

**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,	:	CIVIL ACTION
and HAROLD L. GARRISON, JR.,	:	
Individually,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	NO. 06-3024
SMITHKLINE BEECHAM d/b/a	:	
GLAXOSMITHKLINE,	:	
	:	
Defendant.	:	

MEMORANDUM

BUCKWALTER, S. J.

October 28, 2008

Currently pending before the Court is Defendant GlaxoSmithKline's ("GSK") Motion for Reconsideration of the Court's August 28, 2008 Order, or Alternatively for Certification of an Interlocutory Appeal. For the reasons discussed below, the Motion for Reconsideration is denied and the Request for Certification of an Interlocutory Appeal is granted.¹

I. MOTION FOR RECONSIDERATION

A. Standard of Review

A motion for reconsideration may be granted if the moving party shows: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available

¹ This Court provided a full summary of the facts relevant to Defendant's Motion for Summary Judgment on Grounds of Federal Preemption in the Opinion and Order dated August 28, 2008. Knipe v. SmithKline Beecham, Civ. A. No. 06-3024, 2008 WL 4090995, at *1-9 (E.D. Pa. Aug. 28, 2008). In lieu of repeating these facts, that synopsis is incorporated by reference into this Opinion.

when the court issued its order; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. Max's Seafood Café v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999). Motions for reconsideration are granted sparingly. Cont'l Cas. Co. v. Diversified Indus., Inc., 884 F. Supp. 937, 943 (E.D. Pa. 1995). The grant of such a motion is not proper where it simply asks the court to “rethink what [it] had already thought through – rightly or wrongly.” Glendon Energy Co. v. Borough of Glendon, 836 F. Supp. 1109, 1123 (E.D. Pa. 1993) (internal quotations omitted). Motions for reconsideration may not be used “as a means to argue new facts or issues that inexcusably were not presented to the court in the matter previously decided.” Brambles USA, Inc. v. Blocker, 735 F. Supp. 1239, 1240 (D. Del. 1990). “Nor may a motion for reconsideration be used to revisit or raise new issues with the benefit of ‘the hindsight provided by the court's analysis.’” Marshak v. Treadwell, Civ. A. No. 95-3794, 2008 WL 413312, at *7 (D.N.J. Feb. 13, 2008) (quoting United States v. Jones, 158 F.R.D. 309, 314 (D.N.J. 1994)).

B. Discussion

Defendant's current Motion for Reconsideration reflects its attempt to take another bite at the preemption apple. In support of its initial Motion for Summary Judgment on Grounds of Federal Preemption, Defendant previously provided a lengthy brief, multiple declarations and exhibits, and an additional reply brief – all of which emphasized that the Third Circuit decision in Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008), mandated a finding of preemption. Having failed to convince the Court via these submissions, Defendant has effectively abandoned this argument and now seeks reconsideration on the basis of new evidence and alternative tactics.

Weaving together multiple individual events in the course of Paxil's regulatory history, GSK contends that the federal Food and Drug Administration (“FDA”), despite never

directly regulating pediatric use of Paxil, had implicitly and effectively preempted any efforts by GSK to warn about its associated dangers during the relevant period prior to September 2002. This current argument, however, again asks the Court to ignore the forest for the trees. For conflict preemption to apply, GSK must allege an actual conflict between federal and state law, such that GSK could not possibly comply with both state tort law cited by Plaintiffs and federal labeling provisions. See 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, 1935 (2000)); see also Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 685 (E.D. Pa. 2006) (“[w]e 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). Defendant, however, cites no established federal law, clear public FDA pronouncement or explicit FDA rejection of a proposed pediatric suicidality warning that would have legally foreclosed GSK’s attempt to include such a warning on its Paxil label prior to Jake Garrison’s suicide in 2002. Quite to the contrary, and as consistently emphasized on previous occasions by this Court, the FDA, during the relevant period prior to September of 2002, never approved Paxil for pediatric use and, thus, never opined on the propriety of a pediatric warning. When subsequently considering GSK’s efforts to obtain such approval, the FDA found cause to warn the public of a potential pediatric risk and, by October 2004, mandated a black box warning against pediatric use. Given the recently reaffirmed presumption against preemption, the Court declines to conjure a preemptive conflict out of virtually thin air. Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 249 (3d Cir. 2008) (emphasizing continued viability of

presumption against preemption in state tort action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product).

In light of this void in the FDA's regulation of off-label, pediatric use of Paxil prior to September of 2002, GSK was free to add a warning of risks associated with that use "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." 21 C.F.R. § 201.57(e). This Court previously found that Plaintiffs made a substantial showing of reasonable evidence of an association between pediatric use of Paxil and increased suicidality. Knipe, 2008 WL 4090995, at *22. As such, GSK would not have faced any penalties or retroactive misbranding of its drug had the FDA ultimately not approved the added warning. 21 C.F.R. § 314.70(c)(7) (2003) ("[i]f the agency disapproves the supplemental application, it may order the manufacturer to cease distribution of the drug products made with the manufacturing change."); see also Tucker v. SmithKline Beecham Corp., Civ. A. No. 04-1748, 2008 WL 2788505, at *3 (S.D. Ind. Jul.18, 2008) (citing 21 C.F.R. § 314.70).

Although the Court stands unpersuaded by Defendant's current efforts, we nonetheless remain cognizant that preemption of tort claims involving prescription drugs has become a hotly debated issue resulting in a recent flood of federal litigation. As fully explained below, the issues before us are prime for interlocutory appeal. Accordingly, for the sake of comprehensiveness, the Court briefly addresses each of the specific challenges raised by Defendant in its Motion.

1. **Whether the Court Deprived Defendant of Its Opportunity to Respond to New Arguments Raised by Plaintiffs in Their Sur-reply**

In its first argument, Defendant contends that the Court “relied upon Plaintiffs’ inaccurate representation in their sur-reply that GSK did not submit *any* pediatric data to FDA until April 2002.” (Def.’s Mem. Supp. Mot. Recons. 1-2.) It goes on to assert that although GSK attempted to respond to this erroneous representation via a response to Plaintiffs’ Sur-reply Brief, the Court declined to permit further briefing. (*Id.*) Defendant’s argument concludes that because the Court did not have the benefit of a complete factual record prior to its decision, the Court should now consider newly-proffered evidence establishing that GSK provided the FDA with pediatric Paxil data prior to April 2002.

Defendant’s effort to submit such new evidence is flawed at its core, as Plaintiffs’ sur-reply argument was not new. Defendant initially filed a thirty-four page memorandum in support of its Motion for Summary Judgment on Preemption, accompanied by a seven page Statement of Undisputed Facts and a myriad of exhibits. Plaintiffs thereafter responded with an extensive brief that argued, in large part, as follows:

GSK’s entire preemption argument rests on its false premise that “Plaintiffs here assert claims based on warnings which FDA has considered and rejected during the relevant time period.” . . . However, GSK fails to cite a single document that establishes that, prior to September 2002 (the “relevant time period”), the FDA “considered and rejected” a pediatric suicidality warning for Paxil. The fact is that, prior to this time, GSK never submitted a proposed pediatric warning to the FDA, thus, there was no warning for the FDA to consider or reject. *In its memorandum of law (as well as the voluminous exhibits), GSK equally fails to reference a single document that demonstrates that, prior to Jake’s suicide, the FDA actually reviewed and considered populations other than adults for the approved indications. The reason GSK is unable to cite to a single piece of evidence is because, for each instance in which GSK sought approval for an indication for Paxil, it was adults, never children or adolescents. Accordingly, the FDA never received (and thus never reviewed) any significant Paxil safety and efficacy data regarding pediatric or adolescent use.*

(Pls.’ Mem. Opp. Mot. Summ. J. Preemption, Knipe v. SmithKline Beecham, Civ. A. No. 06-3024, 15 (E.D. Pa. Jun. 19, 2008) (emphasis added).)

The first time GSK sought approval for a pediatric indication was on April 11, 2002, when GSK submitted an Application to the FDA “proposing the use of Paxil to treat children and adolescents with major depressive disorder and obsessive compulsive disorder.” . . . *Prior to this time, GSK had never submitted any pediatric clinical trials data to the FDA for approval of pediatric indications.*

(Id. at 17 (emphasis added).)

Despite these patent arguments, Defendant submitted a twenty-three page Reply Brief that failed either to contest Plaintiffs’ representations or to provide the exhibits now attached to its Motion for Reconsideration. In their ensuing Sur-reply Brief, Plaintiffs simply re-raised their earlier argument as follows: “[a]s outlined in Plaintiffs’ Opposition, GSK withheld [pediatric data] from the FDA for over four years and did not disclose it to the FDA until April 2002 when it submitted an application to the FDA to obtain pediatric approval of Paxil.” (Pls’ Reply Br. to Mot. Summ. J. Preemption, Knipe v. SmithKline Beecham, Civ. A. No. 06-3024, 3 (E.D. Pa. Aug. 4, 2008).)

In short, GSK failed to seize its ample opportunity to respond to Plaintiffs’ claims.² Defendant’s contention, in its Reply Brief, that it was not aware of the precise contours of this argument, and thus could not respond accordingly, is disingenuous. The law is well established that “when evidence is not newly discovered, a party may not submit that evidence in support of a motion to reconsider. . . .” Pavlik v. Lane Ltd./ Tobacco Exp. Int’l, 135 F.3d 876, 882 n.2 (3d Cir.

² Notably, Plaintiffs also aver that GSK did not produce much of this evidence to them prior to attaching it to the Motion for Reconsideration. Defendant disputes this allegation. For purposes of this motion, the Court need not resolve this dispute.

1998) (citing Harsco Corp. v. Zlotnicki, 779 F.2d 906, 909 (3d Cir. 1985)). The Court now declines to permit GSK to act in hindsight to correct its own omission.³ We thus decline to consider the new evidence as a basis for granting reconsideration.

2. Whether the New Evidence Alters the Court's Determination

Assuming *arguendo* that the new evidence submitted by Defendant was properly before the Court, our decision would nonetheless remain unchanged. While the new evidence refutes the Court's finding that GSK submitted no pediatric Paxil data prior to April 2002, the data reflected in that evidence was incomplete and, arguably, misleading. Thus, far from showing that the FDA had information on which to base a decision about the propriety of the pediatric warning, Defendant's new evidence suggests that the FDA remained quite uninformed of the risks uncovered by GSK's own studies.

For example, Defendant first references an Investigational New Drug ("IND") Annual Report⁴ for Paxil submitted, on March 20, 1998, by GSK to the FDA. That report included

³ Defendant takes issue with the Court's statement in the Memorandum and Order that "as agreed by the parties in this case, Paxil has never been approved for pediatric use and, therefore, the FDA never reviewed any safety data and efficacy data regarding pediatric use prior to approval of the drug." Knipe, 2008 WL 4090995, at *15. It argues that it "never stated or agreed that FDA had not reviewed pediatric data prior to approval of Paxil." (Def.'s Mem. Supp. Mot. Recons. 5.)

As a primary matter, the Court's statement was meant only to indicate that the parties agreed that Paxil had never been approved for pediatric use – a fact that, to date, is not in dispute. Moreover, to the extent the statement purported to suggest Defendant's concession that the FDA never reviewed any safety and efficacy data for pediatric use of Paxil prior to the drug's approval, the Court would not have spoken in error based on the record before us. As noted above, despite Plaintiffs' repeated arguments to that effect, Defendant submitted no contrary evidence in either of its two briefs provided during summary judgment proceedings.

⁴ Drug manufacturers 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). The

some data from Study 329 relating to adverse events in the form of summaries and individual line listings, which included suicide or suicide attempts in pediatric patients. (Def.’s Mem. Supp. Mot. Recons., Ex. A (“Arning Decl.”), ¶ 7, Ex. 1.) Notably, however, the line listings showing pediatric patients who experienced suicidal ideations indicate that the blind phase of the study had not yet been broken. (Id. at Table 4A.) As Study 329 had not yet been completed as of that reporting period, it is disingenuous for Defendant to now claim that the FDA was fully apprised of the results of the study at that time.

Defendant also cites to another IND Annual Report, dated March 22, 1999, that included a summary of data from Study 329. (Arning Decl., ¶ 8, Ex. 2, Bates No. 000007.) GSK informed the FDA that Study 329 involved “[a] multicenter, double-blind, placebo-controlled study of paroxetine and imipramine in adolescents with unipolar major depression.” (Id. at Bates No. 000015.) In the table of adverse experiences most frequently reported, however, GSK listed only “emotional lability” without clarifying whether that experience included episodes of suicidality. (Id. at Bates No. 000027.) As fully explained in the Court’s previous memorandum, the coding of such events as “emotional lability” failed to clearly indicate to the FDA which of those events involved suicidality. Knipe, 2008 WL 4090995, at *21. Indeed, when the entirety of the data was ultimately submitted in April of 2002, the listing of adverse events under the term “emotional lability” caused the FDA to seek clarification from GSK.⁵ Id.

required safety reports must be filed every three months during the first few years of marketing of a drug. The adverse event reporting system, however, is “largely voluntary.” In re Zyprexa Prods. Liab. Litig., ___ F. Supp. 2d ___, 2008 WL 4097408, at *47 (E.D.N.Y. Sep. 5, 2008).

