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PAXIL PREGNANCY

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(Exhibits Filed Under Seal)

Attention: Donna Candelora, Esq.
The Honorable Sandra Mazer Moss
JUDGE, Philadelphia County Court of Common Peas
Complex Litigation Center
City Hall – Room 622
Philadelphia, PA 19107

Re: ***Cause No. 3220; In re: Paxil Pregnancy Cases; In Philadelphia Court of Common Pleas.***

Case No. 070903247; *Roy Ayala and Kelly Capito, Individually and as Parents and Natural Guardian of Gabrielle R. Ayala, a Minor v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline;* In Philadelphia Court of Common Pleas.

Cause No.070903266; *Amy Davis, Individually and as Parent and Natural Guardian of Joey L. Davis, a Minor v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline, Inc. and PAR Pharmaceuticals, Inc.*; In the Philadelphia Court of Common Pleas.

Cause No.070903296; *Melanie Lacambra, Individually and as Parent and Natural Guardian of Kai A. Lacambra, a Minor v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline, Inc.*; In the Philadelphia Court of Common Pleas.

GLOBAL MOTION REGARDING THE ADMISSIBILITY OF CERTAIN EVIDENCE AT ISSUE IN ALL PAXIL PREGNANCY CASES

ARNOLD & ITKIN LLP

Executive Summary
Motion *In Limine* -
Plaintiffs' Global Motion Regarding the Admissibility of Certain Evidence at Issue in all Paxil Pregnancy Cases

EXECUTIVE SUMMARY

The parties in prior cases received inconsistent rulings with respect to certain motions *in limine* concerning evidentiary issues that do not turn on case-specific facts. Evidence is admitted in some cases, and not in others, for reasons having nothing to do with the particular facts of each case. In order to resolve the conflicting decisions to date, and to avoid the risk, uncertainty, and potential unfairness of continued inconsistent rulings, the Plaintiffs submit that this Court should decide the following evidentiary issues should now through a global ruling:

1. Evidence of GSK's Paxil-related marketing and promotional activities, and the testimony of its sales representatives, is admissible.

GSK seeks in each case to exclude evidence of its marketing and promotional activities related to Paxil and the testimony of GSK's sales representatives. GSK argues that unless marketing materials or a sales representative specifically went to the plaintiff or physician in each individual case, such evidence should not be admitted at trial in that case.

Evidence of GSK's marketing and promotion of its Paxil drug to the medical community as a whole is relevant, in every case, to (i) GSK's knowledge of the risks of Paxil but failure to warn the medical community of those risks; (ii) promotional materials directed to the medical community generally could cause treating physicians to unconsciously rely upon the promotional material and influence prescribing physicians to prescribe Paxil; (iii) over-promotion of prescription drugs can nullify or erode warnings by subconsciously or consciously influencing physicians; and (iv) information provided to all physicians is evidence of GSK's overall strategy to manipulate and control the dialogue within the medical community regarding Paxil and its safety profile. The Pennsylvania Supreme Court has held that evidence of a manufacturer's promotion of a drug to the entire medical community is relevant and admissible, and this Court should do the same. *See Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971).

2. Evidence of the Case Study Publication for Peer Review ("CASPPER") Program is admissible.

GSK also seeks in each case to exclude evidence of a GSK program, known as CASSPER, whereby GSK actively worked to manipulate peer-review literature by having positive articles about Paxil ghost-written and published in journals without disclosing GSK's involvement. That evidence is relevant to the issues of GSK's state of mind, and its efforts to influence the literature to downplay the risks of Paxil. Evidence of the CASPPER program also rebuts GSK's argument that it at all times acted as an ethical and responsible corporate citizen in the marketing of its Paxil drug. Plaintiffs in the Paxil cases should be permitted to put on evidence of GSK's manipulation of scientific literature, and to explain to the jury the implications of GSK's efforts in that regard.

IN RE: PAXIL PREGNANCY CASES	§	**COURT OF COMMON PLEAS** **TRIAL DIVISION** **PHILADELPHIA COUNTY** **DOCKET NO. 3220**
ROY G. AYALA And KELLY M. CAPITO, Individually and as Parents and Natural Guardians of GABRIELLE R. AYALA, A Minor Plaintiffs, **vs.** **SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC.** Defendant.	§	**COURT OF COMMON PLEAS** **TRIAL DIVISION** **PHILADELPHIA COUNTY** **DOCKET NO. 070903247** **PAXIL PREGNANCY**
AMY L. DAVIS, Individually, and as Next Friend of JOEY L. DAVIS, A Minor **Plaintiffs,** **vs.** **SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC. and PAR PHARMACEUTICALS, INC.** **Defendants.**	§	**COURT OF COMMON PLEAS** **TRIAL DIVISION** **PHILADELPHIA COUNTY** **DOCKET NO. 070903266** **PAXIL PREGNANCY**

MELANIE L. LACAMBRA, Individually and as Parent and Natural Guardian of KAI A. LACAMBRA, A Minor	§	**COURT OF COMMON PLEAS**
	§	**TRIAL DIVISION**
	§	**PHILADELPHIA COUNTY**
Plaintiffs,	§	
	§	**DOCKET NO. 070903296**
vs.	§	
	§	
SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC.	§	
	§	
Defendant.	§	**PAXIL PREGNANCY**
	§	

