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Civil Administration

LAVIN, O'NEIL, THOMPSON, RIZZI, CEDRONE & DISIPIO

ATTORNEYS AT LAW

SUITE 500

190 NORTH INDEPENDENCE MALL WEST

6TH & RACE STREETS

PHILADELPHIA, PA 19106

(215) 627-0303

FAX: (215) 627-2551

WWW.LAVIN-LAW.COM

NEW YORK OFFICE
420 LEXINGTON AVENUE
GRAYBAR BUILDING
SUITE 2900
NEW YORK, NY 10170
(212) 319-6898
FAX: (212) 319-6932

NEW JERSEY OFFICE
1300 ROUTE 73
SUITE 307
MT. LAUREL, NJ 08054
(856) 778-5544
FAX: (856) 793-0237

WRITER'S DIRECT DIAL NUMBER
(215) 351-7901

WRITER'S E-MAIL ADDRESS
JONEIL@LAVIN-LAW.COM

September 7, 2010

PAXIL – PREGNANCY

CONTROL NO. _____

Response Date:

Opposing Counsel:

Feldman & Pinto, P.C.

Blizzard McCarthy & Nabers

The Honorable Sandra M. Moss
Court of Common Pleas
of Philadelphia County
Complex Litigation Center
City Hall – Room 622
Philadelphia, PA 19107
Attention: Donna Candelora, Esquire

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

**DEFENDANT, GLAXOSMITHKLINE LLC, FORMERLY SMITHKLINE
BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE'S
MOTION FOR ENTRY OF A LONE PINE CASE MANAGEMENT ORDER**

Case ID: 070203220
Control No.: 10090866

In Re Paxil Pregnancy Cases

Executive Summary **GSK's Motion For Entry Of A *Lone Pine* Case Management Order**

Since Plaintiffs' Master Complaint was filed more than 3 ½ years ago, much progress has been made through document production, depositions, and the *Kilker* trial. Hundreds of cases have been settled or dismissed, reducing the Court's docket to approximately 160 cases from its peak of approximately 660. And although Paxil has not been shown to cause any birth defect, the science has now evolved sufficiently to distinguish the types of defects (and exposures) that are potentially at issue from those that clearly are not. As a result, it is now possible to determine at the very earliest stage of a case that a plaintiff has no basis upon which to recover.

In light of these developments, it makes sense to consider whether additional case management tools -- such as the entry of a *Lone Pine* case management order -- are needed to help the Court achieve its goal of wrapping up this litigation by the end of 2011. A *Lone Pine* order requires plaintiffs to provide basic evidence substantiating their claims of exposure, injury, and causation before their claims can proceed. In this way, *Lone Pine* orders are similar to the certificate of merit requirement applicable to medical malpractice claims in Pennsylvania under Rule 1042.3. Issuance of such an order here would help the Court achieve its goal by resolving the main obstacle to concluding this litigation in 2011: there are too many plaintiffs left in the MTP who do not belong. Examples include both existing and *newly filed* cases in which the alleged injury has never been associated with Paxil exposure and cases in which the alleged exposure occurred long after Paxil was reclassified as pregnancy Category D. Entry of a *Lone Pine* order would also: (1) deter would-be claimants who have read about GSK's prior settlements from flooding the docket with frivolous claims (a trend that may have already begun); and (2) facilitate settlement negotiations by helping the parties focus on claims that should be settled and avoid wasting resources on those that should not.

Although a *Lone Pine* order would be appropriate for all remaining claimants, it is particularly appropriate for three specific groups: (1) plaintiffs who assert an injury that has not been specifically identified as possibly associated with Paxil exposure in published, peer-reviewed epidemiological literature; (2) plaintiffs who claim an injury associated only with first trimester exposure to Paxil but have not introduced any evidence of Paxil use during the first trimester; and (3) plaintiffs who assert claims on behalf of minors wherein the first trimester of pregnancy occurred after the FDA-approved label for Paxil was changed to a Pregnancy Category D in December 2005.

Accordingly, GSK respectfully requests the Court enter its proposed *Lone Pine* case management order (attached as Exhibit 1).

IN RE: PAXIL PREGNANCY CASES

:
:
: PHILADELPHIA COUNTY
: COURT OF COMMON PLEAS

:
: FEBRUARY TERM, 2007
: NO.: 3220

:
: PAXIL - PREGNANCY

ORDER

AND NOW, this _____ day of _____, 2010, upon consideration of Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation, d/b/a GlaxoSmithKline's Motion for Entry of a *Lone Pine* Case Management Order, and any responses thereto and for good cause shown, it is hereby **ORDERED** that said Motion is **GRANTED** and the proposed *Lone Pine* Case Management Order, attached as Exhibit 1 to GSK's Motion, will be entered.

BY THE COURT:

MOSS, J.

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Dear Judge Moss:

Plaintiffs' Master Complaint was filed in March 2007, more than three and one-half years ago. Since that time, much progress has been made. GSK has produced more than a million pages of documents, dozens of witnesses have been deposed, a "bellwether" case (*Kilker*) has been tried, and several hundred cases have been resolved through settlement. To date, roughly 160 cases remain on the Court's docket, down from a peak of approximately 660. It is also true that the science has evolved as to whether Paxil is associated with birth defects (and, if so, what *type* of defects) over the past three years with the publication of a number of epidemiological studies. Although causation has not been established with respect to any birth defect, there have now been enough studies to distinguish the types of defects (and exposures) that are *potentially* at issue from *those that clearly are not*. As a result, it is now (more than ever) possible to determine at the very earliest stage of a given case that the plaintiff has no basis upon which to recover.

This Court has set a goal of concluding the pregnancy cases by the end of 2011. There is, however, a major obstacle to achieving this goal. As this Court is already aware, "in cases involving mass tort filings, there are almost always plaintiffs who do not belong." Joseph F. Madonia and Anthony G. Hopp, *Case Management Techniques in Complex Tort Litigation*, 17 NAT. RESOURCES & ENV'T 238, 240 (Spring 2003). This litigation is no exception.

This basic rule of numbers first came to light in this litigation last year when plaintiffs' counsel began to dismiss (not settle) cases *after* they were first set for trial. On May 11, 2009, CMO 5 was issued setting 24 cases for trial. On May 29, 2009, at the very next scheduled Case Management Conference, plaintiffs' counsel announced that some of the cases already set for trial in CMO 5 would be dismissed because plaintiffs conceded that they were without merit. The next month, plaintiffs' counsel informed the Court they were going to dismiss nearly *half* of the cases (11 out of 24) set for trial in CMO 5. And although the Court then directed plaintiffs' counsel to evaluate *all* of the approximately 300 cases filed in 2006 and 2007 for dismissal¹, plaintiffs' review only resulted in the dismissal of 42 cases – barely 14%.²

¹ No similar instruction has been issued for cases filed after 2007.

² On January 28, 2010, this Court signed an omnibus order dismissing 40 of 43 cases listed on the order. Two of the cases on the draft order *Alecia Kilgore, a Minor, by Casey Kilgore, Guardian; and Casey Kilgore, Individually v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 001098, December 2007 Term, and *Gary J. Lee, A Minor, by Yagini A. Montas, Guardian; and Yagini A. Montas and John G. Lee, Individually v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 000909, December 2007 Term were dismissed before the omnibus order was signed, bringing the total number of cases dismissed from plaintiffs' counsel review to 42. A dismissal has not been obtained yet for the third case listed on the draft order, *John M. Resmini and Chasley Resmini, Individually and as Parents and Natural Guardians of Jaci E. Resmini, A Minor v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 003335, September 2007 Term.

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Despite the Court's efforts to weed out cases that do not belong, the problem persists and will make it impossible for the Court to meet its goal of closing the Paxil Pregnancy MTP litigation by the end of next year. Many of the cases that remain in the MTP are comparable to the 42 that were dismissed in 2009. As shown below, these include cases in which: (1) there is no epidemiological evidence even *associating* Paxil use during pregnancy with the injury alleged (much less establishing causation); (2) plaintiffs assert a cardiac defect but have presented no evidence of Paxil use during the first trimester (the relevant window for the formation of the heart); or (3) a minor was exposed to Paxil during the first trimester after the FDA-approved label for Paxil was changed in December 2005 to describe Paxil's pregnancy status as Category D. Compounding and delaying matters further, recently filed (and threatened) cases suffer from the same fatal flaws. There also appear to be cases that have been dropped by settling plaintiffs' counsel because of their obvious lack of merit only to be picked up by other counsel. For example, in *Dawn Egelseer, Individually And Representative of the Estate of Christina Faith Egelseer, A Deceased Minor Child v. GlaxoSmithKline, PLC, SmithKline Beecham Corporation d/b/a GlaxoSmithKline* -- a wrongful-death case squarely barred by the statute of limitations -- the law firm of Arnold & Itkin has appeared as counsel after Sean Tracey dropped the case from his settlement group and withdrew as counsel.

This Court has broad authority and discretion to design a case management procedure that will promote the efficient resolution of cases pending before it. That authority and discretion includes providing mechanisms for weeding out, at an early stage, claims that are frivolous and cannot be substantiated. For example, this Court issued Case Management Order No. 2, which provides for dismissal of claims against a manufacturer of generic paroxetine in a case if the manufacturer can establish that it did not have FDA approval to sell generic paroxetine prior to the birth of the minor plaintiff. (CMO 2 ¶¶ 2-9.)

Although no similar order has been entered to winnow out frivolous claims brought against GSK, the Court can and should do so now. Indeed, it is well recognized in mass tort litigation that case management procedures that may not have been necessary at the beginning of litigation can become essential as litigation progresses. In the Vioxx MDL, for example, Judge Fallon faced a similar problem to that facing the Court here. As the science matured, it became clear that many of the cases in the Vioxx MDL did not belong there. To address this problem, Judge Fallon issued a "*Lone Pine*" case management order³ some three years after the MDL was created (and seven years after the first Vioxx cases were filed). The order required each remaining plaintiff to provide an expert report to substantiate his or her claims of injury and causation because the litigation was "no longer at its embryonic stage," and therefore it was "not too much to ask a Plaintiff to provide some kind of evidence to support their claim that Vioxx caused them personal injury." *In re Vioxx Prods. Liab. Litig.*, 557 F. Supp. 2d 741, 744-45 (E.D. La. 2008).

³ "*Lone Pine*" case management orders take their name from *Lore v. Lone Pine Corp.*, No. L-336056-85, 1986 WL 637507 (N.J. Super. Ct. Nov. 18, 1986) (Ex. 2).

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This Court should do the same here. As discussed below, a *Lone Pine* order requiring these plaintiffs and others to provide basic evidence at the outset to support their claims will ensure fairness and promote the efficient resolution of the remaining cases. Indeed, even if some plaintiffs can make such a showing, judicial efficiency is advanced by removing, at the earliest possible stage, clearly frivolous claims from those that have might have some prima facie validity. Neither the Court nor GSK should be burdened with lengthy proceedings only to discover that a plaintiff lacks the most fundamental evidence to support his or her claims.

Entry of a *Lone Pine* order will have two equally important benefits, both directly supportive of the Court's goal of resolving this litigation by 2011. *First*, it will deter would-be claimants who have read reports about GSK's prior settlements in the media from flooding the docket with frivolous claims thinking there is "easy" money to be had.⁴ *Second*, it will facilitate settlement negotiations in the cases that remain in the MTP by helping the parties to focus on those claims that should be settled and avoid wasting time and resources (or becoming deadlocked) on those that should not.

ARGUMENT

A. The Court should enter a *Lone Pine* case management order that will weed out meritless claims and streamline this litigation.

Like many courts before it, this Court should enter a *Lone Pine* case management order to facilitate efficient management of its large docket. A *Lone Pine* order focuses the parties and the court's attention in complex tort litigation to scientific and technical issues - typically those pertinent to causation - at an early stage of a case, often prior to the initiation of discovery. *Lore v. Lone Pine Corp.*, No. L-336056-85, 1986 WL 637507 (N.J. Super. Nov. 18, 1986) (Ex. 2).⁵

⁴ This may already be happening. For example, the minor plaintiff in a case filed July 12, 2010, was born almost four years *after the label for Paxil was changed to Pregnancy Category D*. (See *Jessica Dean, Individually and as the Mother and Natural Guardian of Jacob Dean, a Minor Child v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 00893, July 2010 Term, Short Form Complaint (Ex. 30).) GSK filed a Notice of Removal for *Dean* on September 1, 2010.

⁵ In *Lone Pine*, the trial court entered a case management order that required each plaintiff asserting a personal injury claim to provide, within four months, facts of his or her exposure to the alleged toxic substances and "[r]eports of treating physicians and medical or other experts, supporting each individual plaintiff's claim of injury and causation." 1986 WL 637507, at *1-2. The court explained that "[t]hese were considered to be the basic facts plaintiffs must furnish in order to support their claims of injury." *Id.* at *3. The plaintiffs did not provide medical records or expert reports. The court, concluding that in a toxic tort case "preliminary expert reports should have been obtained prior to filing suit," *id.*, dismissed the action with prejudice, concluding:

[I]t appears that plaintiffs' counsel is moving things along without complying with discovery orders, hoping that some of the defendants, to avoid further delay and expense, would recommend a settlement of the case. However, there is nothing to be settled because there is total and complete lack of information as to causal relationship and damages.

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The logic of *Lone Pine* is simple and compelling: “prior to the institution of [a lawsuit], attorneys for the plaintiffs must be prepared to substantiate, to a reasonable degree, the allegations of personal injury [] and proximate cause.” *Id.* at *4; *see also Acuna v. Brown & Root Inc.*, 200 F.3d 335, 340 (5th Cir. 2000) (“*Lone Pine* orders are designed to handle the complex issues and potential burdens on defendants and courts in mass tort litigation” by enabling a court to enter a single detailed order that requires each plaintiff to produce evidence and information she “should have had before filing [her] claims”) (affirming use of pre-discovery order that required plaintiffs to substantiate their claims of exposure and causation). And because Pennsylvania is a “fact-pleading state,” a *Lone Pine* order is entirely consistent with the requirement that “the complaint not only apprise the defendant of the claim being asserted, but it must also summarize the *essential facts* to support the claim.” *McShea v. City of Philadelphia*, 995 A.2d 334, 339 (Pa. 2010) (emphasis added). Here, of course, this requirement means that plaintiffs must plead the facts (with sufficient particularity) supporting their claim that Paxil caused their alleged injuries.

In personal injury actions, *Lone Pine* orders typically require each plaintiff to make a *prima facie* showing of causation through submission, by a date certain, of valid expert affidavits and other evidence identifying: (1) the precise injury suffered by the plaintiff, (2) the level of exposure, (3) the dates/duration of exposure, and (4) the evidence supporting the expert’s opinion that exposure to the chemical(s) caused the plaintiff’s injury. *See, e.g., Acuna*, 200 F.3d at 338; *Baker v. Chevron USA, Inc.*, No 05- 227, 2007 WL 315346, at *1 (S.D. Ohio Jan. 30, 2007) (Ex. 3); *Eggar v. Burlington Northern R.R. Co.*, Nos. 89-159, 89-170, 89-179, 89-181, 89-236, and 89-291, 1991 WL 315487, at *5 (D. Mont. Dec. 19, 1991) (Ex. 4), *aff’d*, 29 F.3d 499 (9th Cir. 1994); *Cottle v. Superior Court (Oxnard Shores Co.)*, 5 Cal. Rptr. 2d 882 (Cal. App. 1992). A plaintiff who fails to make the required *prima facie* showing, with detailed, verifiable proof of exposure, causation, and injury, faces immediate dismissal of his or her claims. *Acuna*, 200 F.3d at 338.

Because a *Lone Pine* order simply puts the burden of weeding out legally deficient claims where the law puts it in the first place - on the plaintiffs - *Lone Pine* orders have become a recognized and preferred method for dealing with and managing the complex issues and discovery in mass tort litigation in both federal courts⁶ and state courts.⁷ *Lone Pine* orders are

The Court is not willing to continue the instant action with the hope that the defendants eventually will capitulate and give a sum of money to satisfy plaintiffs and their attorney without having been put to the test of proving their cause of action.

Id. at *4.

⁶ *See, e.g., In re Vioxx Prods. Liab. Litig.*, No. 09-30446, 2010 WL 2802352, at *6 (5th Cir. July 16, 2010) (rejecting challenges to Master Settlement and affirming dismissal of plaintiffs’ claims who did not meet the requirements of a *Lone Pine* order) (Ex. 5); *Acuna*, 200 F.3d at 340 (staying discovery and requiring plaintiffs to produce expert affidavits opining their injuries were more likely than not caused by exposure to the substance at issue); *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 500-01, 503 (9th Cir. 1994) (affirming order requiring plaintiffs to submit affidavits from physicians setting forth the scientific basis for physicians’ opinion that the injuries were caused by exposure to the chemical at issue); *McManaway v. KBR, Inc.*, 265 F.R.D. 384, 389 (S.D. Ind. 2009) (granting *Lone Pine* order requiring Plaintiffs to provide expert evidence of exposure, injury, and

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particularly common in pharmaceutical cases. For example, in the *Vioxx* MDL, Judge Fallon entered a *Lone Pine* order under circumstances similar to those here, namely that the science and litigation had developed such that it was now appropriate to require the remaining plaintiffs to provide basic evidence substantiating their claims:

[I]n the present case, a *Lone Pine* order may not have been appropriate at an earlier stage before any discovery had taken place since little was known about the structure, nature and effect of *Vioxx* by anyone other than perhaps the manufacturer of the drug. But this case is no longer in its embryonic stage. It has

causation); *In re Vioxx Prods. Liab. Litig.*, 557 F. Supp. 2d 741, 744 (E.D. La. 2008) (*Lone Pine* order appropriate because "at this advanced stage of the litigation, it is not too much to ask a Plaintiff to provide some kind of evidence to support their claim that *Vioxx* caused them personal injury"); *In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab. Litig.*, MDL No. 1699, Pretrial Order No. 29 (N.D. Cal. Aug. 1, 2008) (*Lone Pine* order) (Ex. 6); *Baker v. Chevron USA, Inc.*, No 05- 227, 2007 WL 315346, at *1 (S.D. Ohio Jan. 30, 2007) (dismissing claims for failure to satisfy *Lone Pine* order) (Ex. 3); *Burns v. Universal Crop. Alliance*, No. 07-535, 2007 WL 2811533, at *3 (E.D. Ark. Sept. 25, 2007) (granting *Lone Pine* order requiring plaintiff farmers to provide expert proof that herbicide caused crop damage) (Ex. 7); *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 575 (S.D.N.Y. 2006) (granting summary judgment where *Lone Pine* reports provided insufficient evidence to support causation); *In re Rezulin Prods. Liab. Litig.*, MDL No. 1348, 2005 WL 1105067 (S.D.N.Y. May 9, 2005) (initial *Lone Pine* order) (Ex. 8); *In re Baycol Prods. Liab. Litig.*, MDL No. 1431, 2004 WL 626866, at *1 (D. Minn. Mar. 18, 2004) (initial *Lone Pine* order) (Ex. 9); *In re 2000 ExxonMobil Release Litig.*, Master Docket No. 00-MD-1-C, C.A. Nos. 01-1047, 01-1048, 01-1074, 01-1090, 01-1112, Order at 6 (M.D. La. Mar. 3, 2003) (ordering plaintiffs to produce affidavits from physicians identifying alleged exposure and injury and stating causation opinion to a reasonable degree of medical certainty) (Ex. 10); *Grant v. E.I. Du Pont De Nemours*, No. 91-55-Civ-4H, 1993 WL 146634, at *4-5 (E.D.N.C. Feb. 17, 1993) (requiring plaintiffs to provide expert affidavits) (Ex. 11); *Eggar v. Burlington N. R.R. Co.*, Nos. 89-159, 89-170, 89-179, 89-181, 89-236, and 89-291, 1991 WL 315487, at *5 (D. Mont. Dec. 18, 1991) (requiring physician affidavits on issues of injury and causation) (Ex. 4), *aff'd*, 29 F.3d 499 (9th Cir. 1994).

⁷ See, e.g., *Bell v. Exxonmobil Corp.*, No. 01-171, 2005 WL 497295, at *4 (Tex. App. Mar. 3, 2005) (affirming dismissal of plaintiffs' claims who failed to satisfy requirements of *Lone Pine* order) (Ex. 12); *In re: New York Rezulin Prods. Liab. Litig.*, Master Index No. 752, 000/00, Order (N.Y. Sup. Ct. N.Y. County July 7, 2004) (ordering plaintiffs to serve expert reports before depositions started) (Ex. 13); *In re Baycol Litig.*, Nov. Term 2001, Order (Pa. Ct. Com. Pl. Phila. Co. Dec. 12, 2003) (same) (Ex. 14); *Adjemian v. Am. Smelting & Ref. Co.*, No. 08-336, 2002 Tex. App. LEXIS 9360, at *19 (Tex. App. Mar. 7, 2002) (affirming dismissal for failure to comply with *Lone Pine* order) (Ex. 15); *Martinez v. City of San Antonio*, 40 S.W. 3d 587, 591 n.1 (Tex. App. 2001) (same); *In re Mohawk Rubber Co.*, 982 S.W.2d 494, 498-99 (Tex. App. 1998) (reversing trial court and directing entry of *Lone Pine* order in toxic exposure case); *Schelske v. Creative Nail Design, Inc.*, 933 P.2d 799, 802 (Mont. 1997) (affirming use of a case management order that required the plaintiffs to file a statement with evidence substantiating their personal injury claims); *Cottle v. Superior Court (Oxnard Shores Co.)*, 5 Cal. Rptr. 2d 882, 890 (Cal. App. 1992) (same); *Atwood v. Warner Electric Brake and Clutch Co., Inc.*, 605 N.E.2d 1032, 1037 (Ill. App. Ct. 1992) (same); *In re Love Canal Actions*, 145 Misc. 2d 1076, 1084 (N.Y. Sup. Ct. 1989) (modifying case discovery order to require early provision by plaintiffs of evidence "supporting each individual plaintiff's claim of injury and causation thereof by exposure to [the] chemicals [at issue]").

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existed in state courts for over seven years and in this Court for over three years, and much discovery has taken place. In this MDL, the Plaintiffs' Steering Committee ("PSC") has established and organized a document depository to house materials produced by Merck and has made those materials available to Plaintiffs' counsel in individual cases. In total, Merck has produced over 22 million pages of documents. Hundreds of depositions have taken place. . . [m]onthly status conferences, at which liaison counsel reported on all developments in the case, have been held in open court since the inception of this MDL.

In re Vioxx Prods. Liab. Litig., 557 F. Supp. 2d at 744. Recently, in rejecting challenges to the Vioxx Master Settlement, the Fifth Circuit affirmed the dismissal of plaintiffs' claims who did not meet the requirements of the *Lone Pine* order. 2010 WL 2802352, at *6 (5th Cir. July 16, 2010) (Ex. 5).

Lone Pine orders have also been used successfully in the Philadelphia MTP in the *Baycol* litigation and in other courts in litigation involving Bextra, Celebrex, and Rezulin. *In re Baycol Litig.*, Nov. Term 2001, Order (Pa. Ct. Com. Pl. Phila. Co. Dec. 12, 2003) (ordering plaintiffs to serve expert reports before depositions started) (Ex. 14); *In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab. Litig.*, MDL No. 1699, Pretrial Order No. 29 (N.D. Cal. Aug. 1, 2008) (*Lone Pine* Order) (Ex. 6); *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 474 (S.D.N.Y. 2006) (granting summary judgment for failure to satisfy *Lone Pine* order); *In re Rezulin Prods. Liab. Litig.*, MDL No. 1348, 2005 WL 1105067 (S.D.N.Y. May 9, 2005) (*Lone Pine* order) (Ex. 8); *In re Baycol Prods. Liab. Litig.*, MDL No. 1431, 2004 WL 2578976 (D. Minn. Nov. 1, 2004) (Ex. 16) (amending initial *Lone Pine* Order) (Ex. 9); *In re Baycol Prods. Liab. Litig.*, MDL No. 1431, 2004 WL 626866 (D. Minn. Mar. 18, 2004) (initial *Lone Pine* Order) (Ex. 9); *In re N.Y. Rezulin Prods. Liab. Litig.*, Master Index No. 752,000/00, Order (N.Y. Sup. Ct. N.Y. Co. July 7, 2004) (ordering plaintiffs to serve expert reports before depositions started) (Ex. 13).

Courts entering *Lone Pine* orders have acknowledged the orders tend to produce three main case management benefits. *First*, they allow for the disposal of meritless claims before the parties expend substantial resources (theirs and the court's) on discovery and trial preparation. *See Acuna*, 200 F.3d at 340; *Baker*, 2007 WL 315346, at *1 ("The basic purpose of a *Lone Pine* order is to identify and cull potentially meritless claims and streamline litigation in complex cases involving numerous claimants . . .") (dismissing claims for failure to satisfy *Lone Pine* order) (Ex. 3); *see also* Muehlberger and Hopp, *supra*, at 368 ("By requiring plaintiffs to produce *prima facie* evidence supporting their causes of action, both the court and the defendants learn at the beginning of the case whether the plaintiffs' claims have merit. This increases efficiency in the civil justice system."). *Second*, they encourage the narrowing of main issues in a case so the parties can focus on resolving main issues without using time-consuming discovery to parse out meritless issues. *See Acuna*, 200 F.3d at 340; *Kinnick v. Schierl, Inc.*, 541 N.W.2d 803, 806 n.1 (Wis. Ct. App. 1995). *Third*, they promote speedy settlements of litigation by allowing the parties to identify potentially meritorious claims and to assess the value of those claims early on,

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instead of going through years of plaintiff depositions, medical records analysis, and expert discovery before reaching the question of whether a plaintiff's claims have a legitimate scientific underpinning. See Scott A. Steiner, *The Case Management Order: Use and Efficacy in Complex Litigation and the Toxic Tort*, 6 HASTINGS W.-NW. J. ENV'T'L. L. & POL'Y 71, 85 (1999); Muehlberger and Hopp, *supra*, at 368 ("By forcing plaintiffs to bring forth evidence of causation early in the proceedings, *Lone Pine* orders also aid defense counsel in evaluating cases for settlement. If plaintiffs can produce credible medical causation affidavits, then defendants can assign a value to the case more accurately."). These three benefits are in harmony with, and will advance, the Court's desire to implement a procedure that will lead to the efficient resolution of cases remaining in the MTP.

B. A *Lone Pine* order is particularly appropriate for certain groups of plaintiffs whose claims are not legally plausible.

As discussed above, numerous courts have entered *Lone Pine* orders requiring all plaintiffs to produce evidence of the "basic facts" substantiating their claims, typically of injury, exposure, and causation. Although such an order would also be appropriate here, it is particularly appropriate for three specific groups of plaintiffs whose claims are not legally plausible.

First, as detailed in multiple briefs filed with this Court, the generally accepted view of the scientific community is that maternal use of Paxil during pregnancy has not been shown to **cause any** birth defects, including congenital heart defects. (See, e.g., Anthony R. Scialli, *Paroxetine Exposure During Pregnancy and Cardiac Malformations*, 88 Birth Defects Research Part A 175, 177 (Mar. 2010) ("The scientific evidence . . . does not support the conclusion that paroxetine causes cardiovascular defects.") (Ex. 17); Yonkers, et al., *The management of depression during pregnancy: A report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists*, 113 Obstet. & Gyn. 703, 706 (Sept. 2009) ("To summarize, the current data on SSRI exposure show **no consistent information** to support specific morphological teratogenic risks. Concurrent medication use or health habits **confound possible associations and create methodological challenges** in this area of investigation." (emphasis added) (Ex. 18).) To the extent certain epidemiological studies have reported a possible **association** between maternal use of Paxil during pregnancy and birth defects, those findings have been limited to specific cardiac defects (primarily certain types of septal defects and, potentially, right ventricular outflow tract obstruction defects).⁸ (See generally Marco Tuccori, et al., *Use of Selective Serotonin Reuptake Inhibitors During Pregnancy and Risk of Major and Cardiovascular Malformations: An Update*, Postgraduate Medicine, Vol. 122, Issue 4 (July 2010) (reviewing the current evidence on the safety of SSRI's in pregnancy) (Ex. 19).) As noted by the authors of a recent article, however, even those findings are "controversial" and

⁸ Persistent pulmonary hypertension of the newborn ("PPHN"), although not a structural malformation has also been associated with exposure to SSRIs (including Paxil) as a class in the medical literature, but has not been associated specifically with Paxil exposure.

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“derived from studies with methodological weaknesses.” *Id.*⁹ In any event, there is ***no support*** for the hypothesis that Paxil causes or is even associated with ***birth defects of every kind***. Indeed, there are “no known teratogenic exposures that cause every type of birth defect.” (Scialli, *supra*, at p. 176 (Ex. 17).)

Despite all this, plaintiffs in this MTP continue to claim injuries for which there is no scientific support even remotely comparable to the data applicable to certain cardiac defects (which, as noted above, is itself “controversial” and “inconsistent”). For example, the minor plaintiff in *Brenda Jenkins, Individually and as Parent and Natural Guardian of Matthew Hanson, A Minor v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 003307, September 2007 Term, was diagnosed with encephalopathy, Landau-Kleffner type syndrome (a neurological syndrome involving aphasia), neonatal seizures and autism. (St. Mary’s Medical Center Records at 559425.010.MED00004-005 (Ex. 20) (filed under seal).) Although three years have passed since these plaintiffs filed suit, no study has been published linking these alleged injuries with exposure to Paxil.

There are many other examples, including:

- Sarah Ann Voigt - epilepsy, encephalopathy, and learning disability
- Angeline Pinho - limb-body wall complex/stillborn
- Britain Williamson - pneumothorax
- Richard Smith - underdeveloped lungs; scoliosis
- Hunger Cyprian - RSV and chronic lung disease
- Jeremiah Hadden - multi-organ failure; sepsis; duodenal atresia
- Darchene Wilson - fetal demise due to unknown cause
- Kyle Hutchings - inguinal hernia; short bowel; seizures
- Harmony (Christian) Jordan - ambiguous genitalia

Accordingly, these and other current (and future) claimants who assert an injury that has not been specifically identified as possibly associated with Paxil exposure in the published, peer-reviewed epidemiological literature (*e.g.*, an injury other than certain cardiac defects and PPHN) should be required to come forward with competent evidence to support their claims of causation before their cases are allowed to proceed. To be very clear: a study’s reference to “congenital malformations” as a class of defects would not be sufficient to satisfy this requirement with

⁹ There is also a marked lack of consistency from study to study. (*See Scialli, supra*, at p. 175 (Ex. 17).)

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respect any alleged defect or type of defect not specifically identified by the study as associated with Paxil exposure.

Second, the few epidemiological studies that have reported an association between Paxil use during pregnancy and specific cardiac defects have been based on Paxil use during the first trimester.¹⁰ (See, e.g., Tuccori, et al., *supra* at p. 54-55 (Ex. 19).) This is, of course, because the relevant structures of the heart are already formed by the end of the first trimester. In fact, human structural heart development is generally accepted to be complete by approximately 60 days post conception, or approximately 74 days after the last menstrual period, which is well before the end of the first trimester. (See Keith L. Moore & T.V.N. Persaud, *THE DEVELOPING HUMAN: CLINICALLY ORIENTED EMBRYOLOGY* 73, 97 (8th ed. 2008) (Ex. 21).) Several remaining plaintiffs in this MTP, however, claim a cardiac injury but have not introduced any evidence of Paxil use during the period of heart development, or indeed any time during the first trimester. For example, in *Chelsea Cope, Individually and as Parent and Natural Guardian of Trenton Cope, A Minor v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 001815, November 2007 Term, the minor plaintiff was born September 5, 2003 and diagnosed with a heart murmur. (*Cope v. GSK*, Short Form Complaint (Ex. 22).) Ms. Cope's last menstrual period was December 13, 2002 giving her an estimated date of conception of December 27, 2002, or approximately 14 days after the first day of her last menstrual period. (Unity Health Center Medical Records at 559670.025.MED00078 (Ex. 23) (filed under seal).) Thus, the first trimester of Ms. Cope's pregnancy was from December 13, 2002 through March 14, 2003. Her prenatal records note that she was to "start" Paxil on May 9, 2003, well beyond the first trimester, and long after Trenton's heart had formed. (*Id.*)

Similarly, in *Delliere Clark Individually and as Parent and Natural Guardian of Deliah B. Franklin, A Minor v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 001335, August 2008 Term, the minor was born on November 29, 2002 and diagnosed with an irregular heart rate. (*Clark v. GSK*, Short Form Complaint (Ex. 24).)¹¹ Ms. Clark's last menstrual period was April 18, 2002, giving her an estimated date of conception of May 1, 2002. (Sinai Hospital Center Medical Records at 560497.011.MED00083 (Ex. 25) (filed under seal).) Ms. Clark's first trimester was from April 18, 2002 through July 24, 2002. Her prenatal records note, however, that she "will start" Paxil on September 17, 2002 -- again, nearly **two months after** the completion of the first trimester of her pregnancy, and long after her child's heart was already formed. (*Id.*) Plaintiffs who claim a cardiac or other injury associated only with first trimester exposure to Paxil but have not introduced any evidence of Paxil use during the first trimester

¹⁰ The duration of pregnancy is approximately 40 weeks, measured from the date of the last menstrual period ("LMP"). The first trimester of pregnancy is generally considered to have been completed by 13 weeks after the LMP. (See Keith L. Moore and T.V.N. Persaud, *THE DEVELOPING HUMAN: CLINICALLY ORIENTED EMBRYOLOGY* 7, 97-98 (8th Ed. 2009) (Ex. 21).)

¹¹ An irregular heart beat is not a structural heart malformation and not included as a heart defect in any epidemiologic study. Thus, Ms. Clark's claim fails not only because she allegedly took Paxil long after heart formation was complete, but because her child's alleged injury has never been associated with Paxil exposure in the scientific literature.

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should be required to come forward with competent evidence to support their claims of causation before their cases are permitted to proceed.

Third, because plaintiffs' claims are all premised on a theory that GSK failed to warn about an alleged association between maternal Paxil use during pregnancy and congenital defects prior to December 2005, when the FDA-approved labeling for Paxil was changed to Pregnancy Category D, any claims based on Paxil use during pregnancy after the change to Category D necessarily fail. Several such cases remain in the MTP. For example, the minor plaintiff in *Wesley Woodring and Sarah Woodring Individually, and as Parents and Natural Guardians of Cullen Andrew Woodring, a Mminor child v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 003715, May 2009 Term, was born on February 21, 2008, more than two years after Paxil was changed to Pregnancy Category D. (*Woodring v. GSK*, Short Form Complaint (Ex. 26).) Similarly, the minor plaintiff in *Cyrus Moreno, a Minor, by Amy Potter Moreno and Ed Moreno, Guardians; and Amy Potter Moreno and Ed Moreno, Individually v. SmithKlineBeecham Corporation d/b/a GlaxoSmithKline*, No. 001692, November 2008 Term, was born on October 20, 2007, almost two years after Paxil was changed to pregnancy Category D. (*Moreno v. GSK*, Short Form Complaint (Ex. 27).)

There are many others like Woodring and Moreno:

- Natalia Hulkon - DOB: 1/29/2007
- Joseph Chase - DOB: 2/21/2007
- Kale Stoneroad - DOB: 3/13/2007
- Ethan Passano - DOB: 4/10/2007
- Kayden Mahaffey - DOB: 4/16/2007
- Samantha Murriner - DOB: 5/25/2007
- Khaliah Magee - DOB: 7/13/2007

These plaintiffs and others who assert claims on behalf of minors wherein the first trimester of pregnancy occurred *after* the FDA-approved label for Paxil was changed to a Pregnancy Category D in December 2005 should be required to come forward with competent evidence to support their claims that GSK's alleged failure to warn "caused" their injuries before their cases are permitted to proceed.

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C. GSK's proposed *Lone Pine* case management order is consistent with orders entered by courts in pharmaceutical and other mass tort cases.

GSK's proposed *Lone Pine* case management order is attached as Exhibit 1 to this brief. The proposed order tracks what other courts have required of plaintiffs both in pharmaceutical tort cases and other mass tort cases (if anything, it is more modest in scope).

For example, in the Vioxx litigation, Judge Fallon entered a *Lone Pine* order requiring all remaining plaintiffs to serve an expert report from a medical expert "attesting (i) to a reasonable degree of medical probability that the Plaintiff or Claimant suffered an injury and (ii) Vioxx caused that injury." *In re Vioxx Prods. Liab. Litig.*, Pretrial Order No. 28 ¶ II.A.8 (E.D. La. Nov. 9, 2007) (Ex. 28). The report was also required to include "(i) an explanation of the basis of the attestation that Vioxx caused the Plaintiff or Claimant to suffer the injury, (ii) an identification of any other causes that were considered in formulating the opinion, (iii) a description of the specific injuries allegedly suffered, (iv) a description of the specific medical findings that support the diagnosis of those injuries, and (v) identification of all documents relied on by the expert in forming his opinions." *Id.*

Similarly, in litigation involving Rezulin, a New York state court entered a *Lone Pine* order requiring each plaintiff to "serve a disclosure to substantiate and document plaintiff's alleged claims" that included, among other details, "[t]he dates of Rezulin use, specifying the documentary evidence of such use," "[t]he injuries that the medical expert opines were caused by plaintiff's Rezulin use and the summary of the grounds for such opinion," "[t]he diagnosis made by the medical expert or any other provider whom the expert relied on," and "[t]he date(s) that plaintiff was injured by Rezulin use." *In re N.Y. Rezulin Prods. Liab. Litig.*, Master Index No. 752,000/00, Order (N.Y. Sup. Ct. N.Y. Co. July 7, 2004) (Ex. 13). In litigation involving Bextra and Celebrex, the court entered a *Lone Pine* order which provided that "[i]n addition to each plaintiff's obligation under Pretrial Order No. 6 to serve a Plaintiff Fact Sheet ("PFS"), all responsive documents (or a written notice that none are in the possession of plaintiff or plaintiff's counsel), and properly executed authorizations, each plaintiff [] and the plaintiff's counsel, in consultation with such medical advisor(s) as they see fit to consult, shall consider whether there are good grounds to continue the action in light of the plaintiff's individual circumstances." *In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab. Litig.*, MDL No. 1699, Pretrial Order No. 29, ¶ 2 (N.D. Cal. Aug. 1, 2008) (Ex. 6). Any plaintiff who wished to continue his or her case was required to serve an expert report containing verified information on exposure and injury. (*Id.*)

Orders from non-pharmaceutical mass tort cases have required plaintiffs to make similar showings. For example, in *Baker v. Chevron USA Inc.*, *supra*, a toxic tort case, the court entered a *Lone Pine* order that required each plaintiff to provide a submission that included, among other information, "the specific illness allegedly sustained," "the toxic chemical which allegedly caused the identified illness, supported by an explanation of the manner of exposure (*i.e.*, the exposure pathway), the date(s) of exposure, the duration of exposure, and the dose of exposure" and "citation to the scientific literature supporting any claim that any plaintiff's illness was

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caused by the described exposure to the identified toxic chemical.” Case No. 05-227, Case Management Order ¶ 1 (S.D. Ohio Aug. 3, 2005) (Ex. 29). Similarly, in *Schelske v. Creative Nail Design, Inc.*, 933 P.2d 799 (Mont. 1997), the trial court issued a *Lone Pine* order directing the plaintiff to submit an affidavit from a physician that “(1) list[ed] all injuries, illness, or conditions suffered by [the plaintiff]; (2) specif[ied] the chemical(s) that caused each illness, injury or condition; and (3) state[d] the scientific bases for the physician's opinion.” *Id.* at 801 (quoting, in part, trial court's case management order).

As these cases demonstrate, courts have not hesitated to put plaintiffs to their proof regarding exposure and causation, even before any formal discovery has commenced. Such an order is appropriate in this litigation at this point in time.

LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO
Joseph E. O'Neil, Esquire (ID No. 29053)
Mary Grace Maley, Esquire (ID No. 37610)
Carolyn L. McCormack, Esquire (ID No. 87800)
190 North Independence Mall West, Suite 500
6th & Race Streets
Philadelphia, PA 19106
215-627-0303
215-627-2551 (facsimile)

Counsel for Defendant,
SmithKline Beecham Corporation
d/b/a GlaxoSmithKline

IN RE: PAXIL PREGNANCY CASES

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PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
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FEBRUARY TERM, 2007
NO.: 3220
:
:
PAXIL - PREGNANCY

ATTORNEY CERTIFICATION OF GOOD FAITH

I, Carolyn L. McCormack, Esquire, hereby certify that counsel for GSK spoke with opposing counsel in an effort to resolve the specific dispute at issue. Plaintiffs and GSK were unable to reach a resolution on this issue. Accordingly, GSK files the within Motion.

/s/
Carolyn L. McCormack, Esquire
Counsel for Defendant,
GlaxoSmithKline LLC, formerly
SmithKline Beecham Corporation,
d/b/a GlaxoSmithKline

CERTIFICATE OF SERVICE

I hereby certify that, on September 7, 2010, I will serve a true and correct copy of **DEFENDANT GLAXOSMITHKLINE LLC, FORMERLY SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE'S MOTION FOR ENTRY OF A *LONE PINE* CASE MANAGEMENT ORDER** 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.

Rosemary Pinto, Esquire
Feldman & Pinto, P.C.
1604 Locust Street, 2R
Philadelphia, PA 19103
Liaison Counsel for Plaintiffs

Edward Blizzard, Esquire
J. Scott Nabers, Esquire
Blizzard, McCarthy & Nabers, LLP
440 Louisiana, Suite 1710
Houston, TX 77002
Liaison Counsel for Plaintiffs

Jamie L. Sheller, Esquire
Sheller, PC
1528 Walnut Street
3rd Floor
Philadelphia, PA 19102
Liaison Counsel for Plaintiffs

Alice S. