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March 7, 2011

PAXIL PREGNANCY

Opposing Counsel:
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The Honorable Sandra Mazer Moss
Court of Common Pleas
of Philadelphia County
Complex Litigation Center
City Hall – Room 622
Philadelphia, PA 19107

Attention: Donna Candelora, Esquire

Re: ***In Re Paxil Pregnancy Litigation***
Philadelphia CCP, February Term 2007, No. 3220
Our File No.: 8014-2152F
CONTROL NO. 11023118

Amy L. Davis, Individually and as Parent and Natural Guardian of Joey L. Davis, a minor vs. SmithKline Beecham Corporation d/b/a GlaxoSmithKline and Par Pharmaceutical, Inc.
Philadelphia CCP, September Term 2007, No. 03266
Our File No.: 8014-2119A
CONTROL NO. 11023183

Case ID: 070203220
Control No.: 11023118

Melanie L. Lacambra, Individually and as Parent and Natural Guardian of Kai A. Lacambra, A Minor vs. SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Philadelphia CCP, September Term 2007, No. 003296
Our File No.: 8014-2137A
CONTROL NO. 11023139

Roy G. Ayala and Kelly M. Capito, Individually and as Parents and Natural Guardians of Gabrielle R. Ayala, a Minor vs. SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Philadelphia CCP, September Term 2007, No. 03247
Our File No. 8014-2103A
CONTROL NO. 11023121

DEFENDANT, GLAXOSMITHKLINE LLC, FORMERLY SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE'S RESPONSE TO PLAINTIFFS' GLOBAL MOTION REGARDING THE ADMISSIBILITY OF EVIDENCE ON CHANGES TO PAXIL'S LABELING AND OTHER POST-INJURY CONDUCT

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Ayala v. GSK
September Term 2007, No. 003247
Davis v. GSK
September Term 2007, No. 003266
Lacambra v. GSK
September Term 2007, No. 003296
In re: Paxil Pregnancy Cases
February Term, 2007 No. 003220

Executive Summary
GSK's Response To Plaintiffs' Global Motion Regarding the Admissibility of Evidence On Changes To Paxil's Labeling and Other Post-Injury Conduct

In a conference held on June 30, 2010, this Court decided (1) that the admissibility of subsequent label changes was a global issue, and that evidence of changes to Paxil® ("Paxil") labeling and warnings is not admissible as proof of subsequent remedial measures in any trial in a Paxil Pregnancy case; and (2) that the admissibility of post-injury conduct was not a global issue, and not subject to a global ruling. These rulings were memorialized in Case Management Order No. 8 ("CMO No. 8"), which Plaintiffs reviewed and approved. Plaintiffs now ask this Court to upend both those rulings – although it is unclear whether they are aware the rulings exist, because nowhere in their motion do they mention CMO No. 8 or the June 30 hearing, nor do they make any reference to the fact that these matters have already been decided. Plaintiffs also do not offer any new evidence or cite any authority that postdates the entry of CMO No. 8. They ask for all this relief even though the time permitted by Pennsylvania law for reconsideration of a court order passed six months ago. PA. CONS. STAT. § 5005.

Instead, Plaintiffs argue that PA. R. EVID. 407 – which bars evidence of subsequent remedial measures – does not apply because GSK's 2005 changes to the label change were made at the insistence of the U.S. Food and Drug Administration. Not only do they provide no evidence for this assertion, the "evidence" they purport to offer is misleading: a letter from FDA that references a different labeling change made 10 years earlier, and a snippet of testimony from a GSK epidemiologist who, surrounding testimony clearly reveals, was discussing another matter entirely. Nor is Plaintiffs' contention that evidence of the 2005 labeling changes serves another purpose availing – GSK makes no argument that labeling change evidence could possibly refute, and offering the evidence to somehow meet Plaintiffs' burden under the learned intermediary doctrine falls squarely under the reason Rule 407 excludes such evidence in the first place.

Nor do Plaintiffs provide a reason why this Court should issue a global ruling admitting three documents when it has already been decided that the admissibility of these documents is dependent on the facts of each individual case. Regardless, under the facts of these cases, the documents should be excluded.