ORDER

ORDER

AND NOW, this _____ day of _____, 2011, this Court considered *Plaintiffs' Global Motion s in Limine Regarding the admissibility of evidence of GSK's Paxil-Related Marketing and Promotional Activities Regardless of their Relation to Plaintiffs' Physicians; Testimony of GSK's Sales Representatives Including Tracey Lepper and Evidence of GSK's Ghostwriting Program – CASPPER*. The Court having considered the briefs, the evidence, and the arguments of counsel, ORDERS AND DECREES that Plaintiffs' Global Motion Regarding the Admissibility of the following Evidence shall be granted and the following evidence admitted:

1. Evidence of GSK's Paxil-related marketing and promotional activities unrelated to Plaintiffs' physicians;

2. Testimony of GSK's sales representatives, including but not limited to Tracey Lepper; and,

3. Evidence of GSK's Case Study Publication for Peer Review ("CASPPER") Program.

BY THE COURT:

_____
SANDRA MAZER MOSS, J.

Dear Judge Moss:

The Plaintiffs in the above-cited cases (*Davis*, *Lacambra*, and *Ayala*) file this motion regarding the admissibility of certain evidence that the Plaintiffs will offer, and the inadmissibility of certain evidence that GSK will seek to offer. The Plaintiffs urge the Court to treat this motion as a global motion and to rule that evidence of (i) GSK's Paxil-related marketing and promotion, and the testimony of GSK's sales representatives; and (ii) GSK's CASPPER Program, are admissible into evidence.

I. INTRODUCTION

The Plaintiffs contend that Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation, d/b/a/ GlaxoSmithKline ("GSK") negligently failed to warn women of Paxil's risks. Specifically, the Plaintiffs contend that Paxil's warning label did not accurately reflect the true level of risk for birth defects, and that GSK engaged in a massive, multi-faceted campaign to market and promote Paxil in such a way so as to downplay the risks of Paxil and influence the medical community.

As part of that campaign, GSK issued a significant amount of marketing and promotional materials. It trained and dispatched sales representatives throughout the country to present a unified, but misleadingly positive, message about Paxil. It created a program to solicit and ghost-write positive Paxil stories in peer-review journals without disclosing GSK's involvement in the process. GSK did all of those things in the face of ever-increasing knowledge about the risks of Paxil and the inadequacy of its warning label. In fact, GSK's marketing and promotion efforts were intentionally designed to "counter" the negative aspects of Paxil that GSK knew, but failed to properly warn the medical community about.

In prior cases, GSK has filed motions in limine to exclude this evidence under Rules 401, 402, and 403 of the Pennsylvania Rules of Evidence. The Plaintiffs expect that an identical motion will be filed in their cases, too.

GSK's motions on these topics have received inconsistent rulings in different cases. For example, in *Kilker v. GSK*, February 2007 Term, No. 1813, the trial court denied each of GSK's motions in limine on these topics.[1] In *Blyth, et al v. GSK*, September Term 2007, No. 3305, however, the trial court granted the same three motions *in limine*.[2] The issues that are the subject of this motion do not turn on the facts of individual cases, yet different plaintiffs have received different rulings as to the admissibility of that evidence. A global ruling that GSK's motions in limine on those topics are denied is needed to reconciles the previous inconsistent rulings.

[1] *See* Ex. A (September 11, 2009 Order at Control No. 09082135 No. 1, Subpart 3, 4, 6)

[2] *See* Ex. B (November 9, 2010 Order at Control No. 10030243 No. 22, Subpart 3, 4, 7)

The Plaintiffs thus urge the Court to do the following:

First, the Court should treat this motion as a global motion to be applied to all Paxil Pregnancy cases. There is nothing case-specific about these evidentiary issues. Trial courts have reached different conclusions in earlier cases, and the risk of inconsistent rulings is simply too high.

Second, the Court should rule that all of the evidence regarding (i) GSK's Paxil-related marketing and promotion and the testimony of GSK sales representatives; and (ii) GSK's CASPPER Program, is relevant and therefore admissible. Such evidence is relevant to GSK's state of mind, its concerted effort to market and promote Paxil without adequately warning the medical community of its risks.

II. ARGUMENT

A. This motion should be treated as a global motion because the evidence referred to above is an integral part of every Paxil Plaintiff's case.

As the Court is aware, this motion can be designated as a global motion while leaving all truly case-specific evidentiary rulings to the trial judge. As the Civil Trial Manual explains, "All Mass Tort motions, except case-specific Motion[s] *In Limine*, are assigned to the Coordinating Judge for disposition. Case-specific Motions *In Limine* are assigned to the trial judge for disposition. The Coordinating Judge may designate any motion a 'global motion' to be applied to all cases in a particular Mass Tort program."[3]

The problem with treating the issues surrounding GSK's marketing and promotion efforts as somehow "case-specific" is that some Plaintiffs will be able to present critical evidence on the failure-to-warn theory, while other Plaintiffs may not. That risk of inconsistent rulings undermines the whole purpose of having a uniform set of procedures for Paxil Pregnancy cases. The risk of inconsistency is not speculative. It has already occurred. In earlier cases, GSK filed motions in limine with respect to the issues raised in this motion. The trial judge in *Kilker* denied the motion in limine on these topics, but the trial judge in *Blyth* granted an identical motion, though he did so without prejudice to consider specific offers of proof at trial.