⁵ Defendant cites to the testimony of Robert Temple, M.D., the FDA’s Director of the Office of Medical Policy to argue that the FDA was not confused about what the term “emotional lability” included. Specifically, Defendant references the following testimony:

Finally, Defendant references a July 9, 1999, submission to the FDA containing

A. What we know is that the – well, whenever you report adverse reactions, you have to group them otherwise it doesn't make any sense.

Q. Right.

A. So you take the individual reports of physicians and you call them something else in – as everybody by now knows, suicidality was incorporated into something called a emotional liability, although it was very clear from reading the reports that some of them were suicidality. That's why we were able to where – where attempted suicides or thinking about suicides. That's why we were able to, um, detect it. I wouldn't characterized it as miscoding. I think it's a consequence of having a coding dictionary.

(Def.'s Opp. Pls.' Evid. Objections and Add. Statements of Undisputed Facts, Ex. 20 (“Robert Temple Dep.”), at 56:14-57:6, Knipe v. SmithKline Beecham, Civ. A. No. 06-3024 (E.D. Pa. Jul. 3, 2008).)

Defendant, however, truncates, and in turn misrepresents, Dr. Temple's testimony. Dr. Temple subsequently stated that “whether [the Paxil adverse events] were optimally grouped or not, you know, could be debated. Now I think now that we're aware of the suicidality issue, if they now appeared under the heading of emotional liability, that would be unsatisfactory. . . [The term emotional liability] would not be appropriate anymore.” (Id. at 58:17-59:9.)

In a later part of his deposition, Dr. Temple indicated as follows:

A. What [Dr. Andrew Mosholder, the FDA reviewer of the Paxil supplemental NDA] noticed in reviewing the Paxil was when you looked the term emotional liability is a collective term. We also get all of the individual reports. So as he looked at what went into emotional liability, he noticed there were a reasonable number of reports that indicated suicidal thinking or suicidal behavior.

Q. Including suicidal attempts?

A. That's behavior.

Q. Okay.

A. Right. Um, and he notice that and I guess he thought there – it looks like there might be more on the drug than on the placebo. And it sort of raised the whole issue of whether we were assuming things that were obscured by that categorization. And the question that Dr. Katz asked which is why are you – why are you characterizing it this way, which is kind of odd because there has always been an attempt to look at suicide, suicidal thinking, suicidal attempts as a separate matter, so I still don't understand why they were characterized as that.

(Id. at 415:16-416:15.)

information relating to its Paxil pediatric studies as a follow-up to discussions regarding a pediatric indication for treatment of obsessive-compulsive disorder. (Arning Decl. ¶ 9, Ex. 3.) Notably, however, this submission was, by GSK's own admission, only a synopsis of Study 329, with a nine-page excerpt from the full 154-page final report that was later produced to the FDA in its entirety on April 11, 2002. (Id. at PAR001146183.) In the synopsis, GSK expressly represented to the FDA that, "[t]he safety of paroxetine has been established in the adolescent population in study 329 and in both children under and over the age of 12 years in the OCD trial 453" and that "[t]he nature and incidence of adverse events reported for the paroxetine group were similar to that reported for adult depressed patients receiving paroxetine." (Id. at PAR 001146170, PAR001146189.) GSK did not highlight the unfavorable data that later triggered the FDA's concerns.

In short, the newly-submitted evidence from GSK shows that it repeatedly offered only snapshots of its studies to the FDA without providing the full data until April 2002. Moreover, GSK obscured the relevancy of that data – either knowingly or unknowingly – by coding suicidal behavior as “emotional lability” and suggesting to the FDA that there was no increased rate of suicidality in pediatric users of Paxil. Ultimately, the fact remains that, when finally provided with the full data from Study 329 and Study 377 in April of 2002, and receiving the requested clarification of that data in May of 2003, the FDA immediately warned the public about the potential risks of pediatric Paxil use and began a full-scale investigation into the precise scope of those risks. To the extent GSK now offers this new and, as noted above, untimely evidence as support for the “transparency with which GSK interacted with the FDA,” its efforts backfire. (Def.'s Mem. Supp. Mot. Recons. 6.) The Court cannot find that this evidence offers any basis on

which to infer an express FDA consideration, rejection, and therefore preemption, of a pediatric suicidality warning.

3. **Whether the FDA’s Failure to Mandate a Pediatric Warning After April of 2002, Despite Its Approval of New Indications for Paxil, Evidences the FDA’s Clear Rejection of Such a Pediatric Warning**

In its next argument, Defendant contends that the FDA’s actions from April 2002 until October 2004 indicated its affirmative refusal to require a warning regarding pediatric use of Paxil. As noted above, in April 2002, the FDA received GSK’s supplemental NDA seeking approval for a pediatric indication for Paxil. Despite its recognition of flags in GSK’s data regarding an increased risk of pediatric suicidality, the FDA did not ultimately require that a warning be included in Paxil’s labeling until 2004. In the interim, the FDA approved three supplemental Paxil new drug applications (“NDA”s) for other indications in August 2003, October 2003 and January 2003, yet chose not to include any language relating to a possible pediatric risk. Defendant claims that “until [the] FDA’s decision in 2004 to mandate a black box [warning], each time [the] FDA had considered and evaluated the issue of pediatric suicidality, [the] FDA did not find that such a risk existed.” (Def.’s Mem. Supp. Mot. Recons. 6.)

Defendant’s claim, however, confuses the FDA’s failure to regulate with an explicit FDA statement that an added warning regarding pediatric suicidality was unwarranted and prohibited. In Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008), the case relied upon by Defendant in its original Motion for Summary Judgment, the Third Circuit expressly declined to 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. Subsequently, in Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237 (3d Cir. 2008), the Third Circuit emphasized that “mere deliberate agency inaction – an agency decision *not* to regulate an issue – will not alone preempt state law.” Id. at 247. “State law is not preempted whenever an agency has merely ‘studied’ or ‘considered’ an issue.” Id. at 254.

In Sprietsma v. Mercury Marine, 537 U.S. 51, 123 S. Ct. 518 (2002), the United States Supreme Court directly confronted the preemptive effect of an agency decision not to regulate. 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 a 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 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 stated that “although the Coast Guard’s decision not to require propeller guards was undoubtedly intentional and carefully considered, it does not convey an ‘authoritative’ message of a federal policy against propeller guards.” Id. at 67. Ultimately, the Court concluded that nothing in the regulatory history would be inconsistent with a jury finding, premised on state law, that some type of propeller guard should have been installed. Id.