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IN RE: PAXIL PREGNANCY CASES	§	COURT OF COMMON PLEAS TRIAL DIVISION PHILADELPHIA COUNTY
	§	FEBRUARY TERM, 2007 NO. 3220

ROY G. AYALA And KELLY M. CAPITO, Individually and as Parents and Natural Guardians of GABRIELLE R. AYALA, A Minor Plaintiffs, vs. SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC. Defendant.	§	COURT OF COMMON PLEAS TRIAL DIVISION PHILADELPHIA COUNTY SEPTEMBER TERM, 2007 NO. 3247 PAXIL PREGNANCY

AMY L. DAVIS, Individually, and as Next Friend of JOEY L. DAVIS, A Minor Plaintiffs, vs. SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC. and PAR PHARMACEUTICALS, INC. Defendants.	§	COURT OF COMMON PLEAS TRIAL DIVISION PHILADELPHIA COUNTY SEPTEMBER TERM, 2007 NO. 3266 PAXIL PREGNANCY

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MELANIE L. LACAMBRA, Individually and as Parent and Natural Guardian of KAI A. LACAMBRA, A Minor	§	**COURT OF COMMON PLEAS TRIAL DIVISION PHILADELPHIA COUNTY**
Plaintiffs,	§	
	§	**SEPTEMBER TERM 2007 NO. 3296**
vs.	§	
SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC.	§	
Defendant.	§	**PAXIL PREGNANCY**

ORDER

AND NOW, this _____ day of _____, 2011, this cause came on for consideration on *Plaintiffs' Global Motion Regarding the Admissibility of Evidence on Changes to Paxil's Labeling and Other Post-Injury Conduct*. The Court having considered same, having heard the arguments of counsel and being otherwise fully advised in the premises, it is thereupon

ORDERED, ADJUDGED AND DECREED that *Plaintiffs' Global Motion Regarding the Admissibility of Evidence on Changes to Paxil's Labeling and Other Post-Injury Conduct* be and hereby is DENIED in all respects.

BY THE COURT:

_____
MOSS, J.

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Dear Judge Moss:

Your Honor should deny Plaintiffs' Motion, just has Your Honor has already done once before. Your Honor has already given this issue full consideration, and there is no reason to revisit the ruling.

Plaintiffs have either forgotten – or they have purposefully failed to inform the Court – that Your Honor has already addressed and rejected both of the requests contained in Plaintiffs' Motion in a written order. In a conference held on June 30, 2010, Your Honor decided (1) that the admissibility of subsequent label changes was a global issue, and that evidence of changes to Paxil® ("Paxil") labeling and warnings is not admissible as proof of subsequent remedial measures; and (2) that the admissibility of post-injury conduct was not a global issue, and not subject to a global ruling. These rulings were memorialized in Case Management Order No. 8 ("CMO No. 8"), which Plaintiffs reviewed and approved.

The Court should adhere to its previous ruling for the same reasons that the Court found compelling in the first instance.

I. INTRODUCTION

On July 28, 2010, this Court entered Case Management Order No. 8 ("CMO No. 8"), adopting a number of global rulings in all Paxil Pregnancy cases. This Order was the result of months of discussions between counsel for GSK and plaintiffs, culminating in a hearing with each side presenting its own list of proposed global rulings, and with the Court deciding which should apply generally throughout the *In re Paxil Pregnancy* cases and which should be decided on the facts of each individual case. Among other rulings, this Court granted GSK's motion to exclude evidence of changes to Paxil labeling and warnings, making such evidence inadmissible in all future trials. The Court also declined Plaintiffs' request to include in CMO No. 8 a prior ruling on certain post-injury conduct, agreeing instead with GSK that the motion was case-specific, rather than global.

Giving Plaintiffs the benefit of the doubt, it appears that Plaintiffs have forgotten that Your Honor ***has already addressed the very issues and rejected the same arguments Plaintiffs offer now***. Their motion was filed six months after the deadline to petition the court to rescind its ruling. PA. CONS. STAT. § 5005 (providing a 30-day window for a court to modify or rescind an order). Plaintiffs' motion makes no mention of CMO No. 8, not even to distinguish the order, and warns that GSK will file a motion *in limine* on subsequent remedial measures in the May cases -- even though CMO No. 8 instructs that motions contained therein are deemed filed and ruled upon.[1] Plaintiffs are apparently unaware that the Court has already issued a global order,

[1] Plaintiffs attached to their motion a certification that they contacted GSK's counsel to resolve these issues, though no GSK counsel was contacted prior to filing. If Plaintiffs had conferred with attorneys for GSK first, they would have been told that the matter was already subject to a global ruling.

