¶ 28, Ex. 5 at 1.) The original FDA-approved labeling did not include any warning or other statement regarding an increased risk of suicide or suicidality from Paxil. (Id. ¶ 28, Exs. 5 and 6.) Indeed, the only references to "suicide" or "suicide attempt" appeared in the description of "a major depressive episode" and a precaution that suicide is "an inherent risk in depressed patients." (Id. ¶ 28, Ex. 5 at 4-5.) In the approval letter, however, the FDA stated, "[p]lease consider conducting post-approval studies with [Paxil] in depressed children and adolescents. Depression is common in these populations and it is likely that [Paxil] will be used in children and adolescents, despite the absence of any relevant data. Consequently, we feel it would be useful for you to obtain data pertinent to the safety and efficacy of [Paxil] in these groups." (Id. ¶ 28, Ex. 5 at 2.)

Another citizen petition was filed with the FDA in 1997, seeking to require a warning in the prescribing information for Prozac that "people who are considered at risk for suicide and who begin to take [Prozac] should be carefully observed and should consider taking a sedative as well." (Howard Decl., Ex. 9.) The FDA rejected this petition, on June 25, 1997, finding that no labeling revisions were warranted. (Id. Ex. 10.)

From the date of the original approval in 1992 to the present, the FDA has reviewed and approved at least twelve supplemental NDAs for new therapeutic indications for Paxil.[12] (Id. ¶ 37.) On each occasion, the FDA conducted a review of the cumulative safety and efficacy data and proposed labeling; and each approval was conditioned on the verbatim use of the FDA-approved prescribing information and warnings. (Arning Decl. ¶ 35-39, and Exs. 18, 19, 20.) When required, SB and/or GSK submitted to the FDA an Integrated Safety Summary ("ISS") summarizing available information about the safety of the drug product, including adverse events. (Id. ¶ 39.) Likewise, on various other occasions between July 1995 and February 2003, in response to FDA requests or on its own, SB and/or GSK submitted data regarding Paxil and its relation to the risk of suicide. (Id. ¶¶ 30-34.) None of the reviews resulted in the FDA requiring GSK to change the Paxil label to reflect a causal connection between Paxil and suicide. (Id. ¶¶ 35-37.)

D. GSK's Efforts to Obtain Approval for Pediatric Use of Paxil and Resulting Label Changes

On April 11, 2002, GSK filed a Supplemental New Drug Application to the FDA "proposing the use of Paxil to treat children and adolescents with major depressive disorder and

[12] The additional indications include the following: May 7, 1996 – Obsessive Compulsive Disorder (Paxil Tablets), May 7, 1996 – Panic Disorder (Paxil), June 25, 1997 – Depression (Paxil Oral Suspension), February 16, 1999 – Depression (Paxil CR), May 11, 1999 – Social Anxiety Disorder (Paxil), April 13, 2001 – Generalized Anxiety Disorder (Paxil), December 14, 2001 – Post Traumatic Stress Disorder (Paxil), February 12, 2002 – Panic Disorder (Paxil CR), October 2, 2002 – Long Term Treatment for Generalized Anxiety Disorder (Paxil), August 28, 2003 – Pre-Menstrual Dysphoric Disorder (Paxil CR), October 16, 2003 – Social Anxiety Disorder (Paxil CR), January 27, 2004 - Pre-Menstrual Dysphoric Disorder – Intermittent (Paxil CR). (Arning Decl. ¶ 37.)

obsessive compulsive disorder."[13] (PSUF ¶ 26, Exs. 36, 37.) In connection with its application, GSK submitted Study 329 and Study 377, both of which had been completed in 1998, and Study 701, which was completed in January of 2001. (Id.) On October 7, 2002, Dr. Andrew Mosholder, the FDA reviewer of the pediatric Supplemental NDA for Paxil completed his review. In the section of his report regarding efficacy, he stated:

> For Study 377: "This trial did not provide any evidence that paroxetine is active in the treatment of adolescent MDD [major depressive disorder]."
>
> For Study 701: "This trial did not provide any evidence that paroxetine is effective in the treatment of pediatric MDD."
>
> For Study 329: "[T]his trial should be considered a failed trial, in that neither active treatment group showed superiority over placebo by a statistically significant margin."

(Id. ¶ 28, Ex. 39.)[14] In his report regarding safety, Dr. Mosholder stated:

> The most prominent adverse reactions not seen in corresponding adult trials appear to involve behavioral effects; these events were coded with terms such as hostility and emotional lability. As previously noted, the sponsor's method of coding these events was potentially confusing, and thus additional information will be helpful for the purpose of definitively assessing the potential behavioral toxicity for paroxetine in pediatric patients. . . . Further assessment of the safety profile will have to await the sponsor's reply to requests for additional information.

(Id. ¶ 29, Ex. 39 at 6.) Accordingly, on October 21, 2002, the FDA issued a letter to GSK regarding its pediatric Supplemental NDA requesting additional information and clarification

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[13] Although Defendant argues that GSK only sought approval for an indication in pediatric obsessive compulsive disorder, not major depressive disorder, that contention is not confirmed by the evidence submitted by Defendant. (Def. Ex. 21, Dep. of David Wheadon, 239-44, May 9, 2007.)

[14] On October 10, 2002, the FDA sent a letter to GSK stating that "Studies 329, 377 and 701 failed to demonstrate the efficacy of Paxil in pediatric patients with MDD. Given the fact that negative trials are frequently seen, even for antidepressant drugs that we know are effective, we agree it would not be useful to describe these negative trials in labeling." (Pls.' Ex. 40.)

including "an expanded version of [a table of adverse events coded under the terms hostility, emotional lability or agitation], including all psychiatric and behavioral adverse events, and also those that occurred among placebo patients" and GSK's "rationale for coding suicide attempts and other forms of self-injurious behavior under the . . . term 'emotional lability.'" (Id. ¶ 30, Ex. 40.)

On May 21, 2003, seven months after the FDA's request for clarification as to GSK's study results, GSK submitted a briefing document to the UK's equivalent of the FDA, the Medicines and Healthcare Products Regulatory Agency ("MHRA"). This document summarized the clinical trial data on Paxil for the treatment of adolescents with depression, obsessive compulsive disorder and social anxiety disorder, in preparation for a meeting at which GSK was seeking approval for this population and for these indications.[15] (Id. ¶ 35, Ex. 43.) On May 30, 2003, the MHRA issued a "Rapid Alert," which stated that Paxil would be contraindicated for the treatment of adolescent depression since the clinical trial data did not show efficacy and that the trial results "demonstrate a significant safety issue in relation to suicidal behavior."[16] (Id. ¶ 30, Ex. 46.)

Dr. Thomas Laughren, team leader of the FDA's Psychiatric Drug Products in the Division of Neuropharmacological Drug Products, contacted GSK on May 23, 2003, indicating that he had received a telephone call from the MHRA "regarding GSK's analysis of suicide events associated with the use of Paxil in pediatric patients." (Id. ¶ 36.) He asked GSK for the same information

[15] Defendant disputes the relevance of the actions of the British agency. Although the Court does not rely on them in reaching a decision on this motion, we deem these facts pertinent to the overall evidence in existence suggestive of a link between Paxil and pediatric suicidality.

[16] That contraindication was replaced by the MHRA, on April 7, 2005, with a "warning" against use in the under eighteen age group. (Def. Ex. 22.)

provided to the MHRA, which GSK indicated was already "in transit." (Id.) Upon receipt of GSK's supplemental submission in partial response to the FDA's October 10, 2002 letter, the FDA drafted a "Request for Consultation" memo, dated June 5, 2003, which noted that GSK's re-analyzed data, clarifying what events were included under the term "emotional lability," suggested an excess risk of suicidality in patients taking Paxil compared to those taking placebo. (Id. ¶ 44, Ex. 48.) At that time, GSK had not proposed labeling changes. (Id. ¶ 42, Ex. 47.) On June 10, 2003, the British Department of Health issued a press release announcing: "Paxil must not be used for the treatment of children," due to "an increase in the rate of self-harm and potentially suicidal behavior in this group when Paxil is used for depressive illness." (Id. ¶ 45, Ex. 49.)

On June 19, 2003, the FDA issued a Talk Paper reporting that it was "reviewing reports of a possible increased risk of suicidal thinking and suicide attempts in children and adolescents under the age of 18 treated with the drug Paxil for major depressive disorder." (Arning Decl. ¶ 42, Ex. 23.) The advisory stated, "[a]lthough the FDA had not completed its evaluation of the new safety data, FDA is recommending that Paxil not be used in children and adolescents for the treatment of MDD, and Paxil is currently not approved for use in children and adolescents." (Id.) In June and July 2003, GSK issued "Dear Healthcare Professional" letters in the United Kingdom and Canada, respectively, informing physicians that Paxil should not be used for the treatment of depression in the children and adolescents under the age of 18. (PSUF ¶ 46, Ex. 50; ¶ 51, Ex. 54.)