The case at bar is closely akin to Sprietsma. Nothing in Paxil’s regulatory history or the FDA’s statements regarding Paxil creates a conflict such that GSK’s addition of a warning

regarding risks of pediatric suicide would have been prohibited by federal law. In its initial efforts to obtain approval for Paxil, GSK neither sought a pediatric indication nor submitted pediatric studies to the FDA. After the initial approval, but prior to April 2002, GSK did not propose labeling changes to warn of pediatric risks, and did not provide the FDA with all the relevant data in its possession. Following the FDA's initial review of GSK's April 2002 supplemental NDA seeking a pediatric indication, the FDA issued a preliminary approvable letter, which actually approved GSK's proposed new labeling warning of an increase in certain adverse events in the adolescent population. (Arning Decl. ¶ 14, Ex. 6.) As the supplemental NDA was never finally approved, however, the proposed new labeling was never implemented.⁶

Upon receipt of the May 2003 clarification from GSK, the FDA proceeded to issue a series of public statements – dated from June 19, 2003, to March 22, 2004 – that failed to discount a link between Paxil and pediatric suicide. Indeed, as more fully explained in the Court's prior decision, these statements repeatedly warned of potential, albeit unconfirmed, dangers in pediatric Paxil use. Knipe, 2008 WL 4090995, at *8 (citing the June 19, 2003 Talk Paper, October 27, 2003

⁶ In its Reply Brief, Defendant argues that the FDA explicitly stated that the Paxil labeling “may be considered to be misbranded under the [FDCA] if it is marketed with these changes prior to approval of this supplemental application.” (Def.'s Reply Br., Ex. 6.) Defendant contends that this letter reveals that the FDA expressly prohibited GSK from including this language in Paxil's labeling in 2002.

The Court interprets this language somewhat differently. The FDA provided GSK with a four-page preliminary approval letter of its supplemental NDA for pediatric use of Paxil. (Id.) It approved the labeling changes warning of increased risks, but still had concerns over some of GSK's coding, as well as some deficiencies in the information provided by GSK. (Id.) The comment that GSK could not make any changes appears at the end of the letter and indicates only that GSK could not list Paxil as approved for pediatric use, with all additional labeling changes, until after the submission of the requested information. (Id.) The FDA did not reject the propriety of a pediatric suicidality warning and, contrary to Defendant's argument, did not “conclusively show[] [that] Plaintiffs would have GSK misbrand Paxil's labeling and risk criminal and civil penalties.” (Def.'s Reply Br. 9.)

Public Health Advisory and corresponding Talk Paper, and March 22, 2004 Public Health Advisory). In that time, the FDA approved three new indications for Paxil – all of which were for adult usage only. None of the labels proposed by GSK for these three new indications included any of the pediatric information that GSK had previously submitted. Id. at *6 n.12.

Thus, as in Sprietsma, the FDA had not decided, as a matter of policy, that a pediatric warning was unsubstantiated or should not be imposed by state law.⁷ The delay, between May 2003 and October 2004, in adding a warning to the Paxil label suggested only that the FDA had not itself confirmed the link between the drug and the adverse reaction. It did not suggest that GSK’s attempt to add such a warning would have been deemed misbranding, or that GSK did not have reasonable evidence of an association between its drug and the pediatric side effects. See 21 C.F.R. § 314.70(c)(7) (2003). Moreover, the FDA’s failure to require a pediatric warning label when approving the new indications resulted not from an affirmative FDA finding that a pediatric warning was not acceptable or improper, but rather from GSK’s own failure to include the warning in the draft labels given to the FDA for the particular indication under review. Finally, even assuming that

⁷ Defendant’s Reply Brief asserts that the Supreme Court’s decision in Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 120 S. Ct. 1913 (2000), is more analogous. Plaintiff, in that case, sued defendant alleging that the car in which she was injured failed to contained a driver’s side airbag. The Solicitor General argued that the promulgation of the Federal Motor Vehicle Safety Standard (FMVSS) 208 embodied a “policy judgment that safety would be best promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car.” Id. at 881. Thus, the court found that a state law requiring all manufacturers of similar cars to install airbags instead of other passive restraint systems “would have presented an obstacle to the variety and mix of devices that the federal regulation sought.” Id. Accordingly, the Court found the state tort law to be preempted. Id. at 886.

In the case at bar, however, Defendant points to no law, regulation or FDA statement with which a warning regarding pediatric dangers in use of Paxil would conflict. Nor does Defendant explain how such a warning would pose an obstacle to the FDA’s accomplishment of its objectives with respect to the regulation of Paxil. Rather, like Sprietsma, the FDA’s inaction towards pediatric use of Paxil reflects nothing more than a decision not to regulate.

the FDA had fully considered the pediatric information previously supplied by GSK when approving the other adult indications, the FDA's decision to not require a pediatric warning at that time did not convey an "authoritative message of federal policy" against a pediatric warning that would conflict with Plaintiffs' state law failure to warn claim. Sprietsma, 537 U.S. at 67. As succinctly stated by the Third Circuit, "[a] mere decision by the FDA not to adopt a federal warnings requirement certainly does not alone preclude states from imposing a duty to warn." Fellner, 539 F.3d at 257; see also Knipe, 2008 WL 4090995, at *23 ("the mere fact that the FDA had not ordered GSK to include a warning prior to 2002, does not mean that it could not have legally done so.")

In short, the law is clear that express or deliberate FDA action causes preemption, not mere inaction. Defendant's argument would flip this concept on its head and prevent a pharmaceutical manufacturer from issuing any warning regarding newfound dangers associated with its already-approved drug absent an explicit FDA permission slip. The well-established presumption against preemption prohibits the Court from expanding the preemption doctrine to this degree.

4. Whether the Court Improperly Discounted the FDA's 1990 Rejection of the Citizen Petitions Relating to Prozac and the FDA's 1996 Finding that There Was No Evidence of an Increased Risk of Pediatric Suicidality in Zoloft

In its next challenge to this Court's prior opinion, Defendant contends that the Court erred in not giving weight to two pieces of evidence. First, in 1990, the FDA rejected two "Citizen Petitions," seeking either the withdrawal of NDA approval for Prozac, which was the only approved selective serotonin reuptake inhibitor ("SSRI") at the time, or alternatively, a warning statement in

the labeling regarding an increased risk of suicide. Knipe, 2008 WL 4090995, at *5. The FDA considered the data, including some pediatric data, and found “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.” Id. In the second piece of evidence at issue, the FDA reviewed the risk of pediatric suicidality relating to Zoloft in 1996, and issued a memorandum concluding that there was no evidence of an increased risk of suicide. (Def. Mem. Supp. Mot. Recons., Ex. B, at 2.) Taking these two pieces of evidence together, Defendant again argues that the FDA had considered and expressly rejected any link between Paxil and pediatric suicidality.