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let alone its disposition, because they open their motion with an appeal to the Court to treat each issue globally. But regardless of whether Plaintiffs know the contents of this Court's orders, they are obligated to follow them, and these matters both have already been decided.

Even if their motion were not mooted by CMO No. 8, there simply is no reason for the Court to change its ruling. As to post-injury label changes, PA. R. EVID. 407 prohibits the use of measures taken after taken after an injury, "which, if taken previously, would have made the injury or harm less likely to occur." Plaintiffs' assertion that subsequent remedial measures required by a regulatory agency do not fall within the purview of Rule 407 is far from the established rule. Moreover, Plaintiffs offer absolutely no evidence in support of their baseless allegations that the government, not GSK, instigated the 2005 Paxil labeling changes, completely ignoring the extent to which GSK undertook precisely the type of voluntary remedial measures that Rule 407 is intended to encourage.

Plaintiffs' request for this Court to also issue a ruling admitting certain specific documents should also be denied. As with subsequent remedial measures, this Court has already decided the matter, ruling at the global motions hearing that any decision as to the admissibility of these very documents is necessarily case-specific and dependant on the date of a plaintiff's injury.

II. ARGUMENT AND CITATION OF AUTHORITY

A. With Regard to Post-Injury Labels or Warnings, Plaintiffs' Motion Is Moot Because This Court Has Already Ruled That This Is a Global Issue, and That Such Evidence Is Inadmissible As a Subsequent Remedial Measure.

In early 2010, this Court instructed the parties in all Paxil pregnancy cases before it to submit lists of trial motions previously decided in *Kilker* that either side believed could be applied to all pending cases. After several attempts to agree on a list of prior rulings that could be adopted globally the parties each created their own proposed lists to the Court. Plaintiffs' list, submitted in advance of a Case Management Conference on May 13, 2010, included as proposed global rulings GSK's Motion *in Limine* in *Kilker* to exclude evidence of labeling changes as subsequent remedial measures and GSK's motion in *Kilker* to exclude evidence of post-injury conduct (subpart 1 of GSK's omnibus Motion *in Limine*), which specifically addressed the same documents Plaintiffs discuss in the present motion. (Pls' Proposed Mot. *in Limine* Global Rulings at 4, 7, attached as Ex. 1.)

After a series of calls between Plaintiffs and GSK to narrow the list of motions for consideration by the Court, the parties appeared at a hearing on June 30, 2010. (GSK attorneys Joseph E. O'Neil and Robert K. Woo attended in person; Plaintiffs' counsel Rosemary Pinto appeared by telephone.) The number of motions to be considered had been reduced, but the subsequent remedial measures and the post-injury conduct motions remained on the list. The Court considered each of the motions in turn, with the post-injury conduct motion fourth on the list. The Court found that because GSK's central argument in its motion was that documents should be excluded because they postdated the *Kilker* plaintiff's injury – and because Plaintiffs

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argued in response that the documents related back to conduct before the injury – the date of injury was crucial to resolution of the motion. Because the date of injury in each case is different, the Court determined the motion was case-specific and declined to enter a global ruling.

The subsequent remedial measures motion was the last to be considered. This time, the Court ruled that the motion was global, but stated that GSK's motion should have been granted in *Kilker* despite Judge Levin's ruling in that case. Specifically, the Court's Order states that as to all cases before it, "evidence of changes to Paxil labeling and warnings are not admissible as evidence of subsequent remedial measures." (Case Management Order No. 8 at 2, attached as Ex. 2.) GSK's counsel prepared a proposed order reflecting the Court's rulings, which Ms. Pinto agreed to on behalf of Plaintiffs on July 27, 2010. (Email from R. Pinto to R. Butterfield, July 27, 2010, attached as Ex. 3.) The proposed order was submitted to the Court the next day and entered as CMO No. 8 on July 29, 2010.