Whether this evidence is admissible is not appropriate for a case-specific motion in limine. It will be a recurring issue in every failure-to-warn claim where the injury occurred before the label was changed. A uniform decision is needed.

[3] *Civil Trial Manual, Complex Litigation Center* at 3, at http://courts.phila.gov/pdf/manuals/civil-trial/complex-litigation-center.pdf. The revised mass tort motion procedures (dated October 29, 2008) do not address motions in limine. *See* http://www.courts.phila.gov/pdf/manuals/civil-trial/Mass-Tort-Motion-Procedures-Rev-2008.pdf .

B. Pennsylvania Rules of Evidence 401 and 403

Rule 401 of the Pennsylvania Rules of Evidence provides: "'[r]elevant evidence' means evidence having any 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." PA.R.E. 401. Relevance has two fundamental components: materiality and probative value. *See, e.g., Commonwealth v. McNeely*, 534 A.2d 778, 779-80 (Pa. Super. 1987), *appeal denied*, 549 A.2d 915 (Pa. 1988) (quoting McCormick, Evidence, § 185, at 541 (Cleary 3rd ed. 1984)); *Gaudio v. Ford Motor Co*., 2009 PA Super 102, P30 (Pa. Super. Ct. 2009). Evidence is immaterial if it is offered to help prove a proposition that is not in issue. *McNeely*, 534 A.2d at 779-80. Evidence is probative "if it tends to establish a material fact, makes a fact at issue more or less probable, or supports a reasonable inference or presumption regarding a material fact." *Com. v. Kennedy*, 959 A.2d 916, 923 (Pa. 2008); *see also, e.g., Com. v. Wynn*, 850 A.2d 730, 733 (Pa. Super. 2004); *Com. v. Gibson,* 400 A.2d 221, 223 (Pa. Super. 1978). Evidence that is not relevant is not admissible. PA.R.E. 402.

Even if the evidence at issue has some relevance, it may nonetheless 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. *See* PA.R.E. 403. The decision to exclude relevant but otherwise prejudicial evidence is soundly within the trial judge's discretion. *See e.g., Commonwealth v. Boyle*, 447 A.2d 250, 254 (Pa. 1982); *Commonwealth v. Ulatoski*, 371 A.2d 186 (Pa. 1977)*; Commonwealth v. Glover*, 286 A.2d 349 (Pa. 1972) (plurality opinion); *Commonwealth v. Barnak*, 54 A.2d 865 (Pa. 1947); J. McCormick, Evidence § 185, at 438-40 (2d ed. 1972).

"Unfair prejudice" means a "tendency to suggest decision on an improper basis or divert the jury's attention away from its duty of weighing the evidence impartially." *Com v. Wright*, 961 A.2d 119, 151 (Pa. 2008); *Official Comment*; *Bernstein, 2009 Pa. Rules of Evidence, Comment 4 to Pa.R.E. 403 (Gann)* (prejudicial evidence is "more likely to direct the jury's attention to matters of no consequence"). Additionally, evidence that confuses the issues is inadmissible, even if relevant, if the evidence would lead to litigation of collateral issues that will distract the jury. *See*, *e.g., Mansour v. Linganna*, 787 A.2d 443, 448 (Pa. Super. 2001), *appeal denied*, 796 A.2d 984 (Pa. 2002); *Daset Mining Corp. v. Industrial Fuels Corp*., 473 A.2d 584 (Pa. Super. 1984); *Moore v. City of Philadelphia*, 19 Phila.Co.Rptr. 180, 191, 1989 WL 817117 *18 (Pa. C.P. 1989).

C. Evidence regarding GSK's marketing and promotion of Paxil, and the testimony of its sales representatives, is admissible.

In each Paxil Pregnancy case, GSK seeks to exclude all evidence of its marketing and promotion of Paxil, as well as the testimony of its sales representatives. GSK argues that such evidence is not relevant unless the plaintiff in each case can show that her doctor specifically received or relied on the materials sought to be admitted, or spoke with the sales representative

whose testimony is offered. The reality is that GSK wants to keep the jury from hearing damaging evidence about GSK's aggressive marketing campaign, and the fact that GSK promoted Paxil to women of childbearing age, even though GSK knew (but failed to warn) of Paxil's teratogenicty. Plaintiffs have repeatedly alleged that, despite ample opportunity, GSK failed to warn the medical community of the known teratogenic risks of Paxil. Instead, GSK spent millions of dollars creating and implementing a marketing campaign, and training its pharmaceutical sales force on the use of promotional materials, which wholly omitted or purposely downplayed Paxil's teratogenicity.

1. GSK's marketing and promotion materials are relevant

GSK marketing and promotional materials are relevant in each case because those materials show, uniformly, how GSK worked assiduously to educate the medical community and encourage dialogue among healthcare providers that was positive about Paxil, while muting the negative. GSK executives would not authorize the spending of millions of dollars and employ thousands of sales representatives to market and promote Paxil if they did not believe that the marketing messages would not actually reach the prescribing medial community and have an impact on sales of Paxil.

The Pennsylvania Supreme Court and the Third Circuit have confirmed that, even without evidence that the plaintiff's physician was exposed to specific promotional materials, those materials are nevertheless relevant and admissible. In *Michael v. Shiley, Inc*., 46 F.3d 1316, 1335 (3d Cir.1995), the Third Circuit, applying Pennsylvania law, noted that when a pharmaceutical manufacturer engages in such promotional activities, it has ample reason to expect and anticipate that it would "lead doctors to recommend, and the physician's patients to choose, [the drug.]" Indeed, this is the reasoning that leads GSK to employ thousands in its sales and marketing departments and spend millions to promote Paxil. The *Michael* court went on to hold that, even though there was no evidence that the prescribing physicians had received the promotional material at issue, it is reasonable to assume they received the materials in light of their nationwide distribution. *See id.* at 1336, n.14.

Similarly, the Pennsylvania Supreme Court has held that a manufacturer's promotional efforts could cause the prescribing physician to *unconsciously* rely upon the promotional material and influence the prescribing physician to prescribe the manufacturer's drug. *Incollingo v. Ewing,* 282 A.2d 206, 221 (Pa. 1971). In approving the admission of evidence relating to over promotion, the Pennsylvania Supreme Court rejected the very argument GSK has advanced on this subject and held that evidence of a manufacturer's promotion to the entire medical community is relevant and admissible:

> Plaintiffs were allowed over objection to introduce, by expert witnesses, evidence directed to showing a failure to warn the Medical profession. This consisted of the custom and practice of the manufacturer, Parke Davis, in 'overpromoting' its product, primarily through the use of detail men who minimized the dangers of

> the drug while emphasizing its effectiveness, wide acceptance and use, and lack of certain objectionable side effects associated with other drugs. The question is whether this evidence was properly admitted.
> . . .
> As a practical matter, it would have been difficult, if not impossible, to show how the promotional efforts of the manufacturer bore on the judgments of these [the doctors] without demonstrating that the efforts were directed to the entire class or group of which they were members: the advertisements and all the literature relative to Chloromycetin were directed to the medical profession; the printed warnings were directed to the medical profession; the detail men were engaged for the purpose of selling the drug by making calls upon the members of the medical profession.

Id. at 221.

Courts around the country have recognized that over promotion of a drug may have the effect of de-emphasizing or nullifying information included in the warnings, thereby rendering them inadequate. *See Hill v. Searle Laboratories*, 884 F.2d 1064, 1071 n.3 (8th Cir. 1989) (over promotion by drug manufacturer may cause prescribing physician not to rely on warnings and package inserts); *Plummer v. Lederle Laboratories*, 819 F.2d 349, 358 (2nd Cir. 1987) (over promotion led to gross minimization of risks in product warnings); *Baldino v. Castagna*, 505 Pa. 239, 244 (1984) (citing *Incollingo*, 282 A.2d at 221); *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973) (over promotion through vigorous sales program can erode or nullify existing warnings by consciously or subconsciously influencing physicians).

Other courts have recognized the impact of aggressive marketing campaigns. As one court noted: "It is undisputable that expenditures for drug marketing increase sales. The billions spent by pharmaceutical industry attest to that. Physicians, despite what most claim, are influenced both consciously and unconsciously by commercial promotional messages. Scientific knowledge and judgment are not impervious shields against fraudulent product claims." *In re Zyprexa*, 253 F.R.D. 69, 105 (E.D.N.Y. 2008).[4]

FDA regulations governing prescription drugs place the duty on manufacturer to add new warnings whenever there exists "reasonable evidence of an association" between a serious

[4] The scientific literature confirms this. According to an analysis of the effects of drug marketing on physicians, titled *Pharmaceutical Marketing in the United States, A Critical Analysis*, by Eric Rose, M.D.: "Predictably, physicians reported that they got their information from non-commercial sources: 68 percent said that advertising was of 'minimal importance' in influencing their beliefs and 62 percent said that scientific papers were 'very important.' In survey answers about the drugs in question, however, the respondents voiced beliefs which could only have come from promotional sources -- from 49 to 71 percent of the time, depending on the question. The authors concluded that heavy promotion, even if contradictory to published data, can decide physicians' beliefs about drugs (Avorn, Chen, and Hartley 1982)." http://faculty.washington.edu/momus/pharm.htm. Dr. Rose also pointed out that "[t]he high association of sample dispensing and simultaneous prescribing of the same brand-name drug supports the contention that sampling influences physician prescribing habits." *Id*. at 1.

hazard and a drug. 21 C.F.R. §201.80(e). As the Supreme Court has recently confirmed, a drug manufacturer's duty to warn does not end with the information contained in the label. *Wyeth v. Levine*, 129 S.Ct. 1187, 1197-98 (2009). This duty is especially important as GSK constantly communicates information about its drugs to doctors through advertising, sales calls, promotional pieces, continuing medical education (CME) programs, and speakers bureau presentations and events, and to the general public through direct-to-consumer advertising.

In each of the Paxil Pregnancy cases plaintiffs have alleged that GSK failed to adequately warn of the risks associated with Paxil use during pregnancy. Plaintiffs also allege that GSK had extensive, and ever-increasing, knowledge about the adverse effects associated with Paxil use during pregnancy, failed to disclose this information, and instead obscured and downplayed the risk of Paxil. Evidence of GSK's marketing and promotional efforts is directly relevant to those issues.

