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March 29, 2011

PAXIL PREGNANCY

CONTROL NO. 11031590

Reply Date: April 14, 2011

Opposing Counsel:
Arnold & Itkin LLP
Feldman & Pinto, P.C.

(Certain Exhibits Filed Under Seal)

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 Cases*, Philadelphia CCP, February Term 2007, No. 3220**
Our File: 8014-2152F

DEFENDANT GLAXOSMITHKLINE LLC, FORMERLY SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE'S OPPOSITION TO PLAINTIFFS' GLOBAL MOTION IN LIMINE REGARDING THE ADMISSIBILITY OF CERTAIN EVIDENCE AT ISSUE IN ALL PAXIL PREGNANCY CASES

Case ID: 070203220
Control No.: 11031590

Ayala v. GSK
September Term 2007, No. 03247

Executive Summary
GSK's Response in Opposition to Plaintiffs' Global Motion *in Limine* Regarding the Admissibility of Certain Evidence at Issue in All Paxil Pregnancy Cases

This Court already has decided that the three issues presented by Plaintiffs' Motion *in Limine* are not appropriate for a global ruling because the admissibility of evidence relating to each of these issues turns on case-specific facts. Thus, GSK opposes Plaintiffs' Motion on the basis of the Court's previous rulings.

Further, with respect to the particular facts of these three individual cases, the evidence Plaintiffs seek to introduce is irrelevant and inadmissible under Pennsylvania Rules of Evidence 104(b), 401, and 402 and unfairly prejudicial under Pennsylvania Rule of Evidence 403. The marketing and promotional evidence is irrelevant because, in all three cases, the physicians Plaintiffs claim prescribed them Paxil® testified that they did not rely on GSK marketing or promotional materials in making their medical decisions. Further, none of the pertinent physicians was called on by the GSK sales representatives from other states who were deposed in other cases, including but not limited to Tracy Lepper. Finally, there is absolutely no evidence that the CASPPER program had any impact on any prescribing physician in the three named cases. This evidence is irrelevant and inadmissible, and the Court should exclude it.

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Control No.: 11031590

IN RE PAXIL PREGNANCY CASES	PHILADELPHIA COUNTY COURT OF COMMON PLEAS FEBRUARY TERM, 2007 No. 03220 PAXIL – PREGNANCY

ORDER DENYING PLAINTIFFS' GLOBAL MOTION *IN LIMINE* REGARDING THE ADMISSIBILITY OF CERTAIN EVIDENCE AT ISSUE IN ALL PAXIL PREGNANCY CASES

AND NOW, this ____ day of _____, 2011, upon consideration of Plaintiffs' Global Motion *in Limine* Regarding the Admissibility of Certain Evidence at Issue in All Paxil Pregnancy Cases, the Response of Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation d/b/a GlaxoSmithKline, and any reply thereto, and having considered the arguments of counsel, it is hereby ORDERED that Plaintiffs' Motion is DENIED.

SO ORDERED, this ____ day of _____, 2011.

BY THE COURT:

_____
MOSS, J.

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Dear Judge Moss:

Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), submits this Opposition to Plaintiffs' Global Motion *in Limine* Regarding the Admissibility of Certain Evidence at Issue in All Paxil Pregnancy Cases.[1]

I. ARGUMENT AND CITATION OF AUTHORITY

Plaintiffs have asked this Court to issue a global ruling admitting certain evidence. But the Court already has ruled that the three issues presented by Plaintiffs' Motion are not appropriate for a global ruling because the admissibility of this very same evidence hinges on case-specific facts and should be decided in the context of individual plaintiffs and their injuries. Plaintiffs offer no reason for the Court to reverse itself; indeed, their Motion does not even acknowledge the ruling already in effect.

Moreover, with respect to the particular facts of these three individual cases, the evidence Plaintiffs wish to introduce is irrelevant, unfairly prejudicial, and, therefore, inadmissible. The marketing and promotional evidence is irrelevant because, in all three cases, the physicians Plaintiffs claim prescribed them Paxil® ("Paxil") testified that they did not rely on GSK marketing or promotional materials in making their medical decisions. Further, none of the pertinent physicians were called on by the GSK sales representatives from other states who were deposed in other cases, including but not limited to Tracy Lepper (a sales representative from Washington state that never had any contact with the prescribers at issue in the three individual cases). Finally, there is absolutely no evidence the CASPPER program had any impact on any prescribing physicians in the three named cases.

A. The Court Previously Has Ruled that the Issues Presented by Plaintiffs Are Not Global.

The Court has already decided that the admissibility of evidence of GSK's Paxil-related marketing (including the testimony of Tracy Lepper) and of the CASPPER program is not a question that can be decided globally for all Paxil Pregnancy cases because the admissibility of this evidence necessarily depends on case-specific facts. Plaintiffs' Motion offers the Court no reason to overturn its ruling – nor do they even mention the Court's prior ruling at all. But regardless of whether they recall that this Court has already decided the very issue they raise in their Motion, Plaintiffs are required to follow the Court's ruling.

In early 2010, the Court instructed the parties in all Paxil Pregnancy cases before it to submit lists of trial motions previously decided in the *Kilker* case that either side believed could be applied to all pending cases. After several attempts to agree on a list of prior rulings that

[1] Identical versions of this response to Plaintiffs' global motion are being filed in *In re Paxil Pregnancy Cases*, February Term, 2007, Case No. 3220; *Ayala v. GSK*, September Term, 2007, Case No. 3247; *Davis v. GSK*, September Term, 2007, Case No. 3266; and *Lacambra v. GSK*, September Term, 2007, Case No. 3296. The only difference in these responses is the caption on the first page.

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could be adopted globally, the parties each created their own proposed lists and provided them to the Court. Plaintiffs' list, submitted in advance of a Case Management Conference on May 13, 2010, included as a proposed global ruling the Court's decision on the portions of GSK's Omnibus Motion *in Limine* in *Kilker* to exclude evidence of (1) GSK's marketing and promotion unrelated to Plaintiff or her physician; (2) testimony of GSK sales representatives with no connection to Plaintiff's physicians, including but not limited to Tracy Lepper; and (3) evidence related to the CASPPER program. In short, Plaintiffs' proposal specifically addressed the same evidence that Plaintiffs discuss in their present motion. (Pls' Proposed Mot. *in Limine* Global Rulings at 5 (attached as Ex. A).)

After a series of calls between counsel for 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 P. 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 motion relating to GSK's marketing, to GSK sales representatives (including the testimony of Tracy Lepper), and to the CASPPER program remained on the list for the Court's consideration. The Court addressed this motion seventh on the list. GSK's central argument was that this evidence should be excluded because the testimony of particular plaintiffs and their prescribing physicians in each case was crucial to the resolution of the motion. Because the exposure of the plaintiffs and their physicians to marketing, sales representatives, and CASPPER documents in each case is different, the Court determined that these issues were case-specific and not fit for a global ruling.

Plaintiffs do not offer the Court a single reason why its decision should be revisited — indeed, Plaintiffs do not mention this hearing or the Court's ruling at all. They do not point to any evidence discovered since the hearing occurred, 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 at the June 2010 hearing. As Plaintiffs themselves state, it is crucial that this Court enact and enforce consistent rulings on this issue. (Pls' Mot. at 3 (discussing "risk of inconsistent rulings" if evidence at issue is admitted in some cases but not others).) That includes the Court's ruling ***on these very issues***. As Plaintiffs insist, a "uniform decision is needed." (*Id.*) And the Court already has reached that uniform decision. The Court should deny Plaintiffs' motion.

B. The Evidence Presented by Plaintiffs Is <u>Not Admissible and Should Be Excluded in These Individual Cases</u>.

Further, with respect to the particular facts of these three individual cases, the Court should exclude, as irrelevant and unfairly prejudicial, evidence of GSK's Paxil-related marketing and promotional activities, the testimony of its sales representatives with no connection to Plaintiffs' physicians, and evidence regarding the CASPPER program. PA. R. EVID. 104(b), 401, 402, 403.

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Under Pennsylvania law, evidence that is not relevant is inadmissible. PA. R. EVID. 401, 402. "Relevant evidence is any evidence that tends to make a fact in issue more or less probable, and the relevance of a given piece of evidence is a prerequisite to its admissibility." *Commonwealth v. DeJesus*, 880 A.2d 608, 614 (Pa. 2005). "When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition." PA. R. EVID. 104(b). "It is the responsibility of the judge, not the jury, to resolve preliminary factual questions which form a basis for the legal admissibility of evidence." *Harris v. Toys "R" Us-Penn, Inc.*, 880 A.2d 1270, 1278 (Pa. Super. Ct. 2005). Here, the relevance of the evidence Plaintiffs seek to admit is conditional on whether that evidence played some role in a Plaintiff's decision to take Paxil or her doctor's decision to prescribe it.

The proponent of the conditional evidence bears the burden of proof and must convince the Court that the conditional evidence is admissible. *See id.* (holding that the trial court properly performed its gatekeeping function by excluding conditional evidence when plaintiff failed to present sufficient factual evidence to support admissibility). When one party challenges the admissibility of evidence having only conditional relevance, the focus of the Court's inquiry is whether there is sufficient evidence to support the existence of the condition: "The judge makes a preliminary determination whether the foundation evidence is sufficient to support a finding of fulfillment of the condition. If so, the item is admitted." FED. R. EVID. 104(b), advisory committee's note.[2] In determining whether the proffering party has met its burden, "[t]he court simply examines all the evidence in the case and decides whether the jury could reasonably find the conditional fact . . . by a preponderance of the evidence." *Huddleston v. United States*, 485 U.S. 681, 690 (1988).

Even if evidence is relevant, the Court can exclude it. "Although relevant, evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." PA. R. EVID. 403; *see also Mahan v. Am-Gard, Inc.*, 841 A.2d 1052, 1057 (Pa. Super. Ct. 2003) ("[R]elevant evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice. For this purpose, 'prejudice' … [means] an undue tendency to suggest a decision on an improper basis." (internal citations omitted)); *Commonwealth v. Parker*, 882 A.2d 488, 492 (Pa. Super. Ct. 2005) ("Trial judges [] have the authority to exclude relevant evidence if its probative value is substantially outweighed by the danger of unfair prejudice."), *aff'd on other grounds*, 919 A.2d 943 (Pa. 2007).

The Court should exclude the evidence that Plaintiffs seek to have the Court deem admissible in these three Paxil Pregnancy cases based on these rules of evidence.

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[2] The Comment to Pennsylvania Rule of Evidence 104(b) provides that "[p]aragraph 104(b) is identical to F.R.E. [Federal Rule of Evidence] 104(b) and appears to be consistent with prior Pennsylvania case law."

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1. Evidence of GSK Marketing and Promotion Unrelated to Plaintiffs or their Physicians.

There is no evidence in the record that any of the putative Paxil-prescribing physicians in these three cases relied on GSK promotional materials or representations by GSK sales representatives. Thus, these materials are irrelevant to Plaintiffs' claims. Further, Plaintiffs cannot offer competent evidence that the Plaintiffs in these cases (1) ever saw any GSK promotional materials before Paxil was prescribed to them; (2) ever read any print advertisements about Paxil before it was prescribed to them; or (3) ever had any communication with anyone from GSK.

In the most recent Paxil Pregnancy trial, *Blyth v. GSK*, Judge Glazer granted GSK's Motion *in Limine* to exclude evidence of GSK's marketing and promotional materials and efforts that were unrelated to the plaintiff or her prescribing physician. (*See* Order, *Blyth v. GSK* Nov. 9, 2010 (Control No. 10030243) (attached as Ex. B) (granting Subpart 3 of GSK's Omnibus Motion *in Limine*); *see also In re Paxil Pregnancy Cases*, Mar. 11, 2011 Teleconf. Tr. at 6:7-7:5 (attached as Ex. C) (Justice Nigro denying plaintiffs' request for commission for subpoena because plaintiffs could not show connection between evidence sought and doctors in cases at issue).) The relevant facts in *Blyth* are similar to the facts in these three cases. And other courts considering similar facts have agreed that, absent a showing that the prescribing physician was exposed to "promotional and advertising materials, such evidence is not relevant evidence." *In re Norplant Contraceptive Prods. Liab. Litig.*, No. MDL 1038, 1997 WL 81092, at *1 (attached as Ex. D); *see also Skibniewski v. Am. Home Prods. Corp.*, No. No. 99-0842-CV-W-FJG, 2004 U.S. Dist. LEXIS 31014, at *3, *30 (W.D. Mo. Apr. 1, 2004) (attached as Ex. E) (excluding evidence of defendant's publications and marketing campaigns where there was nothing in the record that established that the plaintiff or her physician relied on or were influenced by such publications or marketing campaigns). "Plaintiffs have not shown that their prescribing physicians were exposed to the promotional materials; thus, the evidence [should be] excluded." *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 223140, at *4–*5 (M.D. Fla. Jan. 30, 2009) (attached as Ex. F) (holding that marketing evidence was not admissible to show that defendant "controlled and manipulated" safety information).[3]

The issue is not whether marketing ***may have*** influenced ***some*** doctors. What matters is whether it ***actually*** influenced ***Plaintiffs'*** prescribing physicians. Thus, the relevance of such evidence is dependent upon the specific facts of each case, and its admissibility cannot be decided through a global ruling. Further, if Plaintiffs cannot offer evidence that their particular physicians relied upon GSK's marketing or promotion in prescribing Paxil for Plaintiffs, then

[3] The cases cited by Plaintiffs in their Global Motion are distinguishable on this point. For example, in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995), the court clarified that the plaintiff's doctors had received letters (which they did not retain) from the defendant regarding its product and that they read standard cardiac journals in which the defendant's ads had appeared — hence, there was evidence that the plaintiff's physicians actually were exposed to the defendant's marketing. *See id.* at 1336 n.14. Similarly, in *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971), the court stated that "[t]here was direct testimony [which] includ[ed] both the printed warning and the promotional efforts of the detail men[] by both doctors" of the plaintiff in the case. *Id.* at 221.