Plaintiffs do not offer the Court a single reason why its rulings should be revisited – indeed, Plaintiffs do not mention CMO No. 8 at all. They do not point to any evidence discovered since the CMO was entered, nor do they cite any legal authority decided in the interim. It is worth noting that Plaintiffs do not cite a single case that postdates this Court's ruling in CMO No. 8. As Plaintiffs themselves state, it is crucial that this Court enact and enforce consistent rulings on this issue.[2] (Pls' Mot. at 2 (discussing "risk of inconsistency" if subsequent remedial evidence is admitted in some cases but not others).) As Plaintiffs insist, a "uniform decision is needed." (*Id.*) That uniform decision has been reached and this issue has already been decided. This Court should deny Plaintiffs' motion.

B. The Court's Current Ruling Is Correct: Post-Injury Labeling Changes are Inadmissible Subsequent Remedial Measures Under PA. R. EVID. 407.

But even if this Court had not already excluded evidence of subsequent remedial measures, Plaintiffs' motion should still be denied. PA. R. EVID. 407 excludes evidence of measures taken after a harm-causing event, "which, if taken previously, would have made the injury or harm less likely to occur." Evidence of those measures ***is not admissible to prove that the party who took the measures was negligent or engaged in culpable conduct***, or produced, sold, designed, or manufactured a product with a defect ***or a need for a warning or instruction***." *Id.* (emphasis added). The underlying purpose of Rule 407 is to encourage the taking of reasonable precautions to avoid injury by removing a potential defendant's concern "that [such precautions] will be employed adversely in an action at law." *Duchess v. Langston Corp.*, 769 A.2d 1131, 1141 (Pa. 2001).

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[2] Plaintiffs' claim that judges within this Court are ruling inconsistently on this issue is further proof that Plaintiffs have forgotten about CMO No. 8. While it is true that Judge Levin allowed evidence of post-injury labels in the ***Kilker*** trial, and that Judge Glazer later excluded such evidence in the *Blyth* trial, what Plaintiffs omit is that in the interim Your Honor entered CMO No. 8, directing future courts to exclude such evidence. (*Blyth v. GSK*, Nov. 9, 2010 Order, attached as Ex. 4.)

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1. There is no exception to Rule 407 for labels or warnings.

Among the types of subsequent measures protected by Rule 407 is the post-injury provision of product warnings, which are generally inadmissible in products liability cases alleging failure to warn. MARK I. BERNSTEIN, PENNSYLVANIA RULES OF EVIDENCE § 407(1)(b) (2007 ed.).

Here, GSK changed its Paxil label in September and December 2005, well after the birth of either of the three minor plaintiffs in the cases in which Plaintiffs filed their motion, and after the development of the alleged birth defects in the vast majority of Paxil pregnancy cases. GSK undertook the 2005 label changes, based on new information not available at the time of the injury of any of the named minor Plaintiffs, to reduce the potential for future injury to those using Paxil. This effort comports with the policies underpinning Rule 407, and Plaintiffs' anticipated use of the evidence – to show negligence or culpability on the part of GSK for not making the change earlier – is exactly the type of use proscribed by the Rule. As this Court has already ruled, it is inadmissible.

This Court's ruling is in line with others around the country in pharmaceutical failure to warn cases. *See Hardin v. Upjohn Co.*, 47 Pa. D. & C. 3d 66, 67-68 (Phila. Cty. Ct. 1986) (suit for birth defect sustained by son allegedly from mother's use of Upjohn drug; Upjohn later issued new labeling warning of possible risks, and later withdrew drug; court excluded evidence of recall and label change, noting that "as a matter of law, post-administration package inserts and recall memoranda, as subsequent remedial measures, are . . . inadmissible."); *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 263-64 (5th Cir. 2002) (in failure to warn case, "evidence of subsequent remedial measures cannot be considered in evaluating whether the [warning in place at the time plaintiff took drug] was adequate."); *DeLuryea v. Winthrop Labs.*, 697 F.2d 222, 229 (8th Cir. 1983) (trial court erred in admitting evidence of post-injury changes to package inserts and Physician's Desk Reference warnings for drug because evidence is barred under Rule 407).

2. There is no evidence that FDA had to force the 2005 labeling changes on GSK.

Plaintiffs then attempt to evade Rule 407 by arguing that the rule does not apply here by falsely claiming that GSK only changed its labeling "at the insistence of the FDA." (Pls' Mot. at 4.) This is the exact same position taken by plaintiffs in their opposition to GSK's Motion in *Limine* on this issue in *Kilker* (*see* Pls' Opp'n to Def's Mot. *in Limine* No. 9, Control No. 09082138, at 3-7) – a position this Court fully rejected when it granted GSK's motion globally in CMO No. 8. Plaintiffs' "proof" that Paxil was changed from a Category C to a Category D appears on page 9 of their Motion.