Rather than disclosing relevant safety information to the medical community, GSK launched massive promotional campaigns were comprised of the following: (1) prolific publication of scientific articles relating to the efficacy of Paxil; (2) CME programs and speakers bureau presentations touting the safety and efficacy of Paxil for use by women of childbearing age; (3) continuous sales visits to doctors' offices; and (4) providing promotional materials, samples and vouchers for Paxil to doctors. GSK advertised to physicians in medical journals, during medical industry related events and in corresponding publications. GSK advertised to the public through direct-to-consumer advertising such as television and magazines. GSK launched a sophisticated and integrated promotional campaigns designed to encourage physicians to prescribe Paxil to women who were pregnant or of childbearing age.

To suggest that these campaigns were not designed to influence physician prescribing practices on a larger scale belies the evidence. GSK's marketing documents demonstrate its failure to disclose the known risks of taking Paxil during pregnancy. Evidence of GSK's marketing plans and tactics is thus relevant to underscore the disconnect between what GSK knew and learned about the risks of Paxil versus what it chose to disclose and how it chose to promote Paxil. GSK is obviously free to explain this evidence to the jury, but it should not be permitted to exclude it. Such evidence is relevant to the issues of whether GSK acted as a reasonable and prudent pharmaceutical company with respect to its Paxil drug.

Information that GSK provided to prescribing healthcare providers generally – not just those who prescribed Paxil to the *Ayala*, *Davis*, and *Lacambra* plaintiffs – is central to GSK's overall scheme to manipulate and control the dialogue within the medical community regarding Paxil and its safety profile. Documents relating to GSK's promotional campaign demonstrate GSK's efforts to influence the opinions and prescribing habits of physicians on a nationwide scale and, as such, are relevant to the issues in this case.

2. Testimony of GSK's sales representatives, including Tracy Lepper, is admissible.

GSK also argues in each case that testimony from its sales representatives should not be admitted unless plaintiffs can show that their prescribing doctor spoke with or bought Paxil from a particular sales representative. GSK is particularly concerned about keeping the testimony of one of its sales representatives – Tracy Lepper (as Washington sales representative) from the jury. GSK argues that such testimony is irrelevant.

Neither the facts of the case nor the rules of evidence support GSK's myopic view of what is relevant with respect to its sales representatives. Testimony related to GSK sales representatives, including Tracy Lepper, is relevant to GSK's knowledge of Paxil's risks and its failure to warn the medical community of those risks. The evidence shows that GSK uniformly trained and instructed its sales representatives to disseminate a consistent message – one aimed at avoiding discussion of the potential risks of Paxil.

As demonstrated above**,** Pennsylvania law provides that, when a pharmaceutical manufacturer engages in extensive promotional activities, it has ample reason to expect and anticipate that it would "lead doctors to recommend, and the physician's patients to choose, [the drug.]" *Michael*, 46 F.3d at 1335. Evidence of a drug manufacturer's over promotion, including by sales representatives, targeted to the general medical community is relevant and admissible because manufacturer's promotional efforts ***toward the general medical community*** could cause the prescribing physician to "*unconsciously*" rely upon the promotional material and influence the prescribing physician to prescribe the manufacturer's drug. *Incollingo,* 282 A.2d at 221; *Michael*, 46 F.3d at 1334-1336 (applying Pennsylvania law). It is well known that these doctor visits (also known as "detailing") result in increased sales. As one Court noted: "It is undisputable that expenditures for drug marketing increase sales. The billions spent by pharmaceutical industry attest to that. Physicians, despite what most claim, *are* influenced both consciously and unconsciously by commercial promotional messages. Scientific knowledge and judgment are not impervious shields against fraudulent product claims." *In re Zyprexa*, 253 F.R.D. 69, 105 (E.D.N.Y. 2008).

Rather than issuing warnings about Paxil's teratogenic effects, GSK implemented a massive marketing campaign that consisted of publishing medical articles touting the safety of Paxil and making personal sales visits to doctors' offices, as well as a host of other activities all specifically devoted to increasing sales of Paxil.

GSK specifically contends that the testimony of Tracey Lepper, a sales representative in Washington state should be excluded. However, Ms. Lepper's own testimony establishes that the information she relayed to her assigned physicians was part of a uniform training and common message:

Q. And I assume that everybody in the country goes through the same kind of program?
A. (By Ms. Lepper) Yes.
Q. So in other words, it's uniform training throughout the country on what you need to know to sell Paxil or other products?
A. Yes.

Exhibit C (filed under seal), Excerpts from the Deposition of Tracy Lepper ("Lepper Dep."), 11:14-20. Also as evidenced by Ms. Lepper's own testimony, the uniform message promoted by all sales representatives is relevant to establish both the over promotion and minimization or diluting of potentially adverse effects of Paxil by GSK. For example, referring to an "info-mail" disseminated by Bonnie Rossello, an executive at GSK, regarding a Wyoming lawsuit, Ms. Lepper testified:

Q. She (Ms. Rossello) used the phrase "entire Paxil selling team." Would that include you, as a sales rep here in Seattle?
A. (By Ms. Lepper) I think so.
Q. And -- and she said that there was no -- she said at the end, "As always, do not bring this up with your physicians."
A. Uh-huh. (Witness answers affirmatively.)
Q. If those were the marching orders that you got from the vice president of marketing for GSK, would you follow those orders?
A. Yes.
Q. So you wouldn't bring it up; right?
A. No. I'm out there to sell Paxil. I'm not out there to scare people away from Paxil, so ...

See id. at 56:21-57:8.

GSK's sales representatives' statements are therefore relevant to establish that GSK's custom and practice in "overpromoting" its product, primarily through use of "detailmen" who minimized the dangers of the drug while emphasizing its effectiveness, wide acceptance and use, and lack of objectionable side effects associated with other drugs "were directed to the entire class or group of physicians." Accordingly, under *Incollingo*, Ms. Lepper's testimony and statements made to the medical community, on their own, are relevant to the Paxil pregnancy cases generally.

D. Evidence of GSK's ghostwriting program - CASPPER – is admissible to demonstrate the control GSK asserted over published articles or other literature relating to the safety and efficacy of Paxil

In each case GSK also moves to exclude evidence of its CASPPER program from the jury.

GSK implemented a program – called Case Study Publication for Peer Review (CASPPER) – for the purpose of ghostwriting and publishing articles favorable to Paxil in peer review literature, all without disclosing GSK's involvement. The goal of the program is self-evident: GSK wanted to control the public discourse about Paxil in order to disseminate positive reports about the drug while downplaying and diluting the risks. GSK's internal documents characterize CASPPER as a program implemented by GSK to: (1) to "strengthen the product [Paxil] positioning," *i.e.*, market share; and (2) to "overcome competitive issues," *i.e.*, sales. *See* Exhibit D (filed under seal), CASPPER booklet.[5]

CASPPER was part of a larger tactical plan designed to refute any negative issues that would arise with Paxil and increase sales of Paxil by building relationships with prescribing physicians and by controlling the literature on Paxil, without disclosing GSK involvement. This is demonstrated by a video featuring GSK's Paxil marketing team:

> VIDEO SPEAKER: Thank you, Major. We know that Prozac is putting all their resources behind launching scud missiles at our field force. We **planned an all-out counterattack using the new anti-aircraft missile called CASPPER**.
>
> VIDEO SPEAKER: CASPPER, as in goat?
>
> VIDEO SPEAKER: Hear me out, Sproull. It's military code for Case Study Publications for Peer Review. Deploying the latest in **sales technology**, **our troops recruit physicians to publish positive case reports of Paxil which counter every negative issue we're being hit with**.
>
> VIDEO SPEAKERS: Right on.
>
> VIDEO SPEAKER: **These positive case reports are then published in peer review journals.** It's a completely turnkey program, and physicians receive support from initiation to publication.
>
> VIDEO SPEAKER: Yeah.

Exhibit E (filed under seal), Proeschel Dep., 89:11–90:3.

[5] Complete Healthcare Communications (CHC) was the agency hired by GSK to "assist" the physicians in writing the articles.

Included within the CASPPER campaign literature, was the booklet[6] described above, "Paxil, CASPPER ...Confidential For Consultant Use Only."[7] *See* Exhibit D, CASPPER booklet; Exhibit F, Excerpts from the Deposition of Scott Sproull at 631:9–633:2. The detailed booklet advises the GSK sales force who were "recruiting physicians for this valuable program" that "[t]o maintain the ***strong sales growth*** of Paxil, SmithKline Beecham (SB) must continue to provide value to our customers and respond to the key issues affecting our prescribing base." See Exhibit D, CASPPER booklet at PAR000570547 (emphasis added). The booklet details the steps to recruit those physicians who have favorable positions on Paxil to write case reports for journals. *Id*. at PAR000570548-56. The clear purpose was to reduce any potential discussion regarding the *risks* of Paxil and increase sales by encouraging interaction between the Paxil sales representative and physicians. *Id*. One of the suggested topics was "SSRI use in women." *Id*. at PAR000570549. This topic was discussed in detail during the deposition of GSK employee John Constantine, who testified that the purpose of the CASPPER program was to recruit authors to publish studies which focus on positive experiences with Paxil in order to promote Paxil. *See* Exhibit G, Constantine Dep. at 190-207. Sales representatives would suggest topics such as "SSRI use in women," and a third party marketing firm would prepare the publications. *See id.* None of this would be disclosed in the publication. *See id.*

The "Closing Remarks" of the booklet further refute GSK's altruistic statements that this program was merely to benefit doctors wanting to publish about Paxil. It provides:

> PAXIL Product Management has budgeted for ***50 articles*** for 2000. Your participation in CASPPER will enable your physicians to ***add to the literature supporting*** the use of PAXIL, ***strengthen your relationship with key physicians*** and thought leaders in the psychiatric field, and ultimately, help you ***meet your sales goals***.

Exhibit D, CASPPER booklet at PAR000570557 (emphasis added).

The booklet ends with a diagram of a bulls-eye with the heading, "Hitting Your Target," which, of course is a sales and market share target. *Id*. GSK's Paxil marketing executive, Bonnie Rosello, confirmed the tactics and goals of CASPPER:

> Q: Okay. And let's just look -- over here on the next page, it's talking about the competitive challenges in the first paragraph. And then in the second, it says, "To meet these objectives" -- and read on for me. What's GSK going to do?

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[6] The indication of ST4715 Apr 2000 on the last page of the booklet indicated that this was a final publication distributed to the sales force.

[7] A "consultant" was a member of the Paxil sales team. *See* Exhibit G (filed under seal), Excerpts from the Deposition of John Constantine ("Constantine Dep."), June 12, 2008, at 190:19-23.

A: "To meet these objectives, Paxil product management has launched CASPPER. This innovative program was developed to allow you to bring value to your important psychiatrists by: Offering assistance in the preparation and publication of case studies and other short communications relevant to the features and benefits of Paxil."
Q: "Paxil product management has budgeted for 50 articles for 2000." And read on. What -- what will it help the sales reps do?
A: **Your participation in CASPPER will enable your physicians to add to the literature supporting the use of Paxil, strengthen your relationship with key physicians and thought leaders in the psychiatric field, and ultimately help you to meet your sales goals.**
Q: **Meet sales goals; that -- that was the -- the focus of the CASPPER program, right?**
A. **It -- it's part of the proposal, yeah.**

See Exhibit H, Rosello Dep., 131:2-134:24.

In regards to the issue of the use of advertising agency-assisted medical literature, Justice Castille's dissent in *Blum v. Merrill Dow Pharmaceuticals, Inc.,* 764 A.2d 1 (2000), which is reiterated in *Grady v. Frito-Lay, Inc.*, 839 A.2d 1038, 1048-49 (Pa. 2003) (Castille, J. concurring), is particularly pertinent:

> [T]he trial court had heard extensive evidence concerning Merrell Dow's active and deliberate role, motivated by its litigation interests in defending lawsuits involving Bendectin, in actually creating and influencing the scientific orthodoxy that would then operate to suppress any contrary opinion that might harm its Bendectin litigation interest. As the trial court succinctly put it: "**The testimony in this case demonstrates how 'scientific consensus' can be created through purchased research and the manipulation of a 'scientific' literature,** funded as part of litigation defense, and choreographed by counsel."...
>
> In such an instance, where the supposed "consensus" of "scientific opinion" in the relevant "scientific community" had been manipulated by the financial and litigation interests of an interested party, the trial court determined that cross-examination of contrary scientific conclusions, rather than their outright exclusion, was sufficient gatekeeping under *Frye. Id.* at 71-72.

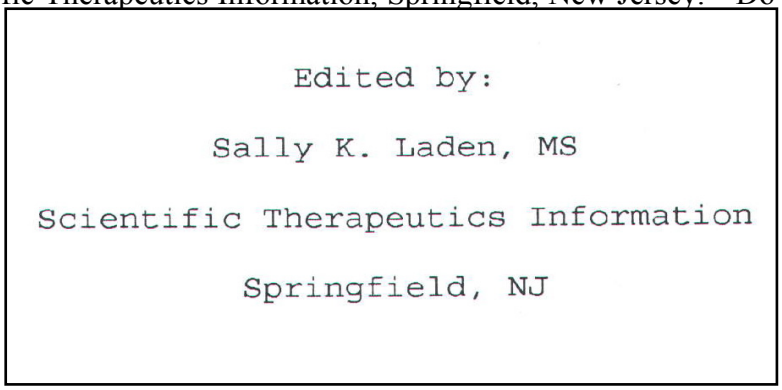
Blum, 764 A.2d 14-15 (emphasis added).

GSK will undoubtedly introduce into evidence studies regarding the safety and efficacy of Paxil. Evidence relating to the CASPPER program demonstrates GSK's efforts to control the

content of scientific literature in order to emphasize favorable data on Paxil, and downplay Paxil's negative safety profile, all in an effort to increase Paxil sales. Evidence of the CASPPER program is relevant evidence as it has 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." *Com. v. A.W. Robl Transp.*, 747 A.2d 400, 404 (Pa. Super. 2000) (citing Pa.R.E. 401). "In particular, evidence of the habit of a person or of the routine practice of an organization, whether corroborated or not and regardless of the presence of eyewitnesses, is relevant to prove that the conduct of the person or organization on a particular occasion was in conformity with the habit or routine practice." *Id*. (citing Pa.R.E. 406) (emphasis added). "The probative value of a person's habit or custom, as showing what was done on a particular occasion, is not open to doubt." *Baldridge v. Matthews*, 106 A.2d 809, 811 (Pa. 1954) (citing 1 Wigmore on Evidence (Third Edition), § 92, p. 519 et seq.). The evidence of GSK's conduct with regards to the creation and/or sponsorship of ghostwritten literature is relevant to show that when GSK failed to adequately warn Plaintiffs or their prescribers about the safety risks associated with Paxil, it was acting in conformity with its routine practice.

GSK manipulated scientific literature by having its marketing firm, Scientific Therapeutics Information ("STI"), draft and edit papers without providing full disclosure. GSK employee David Carpenter acknowledged that a paper on Paxil's obstetrical outcomes was edited by STI:

Q: And this is a study – this is Exhibit 25. It's called "Clinical Management of Perinatal Depression: Focus on Paroxetine." Do you see that?
A: Yes
Q: All right. Authors Jeffrey Newport and Zach Stowe. Now, the document on top of it, it says "STI cover to be removed before submission." Did I read that right? And then it's got a little title there, "Clinical Management of Perinatal Depression: Focus on Paroxetine." It's the same title, isn't it?
A: It appears to be, yes.
Q: And then if you look right below that, it says, "Authored by Jeffrey Newport and Zachary Stowe." The same authors, right? Right?
A: Yes.
Q: And then it says right here -- do you see that – it says, "Edited by Sally Laden, Scientific Therapeutics Information, Springfield, New Jersey." Do you see that?
A: Yes.



Q: So we know for a fact, do we not, that STI got to edit this paper, right?
A: Well, we know that STI was involved and yes, whatever -- it says edited by. What that many people have different definitions of edited. I don't know what that means, whether she just collected everyone's comments and collated them and she did the writing.
Q: Regardless of the definition of edited, she was involved, right?
A: Yes, she was.

Exhibit I (filed under seal), Excerpts from the Deposition of David Carpenter, 697-98, 702-06, 716, 719-21, 722-24.

Through the depositions of its corporate witnesses, GSK has asserted that it is an ethical company that prioritizes patient safety. Evidence of the manipulation of scientific literature for the purpose of increasing sales is relevant and admissible as impeachment evidence and to rebut such assertions. Additionally, such evidence is relevant to GSK's state of mind, intent, and motive to maximize sales while compromising patient safety.

In similar cases, courts have admitted evidence related to unethical conduct associated with published articles and the reporting of clinical trials data. *See In re Vioxx Prods. Liab. Litig.*, No. MDL 1657, 2005 WL 3164254, at *2, 4 (E.D. La. 2005) (the "*Vioxx* MDL"). In the *Vioxx* MDL, United States District Judge Fallon, denied Merck's Motion *in Limine* to exclude alleged unethical conduct associated with its clinical trials, including evidence that certain trials were conducted and manipulated solely for marketing purposes, stating that it was "[d]ependent on proof and may involve credibility." *Id*. at *4. Merck also moved to exclude claims that it paid individuals to be listed as authors of Merck-commissioned literature; that it removed individuals' names as authors of Merck-sponsored studies for improper reasons; and that authors of Vioxx articles did not disclose their financial ties to Merck. *Id*. at *2. Again, Judge Fallon refused to grant defendant's broad-based motion *in limine* rejecting Merck's attempt to prematurely label the evidence as irrelevant or overly prejudicial. *Id*. (reserving ruling on specific material until trial).

In the Seroquel multi-district litigation pending in the United States District Court for the Middle District of Florida, Magistrate Judge David A. Baker denied a motion *in limine* to exclude evidence that is virtually identical to the one GSK presents in this case. *In re Seroquel*, 2009 WL 223140, at *2-3. The Court agreed that plaintiffs "should be permitted to explain to the jury the implications of AstraZeneca's misrepresentations in the creation and/or sponsorship or ghostwritten publications and other literature related to . . . the safety and efficacy of Seroquel." *Id*. at *3. Similarly, in the Paxil Pregnancy cases, the Court should allow Plaintiffs to present evidence related to CASPPER in order to explain to the jury the implications of GSK's control over the content of published articles or other literature relating to the safety and efficacy of Paxil.

Finally, the probative value of evidence of a program that manipulates the science and literature of Paxil that GSK will present to the jury is not unfairly prejudicial as this information gives the jury a complete understanding of the totality of the evidence and the conduct at issue.

III. CONCLUSION

For the reasons set forth above, the Plaintiffs urge the Court to treat this motion as a global motion and to rule that: (1) evidence of GSK Paxil-related marketing and promotion activities, and the testimony of its sales representatives, is admissible; and (2) Evidence of GSK's ghostwriting program - CASPPER – is admissible.

Respectfully submitted,

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IN RE: PAXIL PREGNANCY CASES	§	**COURT OF COMMON PLEAS** **TRIAL DIVISION** **PHILADELPHIA COUNTY** **DOCKET NO. 3220**
ROY G. AYALA And KELLY M. CAPITO, Individually and as Parents and Natural Guardians of GABRIELLE R. AYALA, A Minor Plaintiffs, **vs.** **SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC.** Defendant.	§	**COURT OF COMMON PLEAS** **TRIAL DIVISION** **PHILADELPHIA COUNTY** **DOCKET NO. 070903247** **PAXIL PREGNANCY**

AMY L. DAVIS, Individually, and as Next Friend of JOEY L. DAVIS, A Minor **Plaintiffs,** **vs.** **SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC. and PAR PHARMACEUTICALS, INC.** **Defendants.**	§	**COURT OF COMMON PLEAS** **TRIAL DIVISION** **PHILADELPHIA COUNTY** **DOCKET NO. 070903266** **PAXIL PREGNANCY**
MELANIE L. LACAMBRA, Individually and as Parent and Natural Guardian of KAI A. LACAMBRA, A Minor **Plaintiffs,** **vs.** **SMITHKLINEBEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, INC.** **Defendant.**	§	**COURT OF COMMON PLEAS** **TRIAL DIVISION** **PHILADELPHIA COUNTY** **DOCKET NO. 070903296** **PAXIL PREGNANCY**

ATTORNEY CERTIFICATION OF GOOD FAITH

I hereby certify that counsel for Plaintiff contacted opposing counsel in an effort to amicably resolve the issues and relief sought in this motion, to no avail.

/s/ Jason A. Itkin

ATTORNEYFOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing instrument will silmutaneously be served via ☒ U.S. Mail; ☐ Facsimile; ☒ Electronically; ☐ Overnight Delivery; and/or ☐ Hand Delivery, on this 8th day of March, 2011, to the following:

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