Defendant’s arguments are unconvincing on multiple grounds. First and foremost, both the Citizen Petitions and the 1996 FDA memorandum involved drugs other than Paxil. Although GSK repeatedly attempts to equate Paxil with the other SSRIs for purposes of preemption, the differences are significant. Both Prozac and Zoloft were approved for treatment of pediatric mental disorders. (Pls.’ Mem. Opp. Mot. Recons., Exs. A, B.) Paxil, on the other hand, has never been approved for pediatric indications, and, as of June 2003, was the only SSRI that was the subject of an FDA public advisory regarding pediatric use. Knipe, 2008 WL 4090995, at *8.

Second, even after the FDA’s 1991-1992 rejection of the Citizen Petitions regarding *Prozac*, the FDA clearly had yet to consider a linkage between pediatric usage of *Paxil* and suicidality. Indeed, the FDA’s approval letter for Paxil to GSK in 1992, expressly 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. at *6.

Third, Defendant’s citation to the FDA’s October 25, 1996, internal memorandum regarding Zoloft’s risk of pediatric suicidality is both improper and unpersuasive. Primarily, GSK failed to bring this to the Court’s attention in either of its two briefs submitted in support of its Motion for Summary Judgment. Accordingly, the Court may not now consider it. Moreover, this memorandum was not a response to any request by Pfizer to add a pediatric warning to its label, but simply a comment that the current studies, as of 1996, showed no signal of risk for suicidality for either adults or children. (Def.’s Mem. Supp. Mot. Recons., Ex. B.) The memorandum went on to note that the information in the FDA’s possession was incomplete and, thus inconclusive: “[s]upplements are planned for both depression and OCD in pediatric patients, and when we have more complete data, include HAMD data, we can look more critically at this issue, using the now standard approach of comparing the proportions of drug and placebo exposed patients who show worsening on Item 3 (suicidality item) of the HAMD during treatment.” (*Id.*) As the FDA, in 1996, did not have the “more complete” data – specifically GSK’s yet uncompleted Study 329 – it had not yet “looke[ed] more critically” at the propriety of a proposed pediatric suicidality warning.

Such evidence by no means establishes the FDA’s express statement or action that a state law claim to add a pediatric warning to Paxil’s label would have been preempted prior to Jake Garrison’s suicide. Defendant’s contrary arguments disregard the fundamental principle that “federal law capable of preempting state law 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*, 539 F3d at 245. The Court thus declines to find that this argument merits reconsideration of our earlier decision.

5. **Whether the Court Improperly Found that Reasonable Evidence of an Association Between Paxil and Pediatric Suicidality Existed**

Next, Defendant argues that the FDA's 2004 analysis of GSK's pediatric studies showed no statistically increased risk of pediatric suicidality. Moreover, the FDA never adopted GSK's proposed labeling submitted in June 2003. Considering this evidence collectively, Defendant again asserts that there was no reasonable evidence of an association between Paxil and adverse effects in the pediatric population prior to September of 2002.

The Court declines to rethink its prior determinations on this issue. Both FDA regulations and state tort law ask only whether the manufacturer knows or has reasonable evidence of an association between a drug and the complained-of adverse effect – not whether the FDA had such evidence. This Court previously concluded that, “Plaintiffs . . . made a showing, sufficient to survive summary judgment, that had GSK unilaterally added a pediatric warning pursuant to a CBE [changes being effected] supplement prior to September of 2002, that change would have been neither rejected by the FDA nor deemed a misbranding of the drug.” *Knipe*, 2008 WL 4090995, at *24. Such proof is sufficient to establish a genuine issue of material fact that GSK, if not the FDA, had reasonable evidence of an association between Paxil and pediatric suicidality. Defendant presents no new evidence or arguments on this issue that have not already been thoroughly considered and rejected.

6. **Whether the Court Erred in Its Consideration of the *Kallas* Amicus Brief**

Defendant also challenges this Court's handling of the *amicus curiae* brief, filed in *Kallas v. Pfizer, Inc.*, Civ. A. No. 04-998 (D. Utah Sep. 15, 2005) (“*Kallas Amicus Br.*”), on several

levels. First, it contends that the Court read an unwarranted limitation into the brief when finding that the FDA's determinations pertained only to Pfizer and not to SSRI's generally. Second, it claims that the Court mistakenly dismissed the FDA's factual determination that there was no reasonable evidence of a pediatric risk and SSRIs on the whole in late 2002. Finally, Defendant asserts that the Court erred in characterizing the FDA's *amicus* brief as an informal policy opinion that was insufficient to effect a preemption of a state lawsuit.

Again the Court finds no merit to any of these arguments. First, Defendant's claim that the FDA's factual analysis in Kallas was applicable to all SSRI drugs, including Paxil, is belied by the FDA's own language in that brief. As this Court previously explained, the FDA, in Kallas, noted that *Zoloft's* pre-November 2002 history did not reveal a signal of an increased risk of suicidality in pediatric patients. Kallas Amicus Br. 13-15. Upon conducting their October 2002 review of *Paxil's* supplemental NDA containing the requested studies of its use in children, "the FDA reviewers noted a greater number of adverse events coded under the term 'emotional lability' in the group of patients treated with Paxil compared to placebos in some, but not all, of the studies." Id. at 16. The brief went on to comment that "[u]ltimately . . . FDA's concerns regarding the coding of *Paxil* data in the New Drug Application supplement for pediatric Major Depressive Disorder for that drug triggered a series of events that led the agency to conclude that there is reasonable evidence of an association between SSRIs and suicidality in children and adolescents." Id. at 36. At that time, it was not clear to the FDA "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. The June 2003 Talk Paper was then limited to a warning about pediatric use of Paxil, and did not

encompass any other SSRI. Id. at 17. Thus, the Court’s factual distinction finds ample support within the brief itself.

Second, there was no error in the weight accorded to the FDA’s factual determinations in that case. Contrary to Defendant’s arguments, this Court – consistent with Third Circuit precedent – took full notice of the FDA’s factual and scientific determinations regarding the regulatory history of the various SSRIs. See Colacicco v. Apotex Corp., 521 F.3d 253, 270 n.15 (3d Cir. 2008) (finding that the Court should “take notice” of “[t]he FDA’s summary of its scientific determinations” as distinguished from “the agency’s construction of a statute.”). The Court then properly found that the FDA’s legal determination – that there was no “reasonable evidence of an association” between all SSRIs and pediatric suicidality as of late 2002, as defined in 21 C.F.R. § 201.57(c)(6)(I) (2003) – was entitled only deference to the extent it had the “power to persuade.” Id. at 278-79 (an agency’s informal position regarding preemption is subject to a level of deference approximately that set forth in Skidmore v. Swift & Co., 323 U.S. 134, 65 S. Ct. 161 (1994), and is entitled to respect only to the extent it has the power to persuade). As we found sufficient contrary proof that GSK had such reasonable evidence of an association between Paxil and pediatric suicidality, the Court properly acknowledged the existence of a genuine issue of material fact on this issue.