At best Plaintiffs' "evidence" is empty; viewed less charitably, it is actually misleading. First, Plaintiffs quote a letter they say "indicates that the FDA was responsible for the change." In their Motion, Plaintiffs claim:

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> In the fall of 2005, GSK changed the warnings for Paxil at the FDA's behest. The changes were not made voluntarily.
>
> * * *
>
> Then in December 2005, at the FDA's insistence, Paxil was changed from a Category C drug to a Category D drug.
>
> * * *
>
> The FDA's correspondence with GSK indicates that the FDA was responsible for the change. In a letter to GSK, FDA officials wrote that the agency found "it necessary to request that the decreased survival of rate pups" in the animal studies "receive more emphasis in labeling" and recommended that additional animal studies be done. [Ex. B., October 12, 1995 FDA Letter.]

(Pls' Mot. at 8-9.) But that letter is discussing the proposed change from Category B to C a decade earlier -- ***not the 2005 change that is the subject of Plaintiffs' motion***. Plaintiffs must be aware of this, because they correctly cite the date of the letter: October 12, 1995. (Pls' Mot. at 9.) To claim that this letter supports the 2005 label change is plainly wrong.

Second, Plaintiffs quote GSK epidemiologist Dr. Sara Ephross, who they contend "testified that the FDA took the lead in changing the Paxil label in late 2005." (*Id.*) But as is clear from the testimony surrounding the snippets excerpted in their motion, Dr. Ephross was actually speaking about an epidemiological study, ***not a labeling change***. Here is the testimony immediately proceeding and following the exchange that Plaintiffs quote in their motion, with the language quoted by Plaintiffs appearing in context within the box below:

> Q. Prior to the FDA mandate had GSK made any commitment, to the best of your knowledge as you sit here today, ***to fully explore the Ingenix data*** and specifically look at Paxil and birth defects?
>
> A. I think, first of all, you used the words mandate, the FDA mandate, here the word that you used is request of the FDA. And, again, ***this was a study*** that was designed to evaluate a possible signal in the bupropion pregnancy registry, and it was designed expressly to evaluate all of the bupropion pregnancy exposures in Ingenix versus all of the other antidepressants. That was its express purpose.
>
> Q. Ma'am, the last two words say, "FDA mandate," don't they?
>
> A. Yes. That is correct.
>
> Q. That's what they say; right?

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A. That is correct, but earlier in that same bullet point it says, "at the request of the FDA."

Q. Whether it was a mandate or a request, it wasn't something GSK voluntarily did?

A. But GSK did do it.

Q. After the FDA mandate/request; right?

A. The FDA did request it, and GSK did do it.

Q. And never did it before; right?

A. ***Again, it was a study*** to evaluate bupropion exposures and pregnancy outcomes compared to all other antidepressants.

(4/23/09 Ephross Dep. at 105-07 (emphasis added).) For Plaintiffs to quote the boxed language, and to suggest that Dr. Ephross was talking about the 2005 labeling changes instead of epidemiological studies, is simply disingenuous. Thus, examined closely, the "evidence" Plaintiffs put forth in support of their argument proves illusory.

Moreover, Plaintiffs deliberately fail to mention the extent to which GSK voluntarily participated in the two labeling changes at issue. GSK formally initiated the process for implementing the labeling changes by filing Changes Being Effected supplements ("CBE") for both changes after extensive consultation with FDA. (See Sept. 6, 2005 and Dec. 5, 2005 letters to FDA (attached as Ex. 5 and Ex. 6, respectively).) Thus, GSK requested FDA's input prior to filing its CBE to change Paxil's labeling. These are exactly the types of voluntary remedial measures that Rule 407 is intended to encourage. See *Duchess*, 769 A.2d at 1137 ("the aim is to encourage measures that further necessary or added safety, or at least to avoid discouraging such measures, by removing the concern that they will be employed adversely in an action at law").[3]