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evidence of GSK's promotional materials or representations by GSK sales representatives is irrelevant and inadmissible, and admitting such evidence would require GSK to waste the Court and jury's time demonstrating repeatedly that such materials or representations had no influence on Plaintiffs' prescribing physicians. *See* PA. R. EVID 104(b), 402, 403; Ex. D, *In re Norplant Contraceptive Prods.*, 1997 WL 81092, at *1.

Even if materials relating to GSK's marketing or promotion had some probative value to the issues in these particular cases — which they do not — the Court nevertheless should exclude any such marketing or promotional materials pursuant to Rule 403 because they are unfairly prejudicial, would confuse the jury, and would result in a waste of time. If these materials were admitted, GSK would be forced to defend itself by explaining each of the marketing and promotional documents, the circumstance of their origins, and whether, when, and how they actually were used. This would have the effect of creating several, lengthy, collateral trials-within-a-trial, which undoubtedly would divert the jury's attention from the main issues of the specific case. At the end of all this extraneous evidence, the jury would be no further along in deciding the heart of the individual case — namely, whether Paxil caused a particular child's alleged cardiac defect and whether GSK adequately warned these Plaintiffs' prescribing physicians concerning use of the medication during pregnancy. Because such marketing and promotional evidence would prolong the trial of each case unnecessarily and because it would hamper, not help, the jury in its work, the Court should exclude it. *See* PA. R. EVID. 403.

a. Testimony of GSK Sales Representatives, Including but not Limited to Tracy Lepper.

Additionally, Plaintiffs seek to have the Court rule as admissible the deposition testimony of GSK sales representatives from other states, taken in other cases. This includes Tracy Lepper, a sales representative in Washington state who never called upon ***any*** of the healthcare providers in these three cases, which involve Plaintiffs and prescribers from Texas, Oklahoma, and Florida. In *Blyth*, the Court granted GSK's Motion *in Limine* to exclude testimony of GSK sales representatives with no connection to the plaintiff's physicians, including but not limited to Tracy Lepper. (*See* Ex. B, Order, *Blyth*, Nov. 9, 2010 (Control No. 10030243) (granting Subpart 7 of GSK's Omnibus Motion *in Limine*).) Likewise, in these three named cases, the Court should exclude as irrelevant any testimony of sales representatives who never called upon any of the Plaintiffs' health care providers because it does not bear upon the decisions of those providers.[4] Ex. D, *In re Norplant Contraceptive Prods.*, 1997 WL 81092, at *1.

[4] "Objections to the . . . relevancy or materiality of [a witness's] testimony are not waived by failure to make them before or during the taking of a deposition, unless the ground of the objection is one which was known to the objecting party and which might have been obviated or removed if made at that time." PA. R. CIV. P. 4016(b). GSK has not waived its objections to the relevancy of the sales representatives' deposition testimony, taken in other cases by other plaintiffs, because GSK was not aware at the time of those depositions that Plaintiffs in these three cases would seek to introduce the testimony in these cases. Similarly, the reason for the relevancy objection — the lack of a connection between those sales representatives and Plaintiffs and their doctors — could not have been removed or obviated if the objection had been made at that time. *See, e.g., Turner v. Valley Hous. Dev. Corp.*, 972 A.2d 531, 536 (Pa. Super. Ct. 2009) (concluding defendant did not waive objection to use of a witness's deposition because the

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Even if there arguably were some minimal probative value to this evidence, it would be substantially outweighed by the risk of unfairly prejudicing GSK, confusing the jury, and causing undue delay. Given their lack of evidence of alleged misrepresentations by sales representatives in any of Plaintiffs' home states, Plaintiffs want to inject into this case unrelated evidence from far-flung states, even though it has no connection to these particular Plaintiffs or their prescribers. With no context to her testimony, Ms. Lepper's statements might be viewed by the jury as authoritative and representative of GSK's sales force nationwide, which would be an inaccurate and unfairly prejudicial impression. *See* PA. R. EVID. 403.

In their Motion, Plaintiffs isolate statements from Ms. Lepper's deposition in an effort to support just such a conclusion. (*See* Pls. Mot. at 8-9.) However, when put in context, Ms. Lepper's statements cannot reasonably be construed to be as far-reaching as Plaintiffs would have the Court, and presumably the jury, believe. Indeed, Ms. Lepper states that she does not even remember receiving the "info-mail" disseminated by Bonnie Rossello that Plaintiffs characterize as "marching orders" for the Paxil sales team. (*See* Dep. of T. Lepper, *Mendoza v. GSK* (Apr. 21, 2009) at 56:10-17 (attached as Ex. G).) Ms. Lepper also testifies that the sales representative training program was primarily composed of four weeks of "home study." (*Id.* at 10:8-14.) During this training phase, potential representatives were expected to learn a considerable amount of information in a ***self-directed*** manner. (*See id.* at 10:16-11:13.) Further, nothing in Ms. Lepper's deposition indicates that all GSK sales representatives acted in the same manner or were even taught to do so — particularly with regard to the conduct Plaintiffs hope to attribute, by extrapolation from Ms. Lepper's testimony, to every sales representative who may have called on any of Plaintiffs' prescribing physicians. The mere fact that GSK held national training sessions does not mean that an individual sales representative's actions can be imputed to all sales representatives. Ms. Lepper's testimony about her experience is not relevant to Plaintiffs' cases when she had no interactions with their prescribing physicians.

Most importantly, allowing Plaintiffs to play the video of Ms. Lepper's testimony would mislead the jury: her deposition testimony omits the significant facts that her sales territory was limited to the Seattle, Washington area and that she never had dealings with any doctors in any of Plaintiffs' cases, even though these facts are undisputed. (Nor would one expect any such testimony, because Ms. Lepper's deposition was noticed only in the Washington case in which she was involved.) With no evidence before them to the contrary, the jury likely (yet incorrectly) would assume that Ms. Lepper had some connection to the Paxil-providing physicians in the three named cases simply because her testimony is being presented in each of these cases. *See Commonwealth v. Conway*, 49 Pa. D. & C.3d 242, 248–49 (Com. Pl. Jan. 15, 1987) (excluding the audio portion of videotape of defendant taking intoxication tests in part because his verbal questions about the tests might imply intoxication), *aff'd*, 534 A.2d 541 (Pa. Super. Ct. 1987). The Court should exclude Ms. Lepper's testimony because it is uncontroverted that Ms. Lepper has no connection to the prescribing physicians, or any of the doctors, in Plaintiffs' cases.

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ground of the objection, the witness's incompetency, was not known to defendant at the time of the deposition and could not have been obviated or removed at that time).

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Further, the Court should exclude testimony of other GSK sales representatives if shown to have no connection to Plaintiffs or their relevant physicians.

2. Evidence Related to the Case Study Publication for Peer Review Program.

Plaintiffs also seek to have the Court rule as admissible evidence regarding Case Study Publication for Peer Review (also known as "CASPPER"), a short-lived GSK program designed to facilitate the publication of case studies by physicians in peer-reviewed scientific journals. In *Blyth*, Judge Glazer granted GSK's nearly identical Motion *in Limine* to exclude evidence related to the CASPPER program. (Ex. B, Order, *Blyth*, Nov. 9, 2010 (Control No. 10030243) (granting Subpart 4 of GSK's Omnibus Motion *in Limine*).) In its approximately two years of existence, there were perhaps five published items that possibly were connected with the Paxil CASPPER program (although it is uncertain to what extent these items were published as a result of that program). Two of these published items are letters to the editor, and ***none*** relates to the use of Paxil during pregnancy or by women of child-bearing age. (*See* Table of CASPPER Publications, (attached as Ex. H).) Plaintiffs argue that, as part of the CASPPER program, GSK engaged in "ghostwriting" scientific articles that were favorable to Paxil. This fundamentally mischaracterizes the CASPPER program.

CASPPER was developed by GSK to assist physicians interested in publishing peer-reviewed case reports.[5] GSK introduced these doctors to Complete Healthcare Communications ("CHC"), a professional medical editorial service that could aid physicians in the publication process. The core objective of the CASPPER program was to help physicians publish case reports, not, as Plaintiffs argue, to affect sales of Paxil. (*See* Dec. 4, 2008 Dep. of S. Sproull at 634:5–637:14 ("Sproull Dep.") (attached as Ex. J).) The program was conducted by CHC and supported by GSK. (*See id.* at 630:23–631:12; 632:12–633:11.)

Under CASPPER, physicians initiated and drove the substantive drafting process. Physicians would have the option to create the initial draft of the manuscript or to provide the relevant information to a CHC employee, who then would create the first draft based upon conversations with the physician. Regardless of the path chosen, the physician-author retained control over the manuscript throughout the drafting, editing, and submission process. (*See* Apr. 2000 CASPPER Program Brochure at 3, 7–10 (attached as Ex. K); Aug. 14, 2008 Dep. of B. Brand at 102:16–22 ("Aug. 14 Brand Dep.") (attached as Ex. L); Aug. 28, 2008 Dep. of B. Rossello at 152:14–154:7 ("Aug. 28 Rossello Dep.") (attached as Ex. M).) CHC provided technical support in the form of literature searches, copy editing, proofreading, production of tables and graphics, preparation for submission to journals, and peer-review-related correspondence. (*See* Ex. K, Apr. 2000 CASPPER Program Brochure at 4, 7–10; Ex. I, Sproull Dep. at 653:21–656:6.) There is no evidence in the record that GSK's involvement included anything other than: (1) informing physicians about CASPPER through its sales representatives;

[5] A "case report" is a report of one physician's experience with a single patient, as detailed by the physician. (*See* Aug. 29, 2008 Dep. of B. Rossello at 264:19–265:17 ("Aug. 29 Rossello Dep.") (attached as Ex. I).)

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and (2) contracting with CHC. (*See* Ex. K, Apr. 2000 CASPPER Program Brochure at 3, 6; Ex. M, Aug. 28 Rossello Dep. at 157:15; *see also* Ex. L, Aug. 14 Brand Dep. at 102:19–22 ("The case reports would be written ***by the physician*** that had the case report, and we were offering to provide editorial support and also the guidance of how to do this." (emphasis added)).)

As shown on the attached table of CASPPER publications (Ex. H), there exist only five published pieces that may have been connected with the CASPPER program in its short lifetime. Not one discusses Paxil use during pregnancy or by women who could become pregnant. Further, there is no evidence that the prescribing physicians in these three cases viewed or ever were exposed to any of these publications, nor is there any evidence that these doctors ever participated in — or even were aware of — the CASPPER program. As such, evidence of the CASPPER program is wholly irrelevant. *See, e.g.,* Ex. E, *Skibniewski*, 2004 U.S. Dist. LEXIS 31014, at *3, *30. Moreover, any possible relevance of these materials is outweighed by the danger of unfair prejudice, as is illustrated by prior questioning of GSK witnesses. (*See, e.g.*, Ex. L, Aug. 14 Brand Dep. at 307:20–308:17.)

II. CONCLUSION

For the foregoing reasons, GSK respectfully requests that this Court deny Plaintiffs' Global Motion *in Limine* Regarding the Admissibility of Certain Evidence at Issue in All Paxil Pregnancy cases.

Respectfully Submitted,

LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO

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

-and-

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

cc: Jason A. Itkin, Esquire
Alexander G. Dwyer, Esquire
Rosemary Pinto, Esquire

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CERTIFICATE OF SERVICE

I hereby certify that I will serve a true and correct copy of **GLAXOSMITHKLINE LLC'S OPPOSITION TO PLAINTIFFS' GLOBAL MOTION *IN LIMINE* REGARDING THE ADMISSIBILITY OF CERTAIN EVIDENCE AT ISSUE IN ALL PAXIL PREGNANCY CASES** 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 and/or federal express.