On July 22, 2003, the FDA requested adverse event data from the manufacturers of all of the "modern drugs" used to treat major depressive disorder, in order to further assess suicidality in pediatric patients enrolled in clinical studies. (Id. ¶ 53, Ex. 55.) The FDA then issued a Public Health Advisory and corresponding Talk Paper, on October 27, 2003, stating that the "data do not

clearly establish an association between the use of these drugs and increased suicidal thoughts or actions by pediatric patients," but it was "not possible at this point to rule out an increased risk of [increased suicidal thoughts or actions] for any of these drugs, including Paxil." (Id. ¶ 56, Ex. 58.) Thereafter, in February of 2004, the FDA advisory committee convened to "address recent concerns about reports of suicidal ideas and behavior developing in some children and adolescents during treatment of depression with an SSRI or similar newer antidepressants." (Id. ¶ 59, Ex. 61 at 12-13.) Ultimately, the advisory committee recommended that the FDA issue an immediate warning concerning the potential risk of suicidality in pediatric patients and agreed that the data should be analyzed further. (Id. ¶ 61, Ex. 62.) On March 22, 2004, the FDA issued a Public Health Advisory cautioning about the need to closely monitor adults and children being treated with antidepressants to determine whether there is a worsening of depression. (Arning Decl. ¶ 49, Ex. 30.) It also noted that, after initial reports and studies with Paxil, and subsequent reports on studies of other drugs, there appeared to be "an increased risk of suicidal thoughts and actions in the children given antidepressants." (Id.) In May of 2004, GSK sent a "Dear Healthcare Professional" letter to doctors in the United States alerting them to the FDA's Public Health Advisory. (PSUF ¶ 62, Ex. 64.)

The advisory committee met again in September 2004, and concluded that the data, in the aggregate, reflected an increased risk of suicidality in pediatric patients and recommended that the FDA consider new class labeling changes. (Id. ¶¶ 66-67, Ex. 69.) A new Public Health Advisory and letter issued from the FDA on October 15, 2004, directing manufacturers to add a "black box"

warning[17] and expanded warning statements to the labeling of all antidepressant medications describing the increased risk of suicidality in children and adolescents being treated with antidepressants, and to include information about the results of pediatric studies. (Id. ¶ 72, Ex. 74; Arning Decl. ¶ 55, Ex. 34.) On November 12, 2004, GSK filed labeling supplements to the Paxil and Paxil CR NDA's to include the labeling changes requested by the FDA in the October 15, 2004 letter. (Arning Decl. ¶ 56.) On January 26, 2005, the FDA notified GSK that it decided to "modify the new PI [package insert] slightly so that the language in the 'Warnings Section' of the PI more precisely mirrors the language set forth in the black box warning." (PSUF ¶ 74, Ex. 76.)

The FDA approved the labeling supplements for Paxil and other antidepressants, on January 26, 2005, to require the following "black box" warning:

> Suicidality in Children and Adolescents
> Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of [insert established name] or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or other unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. [Insert established name] is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use)
>
> Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events on drug was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

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[17] According to the FDA, a "black box" warning is the most serious warning placed in the labeling of a prescription medication. (Arning Decl. ¶ 55, Ex. 34.)

(Arning Decl. ¶ 59, Ex. 76.)

III. SUMMARY JUDGMENT STANDARD OF REVIEW

Summary judgment is proper "if 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 a judgment as a matter of law." FED. R. CIV. P. 56(c). A factual dispute is "material" only if it might affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986). For an issue to be "genuine," a reasonable fact-finder must be able to return a verdict in favor of the non-moving party. Id.

On summary judgment, it is not the court's role to weigh the disputed evidence and decide which is more probative, or to make credibility determinations. Boyle v. County of Allegheny, Pennsylvania, 139 F.3d 386, 393 (3d Cir. 1998) (citing Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co. Inc., 998 F.2d 1224, 1230 (3d Cir.1993). Rather, the court must consider the evidence, and all reasonable inferences which may be drawn from it, in the light most favorable to the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348 (1986) (citing United States v. Diebold, Inc., 369 U.S. 654, 655, 82 S. Ct. 993 (1962)); Tigg Corp. v. Dow Corning Corp., 822 F.2d 358, 361 (3d Cir. 1987). If a conflict arises between the evidence presented by both sides, the court must accept as true the allegations of the non-moving party, and "all justifiable inferences are to be drawn in his favor." Anderson, 477 U.S. at 255.

Although the moving party bears the initial burden of showing an absence of a genuine issue of material fact, it need not "support its motion with affidavits or other similar materials

negating the opponent's claim." Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553 (1986). It can meet its burden by "pointing out . . . that there is an absence of evidence to support the nonmoving party's claims." Id. at 325. Once the movant has carried its initial burden, the opposing party "must do more than simply show that there is some metaphysical doubt as to material facts." Matsushita Elec., 475 U.S. at 586. "There must . . . be sufficient evidence for a jury to return a verdict in favor of the non-moving party; if the evidence is merely colorable or not significantly probative, summary judgment should be granted." Arbruster v. Unisys Corp., 32 F.3d 768, 777 (3d Cir. 1994), abrogated on other grounds, Showalter v. Univ. of Pittsburgh Med. Ctr., 190 F.3d 231 (3d Cir. 1999).

II. DISCUSSION

A. Preemption Generally

The issue presently before the Court is whether Plaintiffs' state law claims alleging that Defendant improperly failed to warn Plaintiffs of the risk of increased suicidality in pediatric users of Paxil are preempted by federal law. The doctrine of preemption finds its origins in the Supremacy Clause of the United States Constitution, which provides that the "Constitution, and the laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land." U.S. CONST. art. VI, cl. 2. In Gibbons v. Ogden, the United States Supreme Court interpreted the Supremacy Clause to invalidate any state laws that "interfere with, or are contrary to" the federal law. 22 U.S. (9 Wheat) 1, 211 (1824). Preemption occurs in three primary situations: (1) "express" preemption, when Congress explicitly states its intent to preempt state law; (2) "field" preemption, when Congress' intent to preempt state law in particular area is inferred from either the comprehensive scheme of federal regulation in that area

or the dominant federal interest in that area; and (3) "conflict" preemption, when "state law is nullified to the extent that it actually conflicts with federal law," even though Congress has not displaced all state law in that area. Colacicco v. Apotex, Inc., 521 F.3d 253, 261 (3d Cir. 2008) (quoting Hillsborough County v. Automated Med. Labs, Inc., 471 U.S. 707, 713, 105 S. Ct. 2371 (1985)). Conflict preemption occurs "where either (1) the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' or (2) it is 'impossible for a . . . party to comply with both state and federal law.'" Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 307 (E.D. Pa. 2007) (quoting Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 899, 120 S. Ct. 1913 (2000)). The wealth of cases discussing preemption in the case of pharmaceutical failure to warn claims concur – and the parties in this case do not dispute – that the issue here is one of conflict preemption. Colacicco, 521 F.3d at 262; Mason v. SmithKline Beecham Corp., 546 F. Supp. 2d 618, 621 (S.D. Ind. 2008); Dobbs v. Wyeth Pharms., 530 F. Supp. 2d 1275, 1278 (W.D. Okla 2008). Accordingly, the Court limits its discussion to that subject area.

Plaintiffs and Defendant dispute the applicability of what is commonly known as the presumption against preemption. Because states are themselves independent sovereigns, the United States Supreme Court has recognized a general presumption that Congress does not intend to preempt state law causes of action. Bldg. and Constr. Trades Council of Metro. Dist. v. Assoc. Builders and Contractors of Mass./RI, Inc., 507 U.S. 218, 224, 113 S. Ct. 1190, 1194 (1993). In Medtronic, Inc. v. Lohr, the Supreme Court stated that "[i]n all preemption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be

superseded by the Federal Act unless that was the clear and manifest purpose of Congress." 518 U.S. 470, 485, 116 S. Ct. 2240, 2250 (1996) (citations, internal quotation marks and alterations omitted); see also Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 125 S. Ct. 1788, 1801 (2005) (recognizing a "basic presumption against pre-emption" due to long history of tort litigation against manufacturers of poisonous substances.) Notably, however, the application of such a presumption is not proper in all circumstances, particularly where uniquely federal interests are at issue. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347-48, 121 S. Ct. 1012, 1017 (2001) (finding no presumption against preemption where interests at stake were uniquely federal in nature and were not traditionally regulated by states); Pennsylvania Employees Ben. Trust Fund v. Zeneca, 499 F.3d 239, 251 (3d Cir. 2007) (finding preemption of state law fraud claims in context of prescription drug advertising).

Two recent Third Circuit cases have attempted to further define the contours of this presumption. In Colacicco v. Apotex, the Third Circuit explicitly discussed the application of the presumption against preemption in a state law failure to warn case against two pharmaceutical manufacturers. 521 F.3d 253, 265 (3d Cir. 2008). The Court rejected the defendants' arguments that a presumption was completely inapplicable in such cases. Id. at 265 n.11. It recognized, however, that the presumption was more appropriate in a case of field preemption, "where Congress' mere presence in a given field indiscriminately nullifies all state law in the field, than in the context of conflict preemption, which excludes state law only to the extent that it requires individuals to act contrary to conflicting federal obligations." Id. Ultimately, the Third Circuit suggested that the implied conflict preemption inquiry, which analyzes preemption in the absence of any explicit Congressional intent, effectively supplants the presumption. Id. at 265 (internal

citations and quotations omitted).

In its most recent discussion of this issue, however, the Third Circuit qualified its statements in Colacicco and noted that it does not "lightly infer" preemption where "state compensatory regimes have traditionally played an important role." Fellner v. Tri-Union Seafoods, L.L.C., ___ F.3d ___, 2008 WL 3842925, at *7 (3d Cir. Aug. 19, 2008). The court noted that, "it is hard to imagine a field more squarely within the realm of traditional state regulation than a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product." Id. Such state tort law is often complementary to federal regulatory regimes and "preemption may leave individuals with no private remedy, where traditionally there has been one." Id. Accordingly, it distinguished Colacicco and emphasized that it would continue to apply the traditional presumption absent Supreme Court guidance to the contrary. Id.

Based on the Third Circuit's varying pronouncements, this Court now finds that although the outcome of this case turns ultimately on the existence or non-existence of an actual conflict between state and federal law, the general presumption against preemption remains viable. Guided by these principles, the Court turns to the specific claims at issue.