[3] Contrary to Plaintiffs' argument, admitting evidence of the labeling changes would undermine the purpose of Rule 407 by discouraging such voluntary action in the future. *See Werner*, 628 F.2d at 857. Plaintiffs also ignore cases in other jurisdictions requiring exclusion of such mandated remedial measures. *See, e.g.*, *Ortho Pharm. Corp. v. Chapman*, 180 Ind. App. 33, 59-66 (Ind. Ct. App. 1979) (holding that trial court erred in failing to exclude evidence of a "Federal Drug Administration-mandated 'Patient Warning'" as a subsequent remedial measure). Further, even if for some technical reason the 2005 labeling changes did not fall under the purview of Rule 407, they would still be inadmissible under PA. R. EVID. 403. Pennsylvania law is clear that evidence of subsequent remedial measures are exactly the type of overly prejudicial evidence Rule 403 excludes. *Duchess*, 769 A.2d at 1142 (noting that "although their relevance may be limited, remedial measures can be viewed by jurors as suggesting an effective concession on the part of a manufacturer that its product, in an earlier form, was defective"). Thus, even if this Court were to find that evidence of the subsequent changes to Paxil's labeling and warnings should not be excluded under Rule 407, the evidence should be excluded as overly prejudicial under Rule 403.

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3. Plaintiffs' policy arguments for making an exception to Rule

Plaintiffs offer other arguments – none of which are new – that the Paxil warning should for some reason be exempted from Rule 407. But none of these are compelling. First, Plaintiffs suggest that the 2005 labeling changes is "highly relevant to the issue of causation" for the learned intermediary doctrine. (Pls' Mot. at 4.) To Plaintiffs, the 2005 warnings are "critical" evidence because they have the burden of proving that had a different warning been provided at the time they were prescribed Paxil, their physicians would not have prescribed it. (*Id.* at 2-3.) But they offer no explanation why they need to introduce the 2005 label changes to the jury to meet that burden, and no legal authority to support their contention. Nor does their position make much sense: Plaintiffs can argue that GSK should have provided a different warning without offering evidence that it later did so. By Plaintiffs' logic, a plaintiff could ***never*** assert a failure to warn claim unless a manufacturer had subsequently changed its warning.[4] The "policy behind Rule 407 does not allow for a new exception to prove causation." *Werner v. Upjohn Co.*, 628 F.2d 848, 859 (4th Cir. 1980) (discussing similar federal rule).

Plaintiffs also suggest that the 2005 labeling change should be admitted notwithstanding Rule 407, for other purposes, but they are surprisingly mum on what those reasons are. First, they argue that the evidence is admissible under Rule 407 to show feasibility on the ground that "GSK has suggested in pleadings, motions, and at trials that it was not feasible ***to perform additional studies*** to examine Paxil's teratogenicity." (Pls. Mot. at 9 (emphasis added).) Plaintiffs do not explain what a dispute about feasibility of testing has to do with a warning label, or why it would be appropriate to disprove the contention that testing is not feasible with a warning label rather than with evidence of actual testing.[5] Nor, despite the voluminous record that has been generated in this litigation, do Plaintiffs provide a single citation or example of GSK making such a suggestion.

In any event, Plaintiffs' view of Rule 407's exceptions is considerably broader than what the law actually reflects. In their estimation, GSK will "open the door to relevance of subsequent remedial measures" if it discusses "GSK's compliance with federal regulations, its review of scientific data on the association between Paxil and birth defects, and safety and pharmacovigilance practices" – in essence, if it puts forth any defense at all. (Pls. Mot. at 9-10.) Contrast that with Pennsylvania law, which instructs courts to apply Rule 407 exceptions "cautiously . . . to prevent [them] from overwhelming the general rule, thus undermining its supporting policy goals." *Duchess*, 564 Pa. at 554.

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[4] It is interesting that Plaintiffs concede that without the evidence this Court has already excluded in CMO No. 8, they will be unable to meet their burden of proof in this case: "To prove causation under the learned intermediary doctrine, a plaintiff ***must*** be able to present evidence of the label change." (Pls' Mot. at 4 (emphasis added).)

[5] Plaintiffs also make the argument that the labeling change is relevant to causation because studies allegedly linking Paxil to birth defects is relevant to causation. (Pls. Mot. at 10.) Despite the uncontested authority that relevance to causation does not create an exception to Rule 407, *supra*, it is unclear why the purported relevance of a scientific study has any bearing on the admissibility of a labeling change.

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C. As to the Documents Regarding Other Post-Injury Conduct, the Court Has Already Ruled That Their Admissibility Is Not Appropriate For a Global Ruling.

Although they have nothing to do with subsequent remedial measures, Plaintiffs also ask this Court to issue a global ruling that three documents are admissible in all cases. But as described *supra*, on June 30, 2010, Your Honor already decided the issue: because the arguments against admission are based on the date of a plaintiff's injury, the issue is not appropriate for global disposition.

Plaintiffs' attempts to argue for their admission in *Kilker* only reinforced the case-specific nature of the admissibility of these post-injury documents. In *Kilker*, the plaintiff-mother's first trimester ended on April 1, 2005. Consequently, plaintiffs argued that each of the documents in question pre-dated -- rather than post-dated -- April 1, 2005:

- As to the 2008 Avandia letter, Plaintiffs argued that the substance of the 2008 letter actually related to a GSK report finalized in April 2000;
- As to the 2006 Pregnancy Follow-Up Working Group Slides, Plaintiffs argued that the document was actually created in April 2000; and
- As to the 2006 Pregnancy Registry slides, Plaintiffs argued that the slides actually discuss the same information as contained in a 1999 article.

(*Kilker* Pls' Opp. to Def.'s Mot. *in Limine* No. 1 - Sub Part 1 at 3-4, 5-7, 8.)

In short, Plaintiffs' argument as to each of these post-injury documents was that the documents were actually pre-injury -- in *Kilker*. This is necessarily a case-specific argument that will vary in each case, depending on the date of conception of each child. Consequently, Your Honor was correct to rule that this was not a global ruling, and to omit this motion in limine from the global rulings in CMO No. 8.

Finally, the documents should be inadmissible in the three cases in which Plaintiffs filed their motion. Both documents were created after ***these*** Plaintiffs' injuries were sustained, making it impossible for anything the documents contain or reflect to have impacted the decision of any of these Plaintiffs' doctors to prescribe Paxil, or to prevent any injury for which these Plaintiffs seek redress.[6] Neither are probative of what GSK knew or did at the time the Plaintiffs

[6] The Avandia letter should be excluded for the independent reason that it simply has nothing to do with Paxil. Plaintiffs argue the letter – which deals with a drug used for treatment of diabetes – is somehow relevant to this litigation because they claim it shows that FDA reprimanded GSK for actions similar to those they contend occurred with Paxil. But Plaintiffs fundamentally misconstrue the letter, which was directed at post-marketing clinical studies, not the spontaneous adverse events that made up the study for Japanese regulators Plaintiffs contend should have been provided to FDA. Nor do Plaintiffs have no foundation for suggesting that any of the deficiencies the Avandia letter stated "may" be symptomatic of underlying failures had anything to do with Paxil, or even existed at any time, let alone the relevant time periods in these cases. It should be excluded.

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in these three cases took Paxil. For similar reasons, both documents were excluded by this Court in *Blyth*. (*Blyth v. GSK*, Nov. 9, 2010 Order.)

III. CONCLUSION

For the foregoing reasons, GSK respectfully requests that this Court deny Plaintiffs' motion and affirm its ruling in Case Management Order No. 8.

Respectfully Submitted,

LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO

By: /s/
Joseph E. O'Neil (ID No. 29053)
Mary Grace Maley (ID No. 37610)
Carolyn L. McCormack (ID No. 87800)

-and-

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Attorneys for Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation, d/b/a GlaxoSmithKline

cc: Kurt Arnold, Esquire
Jason Itkin, Esquire
Alexander Dwyer, Esquire
Rosemary Pinto, Esquire

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CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2011, I will serve a true and correct copy of DEFENDANT, GLAXOSMITHKLINE LLC FORMERLY SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE'S OPPOSITION TO *PLAINTIFFS' GLOBAL MOTION REGARDING THE ADMISSIBILITY OF EVIDENCE ON CHANGES TO PAXIL'S LABELING AND OTHER POST-INJURY CONDUCT* in accordance with Pa. R.C.P. 440 on all parties not served electronically. All other parties will be electronically served by the court in accordance with Pa. R.C.P. 205.4(g) and by electronic mail.

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BY:/s/ Carolyn L. McCormack
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