Finally, the Court finds no merit to Defendant’s argument that, under the Third Circuit decision in Colacicco, an *amicus* brief, standing alone, is sufficient to effect a preemption of state law. In Colacicco, the Third Circuit held that the FDA’s informal but explicit rejection of proposed warning could preempt a state action, even where the agency’s statement was not subject to notice-and-comment rulemaking. 521 F.3d at 275. The court expressly limited its holding to the

circumstances where the FDA had taken such informal action *prior* to the purportedly preempted action. It chose not to opine on the situation “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.” Id. at 272. Subsequently, in Fellner, the Third Circuit expressly considered the weight to be given to a letter sent by the Commissioner of the FDA, indicating that the FDA had preempted the lawsuit at issue. 539 F.3d at 241. The court noted that where an agency’s statement is not simply an interpretation of regulations claimed to preempt state law, but rather is the “very agency action[] which [is] claimed to preempt state law,” the statement is not entitled to any deference. Id. at 250. The court went on to find that “[a] mere decision by the FDA not to adopt a federal warnings requirement certainly does not alone preclude states from imposing a duty to warn, and . . . [there is] no authority for the proposition that the FDA could institute a regime affirmatively proscribing all warnings obligations via mere informal expressions of policy [submitted after the lawsuit].”⁸ Id. at 253-54.

Similarly, in this case, Defendant points to no statement by the FDA prior to Jake Garrison’s suicide that could effect a preemption. The Kallas Amicus Brief, like the letter in Fellner, is not an interpretation of regulations claimed to preempt state law, but rather is the very agency action upon which Defendant asks the Court to find preemption. While perhaps more formal than a simple letter, the Brief does not constitute agency action taken prior to the allegedly

⁸ Defendant attempts to distinguish Fellner by noting that Fellner involved only a letter sent by the FDA Commissioner, whereas this case involves an FDA *amicus* brief which is a formal filing with a court. This is a distinction without a difference. Like the letter in Fellner, views expressed in the the Kallas amicus brief are “not the product of any agency proceeding, were not expressed at the time . . . [Plaintiffs’] damages allegedly arose, and [are] certainly not self-evident from the nature of the [agency] actions themselves.” Id. at 250-51.

tortious failure to warn. Thus, the Court properly declined to find that the Brief was sufficient, in and of itself, to create a conflict between state and federal law.

7. **Whether Court Erred in Allowing Plaintiffs' Fraud-on-the-FDA Claims to Proceed**

Finally, in an oft-repeated argument, Defendant contends that Plaintiffs' state law claims are premised entirely on the proposition that had Defendant submitted the pediatric data in its possession prior to Jake Garrison's death, the FDA would have discovered the risks and issued a warning sooner. Such allegations, according to Defendant, fit precisely within the parameters of a "fraud-on-the-FDA" claim, which the United States Supreme Court has explicitly preempted in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 621 S. Ct. 1012 (2001).

The Court has twice addressed and rejected this argument. See Knipe, 2008 WL 4090995, at 24 n.31; Knipe v. SmithKline Beecham, Civ. A. No. 06-3024, 2008 WL 4442635, at *24-35 (E.D. Pa. Sep. 30, 2008). Nonetheless, for sake of clarity, we again dismiss it here. As the Court previously explained, the United States Supreme Court has defined fraud on the FDA claims as violations of the FDA disclosure requirements, which are "various provisions aimed at detecting, deterring and punishing false statements made *during the approval process.*" Buckman, 531 U.S. at 349 (emphasis added). Had Plaintiffs argued that GSK improperly secured approval for a pediatric indication for Paxil by hiding data from the FDA, the Court would deem the claim preempted. In this case, however, the gist of Plaintiffs' argument does not contend that GSK committed any fraud on the FDA during its efforts to secure approval for a pediatric indication for Paxil. Rather, Plaintiffs present a pure state law claim that (1) after initial FDA approval, GSK learned of dangers associated with an off-label use of its drug; (2) GSK failed to warn either the public or the medical

community of the dangers associated with that drug; and (3) this failure to warn resulted in Jake Garrison's injuries. Feldman v. Lederle Labs., 479 A.2d 374, 388-89 (N.J. 1984) (noting that, under New Jersey law, a manufacturer has a duty to warn of all known adverse effects of a drug as soon as reasonably feasible upon actual or constructive knowledge of the danger). Defendant did not require FDA approval to issue any such warning. See Weiss v. Fujisawa Pharm. Co., 464 F. Supp. 2d 666, 676 (E.D. Ky. 2006) (recognizing that the FDA's regulations provide several avenues by which a drug manufacturer may warn patients and healthcare providers should they discover new evidence of a particular risk following the approval of the original label). To the extent Plaintiff has alleged that Defendant did not timely produce its pediatric data to the FDA prior to seeking approval for a pediatric indication, such claims were made only in connection with rebutting Defendant's claim that the FDA explicitly rejected a pediatric warning;⁹ they do not allege fraud on the FDA.¹⁰

⁹ Defendant's Reply Brief lists a series of statements made by Plaintiffs in their Opposition Brief to the Motion for Summary Judgment on Preemption, which, taken in isolation, seem to assert a fraud-on-the-FDA claim. (Def.'s Reply Br. 12.) Considered in context, however, the Court deems them nothing other than vigorous responses to Defendant's equally adamant assertion that the FDA clearly considered and rejected a pediatric suicidality warning.

¹⁰ In Colacicco, the plaintiff argued that the FDA's rejection of an adult suicidality warning on Paxil was not preemptive of a state failure to warn claim because GSK had manipulated or withheld information from the FDA. 521 F.3d at 272. The Third Circuit deemed this argument preempted, under Buckman, as a fraud-on-the-FDA claim. Id. As noted above, however, the court in that case determined that the FDA had expressly rejected an adult suicidality warning for Paxil in the course of GSK's efforts to obtain approval for adult usage of the drug. Thus, any argument by the plaintiff that the FDA's action was founded on fraud by GSK fell within the precise contours of a fraud-on-the-FDA claim. Id.

In this case, however, this Court has found that the FDA never made an explicit decision as to the propriety of a pediatric suicidality warning. Thus, Plaintiffs' argument that GSK never submitted the crucial data to the FDA prior to its seeking pediatric approval in April 2002, merely goes to prove that the FDA was never asked to approve or disapprove a pediatric warning. It does not attempt to establish fraud during the approval process for Paxil. Buckman, 531 U.S. at 349.

In short, and contrary to Defendant's arguments, Plaintiffs' claims do not exist by virtue of the FDCA disclosure requirements, but rather are premised entirely on state tort theories.

C. Conclusion as to Reconsideration

While the Court does not begrudge Defendant's repeated and vigorous efforts to dismiss this case on preemption grounds, the simple fact remains that no conflict existed between federal law and state law, such that the addition of Plaintiffs' proposed warning to the Paxil label prior to September 2002 would have subjected Defendant to some form of sanctions. The Court's August 28, 2008, Memorandum and Order fully and completely explained the rationale behind such a finding. Defendant now presents nothing other than evidence that could have previously been presented to the Court; requests for the Court to rethink issues over which it has already labored; and attempts to raise new issues with the benefit of hindsight provided by the Court's prior analysis. As none of these grounds provide a sufficient basis on which to grant reconsideration, the Court denies the motion.

II. MOTION FOR A CERTIFICATE OF APPEALABILITY

Alternatively, Defendant requests, in the event of a denial of its Motion for Reconsideration, that the Court certify its Order for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). Plaintiffs, as a matter of course, oppose such a request. For the following reasons, the Court grants the request and certifies the August 28, 2008, Order for interlocutory appeal.

Pursuant to 28 U.S.C. § 1292(b):

When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is

substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order.

Id. Thus, under this section, a non-final order may only be certified for interlocutory appeal if the court determines that it: (1) involves a “controlling question of law;” (2) for which there is “substantial ground for difference of opinion;” and (3) which may “materially advance the ultimate termination of the litigation” if appealed immediately. Katz v. Carte Blanche Corp., 496 F.2d 747, 754 (3d Cir. 1974). Each of these elements must be met for certification to issue. Mitchell v. Axcan Scandipharm, Inc., Civ. A. No. 05-243, 2006 WL 986971, at *1 (W.D. Pa. Mar. 13, 2006). Even if all of the elements are satisfied, the decision to certify an interlocutory order for appeal under section 1292(b) “rests within the sound discretion of the trial court.” L.R. v. Manheim Twp. Sch. Dist., 540 F. Supp. 2d 603, 608 (E.D. Pa. 2008) (internal quotations omitted). The burden remains on the party seeking certification to demonstrate that “exceptional circumstances justify a departure from the basic policy against piecemeal litigation and of postponing appellate review until after the entry of a final judgment.” Id. (internal quotations omitted).

This Court finds that this matter presents an exceptional case justifying an immediate interlocutory appeal. As to the first element, the Third Circuit Court of Appeals has held that “controlling question of law” is one in which either: (1) if decided erroneously, would lead to reversal on appeal; or (2) is “serious to the conduct of the litigation either practically or legally.” Katz, 496 F.2d at 755 (citations omitted). “[O]n the practical level, saving of time of the district court and of expense to the litigants was deemed by the sponsors [of 28 U.S.C. § 1292(b)] to be a highly relevant factor.” Id. (citation omitted); see also 19 James W. Moore, et al., MOORE'S

FEDERAL PRACTICE ¶ 203.31[3] (3d ed. 2003) (a controlling question of law is one that “has the potential of substantially accelerating disposition of the litigation”).

Plaintiff argues that the issue of preemption is fact-intensive and, thus, not a pure question of law amenable to interlocutory review. (Pl. Mem. Opp. Mot. Recons. 30-31 (citing Ahrenholz v. Bd. of Trustees of Univ. of Illinois, 219 F.3d 674, 676-77 (7th Cir. 2000); McFarlin v. Conseco Servs. LLC, 381 F.3d 1251, 159 (11th Cir. 2004); EEOC v. Hora, Inc., Civ. A. No. 03-1429, 2005 WL 1745450, at *3 (E.D. Pa. Jul. 22, 2005).) This argument disregards the very nature of the conflict preemption analysis, which turns precisely on whether two laws or regulations – one state, one federal – conflict, such that the latter preempts the former. Repeatedly, the Third Circuit has recognized that preemption, by its very nature, lends itself to interlocutory appeals. See, e.g., Fasano v. Fed. Reserve Bank of New York, 457 F.3d 274, 279 (3d Cir. 2006), cert. denied, 127 S. Ct. 777 (2007); C.E.R. 1988, Inc. v. Aetna Cas. and Sur. Co., 386 F.3d 263, 266 (3d Cir. 2004); Green v. Fund Asset Mgmt., L.P., 245 F.3d 214 (3d Cir. 2001); Cipollone v. Liggett Group, Inc., 789 F.2d 181, 183 (3d Cir. 1986).

The preemption issue here is undoubtedly a controlling question of law. If the Third Circuit were to disagree with this Court’s ruling, the summary judgment order would be reversed and Plaintiffs’ remaining claims would be foreclosed. In turn, both the Court and the parties would be spared the cost and time of both litigating the multiple, pending evidentiary motions and engaging in a lengthy jury trial. The mere fact that the preemption issue may require a detailed review of the regulatory records does not deprive it of its dispositive nature. As such, Defendant has satisfied the first element.

Under the second element, there is a “substantial ground for difference of opinion” about an issue when the matter involves “one or more difficult and pivotal questions of law not settled by controlling authority.” McGillicuddy v. Clements, 746 F.2d 76, 76 n.1 (1st Cir. 1984). In other words, “[s]ubstantial grounds for difference of opinion exist where there is genuine doubt or conflicting precedent as to the correct legal standard.” Bradburn Parent Teacher Store, Inc. v. 3M, Civ. A. No. 02-7676, 2005 WL 1819969, at *4 (E.D. Pa. Aug. 2, 2005). Conflicting and contradictory opinions can provide substantial grounds for a difference of opinion. White v. Nix, 43 F.3d 374, 378 (8th Cir. 1994). Additionally, the absence of controlling law on a particular issue can constitute substantial grounds. Chase Manhattan Bank v. Iridium Africa Corp., 324 F. Supp. 2d 540, 545 (D. Del. 2004).

The particular question at issue in this case – whether the FDA effectively preempted a state law claim for failure to warn of the risk of suicide by pediatric users of Paxil – has generated only one other judicial opinion, which found preemption in the face of highly distinguishable facts. See Knipe, 2008 WL 4090995, at *22 (distinguishing O’Neal v. SmithKline Beecham Corp., 551 F. Supp. 2d 993 (E.D. Cal. 2008)). Thus, this Court’s preemption decision involves a rather novel question of law, which the Third Circuit has not yet had the opportunity to address. The Court would be remiss to ignore the ongoing pendency of nationwide litigation involving this precise issue. Moreover, the contours of the preemption doctrine with respect to pharmaceuticals generally

remains a pressing and hotly disputed topic.¹¹ Given these facts, the Court finds that a substantial ground for difference of opinion exists.