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LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO

Date: March 29, 2011

BY: /s/ Joseph E. O'Neil
Joseph E. O'Neil, Esquire
Counsel for Defendant,
GlaxoSmithKline LLC, formerly
SmithKline Beecham Corporation,
d/b/a GlaxoSmithKline

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Exhibit A

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PROPOSED MOTION *IN LIMINE* GLOBAL RULINGS

PAXIL MTP PREGNANCY LITIGATION

MOTION	RULING	CITATION
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Smoking and Alcohol Use by Plaintiff, Michelle David (Control No. 09081988)	**DENIED**, in regards to smoking and **GRANTED** in regards to alcohol	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Michelle David's Ingestion of All Medications Other than Paxil in Pregnancy with Lyam Kilker (Control No. 09082021)	**DENIED** insofar as: Defendant has medical testimony, Defendant does not exceed scope of expert reports, and, Defendant does not attempt to use other medications to suggest causation	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding HIV Testing for Michelle David (Control No 09082057)	**GRANTED/AGREED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Sexual Conduct and Birth Control of Michelle David (Control No. 09082058)	**GRANTED** as to sexual conduct. Further information requested regarding the relevancy of any birth control products, that decision is postponed until time of trial.	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Arrests or Criminal History of Michelle David (Control No. 09081998)	**GRANTED/AGREED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813

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Control No.: 11031590

Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Plaintiffs' Understanding of the Contents of Prescription Labels, including Paxil, and Physician Warnings Regarding Medication, including Paxil (Control No. 09082052)	**GRANTED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Myles Kilker's Alleged use of Alcohol, Prescription Medication, Cigarette and Illegal Substance (Control No. 09082022)	**GRANTED,** in regards to alcohol/drugs, and **DENIED** regarding smoking	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Criminal Background, Mental or Physical History of any Non-Party Family Member (Control No. 09082023)	**GRANTED/AGREED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Abortion (Control No. 09082059)	**GRANTED/AGREED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Adam David's Child Support and Relationship with Biological Father and Family Members (Control No. 09082024)	**GRANTED/AGREED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813

Case ID: 070203220
Control No.: 11031590

Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference to any Negligence of Plaintiffs or Non-Parties (Control No. 09082060)	**GRANTED** as to precluding evidence or argument of contributory negligence by Plaintiff, and **DENIED** insofar as Defendant is allowed to present evidence regarding prescriber's conduct	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Collateral Sources and Insurance (Control No. 09082064)	**GRANTED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding That Plaintiffs or Plaintiff's Counsel Engaged in Inappropriate Communication with Fact Witnesses and Other Actions and/or Agreements of Attorneys Control No. 09082067)	**WITHDRAWN/ AGREED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding that GSK was not Negligent and should not be held Liable Based on FDA Approval of Paxil (Control No. 09082066)	**DENIED** Without prejudice to the Plantiffs to respond by arguing the philosophy of *Wyeth v. Levine* **DENIED (in part)**	Judge Moss, Sept. 2, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813 Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude any Evidence, Argument and/or Reference Regarding Adverse Impact of a Plaintiffs' Verdict (Control No. 09082061)	**GRANTED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813 Judge Moss, Sept. 2, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813

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Plaintiffs' Motion *in Limine* to Exclude Mention of Reference to, or Evidence of, Prior Judicial Opinions Regarding Dr. Healy (Control No. 09082026)	**DEFERRED** until time of trial	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude Mention of Reference to, or Evidence of, Prior Judicial Opinions Regarding Plaintiffs' Experts Control No. 09082063)	**DEFERRED** until time of trial	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude and Evidence, Argument and/or Reference to Fiction Allegedly Authored by Suzanne Parisian, M.D. (Control No. 09082027)	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Plaintiffs' Motion *in Limine* to Exclude, and/or Limit, Expert Testimony of GSK Employees and Former Employees (Control No. 09082145)	**WITHDRAWN/ AGREED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Defendant Motion *in Limine* to Exclude Certain Irrelevant, Hearsay and Overly Prejudicial Evidence (Control No. 09082135) • SUB PART 1 Evidence to exclude GSK's conduct after April 2005, including but not limited to the 2008 FDA Warning Letter Regarding Avandia, slides from the 2006 Pregnancy Follow-Up Working Group, and the 2006 Slide Presentation Entitled "Pregnancy Registries: GSK	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813

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Experience and Recent Data		
• SUB PART 2 Evidence to exclude GSK's marketing materials never implemented, including but not limited to those related to "Mother Knows Best, " the "war" video, and BabyCenter.com	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
• SUB PART 3 Evidence to exclude GSK's marketing and promotion unrelated to Michelle David or her physicians	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
• SUB PART 4 Testimony of GSK sales representatives with no connection to Michelle David's physicians, including but not limited to Tracy Lepper	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
• SUB PART 5 Evidence of allegations of GSK lawyer involvement in science, including but not limited to allegations involving GSK outside counsel and Dr. David Koren	**DENIED,** however, this does not preclude Defendant from arguing the admissibility of documents. Also, Plaintiff must lay a foundation for testimony relating to the alleged interaction of medical experts and Defense counsel	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
• SUB PART 6 Evidence related to the Case Study Publications for Peer Review program	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813

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• SUB PART 7 Evidence of unrelated adverse events and reports	**GRANTED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
• SUB PART 8 Argument or questioning referencing the September 11, 2001 terrorists attacks	**GRANTED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
• SUB PART 9 Evidence related to the February 23, 2009 interview of Myles Kilker by an attorney for GSK	**GRANTED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
• SUB PART 10 Hearsay evidence of Michelle David's Paxil	**DENIED**, however, counsel may object to possible hearsay statements at trial	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Defendant Motion *in Limine* Motion *In Limine* to Exclude Evidence of and Reference to any Valuation of Plaintiffs' Past Medical Services Beyond the *Amount Paid* by the Pennsylvania Department of Welfare (Control No. 09082136)	**GRANTED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Defendant Motion *In Limine* to Exclude Evidence Alleging That GSK Was "Misleading" Or Deceptive in its Dealing With The FDA and/or Committed "Violations" of the FDCA or FDA Regulation (Control No. 09082144)	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Defendant Motion *In Limine* to Exclude Evidence of, or reference to Spontaneous Adverse Events and Case Reports (Control No. 09082143)	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813

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Defendant Motion *In Limine* to exclude Evidence of or reference to Foreign Investigations or Regulatory Actions, Including Labeling, Related to Paxil (Control No. 09082142)	**GRANTED** Any evidence or reference to investigations, regulatory actions, labeling or "warnings" related to Paxil **"used"** outside the U.S. is hereby excluded. **GRANTED (in part)**	Judge Moss, Sept. 2, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813 Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Defendant Motion *In Limine* to Preclude Plaintiffs' Experts from Characterizing The Motives or Intentions Behind GSK'S Documents or Conduct (Control No. 09082141)	**GRANTED**, with limitation that, although experts cannot speak directly to the motives or intentions behind actions, the experts can testify to the techniques used and duty of care expected	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Defendant Motion *In Limine* to Implement Certain Trial Procedures to Protect GSK's Due Process Rights With Regard to Punitive Damages (Control No. 09082140)	**GRANTED** as Plaintiff is precluded from introducing evidence of other injuries in regards to damages. Partially postponed until time of trial	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Defendant Motion *In Limine* to Exclude any Argument it had a Duty to Warn Patients Directly (Control No. 09082139)	**GRANTED** **GRANTED**	Judge Moss, Sept. 2, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813 Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813
Defendant Motion *In Limine* to Exclude Evidence of Changes to Paxil Labeling and Warnings as Subsequently Remedial Measures (Control No. 09082138)	**DENIED**	Judge Levin, Sept. 11, 2009, Order in *Kilker v. GSK*, February Term, 2007, No. 001813

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Exhibit B

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Control No.: 11031590

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

ANNA CAROLINA BLYTH, a Minor, by DENNIS BLYTH, Guardian; DENNIS BLYTH AND MARSHA BLYTH, Individually	:	SEPTEMBER TERM, 2007
	:	NO. 3305
v.	:	Control No. 10030184
GLAXOSMITHKLINE LLC	:	

DOCKETED
COMPLEX LIT CENTER
NOV 9 2010
J. STEWART

ORDER

AND NOW, this 9th day of November 2010, it is hereby **ORDERED** AND **DECREED** that the following decisions regarding Plaintiffs' Motions in Limine, with reference to the above captioned case, be docketed and made part of the official record.

Control # 10030037 No. 1- DENIED insofar as defendant has medical testimony, defendant does not exceed scope of expert reports, and defendant does not attempt to use other medications to suggest causation. Evidence is limited to first trimester of pregnancy (ending June 1, 1995);

Control # 10030050 No. 2- DENIED;

Control # 10030046 No. 3- DEFERRED / AGREED;

Control # 10030042 No. 4- DEFERRED / AGREED;

Control # 10030102 No. 5- DEFERRED / AGREED;

Control # 10030176 No. 6- DEFERRED / AGREED;

Control # 10030177 No. 7- DEFERRED / AGREED;

Control # 10030051 No. 8- DENIED;

Control # 10030052 No. 9- DEFERRED / AGREED;

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Control # 10030043 No. 10- DEFERRED / AGREED;

Control # 10030044 No. 11- DEFERRED / AGREED;

Control # 10030103 No. 12- DEFERRED / AGREED;

Control # 10030104 No. 13- DEFERRED / AGREED;

Control # 10030045 No. 14- DEFERRED / AGREED;

Control # 10030105 No. 15- GRANTED as to precluding evidence or argument of contributory negligence by plaintiff and **DENIED** insofar as defendant is allowed to present evidence regarding prescriber's conduct;

Control # 10030178 No. 16- DEFERRED / AGREED;

Control # 10030179 No. 17- DENIED;

Control # 10030186 No. 18- DEFERRED / AGREED;

Control # 10030180 No. 19- DENIED; and

Control # 10030181 No. 21- DENIED.

It is further **ORDERED** AND **DECREED** that the following decisions regarding Defendant's Motions in Limine, with reference to the above captioned case, be docketed and made part of the official record.

Control No. 10030182 No. 1- DEFERRED / AGREED;

Control No. 10030183 No. 2- DEFERRED / AGREED;

Control No. 10030184 No. 3- GRANTED;

Control No. 10030185 No. 4- DEFERRED / AGREED;

Control No. 10030187 No. 5- GRANTED;

Control No. 10030188 No. 6- GRANTED;

Control No. 10030196 No. 7- DEFERRED / AGREED;

Control No. 10030211 No. 8- **DENIED** as to any reports dated on or before June 1, 1995 and GRANTED as to any reports dated after June 1, 1995;

Control No. 10030212 No. 9- **DEFERRED / AGREED;**

Control No. 10030214 No. 10- **DEFERRED / AGREED;**

Control No. 10030217 No. 11- **GRANTED;**

Control No. 10030219 No. 12- **GRANTED** to the extent that plaintiff may not allege fraud against the FDA;

Control No. 10030220 No. 13- **GRANTED.** Any such evidence of, or reference to, investigations, regulatory actions, labeling or warnings related to Paxil outside the United States, is hereby **EXCLUDED** pursuant to the Global Order of the Honorable Sandra Mazer Moss, dated October 27, 2010;

Control No. 10030222 No. 14- **DENIED** to the extent the testimony is limited to the time period before June 1, 1995;

Control No. 10030224 No. 15- **DEFERRED / AGREED;**

Control No. 10030231 No. 16- **DENIED;**

Control No. 10030232 No. 17- **GRANTED** without prejudice to consider specific evidentiary offers of proof at time of trial;

Control No. 10030233 No. 18- **DEFERRED / AGREED;**

Control No. 10030234 No. 19- **DENIED;**

Control No. 10030240 No. 20- **DENIED;**

Control No. 10030241 No. 21- **DENIED;**

Control No. 10030243 No. 22-

Subpart 1: **Motion to Exclude Evidence of GSK's conduct after July 24, 1995, including but not limited to the 2008 FDA Warning Letter regarding Avandia, and the 2006 slide presentation entitled "Pregnancy Registries: GSK Experience and Recent Data"**- **GRANTED** as to conduct after June 1, 1995;

Subpart 2: **Motion to Exclude Evidence of GSK marketing materials never implemented, including but not limited to those related to "Mother Knows Best," the "war" video, BabyCenter.com, Ruder Finn b-roll video, and draft manuscripts never published**- **GRANTED;**

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Subpart 3: **Motion to Exclude Evidence of GSK marketing and promotion unrelated to Marsha Blyth or her prescribing physician- GRANTED;**

Subpart 4: **Motion to Exclude Evidence related to the Case Study Publication for Peer Review ("CASPPER") program- GRANTED;**

Subpart 5: **Motion to Exclude Evidence of unrelated adverse events and reports- GRANTED;**

Subpart 6: **Motion to Exclude Argument or questioning referencing the September 11, 2001 attacks- GRANTED;**

Subpart 7: **Motion to Exclude Testimony of GSK sales representatives with no connection to Marsha Blyth's physicians, including but not limited to Tracy Lepper- GRANTED;**

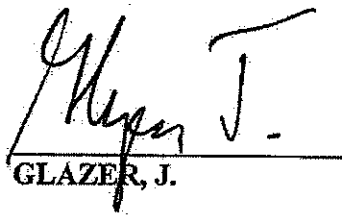
Subpart 8: **Motion to Exclude Evidence of Anna Blyth's family and individual photographs and get well cards- GRANTED** as to get well cards and **DENIED** as to photographs; and

Subpart 9: **Motion to Exclude Evidence of or reference to Paxil and Social Anxiety Disorder and Premenstrual Dysphoric Disorder- GRANTED;**

Control No. 10030244 No. 23- GRANTED; and

Control No. 10110535 No. 24- DENIED.

BY THE COURT:



GLAZER, J.

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Exhibit C

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COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA

- - -

IN RE: PAXIL PREGNANCY CASES
FEBRUARY TERM 2007
MASTER DOCKET NO. 3220

- - -

MARCH 11, 2011

- - -

TELECONFERENCE

BEFORE: JUSTICE RUSSELL M. NIGRO

Reported and transcribed by:
CARRIE A. DUNNE, RPR, CSR, CCR

GOLKOW TECHNOLOGIES, INC.
ph 877.370.3377 | fax 917.591.5672
deps@golkow.com

Case ID: 070203220
9dd604de-1cf2-454d-8056-0ac3d8f65921
Control No.: 11031590

1 work it out, but always mindful of the
2 fact that the trial dates are the
3 trial dates and the cases will go
4 forward. All right. So you know
5 exactly she -- she knows exactly
6 what's going on.
7 With regards to Emory, after
8 our discussions it is determined that
9 the plaintiffs will not be able to go
10 forward with the subpoenas. The
11 thought process is that, I guess, it's
12 somewhat remote in terms of any chance
13 for relevancy, I'm going to make a --
14 my thoughts, again, and this does not
15 indicate her thoughts. You know, we
16 had various discussions, I'm not in a
17 position to speak for her, nor would I
18 do that, but as for myself, it would
19 seem to me that a fair start point
20 would be the two scientists in
21 question and trying to then link up
22 those scientists with whatever doctors
23 may have been at seminars or read
24 literature or whatever in relation to

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1 the drugs that they were prescribing.
2 So we discussed it at length and her
3 position was, you know, in line with
4 my position that the subpoenas would
5 not be forthcoming.
6 Okay?
7 MS. PINTO: Yes.
8 MR. WOO: Yes, your Honor.
9 JUSTICE NIGRO: All right.
10 You're all with me?
11 MS. PINTO: Yes, your Honor.
12 MR. WOO: We are, your Honor.
13 JUSTICE NIGRO: Okay. So next
14 Thursday hopefully you've worked out
15 all of these experts from both sides
16 and hopefully we're making progress
17 with regards to getting some discovery
18 to plaintiffs, Bob, from your side
19 from the Puerto Rican manufacturing
20 plant.
21 MR. WOO: Yes, your Honor.
22 We're working to see what documents
23 are most readily available.
24 JUSTICE NIGRO: Very good.