B. Preemption of Plaintiffs' New Jersey State Law Failure to Warn Claim

Defendant's preemption claim argues that a direct conflict exists between Plaintiffs' failure to warn claims under New Jersey state law[18] and the FDCA. New Jersey law provides that

[18] In response to Defendant's other pending Motion for Summary Judgment (Causes of Action) in this case, Plaintiffs argue that Pennsylvania law, not New Jersey law, applies to this dispute. For purposes of this motion only, however, Plaintiffs presume that New Jersey law

a manufacturer must warn of all known adverse effects of a drug as soon as reasonably feasible upon actual or constructive knowledge of the danger. Feldman v. Lederle Labs., 479 A.2d 374, 388-89 (N.J. 1984). Defendant asserts that had it included, in Paxil's labeling, the warnings on the increased risk of pediatric suicide proposed by Plaintiffs under New Jersey tort law, the drug would have been deemed misbranded within the meaning of 21 C.F.R. §§ 352(a), 352(f)(1). In turn, Defendant claims that it would have been held liable under federal law. Id. at §§ 332-34. Because it could have not remained in compliance with both state and federal law as it stood prior to September 2002 – when Jake Garrison committed suicide – Defendant avers that an actual and direct conflict exists, thus triggering the preemption of New Jersey law.

Defendant's argument, however, offers an overly-simplistic description of the allegedly conflicting federal law. Notwithstanding the FDA's approval of Paxil's labeling in December of 1992 and GSK's obligation to use that labeling, drug manufacturers, at the time relevant to this litigation, maintained a continuing obligation to revise a label "to include a warning *as soon as* there [was] a reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."[19] 21 C.F.R. § 201.57(e). These regulations "contemplate that information may arise before and after application approval that, in the mind of the manufacturer, calls into question the current safety of the drug with respect to any or all

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applies. (Pls.' Mem. Supp. Opp. Mot. Summ. J. Fed. Preemp. 10.) Following the parties' lead, the Court makes the same presumption.

[19] As revised in 2006, the regulations now state that "the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of *a causal association* with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i) (2006) (emphasis added). To the extent this language changes the required standard, the Court need not consider it as this was not the regulation in effect at the time of the events in question.

indications and calls for a strengthened warning." Caraker v. Sandoz Pharms. Corp., 172 F. Supp. 2d 1018, 1033-34 (S.D. Ill. 2001). As noted above, such changes to a drug's labeling to "add or strengthen a contraindication, warning, precaution or adverse reaction," may be made by a CBE supplement, which is at the manufacturer's own initiative and prior to FDA approval. 21 C.F.R. § 314.70(c)(6)(iii). Although such changes must be submitted to the FDA for review and final approval, the FDA's subsequent disapproval does not result in a retroactive "misbranding" of the label or subject the manufacturer to legal sanctions. Tucker v. SmithKline Beecham Corp., Civ. A. No. 04-1748, 2008 WL 2788505, at *3 (S.D. Ind. Jul. 18, 2008); see also 21 C.F.R. § 314.70 ("[I]f the agency disapproves of the supplemental application, it may order the manufacturer to cease distribution of the drug product(s) made with the manufacturing change.").

In short, such provisions hold that a drug manufacturer, upon having "reasonable evidence of an association of a serious hazard with a drug," which has not been considered and rejected by the FDA, may unilaterally add that warning to a drug's labeling and then submit to the change to the FDA for approval without facing any risk of noncompliance with federal law.[20] By the same token, however, a drug manufacturer cannot, without violation of federal law, change the labeling of a drug to include the warning of a potential association between a hazard and the drug in the face of an express FDA rejection of that warning or absent "reasonable evidence" of such an

[20] See Beverly L. Jacklin, Federal Pre-emption of State Common-law Products Liability Claims Pertaining To Drugs, Medical Devices, and Other Health-related Items, 98 A.L.R.Fed. 124, at § 4(b), 1990 WL 675329 (1990) ("If change were permissible without prior FDA approval, there would be no apparent conflict between federal regulations and a state court decision imposing liability for failure to make such a change. On the other hand, if prior approval was required, compliance with both the federal regulations and such a state ruling would be impossible – one criterion for finding federal pre-emption.").

association. See O'Neal v. Smithkline Beecham Corp., 551 F. Supp. 2d 993, 1003 (E.D. Cal. 2008); Mason v. Smithkline Beecham Corp., 546 F. Supp. 2d 618, 626 (C.D. Ill. 2008).

Thus, the resolution of the preemption issue in this case turns on two questions. First, the Court must determine whether the FDA has clearly and publicly stated its position, prior to the prescription and suicide at issue in this case, as to either the substance of the proposed warning regarding increased risk of suicidality in pediatric users of Paxil or the intent to preempt corresponding state tort suits. Second, if the Court finds that the FDA, in fact, took no position on the propriety of a pediatric suicidality warning prior to September of 2002, we must inquire if there was, at that time, reasonable evidence of an association between Paxil and pediatric suicidality, such that GSK could have amended the label without risking non-compliance with federal law. The Court addresses each question in turn.

1. Express FDA Preemption of a Pediatric Suicidality Warning

Defendant first argues that Plaintiffs' state law claims conflict directly with the FDA-mandated labeling and warnings for Paxil. More specifically, it contends that during the relevant period prior to Jake Garrison's suicide, the FDA expressly considered the propriety of the proposed suicidality warning, yet repeatedly declined to require the inclusion of such a warning on Paxil labeling. The FDA's refusal to act on such warnings, according to Defendant, operates as an unequivocal effort to preempt state failure to warn actions. In support of this argument, Defendant relies heavily on two sources: (1) the recent Third Circuit opinion in Colacicco v. Apotex, Inc. and (2) the FDA's 2006 Preamble to its revised regulations.

a. The *Colacicco* Opinion

The bulk of Defendant's argument, both in its initial brief and its reply, asserts that the Third Circuit's recent opinion in Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008) controls this case and clearly requires a finding of preemption. As the Third Circuit is the lone appellate case to explicitly discuss these issues with regard to Paxil, and as its holdings are binding upon this Court, its reasoning merits extensive discussion here.

In Colacicco, the plaintiffs were the surviving relatives of two adults who had committed suicide, one of whom took the antidepressant Paxil and one of whom took the antidepressant Zoloft. Id. at 256-57. The United States District Court for the Eastern District of Pennsylvania considered the Paxil case and found that the plaintiffs' failure to warn claim was preempted by federal law. Id. at 256. The United States District Court for the District of New Jersey, on the other hand, denied the defendant's motion for summary judgment on the grounds of preemption. Id. at 257. The Third Circuit consolidated the two cases to consider the issue of whether the plaintiffs could "maintain their state-law tort actions against the manufacturers of two such drugs on the theory that the drugs' labeling failed to warn of their association with an increased risk of suicidality" or whether the "actions taken by the [FDA] pursuant to its authority under the [FDCA] and the corresponding regulatory scheme preempt the plaintiffs' state-law failure to warn claims." Id. at 256.

After discussing basic preemption law and the presumption against preemption, the Third Circuit noted that the FDA "has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading." Id. at 269 (footnote omitted). To reach this conclusion, the court provided a lengthy history of both Zoloft and Paxil,

particularly with respect to the FDA's consideration of whether antidepressants caused or intensified suicidal thoughts in adults. Id. at 269-270. In doing so, it noted that the FDA had repeatedly approved of the Paxil labeling in effect at the time of the plaintiffs' death and had also approved it for multiple new indications. Id. at 270. Additionally, the court cited to (1) the FDA's June 19, 2003 public statement to address reports associating the pediatric use of Paxil with suicidality, in which it stated: "[t]here is no evidence that Paxil is associated with an increased risk of suicidal thinking in adults," and (2) its October 2003 Public Health Advisory that was limited to increased suicidality in pediatric users of antidepressants, with no mention of a similar warning for adults. Id. at 270-71. Although the court noted that the FDA had not formally rejected such a proposed warning or CBE supplement, id. at 272, it declined to find that, in order to rise to the level of a conflict, the FDA's rejection of a warning must be "imbued with the formality proposed by the plaintiffs." Id. at 272. Rather, it held that "[t]he FDA clearly and publicly stated its position prior to the prescriptions and deaths at issue here." Id. at 271. The court concluded that:

> Because the standard for adding a warning to drug labeling is the existence of 'reasonable evidence of an association of a serious hazard with a drug,' 21 C.F.R. § 201.57(e), and the FDCA authorizes the FDA to prohibit false or misleading labeling, a state-law obligation to include a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA's oft-repeated conclusion that the evidence did not support such an association. Therefore, under the circumstances of this case, the plaintiffs' failure-to-warn claims are preempted by the FDA's actions taken in accordance with its statutory authority.

Id. at 271.

Contrary to Defendant's arguments, the Court does not deem this case dispositive of the

one currently before us. As a primary matter, the Third Circuit explicitly limited is holding "to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires." Id. at 271-72. In light of the FDA's public rejection of an adult suicidality warning, it did not need to decide "whether preemption would be appropriate under different facts – such as where the FDA had not rejected the substance of the warning sought or where the FDA only stated its position after a lawsuit had been initiated or under the broader theories of preemption argued by the parties." Id. at 271. Further, the court did not opine on "whether the FDA's mere approval of drug labeling is sufficient to preempt state-law claims alleging that the labeling failed to warn of a given danger," or "whether FDA approval of drug labeling constitutes minimum standards in the absence of the FDA's express rejection of a specific warning." Id. at 271; see also Fellner v. Tri-Union Seafoods, __ F.3d ___, 2008 WL 2842925, at *4 (3d Cir. Aug. 19, 2008) (confirming that Colacicco finding of preemption was premised on the fact that although the regulations allowed a manufacturer to unilaterally amend warnings with subsequent FDA approval, the FDA "in a number of different agency proceedings had previously considered the scientific evidence relied upon by plaintiffs and had exercised its prerogative under the regulations to reject suicidality warnings based on that evidence.").

Given such limitations, this case is clearly exempted from the Colacicco holding. The Third Circuit focused solely on whether a claim for failure issue a warning regarding adult suicidality was preempted. At no point did the court mention any studies that were done with respect to pediatric use of Paxil. Indeed, as agreed by the parties in this case, Paxil has never been

approved for pediatric use[21] and, therefore, the FDA never reviewed any safety and efficacy data regarding pediatric use prior to approval of the drug. Moreover, the Third Circuit did not cite to any pre-September 2002 FDA document, public announcement or health advisory regarding the FDA's position on pediatric suicidality associated with Paxil. Finally, the court noted that, at the same time the FDA publicly dismissed any link between SSRIs and adult suicidality, it expressly warned of a risk of increased suicidality in pediatric users of antidepressants. Colacicco, 521 F.3d at 271. Quite unlike the concerns regarding adult suicidality, the FDA had not "clearly and publicly stated its position" dismissing any risk of pediatric suicidality prior to the prescriptions at issue.[22] As the Third Circuit left open the question of whether such evidence existed with respect to pediatric use of Paxil, we decline to deem Colacicco controlling of the outcome of this litigation.

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[21] Pediatric use of Paxil is an "off-label" use, which "refers to those prescriptions of drugs for indications that are not described on the drugs approved label. Although drug manufacturers are forbidden from specifically encouraging off-label use, in many clinical areas, it is, apparently, quite common." Perry v. Novartis, 456 F. Supp. 2d 678, 681 n.6 (E.D. Pa. 2006).

[22] This reading of Colacicco is consistent with the United States Supreme Court's previous holding in Sprietsma v. Mercury Marine, 537 U.S. 51, 123 S. Ct. 518 (2002), a case repeatedly cited by Plaintiffs. In that case, the Coast Guard had considered, but declined to promulgate a propeller guard requirement on boat engines. Id. at 61-62. The survivor of a boat passenger who died after falling from the boat and being struck by the propeller blades of the outboard engine filed an action against the engine designer. Id. at 54. The Supreme Court declined to find preemption, noting that the Coast Guard's decision not to regulate a particular aspect of boating was "fully consistent with an intent to preserve state regulatory authority pending the adoption of specific federal standards." Id. at 65. The Coast Guard had not, unlike the FDA in Colacicco, decided that, as a matter of policy, propeller guards were unsafe or should not be imposed by state law. Id. at 66-67. The Court recognized, however, that where an agency's decision not to impose a requirement in a particular setting reflects its judgment that the requirement would be inappropriate or unsound, the agency's decision must be given preemptive effect. Id.

b. The 2006 Preamble

Alternatively, Defendant argues that the FDA has clearly stated its position generally with respect to preemption of state failure-to-warn lawsuits, such as the one brought here, in the 2006 Preamble to the amended regulations. In this Preamble, the FDA remarked that such lawsuits have "directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3922-01, 3934 (Jan. 24, 2006) (effective date June 30, 2006) ("2006 Preamble"). It went on to explain that its position was "long standing," and that its labeling requirements are not simply minimum standards, but rather "establish both a 'floor' and a 'ceiling' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading." Id. at 3934-35. Because the FDA felt that state failure-to-warn lawsuits could "erode and disrupt the careful and truthful representations of the benefits and risks that prescribers need to make appropriate judgments about drug use," it indicated its belief that various state law failure to warn claims are preempted.[23] Id. at 3935-36. Defendant now contends

[23] Notably, the FDA takes the same position in several amicus briefs prepared in support of other litigation. See Brief for the United States as Amicus Curiae Supporting Defendant-Appellees, Colacicco v. Apotex, Inc., Civ. A. No. 06-3107 (3d Cir. Dec. 28, 2006) ("Colacicco Third Circuit Amicus Brief"); Brief for the United States as Amicus Curiae Supporting Defendant, Colacicco v. Apotex, Inc., Civ. A. No. 05-5500 (E.D. Pa. May 10, 2006) ("Colacicco District Court Amicus Brief"); Brief for the United States as Amicus Curiae Supporting Defendant, Kallas v. Pfizer, Civ. A. No. 04-998 (D. Utah Sept. 15, 2005) ("Kallas Amicus Brief"); Brief for the United States as Amicus Curiae Supporting Defendant-Appellee and Cross-Appellant, Motus v. Pfizer, Inc., Civ. A. Nos. 02-55372, 02-55498 (9th Cir. Sept. 10, 2002) ("Motus Amicus Brief"). To the extent these briefs make the same representations as the 2006 Preamble regarding the FDA's general position on preemption of state law failure to warn claims, the Court's determination of their weight is subsumed in the above discussion. To the

that this Court must afford deference to the FDA's view that its regulations preempt certain state tort claims for inadequate warnings, including those similar to the ones brought by Plaintiffs in this case.

The FDA's pronouncement, while due consideration, is likewise not conclusive of preemption. It is well-established that "in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive

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extent, however, that the amicus briefs take a position on the existence of reasonable evidence of an association between use of Paxil and suicidality, the Court discusses their weight in the next section of this opinion.

Plaintiffs have filed a Motion to Strike Evidence seeking to exclude all amicus briefs referenced by GSK in support of its motion for summary judgment. As indicated above, such briefs were submitted by the FDA in other failure to warn litigation relating to SSRIs, specifically Paxil and Zoloft. Plaintiffs now object to this Court's consideration of these briefs on the grounds of hearsay, speculation, improper opinions and conclusions, lack of personal knowledge, denial of due process, failure to properly authenticate, lack of foundation and relevance. (Pls.' Mot. to Strike Evid. 3.) The Court finds no basis for any of these objections.

First, the amicus briefs are not hearsay and are routinely considered in other litigation. See, e.g., Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289, 312-13 (E.D. Pa. 2007); O'Neal v. SmithKline Beecham Corp., 551 F. Supp. 2d 993, 1004 n.12 (E.D. Cal. 2008). In any event, the briefs are admissible under the public records exception to the hearsay rule. FED. R. EVID. 803(8).

Moreover, the Court deems the briefs to be competent evidence of the FDA's position on state failure to warn suits and not a violation of either due process, see United States v. Jiminez, 513 F.3d 62, 76-77 (3d Cir.) ("nontestimonial statements do not violate the Confrontation Clause and are admissible as long as 'they are subject to a firmly rooted hearsay exception or bear an adequate indicia of reliability.'"), cert. denied, 128 S. Ct. 2640 (2008), or the Administrative Procedures Act. Appalachian Low-Level Radioactive Waste Comm'n v. O'Leary, 93 F.3d 103, 112-13 (3d Cir. 1996) (finding that agency action which interprets regulations are exempt from APA rulemaking). Finally, to the extent that Plaintiff argues that these briefs are distinguishable or involve separate facts, the Court considers those factors in determining what weight to give the briefs.

In short, the Court has considered these four amicus briefs and given due weight to the representations therein that are legally supportable. Accordingly, the Court denies this portion of the Motion to Strike Evidence.

effect." Medtronic v. Lohr, 518 U.S. 470, 505, 116 S. Ct. 2240, 2260 (1990) (Breyer, J., concurring in part) (citing Hillsborough County v. Automated Med. Labs, Inc., 71 U.S. 707, 721, 105 S. Ct. 2371, 2379 (1985)). The Supreme Court has noted that "a specific intention of agency intent to pre-empt, made after notice-and-comment and rulemaking," is not necessary to find conflict preemption. Geier v. Am. Honda Motor Co., 529 U.S. 861, 885 (2000). The degree of deference to be attributed to an agency's informal position on preemption, however, depends on the extent of the agency's care, the consistency of the agency's position over time, the coherence of the agency's views, relative expertise to the technicality of the subject matter and the complexity of the background and relevant history. Colacicco, 521 F.3d at 274 (citing Geier, 529 U.S. at 883). Moreover, the Geier case did "not suggest that courts abdicate their duty to examine whether federal and state law actually conflict" or indicate that exclusive reliance must be placed on an agency's views. Fellner, __ F.3d __, 2008 WL 3842925, at *8 (citing Geier).

The Third Circuit has touched on, without conclusively deciding, the weight to be given to the 2006 Preamble at issue in this case. Id. Citing to the Supreme Court's pronouncements, the court stated that, notwithstanding the informality of the statement and the absence of notice-and-comment rulemaking, the statement was still entitled to be considered. Id. at 274-75. Such a position, however, was only "subject to a level of deference approximating that set forth in Skidmore v. Swift & Co., 323 U.S. 134, 65 S. Ct. 161 (1944)," to the extent such an interpretation has the "power to persuade." Id.[24] Ultimately, the court did not deem the 2006 Preamble

[24] In Skidmore, the Court stated

> [R]ulings, interpretations and opinions of the [administrative agency], while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly

dispositive of the issue before it. Rather, it held that "*[i]n light of the circumstances in this case*, . . . the FDA's rejection of the warning plaintiffs proffer preempts a state-law action premising liability on a drug manufacturer's failure to include such a warning in the drug labeling notwithstanding that the agency's view was not subject to notice-and-comment rulemaking." Id. at 275 (emphasis added).

Giving the 2006 Preamble due consideration to the extent it has the power to persuade, this Court rejects Defendant's contention that the labeling provisions of the FDCA preempt the precise suit at issue. Several factors guide our consideration. First, the Court notes that the prior interpretations of the FDCA are inconsistent with the current view set forth in 2006 Preamble, thus reflecting a virtual "180-reversal" from its earlier position. Tucker v. SmithKline Beecham Corp., Civ. A. No. 04-1748, 2008 WL 2788505, at *5 (S.D. Ill. Jul. 18, 2008) (quoting David A. Kessler & David C. Vladeck, A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims, 96 GEO. L.J. 461, 474 n.59 (2008)). In 1994, the FDA remarked on "the sophistication and complexity of private tort litigation in the United States and [stated that] the proposed preemption action is not intended to frustrate or impede tort litigation in this area. Indeed [the] FDA recognizes that product liability plays an important role in consumer protection." Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules, 59 Fed. Reg. 3944, 3948 (Jan. 27, 1994). Thereafter, in 1998, the FDA

> resort for guidance. The weight of such a judgment in a particular case will depend on the thoroughness evident in its consideration, the validity in its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.

Skidmore v. Swift & Co., 323 U.S. 134, 140, 65 S. Ct. 161, 164 (1944).

expressly stated that, "[The] FDA's regulations establish the minimal standards necessary, but were not intended to preclude the states from imposing additional labeling requirements. States may authorize additional labeling, but they cannot reduce, alter, or eliminate FDA-required labeling." Prescription Drug Product Labeling: Medication Guide Requirements, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998). Finally, in a 2000 Proposal of the same amendments at issue in this case, the FDA explicitly stated that it "ha[d] determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082-01, 81103 (Dec. 22, 2000). Numerous courts, even those that have ultimately given deference to the FDA's position in the 2006 Preamble, have similarly recognized this inherent contradiction between the FDA's interpretations prior to 2006 and the interpretation set forth in the 2006 Preamble. See, e.g., In re Zyprexa Prods. Liab. Litig. 489 F. Supp. 2d 230, 273-74 (E.D.N.Y. 2007); Colacicco v. Apotex, 432 F. Supp. 2d 514, 531 (E.D. Pa. 2006); Dobbs v. Wyeth Pharms., 530 F. Supp. 2d 1275, 1288 (W.D. Okla 2008); Sykes, 484 F. Supp. 2d at 315. Such an inconsistency, under the factors set forth in Geier, weighs against giving the 2006 Preamble significant deference.[25]

Second, "while the FDA has a great deal of expertise in regulating the pharmaceutical industry, this expertise does not extend to what is ultimately a question of federal law and

[25] Contrary to Defendant's argument in its Reply brief, the Third Circuit did not find that the FDA position on preemption has been consistent. Indeed, it expressly declined to comment on that issue. Colacicco, 521 F.3d at 276. Rather, the Third Circuit simply held that the FDA's position on its responsibility to determine whether a warning is required has remained consistent. Id.

congressional policy." Tucker, 2008 WL 2788505, at *6. The 2006 Preamble is, by regulation, an advisory opinion, binding only on the agency and changeable at any time without notice and comment. See 21 C.F.R. § 10.85(d)(1), (e), (g). "[F]ederal law capable of preempting is [not] created every time someone acting on behalf of an agency makes a statement or takes an action within the agency's jurisdiction." Fellner, __ F.3d ___, 2008 WL 3842925, at *5. Congress itself has yet to provide a statement on the issue of preemption with respect to prescription drugs. "[T]his silence is telling" since Congress included express preemption provisions in amendments to the FDCA regarding state-law tort claims in certain contexts, such as for medical devices. In re Zyprexa, 489 F. Supp. 2d 230, 276 (E.D.N.Y. 2007). If Congress had intended for all FDCA claims to be preempted, logic suggests that it would have made a similar statement with respect to prescription drugs. Id. Thus, to the extent the Preamble conflicts with Congress's statements or this Court's own legal findings on preemption, it is not entitled to deference.

Finally, and perhaps most importantly, even assuming *arguendo* that the FDA's statements are entitled to full deference, the 2006 Preamble does not clearly effect a preemption of this precise case. The FDA identifies six types of state law claims that it believes would be preempted by the FDA regulation of drug labeling, two of which are possibly applicable here: (1) a state law claim "that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by the FDA at the time plaintiff claims the sponsor had an obligation to warn," and (2) state law claims "that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in the rule." 71 Fed. Reg. at 3936. With respect to the first scenario, and as

discussed in detail above, Defendant has not pointed to any evidence that it either proposed a pediatric suicidality warning to the FDA or that the FDA considered and rejected a pediatric suicidality prior to Jake Garrison's death in 2002. [26]

As to the second scenario, the FDA's own interpretation of this language suggests that this case does not clearly fall within its ambit. In the 2006 Preamble, the FDA remarked that it "recognizes that FDA's regulation of drug labeling will not preempt all State law actions. The Supreme Court has held that certain State law requirements that parallel FDA requirements may not be preempted." Id. 71 FR at 3936 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 495, 116 S. Ct. 2240, 2255 (1996) (holding that the presence of a State law damages remedy for violations of FDA requirements does not impose an additional requirement upon medical device manufacturers but "merely provides another reason for manufacturers to comply with . . . federal law") (O'Connor, J., concurring in part and dissenting in part)); see also Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1011 (2008) (holding state requirements preempted only to the extent they are different from or in addition to requirements imposed by federal law).

Two of the recent amicus *curiae* briefs submitted by the FDA clarify this position. In an amicus brief to the United States Supreme Court in the case of Wyeth v. Levine, the FDA stated:

> Consistent with the stringent statutory and regulatory requirements for approval of a new drug in the first place, a manufacturer ordinarily must submit a supplemental application before making any changes to the drug, including changes in labeling.

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[26] In fact, in the FDA's amicus brief in Kallas v. Pfizer – a case involving the suicide of an adolescent taking Zoloft – the FDA never claimed to have opined, prior to October/November 2002, on the propriety of warnings regarding suicidality in children. Kallas Amicus Brief 28. Thus, the key question regarding preemption, in that case, was whether, in the time period prior to the suicide, "there was reasonable evidence of an association between . . . SSRI's generally . . . an increased risk of suicide or suicidality in children and adolescents." Id.

> 21 C.F.R. 314.70(a)(2)(v). As a general rule, the manufacturer must obtain prior approval by FDA before making such changes. Section 314.70(c) provides a limited exception to that rule permitting "the holder of an approved [new drug] application [to] commence distribution of the [changed] drug product involved upon receipt by the agency of a supplement for the change" if, among other things, the change "add[s] or strengthen[s]" a warning or a statement about administration of the drug in order to promote safety. 21 C.F.R. 314.70(c)(6)(iii)(A) and (C).
>
> As FDA explained when it proposed that regulation in 1982, however, changes may be made without prior FDA approval only "to correct concerns about *newly discovered risks* from the use of the drug." 47 Fed. Reg. at 46,623 (emphasis added). FDA explained that, "[a]lthough most changes in labeling would require the applicant to submit a supplement and obtain FDA approval before making a change," some changes that "would make available *important new information* about the safe use of a drug product" could be made upon submission of a supplemental application. Id. at 46,635 (emphasis added).

Brief for the United States as Amicus Curiae in Support of Appellant, Wyeth v. Levine, No. 06-1249, 2007 WL 4555760, at *13 (U.S. Dec. 21, 2007) ("Wyeth Amicus Brief").[27]

Even more tellingly, the FDA issued a direct caveat to its preemption position in its amicus brief to the Third Circuit in Colacicco:

> In explaining that federal preemption bars the plaintiff's failure-to-warn claim, FDA wishes to make clear that state tort liability is not preempted as a matter of law in every case in which liability is premised on a manufacturer's alleged common-law duty to provide a warning not yet required by the FDA. Federal regulations explicitly recognize that manufacturers can, and in some limited instances must, modify their labels to add new warnings of hazards associated with the drug, without awaiting prior approval. See 21 C.F.R. § 314.70(c)(7); 21 C.F.R. § 201.56. Where, in the light of new scientific evidence or other changed circumstances, a drug label no longer ensures safe and effective use, FDA allows drug manufacturers to work quickly and collaboratively with the agency to make necessary labeling changes. Of course, even in these instances, FDA retains ultimate responsibility to determine whether the proposed change is appropriate,

[27] In that case, the FDA framed the issue as "[w]hether state-law tort claims are preempted to the extent that they would impose liability for a drug manufacturer's use of labeling that the Food and Drug Administration approved after being informed of the relevant risk." Id. at *I.

> and may reject a labeling change and order the drug manufacturer to cease distributing the product with the new label. See 21 C.F.R. § 314.70(c)(5).
>
> In order to determine whether the imposition of state tort liability on a drug manufacturer for failure to warn would conflict with FDA's regulatory authority or interfere with the accomplishment of federal objectives, therefore, a court must analyze the agency's public actions with regard to a particular drug as well as the common-law duty sought to be imposed. If the agency had made a determination at the relevant time that a particular warning was unsubstantiated or would otherwise render a drug misbranded, then federal preemption bars liability for the failure to provide that warning.

Colacicco Third Circuit Amicus Brief, 2006 WL 5691532, at *22 n.10.

These FDA interpretations fully comport with both the plain language of the regulations and the oft-recited standard that where a drug manufacturer has reasonable evidence of an association between a drug and a serious hazard – and that information has not been previously considered and rejected by the FDA – the manufacturer may unilaterally add a warning and then seek FDA approval without fear of repercussion. To reach any other interpretation of the 2006 Preamble would effectively nullify the operation of 21 C.F.R. § 314.70(c)(6)(iii)(A) and 21 C.F.R. § 201.57(c)(6)(I), which jointly permit a drug manufacturer to"add or strengthen" a warning without prior FDA approval based on such reasonable evidence. See Sekula v. F.D.I.C., 39 F.3d 448, 454 (3d Cir. 1994) ("Another fundamental rule of construction is that effect must be given to every part of a statute or regulation, so that no part will be meaningless.").

Several post-Preamble decision have adopted this narrow interpretation and noted that the FDA's preemption position did not operate to bar a state law claim where there was no evidence that the FDA previously considered and rejected the proposed warning, either formally through an express denial or informally through failure to require its inclusion. See, e.g., Tucker, 2008 WL

2788505, at *5-6 (declining to give deference to the FDA's 2006 opinion on preemption); In re Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 776, 788 (E.D. La. 2007) ("Because there are no federal remedies for individuals harmed by prescription drugs, a finding of implied preemption in these cases would abolish state-law remedies and would, in effect, render legally impotent those who sustain injuries from defective prescription drugs. . . .To take such drastic action based solely on a preamble inserted at the eleventh hour and drafted by an agency without the express or implied authority to abolish such remedies is Draconian and unacceptable."); Sarli v. Mylan Bertek Pharms., Inc., Civ. A. No. 07-43, 2007 WL 2111577, at *4 (M.D.N.C. Jul. 19, 2007) (finding no preemption under 2006 Preamble where the warnings at issue had not been rejected by the FDA, submitted to the FDA for approval or did not clearly lack a reasonable basis; thus, the defendant could not show a conflict in complying with both federal and state law); In re Zyprexa, 489 F. Supp. 2d at 273-74 (noting that language of Preamble suggests that the FDA would consider preempted only those state-law adequacy of warning claims which seek to impose liability for failure to include labeling language already rejected by the FDA, not where the suggested language has never been proposed to or considered by the FDA); Weiss v. Fujisawa Pharm. Co., 464 F. Supp. 2d 666, 674 (E.D. Ky. 2006) (noting that the FDA's position is persuasive only insofar as it rejects failure-to-warn claims (1) based on conduct that allegedly occurred prior to and during the labeling approval process and (2) based on proposed warnings that FDA has specifically considered and rejected as scientifically unsubstantiated.); Perry v. Novartis Pharm. Corp., 456 F. Supp.2d 678, 685 (E.D. Pa. 2006) ("We believe it is more in keeping with the narrow scope of preemption to allow state law to require the addition of warnings so long as there has been no specific FDA determination as to the sufficiency of the

scientific evidence to support a particular warning."); Laisure-Radke v. Par Pharm., Inc., Civ. A. No. 03-365, 2006 WL 901657, at *6 (W.D. Wash. Mar. 29, 2006) ("[p]roviding new or additional warnings can hardly be an obstacle to the accomplishment of the full objectives of Congress when federal regulations specifically allow manufacturers to do so, and when Congress has left product liability matters to state law, as long as they do not directly conflict with federal law in that area."); Levine v. Wyeth, 944 A.2d 179, 193 (Vt. 2006), cert. granted 128 S. Ct. 1118 (2008) (noting that, under the 2006 Preeamble, a drug manufacturer can comply with both FDA regulations and duties imposed by state common law.)[28]

In light of the foregoing, the 2006 Preamble does not require a finding of preemption in this case. The Court thus declines to give it controlling weight.

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[28] Notably, even many of the courts that give deference to the 2006 Preamble have limited its operation to the particular facts of the cases before them, without finding preemption of all failure to warn cases. See, e.g., Mason v. Smithkline Beecham Corp., 546 F. Supp. 2d 618, 626 (C.D. Ill. 2008) ("While the Court would not likely reach the same conclusion if presented with a case seeking a finding of conflict preemption based solely on the FDA's rules and regulations, the Court has been persuaded that this situation, where the FDA had consistently considered and rejected the very warning now claimed to have been lacking, merits a different result."); Dobbs v. Wyeth Pharms., 530 F. Supp. 2d 1275, 1288-89 (W.D. Okla. 2008) (recognizing that FDA's current position on preemption conflicts with its view as of 2000; and noting that, although the Preamble was entitled to deference, "on the particular facts of this case, deference to the relatively broad scope of preemption set forth in the Preamble and amicus briefs filed since 2000 is not required because this case presents a narrower issue" where the proposed warning had been considered and rejected by the FDA); Horne v. Novartis Pharms. Corp., 541 F. Supp. 2d 768, 781 (W.D.N.C. 2008) (giving deference to Preamble, but noting that consideration of the stated intent of the FDA as expressed in the Preamble is not necessarily determinative of whether Plaintiff's failure to warn or inadequate labeling claims conflict with the federal regulations.); In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., MDL 1699, 2006 WL 2374742, at *8-9 (N.D. Cal. Aug. 16, 2006) (noting that the FDA's current view of the preemptive effect of its labeling regulations is a 180-degree reversal of its prior position, but giving it deference in a case where the FDA had expressly considered the proposed warnings and found them to be scientifically unsubstantiated.)

c. No Express Preemption in This Case

In sum, no clear conflict exists between the state law failure to warn claim raised by Plaintiffs in this case and the FDA's power to regulate prescription drugs and warning labels. As noted above, the FDA has taken the position that changes may be made to a label without prior approval only "to correct concerns about *newly discovered risks* from the use of the drug" based on "important new information." Wyeth Amicus Brief, 2007 WL 4555760, at *13. This case, in its current posture, falls precisely in that category. During the relevant period in this case, Paxil was not – and to date has not been - approved for pediatric use. As of the original approval in 1992, no evidence exists that the FDA received any pediatric clinical studies from any of the major SSRI manufacturers. In late 2001, the FDA first began receiving controlled studies of the seven major SSRI's in pediatric patients for the treatment of Major Depressive Disorder. Kallas Amicus Brief 13. On September 30, 2002, although the FDA had yet to affirmatively link increased suicidality in adolescents to Paxil, it declined to approve Zoloft, another SSRI, for treatment of pediatric Major Depressive Disorder, on the grounds that it could not prove efficacy. Kallas Amicus Brief 15. At no point did the FDA deem the proposed pediatric warning scientifically unsubstantiated. To the contrary, it ultimately required the inclusion of a "black box" warning linking pediatric use of SSRIs with an increased risk of suicidality. Quite unlike the cases finding state failure to warn cases preempted due to the FDA's clear and considered position on the warning at issue,[29] the FDA had not repeatedly and/or publicly stated its position as to this

[29] See, e.g., Colacicco, 521 F.3d at 269 (finding preemption where the FDA "has actively monitored the association between SSRIs and suicide for nearly twenty years and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading."); Bextra, 2006 WL 2374742, at *10 ("This is not a case where the FDA

warning. Accordingly, if GSK had reasonable evidence of an association between Paxil and increased pediatric suicidality, nothing in the FDA's regulations would have precluded it from adding that warning via a CBE, and subsequently seeking FDA approval, without facing any risk of "misbranding" the drug. Given the still viable presumption against preemption, the Court declines to find that any obvious conflict existed.

2. Reasonable Evidence of an Association Between Paxil and Pediatric Suicidality as of September 2002

Although the FDA has issued no clear statement on the pediatric warning at issue, the inquiry does not end at this juncture. As noted above, a drug manufacturer may unilaterally add a warning on a drug, so long as the drug manufacturer has reasonable evidence of an association of a serious hazard with a drug. 21 C.F.R. § 314.70(c)(6)(iii); 21 C.F.R. § 201.57(c)(6)(i). Having found that the FDA had not, prior to September of 2002, conclusively decided the propriety of such a warning, the Court must then ask whether GSK had reasonable evidence of association between increased suicidality and pediatric use of Paxil, such that the addition of such a warning under a CBE would not have resulted in the drug being deemed "misbranded."

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has not considered the risks of which plaintiffs claim the drug manufacturer should have warned."); Needleman v. Pfizer, Civ. A. No. 03-3074, 2004 WL 1773697, at *5 (N.D. Tex. Aug. 6, 2004) (finding state failure to warn claim alleging link between Zoloft and adult suicide to be preempted due to FDA's consistent determination that no such warning was scientifically substantiated); Dusek v. Pfizer, Civ. A No. 02-3559, 2004 WL 2191804, at *10 (S.D. Tex. Feb. 20, 2004) (finding preemption where if plaintiff prevailed on state failure to warn claim, defendant would be liable for not including warning that the FDA explicitly decided was not warranted, both before and after decedent's death); see also Pa. Employees Ben. Trust Fund v. Zeneca, Inc., 499 F.3d 239, 251 (3d Cir. 2007) (state law claim for fraudulent misrepresentations in prescription drug advertising were preempted where the FDA had approved the precise labeling of the drug which was the subject of the state law claim).

Bound by the summary judgment standard set forth in Federal Rule of Civil Procedure 56, the Court finds that a genuine issue of material fact exists as to whether Defendant possessed such reasonable evidence before September of 2002 – the date of Jake Garrison's refilled Paxil prescription and subsequent suicide. Prior to April of 2002, GSK had never submitted any pediatric clinical trial data to the FDA. It remains undisputed, however, that, as of 1998, GSK had completed Studies 329 and 377, both of which were the first two placebo controlled clinical trials of Paxil in children and adolescents. (PSUF ¶ 5, Ex. 5; ¶ 8, Ex. 14; ¶ 12, Ex. 21.) On July 30, 2001, GSK also issued the Final Clinical Report on Study 701, which was designed to evaluate the efficacy of Paxil in pediatric patients with major depressive disorder. (Id. ¶ 18, Ex. 30.) The first time GSK sought approval for pediatric indication of Paxil was on April 11, 2002, at which time it first submitted the results of the three studies. (Id. ¶ 26, Exs. 36, 37.) This submission, by all accounts, was the catalyst for a series of events culminating in the FDA required "black box" warning.

On October 7, 2002, Dr. Andrew Mosholder, the FDA reviewer of the pediatric Supplemental NDA for Paxil completed his review and noted an increase in "behavioral effects" coded "with terms such as hostility and emotional lability" which was "potentially confusing." (Id. ¶ 29, Ex. 39 at 6.) Accordingly, on October 21, 2002, the FDA requested from GSK clarification of the data regarding behavioral adverse events, as well as GSK's "rationale for coding suicide attempts and other forms of self-injurious behavior under the . . . term 'emotional lability.'" (Id. ¶ 30, Ex. 40.) Seven months later, GSK responded to this request and submitted a report that "suggested an increased risk (Paxil v. placebo) of various thoughts and behaviors coded as events considered 'possibly suicide related' and also for the subgroup of events that met

[GlasxoSmithKline's] criteria for representing 'suicide attempts.'" Kallas Amicus Brief 17 (citing January 2004 Laughren Memo at 7). In an e-mail from Dr. Russell Katz of the FDA to Dr. Andrew Mosholder, dated June 2, 2003, Dr. Katz noted that almost all of the events previously subsumed under the term "Emotional Lability" in GSK's initial Supplemental NDA, "related to suicidality." (PSUF ¶ 41, Ex. 47.) He stated that the FDA was "planning to look at the NDAs for the other SSRIs to see whether or not similar events are being hidden by various inappropriate coding maneuvers. . . ." (Id. ¶ 42, Ex. 47.) The FDA then issued a Talk Paper on June 19, 2003 "recommending that Paxil not be used in children and adolescents for the treatment of MDD." (Id. ¶ 49, Ex. 51.) The FDA thereafter expanded its "investigation of a possible more general link between use of antidepressants in children" by requesting data similar to that submitted by GSK from the manufacturers of the eight other major anti-depressant drugs that had been studied in children. Kallas Amicus Brief 17. The FDA continued to study the issue extensively. (PSUF ¶ 59, Ex. 6.) Following the recommendations of an advisory committee, the FDA, on October 15, 2004, issued a Public Health Advisory and letter directing all manufacturers of SSRIs to add a "black box" warning and expanded warning statements to the labeling of all antidepressant medications describing the increased risk of suicidality in children and adolescents. (Id. ¶ 72, Ex. 74.)

In an effort to argue that this course of events did not meet the reasonable evidence standard prior to September of 2002, Defendant offers several arguments. First, Defendant relies on a case hailing from the Eastern District of California, in which the court considered whether a state law failure to warn claim by parents of an adolescent who committed suicide while on Paxil was preempted under the FDCA. In O'Neal v. SmithKline Beecham Corp., the court remarked

that "GSK could not have changed the Paxil labeling to including a warning of a potential association of suicidality in pediatrics taking Paxil absent 'reasonable evidence' of an association." 551 F. Supp. 2d 993, 1003 (E.D. Cal. 2008). The court went on to note that on the evidence proffered by plaintiffs, it could not find that reasonable evidence of an association between suicidality and pediatric use of Paxil "existed *prior to* [deceased plaintiff's] death in February 1997." Id. (emphasis in original). Ultimately, it concluded that "[a]bsent reasonable evidence of a risk, GSK had no basis to petition FDA and simply did not have the option under federal law to include or secure a lawful warning for that risk in the drug's labeling. Had it done so, GSK would have misbranded the drug in violation of the FDCA . . ." Id. at 1008-09.

This case is neither dispositive nor even suggestive of the correct outcome in this case. In fact, the court's reasoning lends itself to the conclusion that the case at bar is not preempted. The decedent in that case attempted suicide on February 14, 1997, and died on February 15, 1997. Id. at 994. Accordingly, the court examined whether there was reasonable evidence of an association between Paxil and an increased risk of suicidality in pediatric patients *prior* to February of 1997. Id. at 1007. The court indicated that all data submitted to the FDA in 1989 and 1991 related to adults only and did not demonstrate that defendant should have been aware of the increased risk in children. Id. As to Study 329, which involved clinical trials of adolescents taking Paxil, the court remarked that GSK could not have known whether the study revealed a reasonable association of any risk for pediatric patients until after October 1997, when GSK broke the blind on the acute phase. Id. at 1008.

In this case, Jake Garrison committed suicide in September of 2002, after the completion of Study 329 and after the April 2002 supplemental NDA filing. Accordingly, the reasoning of

O'Neal, dealing with a period prior five and a half years earlier, fails to support Defendant's position.

Second, Defendant relies extensively on amicus brief filed in the case of Kallas v. Pfizer, Civ. A. No. 04-998 (D. Utah Sept. 15, 2005),[30] involving the November 2002 suicide of adolescent Shyra Kallas, following her use of prescription Zoloft. The court framed the question to the FDA as "whether the FDA had considered the issue of whether there was an *association* between Zoloft (or similar . . . SSRIs) and an increased risk of suicide prior to November 2002." Kallas Amicus Brief 12 (internal quotations omitted). Upon reviewing the regulatory history of Zoloft, as well as the FDA's initial studies regarding episodes of suicidality in children treated with SSRIs, the FDA concluded that "in October/November 2002, FDA did not believe there was reasonable evidence of an association between Zoloft and an increased risk of suicidality in either adult or pediatric patients." Id. at 36. Given the state of available scientific evidence and information as of that time, the FDA concluded that federal law would have barred Pfizer from giving the warning since any such warning would have misbranded the drug. Id. at 34-35.

While, at first blush, this amicus brief seems conclusive of the issue at bar, the Court, upon closer scrutiny, declines to accord controlling weight to the FDA's statement. First, the case is factually distinguishable. In Kallas, the FDA was concerned with whether, prior to October/November 2002, *Pfizer* had reasonable evidence of an association between *Zoloft*, or

[30] Defendant also references the three other previously-mentioned amicus briefs. These cases, however, involved claims of failure to warn of the link between SSRIs and adult suicidality. As this case involves a question of pediatric suicidality and SSRIs, these briefs are irrelevant to the extent they purport to opine on the existence of reasonable evidence of an association.

other SSRIS *generally*, and an increased risk of suicidality in pediatric patients. Id. at 31-32. The FDA conceded, however, that its general concern about the safety of the SSRIs were first triggered by the "the coding of the *Paxil* data in the New Drug Application supplement for pediatric Major Depressive Disorder," submitted in April of 2002 – information that was not in Pfizer's possession. Id. at 36. GSK's May 2003 report, which better characterized the adverse events identified under the term "emotional lability," then prompted the FDA to issue a public warning against the pediatric use of Paxil, *but not of Zoloft or any other SSRI*. Id. at 17. In fact, at that time, the FDA expressly indicated that it was unaware whether "the apparent increase in suicidal behaviors with pediatric use of Paxil was unique to that drug or occurred with other drugs as well." Id. at 18-19. Ultimately, there was no evidence that Pfizer had any reasonable evidence of the danger associated with pediatric use of Zoloft until the FDA made the definitive causal connection in October of 2004. Id. at 20.

Unlike in Kallas, the relevant question in this case is whether, prior to September of 2002, Defendant *GSK* had reasonable evidence of an association between *Paxil* and an increased risk of suicidality in pediatric patients – a question that yields a potentially different conclusion. Arguably, GSK possessed such reasonable evidence of an association between Paxil and pediatric suicidality as early as 1998, at the conclusion of their own Studies 329 and 377 – the data from which initially triggered the FDA's concerns. The mere fact that GSK elected not to submit the results of those studies until April of 2002, when it filed a supplemental NDA seeking approval of an indication for pediatric use, does not detract from the fact that it may have had reasonable

evidence of a hazard prior to that time.[31] Moreover, the seven month delay between GSK's original submission and its reanalysis of its data for the FDA, while perhaps relevant to the degree of knowledge possessed by the other SSRI manufacturers in that time period, does not bear on the degree of knowledge possessed by GSK. Finally, although the FDA did not make a definitive causal connection between SSRIs and an increased risk of suicidality in pediatric patients until 2004, after additional studies and analyses, such a causal connection, by the express terms of the regulations, was not necessary to trigger GSK's duty to strengthen its warning. See 201.57(c)(6)(i) (2003) ("[t]he 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.*") (emphasis added). Thus, the mere fact that the FDA had not ordered GSK to include this warning prior to 2002, does not mean that it could not have legally done so. See Fellner v. Tri-Union Seafoods, L.L.C., ___ F.3d ___, 2008 WL 3842925, at *12 (3d Cir. Aug.

[31] Defendant argues that Plaintiffs' arguments are essentially "fraud-on-the-FDA" claims alleging that GSK's alleged withholding of data from or manipulation of studies provided to the FDA worked an actual fraud. Such claims, according to Defendant, are preempted by Buckman Co. v. Plaintiffs' Legal Comm., since "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the [FDA], and that this authority is used by the [FDA] to achieve a somewhat delicate balance of statutory objections." 531 U.S. 341, 348, 353, 121 S. Ct. 1012 (2001). The Third Circuit reaffirmed this ruling and held that any argument by a plaintiff that GSK manipulated or withheld information from the FDA borders on a fraud claim and is, therefore, preempted. Colacicco, 521 F.3d at 272.

While Defendant is correct that any claim of defrauding the FDA would be preempted, Defendant either misunderstands the nature of Plaintiffs allegations or attempts to mischaracterize them in an effort to hide behind Buckman. Plaintiffs do not now suggest that Defendant should be penalized by the FDA for not bringing this information to the FDA sooner. Rather, they assert that, having either not received clinical trials regarding pediatric usage of Paxil or having received allegedly improperly coded data, the FDA could not have possibly considered the propriety of the warning proposed by Plaintiffs. Plaintiffs go on to argue that, under FDA regulations, Defendant should have then unilaterally issued a warning sooner based on the evidence in its possession. Such allegations do not fall within the bounds of Buckman's holding.

19, 2008) ("a mere decision not to regulate – in this case, a decision not to require a federal . . . warning – alone will not preempt state law.).

Moreover, even assuming the Kallas brief could be construed to conclusively represent the FDA's opinion that no reasonable evidence of association existed between Paxil and pediatric suicide prior to September of 2002, the Court would likewise not be persuaded. The Third Circuit has affirmatively found that where the FDA has only expressed an informal policy opinion after the plaintiff's injuries were allegedly suffered, such an opinion would not be sufficient to effect a preemption of a state lawsuit. Fellner, __ F.3d ___, 2008 WL 3842925, at *13. As more clearly explained by a fellow court addressing a similar amicus brief filed by the FDA:

> The FDA's statement, made outside of these proceedings is, at most, evidence regarding whether or not GSK was faced with reasonable evidence of an association between Paxil and adult suicidality in the fall of 2002 sufficient to trigger its duty to warn. The FDA's statement, again, would not have retroactively dissolved GSK's 2002 duty to revise its label in the face of the appropriate level of evidence of adult suicidality, if it in fact had such evidence. The FDA's statement, made several years after the fact, that it would not have approved a warning change that was never actually proposed, is speculative and will not serve as the basis for a finding of a preemptive conflict.

2008 WL 2788505, at *9; see also Jackson v. Pfizer, 432 F. Supp. 2d 964, 969 n.4 (D. Neb. 2006) (declining to give the Kallas amicus brief the force of law and finding no preemption in a case involving the October 10, 2002 suicide of an eleven-year old who took Zoloft and Effexor).[32]

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[32] In one of two last ditch efforts to resurrect its preemption motion, Defendant argues that, in August 2003, Wyeth submitted a CBE including stronger warnings to address pediatric suicide in the labeling for its antidepressant Effexor, which the FDA rejected as "confusing and potentially misleading." Based on this evidence, Defendant contends that the FDA would have likewise rejected any similar proposed warning for Paxil.

Defendant's argument is an improper characterization of the FDA's statements to Wyeth. Wyeth actually proposed to add a Precaution, rather than a Warning to its label regarding

To be clear, the Court expresses no opinion on whether or not reasonable evidence of an association between Paxil and increased pediatric suicidality existed, as a matter of fact, prior to September of 2002. Rather, we remain cognizant of our standard of review on summary judgment, which requires us to deny such a motion in the face of a genuine issue of material fact. Plaintiffs have made a showing, sufficient to survive summary judgment, that had GSK unilaterally added a pediatric warning pursuant to a CBE supplement prior to September of 2002, that change would have been neither rejected by the FDA nor deemed a misbranding of the drug. Defendant now fails to establish that any actual conflict existed between Plaintiffs' failure to warn

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increased pediatric hostility and suicide related events. (Howard Decl., Ex. 12.) The FDA rejected this proposal because it felt, as currently written, "the language is uninterpretable" and "confusing and potentially misleading" due to its failure to reference any placebo data. (Id. Ex. 13 at 2.) Instead, the FDA instructed Wyeth to use the proposed class "WARNING," which instructed that those being treated with antidepressants should be observed closely for suicidality, especially at the beginning of a course of therapy. (Id. Ex. 12 at 3-4.) In any event, although Wyeth had already used the Precaution in its labeling, it was not subject to any legal sanctions resulting from the FDA's disapproval, meaning that it faced no conflict with state tort law.

Second, Defendant cites to the deposition of Plaintiff's expert, Dr. Richard Kapit, wherein the following exchange occurred:

> Q. Do you have any evidence in the way of FDA statement or public announcement that they would have approved a warning of increased risk in pediatric patients of suicidality if GSK had submitted such a warning on June 19, 2003?
> * * *
> A. Right, it does call for speculation. I mean GSK submitted the pediatric data in May of 2003, did it not? And so they were – probably it was going to take them awhile to review it. But if they had done a lickety-split review, they probably did have the data to justify a warning at that point.

(Dep. of Richard Kapit, M.D., Jan. 31, 2008, 139:19-140:9). Defendant focuses on Dr. Kapit's statement that FDA approval of the suggested warning "calls for speculation" to argue that Plaintiffs cannot prove reasonable evidence of an association. The Court notes, however, that it is precisely such speculation that creates the genuine issue of material fact in this case.

claims and the FDA's authority. At this stage of the litigation, such a showing is sufficient for the Court to deny summary judgment on the grounds of preemption.

C. Conclusion

To summarize this lengthy, yet far from comprehensive ruling, the Court declines to find that the warning proposed by Plaintiffs in their state law failure to warn claims would clearly conflict with federal regulations. At the time Paxil was prescribed for Jake Garrison for the second time in September of 2002, the FDA had yet to publicly state its position regarding a link between the pediatric use of Paxil, or other SSRIs, and an increased risk of suicidality. Moreover, the evidence submitted by the parties suggests a triable issue of fact as to whether GSK indeed possessed information, not available to the FDA, upon which it could have unilaterally added a warning to its labeling, consistent with FDA regulations. Mere speculation as to whether the FDA would or would not have approved such a warning is insufficient to create a direct conflict upon which the Court can find preemption.

Finally, a point of policy bears mentioning. As the FDA never had the opportunity, prior to Jake Garrison's suicide, to consider the propriety of the warning proposed by Plaintiffs in this case, the "balance of risks and benefits set by the FDA when it approves a drug label," remains unaffected. Kessler & Vladeck, supra, 96 GEO. L.J. at 465. The labeling requirements of the FDCA were designed precisely for the purpose of protecting consumers. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 120 S. Ct. 1291 (2000). Drug manufacturers have best information about the safety of their own products and, thus, under the regulations, they have the ability to alter a drug label prior to FDA evaluation and approval. 21 C.F.R. § 314.70. A state

failure to warn action will not usurp or undermine the FDA's responsibilities to ensure an accurate label, but rather will close the void in the authority of the FDA, which can neither independently regulate off label use nor require additional clinical trials. Likewise, such litigation will not result in exaggerated risks associated with drugs. Because the standard for adding a warning under a CBE requires only reasonable evidence of association of a serious risk with the drug, and because state failure to warn claims under New Jersey law require the more stringent proof of causation between the drug and the injury, Michalko v. Cooke Color & Chem. Corp., 451 A.2d 179, 187 (N.J. 1982), only a drug manufacturer who, in fact, possessed such reasonable evidence, yet failed to add a warning, would be potentially liable under state law. As aptly noted by the court in case of Tucker v. Smithkline Beecham Corp.:

> Tort law can play an important role in filling the gap, and it is consistent with a regulatory system that puts the obligation to warn on the party with the most comprehensive information available: the drug manufacturer. The possibility that a jury might find in favor of a plaintiff advocating an unsubstantiated warning is an insufficient basis for finding that *all* pharmaceutical failure-to-warn plaintiffs should be denied any legal recourse if their theories conflict with current FDA positions. Plaintiffs in such cases . . . face a steep hill to meet their burden of proof. But if they can meet that burden, the court will need to listen.

2008 WL 2788505, at *7.

In sum, the Court declines to grant Defendant's Motion for Summary Judgment on the grounds of federal preemption.[33] An appropriate order follows.

[33] In light of our findings, the Court declines to address either (1) Plaintiffs' allegation that Defendant should have sent "Dear Doctor" letters, as described in Perry v. Novartis Pharms., 456 F. Supp. 2d 678 (E.D. Pa. 2006); (2) Plaintiffs' reliance on the New Jersey Supreme Court case of Feldman v. Lederle Labs., Inc., 592 A.2d 1176, 1195-96 (N.J. 1991); or (3) Plaintiffs' various constitutional arguments.

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARION L. KNIPE, Individually and as Administratrix and Administratrix Ad Prosequendum of the Estate of HAROLD STANLEY JAKE GARRISON, Deceased, and HAROLD L. GARRISON, JR., Individually,	:	CIVIL ACTION
Plaintiffs,	:	
v.	:	
	:	NO. 06-3024
SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE,	:	
Defendant.	:	

ORDER

AND NOW, this 28th day of *August*, 2008, upon consideration of Defendant GlaxoSmithKline's ("GSK") Motion for Summary Judgment on the Grounds of Federal Preemption (Docket No. 60), the Response of Plaintiffs Harold L. Garrison, Jr., individually, and Marion Knipe, individually and as administratrix and administratrix *ad prosequendum* of the Estate of Harold Stanley Jake Garrison (Doc. No. 98), Defendant's Reply Brief (Doc. No. 120), and Plaintiff's Sur-reply Brief (Doc. No. 137), as well as Plaintiffs' Motion to Strike Evidence Submitted by GSK in Support of Its Motion for Summary Judgment (Federal Preemption) (Doc. No. 107) and Defendant's Response thereto (Doc. No. 117), it is hereby **ORDERED** as follows:

1. Defendant's Motion for Summary Judgment on the Grounds of Federal Preemption is **DENIED** and

2. Plaintiffs' Motion to Strike Evidence Submitted by GSK in Support of Its Motion for Summary Judgment (Federal Preemption) is **DENIED**.

It is so ordered.

BY THE COURT:

S/ RONALD L. BUCKWALTER

RONALD L. BUCKWALTER, S.J.