Third, the Court must consider whether an interlocutory appeal would materially advance the termination of this litigation. This requirement is “closely tied to the requirement that the order involve a controlling question of law.” 16 Charles Alan Wright et al., FEDERAL PRACTICE AND PROCEDURE § 3930, 423 (2d ed. 1996). “Several factors are pertinent in determining whether an immediate appeal would materially advance the ultimate termination of the litigation, including: (1) whether the need for trial would be eliminated; (2) whether the trial would be simplified by the elimination of complex issues; and (3) whether discovery could be conducted more expeditiously and at less expense to the parties.” Patrick v. Dell Fin. Svcs., 366 B.R. 378, 387 (M.D. Pa. 2007). On the other hand, “[w]here discovery is complete and the case is ready for trial an interlocutory appeal can hardly advance the ultimate termination of the litigation.” Id. (quoting Bradburn, 2005 WL 1819969, at *4).

Plaintiff argues that this factor has not been met because discovery is complete, expert reports have been exchanged, two dispositive motions have been filed and ruled upon, and

¹¹ Compare Tucker v. SmithKline Beecham Corp., Civ. A. No. 04-1748, 2008 WL 2788505, at *10 (S.D. Ind. Jul. 18, 2008); In re Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 776, 788 (E.D. La. 2007); Sarli v. Mylan Bertek Pharms., Inc., Civ. A. No. 07-43, 2007 WL 2111577, at *4 (M.D.N.C. Jul. 19, 2007); In re Zyprexa, 489 F. Supp. 2d 230, 273-74 (E.D.N.Y. 2007); Weiss v. Fujisawa Pharm. Co., 464 F. Supp. 2d 666, 676 (E.D. Ky. 2006); Perry v. Novartis Pharm. Corp., 456 F. Supp. 2d 678, 685 (E.D. Pa. 2006); Laisure-Radke v. Par Pharm., Inc., Civ. A. No. 03-365, 2006 WL 901657, at *6 (W.D. Wash. Mar. 29, 2006), with Colacicco v. Apotex, 521 F.3d 253, 276 (3d Cir. 2008); Mason v. SmithKline Beecham Corp., 546 F. Supp. 2d 618, 626-27 (C.D. Ill. 2008); Dobbs v. Wyeth Pharms., 530 F. Supp. 2d 1275, 1289-90 (W.D. Okla. 2008); Horne v. Novartis Pharms. Corp., 541 F. Supp. 2d 768, 782 (W.D.N.C. 2008); In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., MDL 1699, 2006 WL 2374742, at *9-10 (N.D. Cal. Aug. 16, 2006).

the parties have submitted a host of Daubert motions. As the parties have already expended considerable resources and costs to litigate to this point, and as a Third Circuit appeal would simply delay the ultimate trial of this case, Plaintiffs argue that interlocutory appeal would have the adverse impact of causing protracted litigation.

While the Court acknowledges the advanced state of this litigation and gives a certain degree of credence to Plaintiffs' arguments, we nonetheless recognize that this case is not standing on the brink of trial. The Court previously ordered that Plaintiffs may be entitled to some further discovery following rulings on summary judgment. (Order, Knipe v. SmithKline Beecham, Civ. A. No. 06-3024 (E.D. Pa. July 28, 2008.) Additionally, the parties have six lengthy Daubert motions currently pending, and have yet to file motions *in limine*. Finally, in light of the wealth of exhibits produced to the Court in support of both the summary judgment motions and the Daubert motions, the Court suspects that the trial of this matter will be long and complicated. Should the Third Circuit reverse this Court's decision on preemption, the entire case will be dismissed and none of these additional aspects of the litigation need occur. In the face of such potentially long proceedings, the Court finds that an interlocutory appeal may very well spare time and expense for both Court and litigants.¹²

¹² Plaintiffs argue that certification should be denied in light of the Court's September 30, 2008 Opinion and Order denying, in large part, Defendant's motion for summary judgment on Plaintiff's causes of action. Specifically, Plaintiffs contend that Defendant will likely seek an interlocutory appeal of that decision, thus resulting in multiple piecemeal appeals.

The Court does not share Plaintiffs' concerns. The Courts' September 30, 2008 Order does not appear to possess any of the qualities of an order ripe for interlocutory appeal. It does not involve any particularly controlling question of law, its highly factual nature does not create a substantial ground for difference of opinion with other courts, and its appeal would not materially advance the litigation.

While the Court is wary of permitting piecemeal litigation, we find the present issue to involve a controlling question of law about which there is a substantial difference of opinion, the appeal of which will materially advance this litigation. Accordingly, we grant the certificate of appealability.

An appropriate order follows.

**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,	:	CIVIL ACTION
and HAROLD L. GARRISON, JR.,	:	
Individually,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	NO. 06-3024
SMITHKLINE BEECHAM d/b/a	:	
GLAXOSMITHKLINE,	:	
	:	
Defendant.	:	

ORDER

AND NOW, this 28th day of *October*, 2008, upon consideration of the Motion of Defendant SmithKline Beecham Corp. d/b/a GlaxoSmithKline (“GSK”) for Reconsideration of this Court’s August 28, 2008 Order and, Alternately, for Certification of the Order for Interlocutory Appeal Pursuant to 28 U.S.C. § 1292(b) (Doc. No. 143), the Response thereto of Plaintiffs Harold L. Garrison, Jr., individually and Marion Knipe, individually and administratrix and administratrix ad prosequendum of the Estate of Harold Stanley Jake Garrison (Doc. No. 147), and GSK’s Reply Brief (Doc. No. 150), it is hereby **ORDERED** as follows:

1. Defendant’s Motion for Reconsideration is **DENIED**;
2. Defendant’s request to certify the Court’s August 28, 2008, Order for interlocutory appeal is **GRANTED**, and the Court certifies the following question as a controlling question of law, as to which there is a difference of opinion, and as to which an immediate appeal will expedite the resolution of the litigation:

Whether the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, the Food and Drug Administration's ("FDA") regulations, and the FDA's scientific determinations conflict with and, therefore, preempt Plaintiffs' state law claims alleging that Defendant failed to warn of an association between pediatric use of Paxil and an increased risk of suicidality.

It is **FURTHER ORDERED** that the proceedings in this case are stayed pending interlocutory appeal.

BY THE COURT:

s/ Ronald L. Buckwalter
RONALD L. BUCKWALTER, S.J.