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Exhibit D

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H
Only the Westlaw citation is currently available.

United States District Court, E.D. Texas, Beaumont Division.
In re NORPLANT CONTRACEPTIVE PRODUCTS LIABILITY LITIGATION
No. MDL 1038.

Feb. 21, 1997.

Chris Parks of Parker and Parks, Port Arthur, TX, Roger Brosnahan of Brosnahan, Joseph & Suggs, Minneapolis, MN, Turner Branch, Branch Law Firm, Alberquerque, NM, for plaintiff.

John W. Vardaman, F. Lane Heard III, Steve Farina of Willams & Connolly, Washington DC, Paul W. Gertz, Larry Germer, Tonya Connell Adams of Germer & Gertz Beaumont, TX, for defendant.

ORDER GRANTING DEFENDANTS' MOTION IN LIMINE

TO BAR REFERENCE TO ADVERTISING AND OTHER

MATERIALS NOT VIEWED BY THE FIVE BELLWETHER PLAINTIFFS

SCHELL, Chief Judge.

***1** This matter is before the court on Defendants' Motion In Limine to Bar Reference to Advertising and Other Materials Not Viewed by the Five Bellwether Plaintiffs filed on January 28, 1997. Plaintiffs filed a response on February 10, 1997. Defendants filed a reply on February 18, 1997. Defendants contend that the following items should be excluded because they are not relevant to the issues of the adequacy of the physician warning and whether the physicians knew when they prescribed Norplant for the plaintiffs that the side effects they complain of were potential risks:[FN1] (1) FDA-approved consumer advertisements of Norplant published in magazines; (2) press articles about Norplant; (3) correspondence with FDA regarding the ads in Item 1; (4) Norplant patient materials to be distributed by doctors; (5) internal Wyeth materials discussing Items 1-4 (including general PR and advertising issues); and (6) correspondence with PR/advertising firms.[FN2] Additionally, Defendants contend that because the plaintiffs never saw the above listed documents, including any direct-to-consumer advertising, the materials have no possible relevance and therefore should be excluded.[FN3]

FN1. Mem. in Supp. of Defs.' Mot. in Limine at 2.

FN2. Reply Mem. in Supp. of Defs.' Mot. in Limine at Tab 16.

FN3. Mem. in Supp. of Defs.' Mot. at 2 (stating that "each of the five bellwether plaintiffs testified in her deposition that she never saw an advertisement for Norplant prior to choosing the contraceptive.")

Plaintiffs counter that Defendants' advertising and promotional materials are directly relevant to whether Wyeth overpromoted Norplant and thus diluted the effect of any warnings given.[FN4] In support of their overpromotion theory, Plaintiffs attached as exhibits internal memoranda and depositions discussing or alluding to a PR campaign but provided the court with no examples of such a campaign, much less proof that the physicians or plaintiffs were even exposed to such a campaign.[FN5] Perhaps realizing the absence of proof that the physicians or plaintiffs were exposed directly to a Norplant PR campaign of overpromotion, Plaintiffs argue that they are entitled to "recreate the circumstances and atmosphere surrounding the overpro-

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motion of [Norplant] at the time the plaintiffs were choosing to use Norplant as a contraceptive device and the doctors were approving this choice."[FN6]

FN4. Pls.' Mem. in Opp'n to Defs.' Mot. at 1.

FN5. *Id.* at 3-5 & Tabs 2-6. Plaintiffs cite as an example of Wyeth's aggressive publicity campaign targeted to consumers the placement of several "puff pieces" in consumer magazines by Wyeth's PR firm. *Id.* at 4. However, Plaintiffs do not attach one of these "puff pieces" as an exhibit or provide evidence that either the plaintiffs or physicians were exposed to one.

FN6. *Id.* at 6-7. Plaintiffs theory appears to be that because physicians are bombarded daily with promotional materials either directly or indirectly, they are incapable of distinguishing one from another but are still subconsciously affected by the material. *Id.* at 5-6.

Because the court is applying the learned intermediary doctrine in these cases, the relevant issue, in addition to causation, is the adequacy of the physician warning. This inquiry involves consideration of all materials to which the physician was actually exposed, including patient materials, such as patient brochures and videos, distributed by Wyeth through the physician, as well as advertisements actually seen by the physician. Absent evidence that the physicians were exposed to the above listed materials, the court finds that the promotional and advertising materials are not relevant evidence.

Accordingly, Defendants' Motion In Limine to Bar Reference to Advertising and Other Materials Not Viewed by the Five Bellwether Plaintiffs is hereby GRANTED

E.D.Tex.,1997.
In re Norplant Contraceptive Products Liability Litigation

Not Reported in F.Supp., 1997 WL 81092 (E.D.Tex.)

END OF DOCUMENT

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Exhibit E

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LEXSEE 2004 US DIST LEXIS 31014

KATHRYN E. SKIBNIEWSKI and MICHAEL G. SKIBNIEWSKI, Plaintiffs, vs. AMERICAN HOME PRODUCTS CORPORATION; WYETH LABORATORIES, INC., WYETH-AYERST LABORATORIES, INC., and A. H. ROBINS COMPANY, INCORPORATED, Defendants.

Case No. 99-0842-CV-W-FJG

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

2004 U.S. Dist. LEXIS 31014

March 31, 2004, Decided
April 1, 2004, Filed

COUNSEL: [*1] For Kathryn E Skibniewski, Plaintiff: William P. Ronan, III, LEAD ATTORNEY, Ronan Law Firm, Overland Park, KS.

For American Home Products Corporation, Defendant: Harvey Lee Kaplan, Jon A. Strongman, Michael B Buser, LEAD ATTORNEYS, Shook Hardy & Bacon LLP, Kansas City, MO; James E. Scarboro, Tim Atkeson, LEAD ATTORNEYS, Arnold & Porter, Denver, CO; Kimberly C. Bartels, H&R Block, Kansas City, MO.

For Wyeth Laboratories, Inc., Wyeth-Ayerst Laboratories, Inc., A.H. Robins Co., Inc., Defendants: Bradley D. Honnold, LEAD ATTORNEY, Goza & Honnold, LLC, Kansas City, MO; Harvey Lee Kaplan, Jon A. Strongman, Michael B Buser, LEAD ATTORNEYS, Shook Hardy & Bacon LLP, Kansas City, MO; James E. Scarboro, Tim Atkeson, LEAD ATTORNEYS, Arnold & Porter, Denver, CO; Kimberly C. Bartels, H&R Block, Kansas City, MO.

JUDGES: Fernando J. Gaitan, Jr., United States District Judge.

OPINION BY: Fernando J. Gaitan, Jr.

OPINION

ORDER

Currently pending before the Court is defendant's Motions in Limine. The Court hereby rules as follows:

1. Motion in Limine No. 1 - Exclude Evidence of Alleged Ghostwriting

Wyeth states that it anticipates that plaintiff may attempt to convince the jury that it improperly influenced the scientific community by hiring [*2] a company called Excerpta Medica, Inc. to "ghost-write" articles published in scientific journals under the names of prominent experts in the treatment of obesity. Wyeth states that this evidence falls into two categories: those articles that were published and articles that were in draft form and never published. As to the published articles, Wyeth states there is no evidence that these articles were ghost written or included any input regarding content from Wyeth or its predecessor in interest, Lederle Laboratories. As to the unpublished articles, Wyeth states that since these articles were in draft form and were never disseminated to the public, there can be no misleading information based on anything contained in the articles.

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Plaintiff states that she will prove that Excerpta Medica wrote nine papers for the defendant at a cost of $ 20,000 per paper, only $ 1,500 of which was to go to the author of the paper. Plaintiff states that there were two specific articles which were funded by Wyeth and/or Lederle. Plaintiff alleges that one of the articles fails to disclose that it was funded by defendant. Plaintiff also states that defendant's statement that the 1996 Stunkard article was [*3] written prior to the time Wyeth was involved with Redux is false and there are a number of internal memos regarding the connection between Redux and PPH, one of which is dated June 1, 1994. As to the unpublished articles, plaintiff states that these are still relevant to show defendant's fraudulent plan or scheme. Plaintiff also states that the articles are relevant to the issue of punitive damages. Plaintiff also states that literature created and/or used by a manufacturer to overpromote its drugs and which reduces a warning's effectiveness is relevant to prove defendant had a duty to warn the patient. Plaintiff also argues that the motion in limine is too vague with respect to precisely what documents AHP is seeking to preclude to allow the court to make an informed ruling.

Wyeth states that plaintiff misunderstood its argument and it was stating not that the articles were irrelevant, but that there was no factual basis to show that Wyeth ghost-wrote these articles. As to the unpublished articles, Wyeth states that plaintiff does not deny that neither plaintiff nor her physician relied on these articles. In order to prove fraudulent misrepresentation, Wyeth states that plaintiff must [*4] show that she justifiably relied on the representations of defendant in using its diet medications. Because she cannot show this, any involvement Wyeth may have had in their development is irrelevant.

Ruling: Defendant's motion in limine is hereby **GRANTED** (Doc. # 108).

2. Motion in Limine No. 2 - Exclude Certain Inadmissible Documents

Wyeth seeks to exclude evidence of: 1) a e-mail sent by Kay Anderson an American Home employee on October 3, 1996; 2) a 1976 memorandum pertaining to use of fenfluramine by chronic alcoholics prepared by C.E. Morton and 3) a September 24, 1996 e-mail sent by Leo Lutwak.

Kay Anderson E-mail - in this e-mail Ms. Anderson makes a flippant remark concerning PPH and obesity that is insensitive, inappropriate and offensive. Wyeth states that this e-mail is irrelevant to any issue in the case and it is also inadmissible because under *Rule 403*, any probative value is outweighed by the unfair prejudice to Wyeth. Wyeth states that Ms. Anderson allegedly sent this e-mail to a fellow employee regarding the logistics of a refund program. The e-mail is as follows:

> No problem with the reschedule. The price is a status on how you are going to handle the checks with accounts [*5] payable. Am I off the hook or can I look forward to my waning years signing checks for fat people who are a little afraid of some silly lung problem.

1976 Memorandum Re: Use of Fenfluramine in Connection with Alcoholism -

In this memorandum which was written 25 years ago, Mr. Morton, an employee of Wyeth's former subsidiary, he mentions a document discussing the use of fenfluramine by chronic alcoholics. He suggests that the fenfluramine label be changed to advise chronic alcoholics not to utilize the drug or alternatively that the underlying document be destroyed. Wyeth argues that this memo is irrelevant, prejudicial, remote in time and inadmissible for any purpose.

September 24, 1996 Electronic Mail Message from Leo Lutwak -

Mr. Lutwak was an FDA official. The e-mail is a response to an e-mail sent by Sol (Solomon Sobel) who is also an FDA official. The e-mail originally sent to Lutwak apparently concerned the drug dexfenfluramine. In his response to Sol's message, Lutwak stated as follows:

> Sol:
>
> I agree strongly with your statements. All the issues should be brought out - possible neurotoxicity, definite pulmonary hypertension, modest efficacy. If this hurts sales, so be it. The company [*6] has gotten away with much manipulation these past 3 years, of the publicm [sic], of the press, of the FDA.

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- Leo

Wyeth states that plaintiff cannot establish any foundation that this message has anything to do with it, as the e-mail refers only to "the company" and provides no other identifying information. Wyeth states that the message refers to the three years before 1996, thus 1993 to 1996 and states that it did not even obtain any rights to dexfenfluramine until February 10, 1995, which means that the e-mail could not refer to Wyeth.

Plaintiff states that the Kay Anderson e-mail is relevant to show that defendant acted with evil motive, complete indifference to and/or conscious disregard for the safety of others. Plaintiff states that this memo is also relevant to the issue of punitive damages. Alternatively, plaintiff states that because the e-mail related to the offering of refunds to Pondimin users, it is an admission against interest.

With regard to the 1976 memorandum, plaintiff states that this memo is relevant to show the culpable mental state of defendant and to show a pattern of conduct on the part of A.H. Robbins/Wyeth. Plaintiff states that this memo is relevant to show [*7] that defendant failed to warn of the known health risks associated with the use of fenfluramine.

As to the Leo Lutwak e-mail, plaintiff states that this e-mail is relevant to show that Pondimin and Redux were not safe and effective and that Mr. Lutwak knew that. Plaintiff states that this e-mail is relevant as proof of defendant's fraudulent scheme to "neutralize" FDA officials who were concerned about the dangers of Pondimin/Redux. With regard to the argument that the memo has nothing to do with Wyeth, plaintiff states that just five days before the memo was written, an internal Wyeth memo indicated, "I just learned that a non-approval letter has been issued by the FDA regarding our modification for the PPH labeling." "The main changes being requested by the FDA include addition of a large font, bold print statement, to the effect that the use of anorexigens increase the risk of PPH, which is often fatal." (AHP document LIND-00000642). Plaintiff also states that several documents demonstrate that defendant's statement that it did not have any rights or interest with respect to dexflenfluramine during the time period referenced in the (September 24, 1996) e-mail is also untrue. Plaintiff [*8] also states that the probative value of the memos is not outweighed by the danger of unfair prejudice and that the e-mails are not hearsay or are covered by an exception to the hearsay rule.

With regard to the Anderson e-mail, Wyeth states that it originally argued that the comments of Ms. Anderson were outside the scope of her employment and that she did not speak for Wyeth or other employees. Wyeth states that plaintiff does not dispute that these remarks were outside the scope of her employment and accordingly they are irrelevant and inadmissible to show Wyeth's evil motive or state of mind. Wyeth states that the only purpose of this e-mail would be to inflame the jury.

As to the Morton memo, Wyeth states that there is no relevant connection between Wyeth and this memo. Wyeth states that this memo was drafted by an employee of A.H. Robbins in 1976 and Wyeth did not acquire Robbins until 1989, mor than 12 years after the memo was drafted. During this twelve years, Wyeth states that it had no involvement with Robbins or Pondimin. Additionally, Wyeth states that plaintiff's claims have nothing to do with the failure to warn chronic alcoholics.

As to the Leo Lutwak e-mail, Wyeth states [*9] that plaintiff fails to point to any document, testimony, or other evidence identifying the "company" described in the e-mail as Wyeth. Wyeth states that the e-mail refers to attempts to manipulate these past three years, which would have been September 1993. Wyeth states that it did not even acquire the rights to dexfenfluramine until February 10, 1995. Thus, it state that this e- mail has no probative value.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 109).

3. Motion in Limine No. 3 - Exclude Evidence Concerning Litigation, FDA Action, or Voluntary Recalls Involving Wyeth Products Other Than Pondimin or Redux

Wyeth anticipates that plaintiffs will attempt to introduce at trial evidence that various other prescription drugs or devices manufactured by Wyeth or its subsidiaries or affiliates other than Pondimin or Redux have been withdrawn from the market, been the subject of litigation or been subject to recalls or seizures by the FDA. Wyeth argues that such evidence is irrelevant, would create a danger of unfair prejudice, confusion or delay and is impermissible "bad character" evidence.

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Plaintiff states that she will prove at trial that AHP deliberately and fraudulently [*10] failed to warn of the risks of PPH and valvular heart disease associated with fenfluramine and dexfenfluramine. Plaintiff states that this evidence is relevant to dispute defendant's claim that it is a "responsible company." Plaintiff states that the Pondimin/Redux experience was not the first product for which defendant failed to adequately warn of known risks and that this is relevant to refute defendant's claim that it had an exemplary record for marketing pharmaceutical products and for complying with regulatory requirements. Plaintiff asserts that defendant's marketing and promotion of the Dalkon Shield, Cordarone and other products is relevant to show character, plan, motive, intent and absence of mistake or accident. Plaintiff also states that the motion in limine is too vague with respect to precisely what document AHP is seeking to preclude to allow the court to make a proper ruling.

Wyeth states that in order to be relevant, evidence must have a tendency to make the existence of any fact that is of consequence to the determination of the action, more probable or less probable than it would be without the evidence. Wyeth states that evidence of litigation, FDA action or voluntary [*11] recalls regarding other Wyeth products does not make it more or less likely that plaintiff's alleged injuries were cause by Pondimin. Simply, evidence relating to different drugs, different injuries, different people and different conditions have no bearing on this case. Wyeth states that in order to prove fraudulent misrepresentation, she must show that Wyeth made a fraudulent misrepresentation intentionally to plaintiff. As plaintiff only took Pondimin, any litigation, FDA action or voluntary recalls regarding other products are irrelevant. Finally, Wyeth argues that contrary to plaintiff's assertions, evidence of other crimes, wrongs or acts is not admissible to prove the character of the person in order to show conformity therewith.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 110).

4. Motion in Limine No. 4 - Exclude Evidence of Labeling in Effect Prior to Plaintiff's Last Prescription

Wyeth states that plaintiff was prescribed Pondimin from February 5, 1996 until June 30, 1997. Wyeth states that it believes that plaintiff will attempt to offer evidence that prior to July 1996, the Pondimin warning labeling was inadequate in its warnings regarding pulmonary hypertension. [*12] In the summer of 1995, an interim report of the first study examining the relationship between diet drugs and primary pulmonary hypertension was completed. The study showed that people who used Pondimin or Redux for 3 months or less were at no increased risk of developing primary pulmonary hypertension. It showed that people who used the drugs for longer than 3 months were at a greater risk, although the risk still remained small. Information from this study - the International Primary Pulmonary Hypertension Study (" IPPHS Study") was incorporated into the Pondimin labeling in July 1996. Wyeth believes that plaintiffs will attempt to introduce into evidence documents and deposition testimony showing that in 1994, Wyeth internally began a process of revising the Pondimin labeling with respect to pulmonary hypertension, but the change was not implemented until July 19, 1996. Specifically, the labeling prior to the change referred to four reports of pulmonary hypertension while Wyeth's database contained more than four reports. Wyeth believes that plaintiff will attempt to introduce evidence of this "4 case" language contained in the Pondimin labeling prior to July 19, 1996 in an attempt [*13] to convince the jury that Wyeth should have included some sort of stronger warning prior to that date. Plaintiffs allege that if there had been a stronger warning, plaintiff would never have been prescribed Pondimin. Wyeth states that this argument is without merit because plaintiff's physician prescribed Pondimin to plaintiff after the labeling was revised in July 1996 to remove the "4 cases" language. Thus, Wyeth argues that only the labeling in effect at the time of plaintiff's last prescription is relevant to the adequacy of the warnings.

Plaintiff states that in June 1994, AHP's Medical Monitor for Pondimin identified the need for and recommended that the Pondimin label be updated because it was inaccurate and did not truthfully disclose the number of cases of pulmonary hypertension or PPH of which defendant knew. Plaintiff states that it wasn't until 2 years later, in the summer of 1996 that AHP initiated a change in the Pondimin label for a PPH warning. However, it was not until January 1997 that the change was put into final form and distributed. Plaintiff also states that during this time AHP had paid consultants write an editorial minimizing the risks of PPH with diet drugs [*14] in the New England Journal of Medicine, without the author's disclosing that they were paid consultants for the company. Plaintiff took Pondimin

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from February 5, 1996 through June 30, 1997. The Pondimin label available to physicians and consumers on February 5, 1996 identified four case of pulmonary hypertension related to Pondimin. Plaintiff states that this representation was untrue and defendant was aware of that. Plaintiff asserts that the reason the label was not updated sooner was defendant was afraid that it would hurt sales of the drug and impair defendant's chances of getting Redux approved. Plaintiff states that the label is relevant to prove: 1) what "warning" defendant gave to plaintiff and her doctor when she began taking the drug; 2) that the warning was false and or inadequate; 3) that plaintiff and her doctor were "precautioned" about pulmonary hypertension and not primary pulmonary hypertension and 4) that plaintiff and her doctor were not warned or precautioned about valvular heart disease.

Wyeth states that plaintiff fails to address their key argument: that plaintiff's physician, Dr. Moore, prescribed Pondimin for plaintiff for almost one year after the 1996 label [*15] change, establishes that she would have prescribed Pondimin even if the label change had been in effect at the time of the original prescription. Wyeth states that in order to succeed on her failure to warn claim, she must show that a different warning would have altered the behavior of the individuals involved. Wyeth states that plaintiff has not disputed that Dr. Moore's behavior would have been the same even if the 1996 labeling change had been in effect at the time of plaintiff's first prescription. Thus, any warning in effect prior to the 1996 change is irrelevant.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 111).

5. Motion in Limine No. 5 - Exclude Evidence Suggesting that Wyeth May Have Concealed Information From Interneuron Pharmaceuticals, Inc.

Wyeth anticipates that plaintiff will attempt to introduce evidence that Wyeth concealed its alleged knowledge of the risks of valvular heart disease from Interneuron Pharmaceuticals, Inc. Interneuron is an independent company with whom Wyeth had a license agreement for marketing the drug Redux in the United States. Interneuron is not a party to this action. Wyeth states that such evidence is irrelevant, unfairly prejudicial [*16] and is based on inadmissible hearsay.

Plaintiff states that this evidence is relevant to prove intent to deceive and a scheme or design to engage in fraudulent activity. Plaintiff states that such evidence is also relevant as part of the res gestae of the fraudulent transaction and on the issue of punitive damages. Plaintiff also asserts that the evidence of AHP's concealment is not limited to a single document and is not hearsay.

Wyeth states that plaintiff fails to refute: 1) that she only took Pondimin and never took Redux and 2) Interneuron was Wyeth's marketing partner solely for Redux and had no involvement with Pondimin. Wyeth states that plaintiff is alleging that it failed to warn her of the dangers of Pondimin. Thus, whatever Wyeth may or may not have privately communicated to Interneuron regarding Redux has no bearing on Wyeth's public warnings as to Pondimin. Interneuron was only involved with Redux.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 112).

6. Motion in Limine No. 6 - Exclude Evidence Concerning Aminorex

Wyeth anticipates that plaintiff may attempt to introduce evidence that a reasonable manufacturer should have anticipated an association between [*17] PPH and the use of Pondimin based on an alleged association between PPH and an unrelated drug, Aminorex. Wyeth states that Aminorex is a completely different drug than Pondimin in that Aminorex is an amphetamine-like in that it causes the release of catecholamines. Conversely, Pondimin has serotonergic effects. Aminorex was never sold or marketed in the United States and was never approved by the FDA.

Plaintiff states that evidence of other injuries, events or accidents that occurred under similar conditions or circumstances are admissible to show that defendant knew or should have known of a particular danger and to prove the existence of a particular defect or condition. Plaintiff also states that evidence regarding Aminorex induced PPH is sufficiently similar to evidence regarding Pondimin/Redux induced PPH and thus is admissible.

Wyeth states that simply because both Aminorex and Pondimin were appetite suppressants does not mean that evidence relating to Aminorex should be admitted. Wyeth states that plaintiff did not refute Wyeth's argument that the drugs have different effects and completely different mechanisms of action. Wyeth states that Aminorex is a different and distinct [*18] drug and is irrelevant to

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plaintiff's claims.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 113).

7. Motion in Limine No. 7 - Exclude Evidence of or Any Reference To Any Medical Condition Arising Out of the Use of Pondimin From Which Plaintiff Does Not Claim to Suffer

Wyeth anticipates that plaintiff will attempt to present at trial evidence of medical conditions of which she does not claim to suffer. For example, plaintiffs in other diet-drug cases have attempted to introduce evidence of alleged neuro-toxic side effects of Pondimin and Redux even though they did not suffer these effects. A neurotoxic substance is one "having a poisonous effect on nerves and nerve cells." Wyeth states that plaintiff has not offered any evidence or expert testimony who claims that she suffered or will suffer any neurotoxic injury in the future. Additionally, Wyeth states that plaintiff will attempt to introduce evidence regarding PPH despite the fact that plaintiff's medical condition does not meet the consensus definition of that disease.

Plaintiff states that the fact that defendant failed to warn of neurotoxic effects is relevant because defendant had a duty to warn of all known serious [*19] risks or side effects and had defendant issued a neurotoxicity warning, plaintiff would not have taken Pondimin. Plaintiff also states that the evidence of neurotoxicity of Pondimin/Redux is relevant to prove that Pondimin/Redux were unreasonably dangerous and defective and also to show defendant's motive for failing to warn.

Wyeth states that failure to warn of a medical condition plaintiff does not have cannot serve as the basis of a failure to warn claim and that evidence regarding injuries plaintiff does not have is irrelevant. Because plaintiff does not have a neuro-toxic injury or PPH, evidence of these should be excluded.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 114).

8. Motion in Limine No. 8 - Exclude Deposition Testimony of Plaintiff's Generic Experts Based on MDL Daubert Rulings

Wyeth moves to exclude all or part of the MDL Preservation Deposition testimony of plaintiff's generic experts John La Puma, Collin Bloor, James Oury, John Gueriguian, Arthur Hayes, Robyn Barst, Stuart Rich, Barry Sears, and Jerome Avorn on Daubert grounds. Wyeth states that the MDL court held that all of La Puma and Bloor's testimony was inadmissible under Daubert, as well as portions [*20] of the testimony of the remaining experts. Wyeth states that these rulings constitute the law of the case and should not be reconsidered except in extraordinary circumstances.

Plaintiff states that this is essentially a Daubert motion and as Daubert motions were to be filed by January 3, 2003 it is out of time. Plaintiff also states that the motion fails to state specifically how it alleges that the testimony in question violates Dauber. Without a more specific identification of the grounds for the objection, plaintiff states it is impossible to file a response. Plaintiff also states that the law of the case doctrine does not prevent this Court from reconsidering a decision made by a different judge in an MDL action.

Wyeth states that this motion in limine is not a Daubert motion, instead it moved the Court to exclude certain deposition testimony under the law of the case doctrine. Wyeth states that the MDL court excluded certain testimony of these generic experts in its Daubert rulings and Wyeth is simply requesting this Court to exclude the testimony that was the subject of that Court's rulings. Wyeth states that one of the purposes of the MDL was to provide centralized discovery and [*21] to prevent inconsistent or repetitive pretrial rulings. Therefore, Wyeth states that this Court should not reconsider the Daubert rulings of the MDL court and should exclude all or part of the deposition testimony of plaintiffs' generic experts: John La Puma, Collin Bloor, James Oury, John Gueriguian, Arthur Hayes, Robyn Barst, Stuart Rich, Barry Sears and Jermone Avron.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 115).

9. Motion in Limine No. 9 - Exclude Evidence of Interneuron Lawsuit

Wyeth seeks to have excluded evidence relating to a lawsuit previously filed by Interneuron in Massachusetts. Wyeth states that this lawsuit has now been dismissed. Interneuron was Wyeth's partner in the marketing of Redux. In the lawsuit, Interneuron alleged that Wyeth had breached its contractual obligation to provide Interneuron

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with any information which might relate to the effect or safety of or questions relating to possible reactions to Redux. Wyeth states that in effect Interneuron was blaming Wyeth for its business losses. Wyeth thus states that evidence relating to this suit is inadmissible and irrelevant to the present action. Any probative value of evidence related to this [*22] suit would be outweighed by the danger of unfair prejudice, confusion of the issues and mislead the jury.

Plaintiff states that defendant's concealment of information from Interneuron regarding the dangers of Pondimin/Redux was part of defendant's scheme to conceal that information from the FDA, physicians and consumers. Plaintiff also states that this information is relevant to show that defendant did not act reasonably and diligently as defendant claims.

Wyeth states that plaintiff in her response does not even mention the Interneuron lawsuit and instead only argues that concealment of the information is relevant. Wyeth incorporates its reply to its Motion in Limine No. 5 above. Wyeth also states that plaintiff must show that Wyeth intentionally made a fraudulent misrepresentation to her, thus whatever Wyeth made have represented to Interneuron is irrelevant to Wyeth's intent to defraud plaintiff.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 116).

10. Motion in Limine No. 10 - Exclude Evidence Concerning Adverse Drug Event Reports

Wyeth states that under FDA regulations, manufacturers are required to create an Adverse Drug Event ("ADE") in their safety surveillance database [*23] whenever they receive information that a patient taking their prescription drug has experienced an adverse event. Wyeth anticipates that plaintiff's experts will attempt to rely on ADE's to prove causation, defect and Wyeth's alleged knowledge or notice of the risks associated with Pondimin. Wyeth states that federal law does not permit this. Wyeth states that ADEs are inadmissible hearsay, secondly, plaintiff is unable to produced evidence that the ADE's occurred under circumstances reasonably similar to the plaintiff's circumstances and third, ADE's may not be used to prove causation because they do not include an assessment of whether a causal relationship exists between diet drugs and the reported adverse events. Fourth, Wyeth states that even if the ADEs were admissible to establish notice or Wyeth's knowledge, only ADEs involving conditions that the plaintiff claims to have and that were received prior to the time that she acquired her last prescription could possibly be relevant.

Plaintiff states that ADEs are relevant to show that defendant knew or should have known that Pondimin/Redux were dangerous. Plaintiff states that the ADEs in this case are not hearsay and will not be [*24] offered to prove the truth of the matter asserted, but only will be offered to show that defendant had notice of the dangers of Pondimin/Redux. Plaintiff also states that the ADEs are admissible as evidence of other acts or occurrences. Plaintiff additionally states that the ADEs filed after plaintiff took Pondimin are relevant on the issue of defendant's fraudulent scheme. Plaintiff states that she does not intend to offer into evidence ADEs that do not relate to heart or lung abnormalities. Plaintiff also states that defendant's motion is too vague with respect to what documents it is seeking to exclude to allow the court to make an intelligent ruling on the motion.

Wyeth states that plaintiff cannot show substantial similarity between the ADE's they would seek to offer and plaintiff's injuries. Wyeth states that to rely on the ADE's plaintiff would have to assume the truth of the matter asserted in the ADE's. Thus, Wyeth states that they are hearsay and do not fall within an exception and cannot be relied upon by plaintiff. Wyeth also states that in *Nelson v. American Home Products, 92 F.Supp.2d 954, 969 (W.D.Mo. 2000)*, [*25] the Court held that ADE's cannot be used to establish causation.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 117), subject to the plaintiff's offer of proof establishing similarity between ADE's and the plaintiff's claimed injury.

11. Motion in Limine No. 11 - Exclude Evidence of Combination Use of Phentermine and Pondimin

Wyeth states that plaintiff's Complaint contains references to Wyeth's alleged promotion of the combination use of Wyeth's product Pondimin with phentermine another prescription anorexigen distributed by various other companies. Wyeth states that plaintiff alleges that Wyeth failed to test the combination of these drugs even though Wyeth never distributed phentermine and had no duty under any federal statute, regulation or common law to test a product that it did not make or

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distribute. Wyeth states that although it can demonstrate that it did not promote the combination use of phentermine and Pondimin, it should not be required to address the issue because the entire subject is irrelevant as plaintiff is not claiming any injuries as a result of the combination of the two drugs.

Plaintiff states that she took Pondimin, Wyeth's product, in combination [*26] with phentermine during the entire course of her drug therapy. Plaintiff states that it was in part due to a study, partially sponsored by defendant that the combination of these two drugs because a craze during the years that plaintiff was taking these drugs. Plaintiff states that prior to the Weintraub study, Pondimin sales were flat, but that after publication of the study, sales skyrocketed. Plaintiff states that it was the promotion of the combination of these two drugs that allowed her to be exposed to Pondimin for 17 months, putting her at much higher risk for the development of valvular heart disease and PPH. Plaintiff also states that defendant's promotion of the long-term combination use is relevant to prove intent to deceive, and also to show that she used Pondimin in a way which was reasonably anticipated and which was foreseeable. Plaintiff also states that defendant's promotion of long-term combination use is relevant to show that her physician would not have reason to realize the dangers and also to prove a violation of the Missouri Merchandising Practices Act.

Wyeth states that plaintiff is not claiming any injury as a result of the combination use of phentermine and [*27] Pondimin. She claims only that Pondimin was responsible for her injuries. Wyeth states that with regard to plaintiff's claim that this evidence is relevant to show its intent to deceive, plaintiff must show that the intent to deceive was specific to plaintiff. Wyeth states that plaintiff does not provide any factual basis establishing tat Wyeth promoted the combination use of phentermine and Pondimin to plaintiff or to her physician. Therefore, they claim that this evidence is irrelevant. As to plaintiff's argument that this evidence is relevant to show that Wyeth failed to test such combination use and that Wyeth breached its duty by failing to discourage such combination use, Wyeth states this is also irrelevant as plaintiff is not claiming any injuries as a result of such combination use.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 118).

12. Motion in Limine No. 12 - Exclude Evidence of Draft Promotional Materials Regarding Pondimin or Redux Including Materials Received From Third Party Advertising and Public Relations Firms

Wyeth anticipates that plaintiff will attempt to introduce evidence at trial of draft promotional materials that were never distributed outside [*28] the company or of third party marketing proposals that were never implemented. Wyeth states that plaintiff makes allegations concerning the manner in which Pondimin and Redux were marketed. However, whether Wyeth influenced the prescribing habits of physicians for these drugs in a misleading or improper way can only be determined by reference to the marketing plans that it actually used and implemented.

Plaintiff states that defendant's motion focuses on two exhibits: July 7, 1997 letter written to the Vice President of Wyeth. Plaintiff states that she anticipates that defendant will attempt to show that it did not know that Pondimin/Redux could cause PPH until the IPPH study was published in August 1996 and that it acted responsibly thereafter in warning of the risks associated. Plaintiff states that the July 7, 1997 letter contradicts this position and is relevant to identify defendant's "post-May Clinic" marketing plan. Plaintiff also states that the letter is relevant to show that instead of warning of the risk of PPH, defendant was attempting to find ways to sell its "dirty drug swimming in a dirty category" by "changing perceptions of Redux." Plaintiff states that defendant wanted [*29] to "rehabilitate Redux" not warn of its dangers.

The second document which plaintiff states is relevant is a February 23, 1995 Cyamanid memo. AHP acquired Cyamamid in 1994. This is an internal memo to Ronald Notvest, New Product Manager for Redux at AHP regarding the impact on the Redux market of information relating to PPH. Plaintiff states that this memo directly contradicts defendant's theory that it did not know of the risks of PPH until the IPPH study was published in August 1996. Plaintiff states that not only did defendant know about the dangers, it was doing marketing research to quantify the impact of PPH on the potential sales of Redux.

Plaintiff states that these marketing and promotional materials are relevant to show that defendant knew that Pondimin/Redux can cause PPH, but that defendant failed to share this information with either plaintiff or her

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doctor. Plaintiff also states that these marketing materials are relevant on this issue of punitive damages as they show that defendant intended to promote and sell these drugs in such as way as to maximize its own profits at the expense of the public's health. Plaintiff also states that the marketing materials are not hearsay [*30] because they are not being offered to prove the truth of the matter asserted. If the marketing materials are considered hearsay, plaintiff states that they would fall under the business record exception and thus would be admissible.

Wyeth states that plaintiff does not deny that the marketing materials were never distributed to the public or implemented. However, plaintiff argues that they are relevant to show Wyeth's alleged "fraudulent scheme." However, Wyeth states that plaintiff must show that the intent to defraud must be specific to plaintiff and that she justifiably relied upon such representations. Wyeth states that nothing in these articles evinces any intent to defraud plaintiff. Also because they were never distributed to the public, neither plaintiff or her physician could have possibly relied upon them.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 119).

13. Motion in Limine No. 13 - Exclude Evidence of Other Lawsuits Involving Pondimin or Redux for Purposes of Establishing Liability

Wyeth anticipates that plaintiff will attempt to offer evidence of other lawsuits involving Pondimin and Redux at trial including settlements for the purposes of establishing [*31] liability. Wyeth states that the implication that plaintiff hopes to make is that the allegations in this suit have validity simply because other lawsuits involving Pondimin and Redux have been filed. Wyeth states that which such evidence may be relevant to the issue of punitive damages, it is irrelevant as to liability and is therefore inadmissible under *F.R.E. 401* and *402*. Wyeth also states that any probative value would be outweighed by the danger of unfair prejudice, confusion and misleading the jury.

Plaintiff states that she wishes to introduce evidence regarding defendant's admissions in previous diet drug cases. Plaintiff states that in those other cases, AHP was the named defendant, there was a final judgment on the merits, the issues presented were identical to those to be decided in this case and AHP had in the earlier actions, a full and fair opportunity to litigate those issues. Therefore, plaintiffs state that offensive collateral estoppel is appropriate and not unfair in this instance. Plaintiff also states that evidence of these other suits is relevant to the issue of punitive damages. Additionally, plaintiff states that if defendant raises rarity of occurrence as part [*32] of its defense, then these other lawsuits would be relevant to refute that argument.

Wyeth states that plaintiff's argument on offensive collateral estoppel fails to rebut their argument and is also untimely as the deadline for filing all other motions was March 3, 2003. Even if this Court were to consider the issue, Wyeth argues that it would not apply because the Texas action was not a final judgment, the Texas action was an interlocutory default judgment and thus issues were not actually litigated and the factual issues were not identical to the issues in this case. Even if these requirements were met, Wyeth argues it would be unfair to apply collateral estoppel in this action. Wyeth also argues that the action in *Linnen* are not relevant to show its fraudulent scheme, as any intent to deceive must be specific to plaintiff and plaintiff has not shown that Linnen bears any relevance to Wyeth's alleged intent to defraud plaintiff. Wyeth states that other lawsuits, claims and settlements are irrelevant and inadmissible to show that Wyeth was liable for plaintiff's injuries.

Ruling: The Court **PROVISIONALLY GRANTS** Defendant's Motion in Limine (Doc. # 120), subject to plaintiff's offer of [*33] proof to the contrary.

14. Motion in Limine No. 14 - Exclude Evidence of FDA Inspection

Wyeth anticipates that plaintiff will attempt to introduce evidence of a 1997 FDA inspection of its adverse event reporting system. However, Wyeth states that such evidence is irrelevant. Wyeth states that the FDA inspection did not identify any failure to report adverse events to the FDA or any other condition affecting the safety of the drugs. Thus, Wyeth argues that such evidence should be excluded under *F.R.E. 401*, *402*, *403* and *404*.

Plaintiff states that the evidence related to FDA's inspection is directly related to liability as plaintiff argues that AHP failed to adequately monitor ADEs with respect to Pondimin/Redux. Second, plaintiffs state that it is relevant to the "FDA defense" that AHP attempts to put on in every case, that is, that the FDA approved of all of defendant's actions as it relates to Pondimin/Redux.

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Third, plaintiffs argue it is relevant on the issue of punitive damages.

Wyeth states that the issues in this case revolve around whether or not Pondimin caused plaintiff's injuries and plaintiff has failed to show how the FDA inspections at issue were in any way tied to the specific [*34] harm alleged. Plaintiffs attempt to allege that this was part of a fraudulent scheme, however, again they state that this intent must be specific to plaintiff.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 121).

15. Motion in Limine No. 15 - Exclude Evidence Regarding Any Alleged Duty of Wyeth to Directly Warn Plaintiff Regarding the Risks of Using Pondimin

Wyeth states that pursuant to the learned intermediary doctrine, adopted by Missouri courts, a prescription drug manufacturer's duty to warn extends only to the patient's physician, and the manufacturer has no duty to warn the patient directly of a drug's risks.

Plaintiff states that defendant has a duty to warn her of the dangers of Pondimin/Redux because defendant failed to properly warn physicians of the dangers of Pondimin/Redux. Plaintiff also states that the learned intermediary doctrine does not apply where the defendant over-promotes its drug or where the defendant is involved in direct to consumer advertising.

Wyeth states that plaintiff has failed to provide any evidence of overpromotion and fails to provide any authority that Missouri recognizes overpromotion as an exception to the learned intermediary doctrine. [*35] Wyeth also states that the learned intermediary doctrine has nothing to do with whether or not a drug manufacturer properly warns a physician, it simply establishes to whom a drug manufacturer owes a duty to warn. Under this doctrine, a drug manufacturer only has a duty to warn the physician and whether or not the drug manufacturer properly satisfied this duty is another issue.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 122).

16. Motion in Limine No. 16 - Exclude Evidence Seeking to Punish Wyeth for Alleged Wrongs to Other Persons; Punish Wyeth for Conduct Unrelated to the Conduct That Allegedly Harmed Plaintiff or To Award Punitive Damages Disproportionate to Plaintiff's Actual Damages

Wyeth states that the Supreme Court in *State Farm Mutual Automobile Ins. Co. v. Campbell, 538 U.S. 408, 123 S.Ct. 1513, 155 L. Ed. 2d 585 (2003)* made it clear that it is impermissible to award punitive damages based on injuries or wrongs allegedly inflicted by the defendant on persons other than the plaintiff, impermissible to award punitive damages based on conduct that did not injure the plaintiff and impermissible to award punitive damages in an amount which is disproportionate to the individual's compensatory damages. [*36] Thus, Wyeth states that the following types of evidence should be excluded: 1) statements concerning the number of persons other than plaintiff who used the products at issue; 2) statements concerning Wyeth's sales volume, gross income, or profit from the sale of the products at issue to persons other than plaintiff; 3) statements concerning Wyeth's net worth, market capitalization or other measurements of alleged wealth; 4) statements concerning any alleged intentional or unintentional wrongdoing by Wyeth with respect to any product manufactured, distributed, marketed, licensed promoted, labeled or sold by them other than the products that allegedly harmed plaintiff and 5) statements concerning the alleged intentional or unintentional wrongdoing by Wyeth with respect to any alleged side effect or risk of the products at tissue other than the side effect or risks that allegedly harmed plaintiff.

Plaintiff states that in *State Farm*, the Supreme Court reinforced the principle that punitive damages are appropriate to punish reprehensible conduct and to deter its repetition. Plaintiff then reviews the three guideposts which the Court discussed in that case. Plaintiff avers that the fraudulent [*37] conduct which she claims AHP engaged in should be punished and that this directly related to plaintiff's injuries. Thus, she claims that a punitive damage award would be appropriate and would not exceed constitutional restrictions.

Wyeth states that plaintiff's argument is wholly unresponsive to its motion and instead they simply argue that the present case is distinguishable from *State Farm* and that they are entitled to a large punitive damage award. Wyeth states that while it denies that punitive damages are appropriate in this case, that was not the focus of its motion and instead it focused on they types of

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evidence relating to plaintiffs' claim for punitive damages which should be excluded.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 123).

17. Motion in Limine No. 17 - Exclude Evidence Alleging that Wyeth Was Misleading or Deceptive in Its Dealings With the FDA and/or Committed Violations of the FDCA or the FDA Regulations

Wyeth anticipates that plaintiff will attempt to present evidence and argument regarding alleged deception and fraud purportedly perpetrated by Wyeth on the FDA. Wyeth states that the Supreme Court has categorically foreclosed the fraud on the [*38] FDA theory and indeed only the FDA can bring such a claim and the FDA has never proceeded against Wyeth for noncompliance regarding Redux or Pondimin or concluded that Wyeth violated any law or regulation involving these drugs.

Plaintiff states that she has not alleged a fraud on the agency claim in her Complaint and that she will prove fraud against her and her physician. She states that she is not alleging noncompliance with FDA regulations as an independent claim of recovery and is not suing AHP's regulatory consultant. She states that her claims include a failure to warn theory and thus her claims are not preempted under federal law.

Wyeth states that the case of *Buckman v. Plaintiffs' Legal Comm.., 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2000)* controls when alleged FDCA violations and assertions that the defendant violated the FDA serve as the basis for a state law claim. Wyeth states that this is what plaintiff has done in the present case. Wyeth also states that plaintiff misunderstood their argument and Wyeth was not arguing that plaintiff's claims should be preempted, but instead was arguing that *Buckman* precludes evidence allegedly showing that Wyeth violated FDA regulations or deceived the FDA from [*39] serving as the basis of their claims. Wyeth urges the Court to follow *Bouchard v. American Home Products, 213 F.Supp.2d 802, 813 (N.D.Ohio 2002)* involving the same type of evidence.

Ruling: Defendant's Motion in Limine is hereby **GRANTED** (Doc. # 124).

18. Motion in Limine No. 18 - Exclude Demonstrative Evidence Descriptions of Heart Valve Surgery

Wyeth moves to exclude demonstrative exhibits of heart valve surgery on the basis that this exhibits would be inflammatory and unduly prejudicial. Wyeth also states that there is no reasonable certainty that plaintiff will have to undergo such a procedure.

Plaintiff states that there is a reasonable degree of medical certainty that she will require heart valve surgery in the future. She states that pictures and/or a videotape will fairly and accurately describe this surgery and are relevant to prove, among other things her future pain and suffering. Plaintiff states that this is highly probative on the issue of punitive damages.

Wyeth states that on their exhibit list, plaintiff listed only one demonstrative exhibit regarding heart valve surgery and nowhere has she listed photographs or videotapes related to such surgery. Accordingly, as plaintiff [*40] did not include this evidence on her exhibit list, Wyeth states it should be excluded. Wyeth also argues that the demonstrative chart should be excluded as plaintiff has not undergone this surgery, is unlikely to undergo it and it would only inflame the jury.

Ruling: Defendant's Motion in Limine is **GRANTED** (Doc. # 125), subject to plaintiff's offer of proof to the contrary.

Any offers of proof referenced in this Order, shall be submitted to the Court forty-five days before trial.

Date: March 31, 2004

Kansas City, Missouri

/s/ FERNANDO J. GAITAN, JR.

Fernando J. Gaitan, Jr.

United States District Judge

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Exhibit F

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Only the Westlaw citation is currently available.

United States District Court, M.D. Florida,
Orlando Division.
In re SEROQUEL PRODUCTS LIABILITY LITIGATION.
No. 6:06-md-1769-Orl-22DAB.

Jan. 30, 2009.

West KeySummary
Federal Civil Procedure 170A ⚷927.5

170A Federal Civil Procedure
170AVII Pleadings and Motions
170AVII(I) Motions in General
170Ak927.5 k. Motions in Limine. Most Cited Cases

Pharmaceutical company's motion in limine to exclude evidence and argument about plagiarism and "ghostwriting" was granted. The company moved to exclude evidence of plagiarism and "ghostwriting" of scientific articles, which may have impugned the reputations of the company or the physician's who wrote the articles on its behalf. They asserted that the evidence was irrelevant to the plaintiffs' claims. The plaintiffs asserted that this practice was a fraudulent manipulation of data through seemingly independent and credible articles.

ORDER

DAVID A. BAKER, United States Magistrate Judge.

*1 Defendant AstraZeneca ("AZ") has filed several motions *in limine* seeking to preclude introduction of certain types of evidence at the trials in individuals cases FN1 within the Multidistrict Litigation *In re Seroquel.* The Court considers each Motion *in Limine* individually and rules as set forth below.

FN1. The individual cases are: *Linda Guinn v. AstraZeneca LP, et al,* Case No. 6:07-cv-10291-Orl-22DAB; and *David Haller v. AstraZeneca LP, et al.,* Case No. 6:07-cv-15733-Orl-22DAB.

STANDARD FOR MOTIONS IN LIMINE

A motion *in limine* presents a pretrial issue of admissibility of evidence that is likely to arise at trial, and as such, the order, like any other interlocutory order, remains subject to reconsideration by the court throughout the trial. *Stewart v. Hooters of America, Inc.,* Civ. No. 8:04-cv-40-T-17-MAP, 2007 WL 1752843, *1 (M.D.Fla.2007). "The real purpose of a motion *in limine* is to give the trial judge notice of the movant's position so as to avoid the introduction of damaging evidence which may irretrievably effect the fairness of the trial. A court has the power to exclude evidence in limine only when evidence is clearly inadmissible on all potential grounds." *Id.* (citing *Luce v. United States,* 469 U.S. 38, 41, 105 S.Ct. 460, 83 L.Ed.2d 443 (1984) (federal district courts have authority to make in limine rulings pursuant to their authority to manage trials).

Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy, and potential prejudice may be resolved in proper context. *See generally* 21 Charles A. Wright & Kenneth W. Graham, Jr., FEDERAL PRACTICE AND PROCEDURE ¶ 5042 (1977 & Supp.1993). It is the better practice to wait until trial to rule on objections when admissibility substantially depends upon what facts may be developed there. *Bowden ex rel. Bowden v. Wal-Mart Stores, Inc.,* Case No. Civ. A 99-D-880-E, 2001 WL 617521, *1 (M.D.Ala. Feb.20, 2001) (citing *Sperberg v. Goodyear Tire & Rubber Co.,* 519 F.2d 708, 712 (6th Cir.1975)).

The movant has the burden of demonstrating that the evidence is inadmissible on any relevant ground. *Bowden,* 2001 WL 617521 at *1 (citing *Plair v. E.J. Brach & Sons, Inc.,* 864 F.Supp. 67, 69 (N.D.Ill.1994)). At trial, the court may alter its *limine* ruling based on developments at trial or on its sound judicial discretion.

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Luce v. United States, 469 U.S. 38, 41, 105 S.Ct. 460, 83 L.Ed.2d 443 (1984). "Denial of a motion *in limine* does not necessarily mean that all evidence contemplated by the motion will be admitted at trial." *Hawthorne Partners v. AT & T Tech.,* 831 F.Supp. 1398, 1401 (N.D.Ill.1993). Instead, denial of the motion means the court cannot determine whether the evidence in question should be excluded outside the trial context. *United States v. Connelly,* 874 F.2d 412, 416 (7th Cir.1989). The court will entertain objections on individual proffers as they arise at trial, even though the proffer falls within the scope of a denied motion *in limine. Id.* A ruling *in limine* does not "relieve a party from the responsibility of making objections, raising motions to strike or making formal offers of proof during the course of trial." *Thweatt v. Ontko,* 814 F.2d 1466, 1470 (10th Cir.1987).

***2** Evidence may be excluded when the probative value is outweighed by its prejudice. Under Rule 403, "[a]lthough relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed.R.Evid. 403. Rule 403 permits a district court to exclude relevant evidence only when "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." *United States v. Ross,* 33 F.3d 1507, 1524 (11th Cir.1994). Rule 403 is "an extraordinary remedy" whose "major function ... is limited to excluding matter of scant or cumulative probative force, dragged in by the heels for the sake of its prejudicial effect." *United States v. Grant,* 256 F.3d 1146, 1155 (11th Cir.2001).

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT ALLEGED "GHOSTWRITING" (Doc. No. 1197)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED** in part and **DENIED** in part.

AZ moves to exclude evidence and argument about alleged "ghostwriting" or the "specter of plagiarism" of scientific articles, which may impugn the reputations of AZ or the physicians who wrote articles on its behalf. Doc. No. 1197 at 2. AZ employs Clinical Research Organizations such as Parexel Corporation to assist with medical communications concerning Seroquel. AZ does not dispute that Parexel assisted AZ in identified appropriate physicians to serve as authors of scientific papers regarding Seroquel and admittedly "often assisted in the preparation of those papers." AZ contends that "Parexel's authorial assistance is not improper, and thus "ghostwriting" allegations are irrelevant to Plaintiffs' claims. AZ contends the evidence is also irrelevant because there is no evidence that any of Plaintiffs' prescribing physicians saw or relied upon any allegedly "ghostwritten" articles.

Plaintiffs respond that "ghostwriting is not a "common practice" in the industry as AZ argues, but a "spurious tool employed by AstraZeneca in its fraudulent manipulation of clinical trials' and studies' data through seemingly independent and credible articles." Doc. No. 1227 at 2. Plaintiffs allege that AstraZeneca misled the healthcare profession, including Plaintiffs' prescribing healthcare providers, about the risks associated with its prescription drug, Seroquel. Doc. No. 1227. Plaintiffs contend that "through ghostwriting, AstraZeneca was able to bury unfavorable trial data regarding Seroquel and, in turn, market Seroquel in an unduly (and dangerously) favorable light to the medical community at large" and " Seroquel prescribers were, therefore, improperly influenced in their prescribing decisions with respect to Seroquel." Doc. No. 1227 at 2. Plaintiffs point to the sales call notes pertaining to Plaintiffs' prescribing physicians as evidence of AstraZeneca's use of

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ghostwritten literature in the deliberate influence of Plaintiffs' physicians' prescribing habits; Plaintiffs contend that through its sales force, AstraZeneca meticulously detailed each Seroquel prescriber on the purported benefits and weight neutral profile of Seroquel with the aid of ghostwritten articles, other literature and related reprints.

*3 Plaintiffs contend that evidence of AZ's exertion of control to influence the content of published articles or other literature relating to the safety or efficacy of Seroquel is relevant to their claims that AZ failed to warn of known safety risks related to Seroquel. Plaintiffs argue that evidence of ghostwriting is also relevant to Plaintiffs' claims that AstraZeneca knew of the dangerous side effects associated with Seroquel but nevertheless sought to suppress such negative data from clinical trials, as well as to Plaintiffs' claims that AstraZeneca's failure to warn. Doc. No. 1227 at 2.

Plaintiffs have agreed not to use the term "ghostwriting," but argue they should be permitted to explain to the jury the implications of AstraZeneca's misrepresentations in the creation and/or sponsorship of ghostwritten publications and other literature related to non-medically necessary uses of Seroquel and the safety and efficacy of Seroquel. The Court agrees. To the extent AZ seeks to preclude Plaintiffs use of the terms "ghostwriting" or "plagiarism" the Motion to Exclude is **GRANTED.** To the extent AZ seeks to preclude all evidence that third-party medical marketing firms, such as Parexel, prepared drafts or literature authored by physicians, the Motion is **DENIED.**

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT THE ALLEGED RISKS OF SEROQUEL USE IN PEDIATRIC AND GERIATRIC POPULATIONS (Doc. No. 1198)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED** as to Trial Group One.

It is undisputed that none of the Plaintiffs in Trial Group One fall into either category of pediatric or geriatric populations (Doc. No. 1224), thus the evidence is not relevant to the Group One cases and will be excluded in these cases. To the extent Plaintiffs wish to use the evidence for any other purpose, such as an example of a stronger label warning, such evidence would lead to jury confusion.

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT CLINICAL INVESTIGATORS' MISCONDUCT (Doc. No. 1199)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED.**

AZ seeks to exclude evidence and argument about alleged or actual misconduct of clinical investigator Dr. Richard Borison, or any other clinical investigator involved in clinical trials of Seroquel at Dr. Borison's research facility, arguing the evidence is irrelevant and any minimal relevance is substantially outweighed by the possibility of prejudice, confusion, misleading the jury and waste of time. Doc. No. 1199. AZ argues that "such evidence of criminality-where, if anything, AZ was the victim-has nothing to do with any of the plaintiffs in these cases and would be unfairly prejudi-

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cial and confusing." Doc. No. 1199 at 1.

AZ explains that Dr. Borison and a colleague Dr. Bruce Diamond were clinical investigators who conducted clinical trials for a number of pharmaceutical companies, including trials of Seroquel prior to its launch in 1997. Doc. No. 1199at 1-2. Dr. Borison was accused of improper conduct in connection with his research facility, failure to turn over payments for clinical studies to his employer the Medical College of Georgia; he pled guilty to RICO, theft, and false statement charges from his financial improprieties, and was incarcerated. Doc. No. 1199 at 2 and n 1. When AZ submitted to the FDA a New Drug Application ("NDA") for Seroquel, it included "all of the data from Dr. Borison's investigator sites," and "an analysis excluding that data" so the FDA had the "benefit of both analyses." Doc. No. 1199 at 2.

*4 Plaintiffs contend the evidence is relevant to their claims because the clinical investigators' financial improprieties are directly related to Plaintiffs' claims and AstraZeneca's defenses. Doc. No. 1228. Plaintiffs contend "the fact that at least two of their hand-picked clinical researchers were routinely investigated and eventually incarcerated for acts related to their research goes directly to the credibility and competency of AstraZeneca's testing and scientific research." Plaintiffs also argue that they have a right to present evidence as to whether or not that "testing was properly performed by qualified personnel." Doc. No. 1228 at 4. The Court does not agree that the researchers' financial improprieties "go directly to the credibility" of the AZ's testing; In fact, Plaintiffs have not shown how the financial improprieties relate to the actual testing. Moreover, Plaintiffs do not contradict AZ's representation that it submitted the Seroquel NDA to the FDA with the "controversial" data from Dr. Borison's investigator sites *excluded* as well as included; thus, the FDA's decision was not based exclusively on the Dr. Borison's information. Additionally, AZ's arguments that evidence of Dr. Borison's misconduct would inject a collateral issue and suggest to the jury AZ's "guilt by association" in violation of Rule 403, are arguments well-taken.

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT 1998, 1999, AND 2006 LETTERS FROM FDA'S DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS (Doc. No. 1200)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED.**

AZ moves to exclude evidence of 1998, 1999 and 2006 Letters ("the Letters") from the FDA's Division of Drug Marketing, Advertising, and Communications FN2 ("DDMAC"), arguing the Letters are not relevant because they are about products not at issue, modifications made as requested by the DDMAC, or concern a withdrawn promotional piece. Doc. 1200. AZ argues that the Letters are irrelevant because there is no evidence the promotional pieces were actually seen by Plaintiffs' prescribing physicians, and the Letters are unfairly prejudicial and will cause delay by necessitating testimony about the complex scheme governing prescription drug promotional pieces. AZ further argues that the Letters cannot be used to show it has a "propensity" for engaging in "misleading" advertising in violation of Rule 404(b) (evidence of other acts is not admissible to prove character).

FN2. Pursuant to 21 C.F.R. § 314.81(b)(3)(I), AZ is required to submit all promotional pieces to DDMAC for review.

Although Plaintiffs do not dispute that they have not

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tied the Letters to a particular prescribers' exposure, they argue that evidence of marketing activities "in general" is relevant to "show the extent to which AZ controlled and manipulated the content and dissemination of relevant Seroquel safety information to healthcare providers." Doc. No. 1229 at 2-3. Plaintiffs contend that evidence of "general 'marketing activities' tends to make the existence of facts of consequence more probable," *i.e.,* that AZ "failed to use reasonable care in promoting Seroquel and AZ's knowledge regarding the truth or falsity of its misrepresentations and omissions." Doc. No. 1229 at 3. Plaintiffs also argue the Letters may be introduced to rebut claims of good character and/or drug efficacy or safety; for impeachment purposes; for showing AstraZeneca's motive, intent, and/or state of mind; and for showing a pattern and practice of misconduct for purposes of punitive damages.

*5 In the case of the 1998 Letter in particular, the promotional materials at issue did not involve Seroquel at all and the 1998 Letter is clearly irrelevant. As to the 1999 and 2006 Letters, which do concern promotional materials on Seroquel, Plaintiffs have not shown that their prescribing physicians were exposed to the promotional materials; thus, the evidence is excluded, except that it *may* be used in rebuttal if Plaintiffs establish facts that support their claim for punitive damages (that decision will be made by the trial judge).

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT FOREIGN SEROQUEL LABELS AND FOREIGN REGULATORY ACTIONS (Doc. No. 1201)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED.**

AZ moves to exclude evidence about foreign labeling and regulatory action, including the regulation of Seroquel in Japan, France, and Holland. Doc. No. 1201. The Japanese regulatory authority required AZ to add a diabetes contraindication to the Japanese label in 2002 and required AZ to send "Dear Doctor" Letters informing Japanese physicians of the changes; the French regulatory authority in 2005 denied AZ permission to market Seroquel in France; and the Dutch regulatory authority asked Astra Zeneca to add language about hyperglycemia and diabetes to the Seroquel label in 2000-2001. Doc. No. 1201 at 2, 5 n. 3. AZ contends that the foreign label changes and French decision show "only that a different regulatory authority, applying different standards in a different social and medical landscape, reached a conclusion different than the conclusion reached by the FDA under the U.S. system." Doc. No. 1201 at 8.

Plaintiffs contend that the foreign labeling and regulatory actions in 2000-2002 and 2004 demonstrate AZ's notice and knowledge of serious hazards reasonably associated with Seroquel and are relevant to their allegations: that AstraZeneca failed to warn of risks of Seroquel that were known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time Plaintiffs ingested Seroquel; that AstraZeneca failed to exercise reasonable care in marketing and selling Seroquel without an adequate warning; that AstraZeneca knew or should have known that the representations it made were false, and that AZ acted in reckless disregard of their truth or falsity and/or omitted information that made other statements misleading. Doc. No. 1225 at 1-2. Plaintiffs contend that they do not seek to introduce evidence of Japanese, French, or Dutch regulatory or legal standards, but plan to argue the "documents" are relevant and probative of AstraZeneca's notice and knowledge of information that its actions failed to meet the standard of care relative to warning about Seroquel's risks.

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Plaintiffs contend that jury confusion, unfair prejudice and waste of time concerns can be alleviated by "an appropriate and simple limiting instruction" that the foreign warning standards are different from the legal standard applicable under Florida law. Plaintiff argues the jury can be told that the foreign regulatory evidence is not offered to determine whether a similar warning should have be given, and "the laws and regulations of those respective foreign countries is irrelevant to the jurors determination as to whether AstraZeneca provided physicians an adequate warning"; the jury should be instructed that the only controlling law on the failure to warn issue and all Plaintiffs' claims is Florida law. Doc. No. 1225.

***6** The foreign Seroquel labels and the foreign regulatory actions have no relevance to Plaintiffs' main case. More importantly, whatever minimal relevance the foreign regulatory actions might have is clearly overwhelmed by the likelihood of jury confusion. *See Deviner v. Electrolux Motor, AB,* 844 F.2d 769, 771 n. 2, 773 (11th Cir.1988). In *Deviner,* the Eleventh Circuit concluded that evidence of foreign regulatory actions in the main case would confuse the jury and is thus irrelevant and unfairly prejudicial. *Id.* (holding that district court did not abuse its discretion in refusing to allow evidence of Swedish law and statistics regarding modification to chainsaws where the issues in the case arose under Alabama and federal law, and involved technical questions of fact regarding the logging business and the operation of chain saws). As in *Deviner,* evidence of prevailing foreign regulations may be relevant in rebuttal on cross-examination of AZ employees as to their general knowledge of whether the foreign regulations/changes are linked to a "diminution in number and severity of injuries" in the foreign countries and the "various possible reasons to explain the phenomena experienced" in those countries. *Id.* at 774.

Plaintiffs cited cases are inapposite and do not hold that the evidence of foreign regulations or actions should be allowed in the case in chief; if anything, Plaintiffs' cited cases lean toward exclusion of such evidence or delay of the decision until trial where context and foundation were not disclosed. *See In re Rezulin Products Liability Litigation,* 309 F.Supp.2d 531, 552 (S.D.N.Y.2004) ("Assuming that evidence concerning foreign regulatory actions is relevant and admissible over Rule 403 objections, plaintiffs' experts are not the appropriate vehicles for its introduction."); *Blevins v. New Holland N.A., Inc.,* 128 F.Supp.2d 952, 959 (D.W.V.2001) (refusing to rule on admissibility of foreign safety standards or testing where no context or foundation had been laid); *Sherry v. Massey Ferguson, Inc.,* No. 1:96-CV-76, 1997 WL 480893, at *1 (W.D.Mich. June 5, 1997) (holding that evidence of foreign designs-as opposed to foreign legal standards-was not inadmissible as matter of law, where evidence *might* be admissible on an issue such as feasibility or alternative designs).

Plaintiffs' approach of allowing the evidence of foreign regulations and dispositions as to Seroquel-which the Court views as akin to evidence of foreign legal standards-even with Plaintiffs' proposed limiting instruction, will not alleviate the risk of jury confusion. *See, e.g., id.* at 1997 WL 480893, at *1 ("I agree that evidence of European legal standards and requirements ... will unnecessarily confuse the jury.").

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT ZOLADEX SETTLEMENT (Doc. No. 1202)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED.**

***7** AZ moves to exclude evidence about AZ's 2003 settlement with the federal government relating to the pricing of Zoladex, an anti-cancer medication, or about the

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Corporate Integrity Agreement ("CIA") that was part of that settlement. Doc. No. 1202. AZ also argues that this evidence would unfairly prejudice AZ. In 2003, AZ settled a claim by the federal government that AZ had overcharged for Zoladex, a cancer medicine; AZ entered into a five-year Corporate Integrity Agreement, which required AZ to report the average sale price for Zoladex and seven other drugs. Doc. No. 11202 at 2; 202-2; 1202-3. AZ argues that the Zoladex Settlement evidence, which deals with a violation of reimbursement rules in the pricing of Zoladex, is irrelevant to the personal injury claims alleged in this case. AZ also argues that the evidence is unfairly prejudicial, misleading, and a waste of time.

Plaintiffs have stipulated that they will not introduce evidence of the Zoladex litigation or settlement except to rebut "any 'good corporate citizen' or similar testimony offered by Defendants at trial." Doc. No. 1223 at 2. However, Plaintiffs contend that evidence regarding the Zoladex CIA is relevant to determining and applying the standard of care for Plaintiffs' marketing, sales, and warning claims against Defendants. Plaintiffs explain that, as part of the CIA, AstraZeneca agreed to establish both a Code of Conduct and Policies and Procedures for its sales and marketing officers, employees, and agents, which they argue is akin to an industry custom, bearing on the standard of care for determining negligence. Again, Plaintiffs contend that a cautionary jury instruction can be given to avoid jury confusion. Doc. No. 1223.

The Court finds that a party's agreement as to a particular standard of care for a completely different medication, used to treat a completely different condition-cancer-is irrelevant to Plaintiffs' claims in this case; its prejudice outweighs any potential probative value, wastes time, and will confuse the jury.

DONE and **ORDERED.**

M.D.Fla.,2009.
In re Seroquel Products Liability Litigation
Slip Copy, 2009 WL 223140 (M.D.Fla.)

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EXHIBIT G
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Exhibit H

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The following list of articles and letters to the editor possibly could be connected with the Paxil CASPPER program, although it is uncertain to what extent they were actually published as a result of the Paxil CASPPER program:

(1) Kirsch, Michael. Paroxetine and irritable bowel syndrome, *American Journal of Psychiatry*, 157(9): 1523-24, 2000 Sep.;

(2) Miller, Mark. Depression after Cardiac Transplant Treated with Interpersonal Psychotherapy and Paroxetine, *American Journal of Psychotherapy*, Vol 56, No. 4, 2002;

(3) Ng, Bernardo. Mania Associated with Mirtazapine Augmentation of Fluoxetine, *Depression and Anxiety*, 15: 46-47 (2002);

(4) Moussavian, Hamid. Improvement of Acne in Depressed Patients Treated with Paroxetine, *Journal of the American Academy of Child and Adolescent Psychiatry*, May 2001, pp. 505-506 (Letter to Editor); and

(5) Lehman, Robert. Rapid resolution of social anxiety disorder, selective mutism, and separation anxiety with paroxetine in an 8-year-old girl, *Revue de psychiatrie & de neuroscience*, Vol. 27, n. 2, 2002 (Letter to Editor).

Exhibit I

(Filed Under Seal)

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Exhibit J

(Filed Under Seal)

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Exhibit K

(Filed Under Seal)

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EXHIBIT L
(Filed Under Seal)

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EXHIBIT M
(Filed Under Seal)

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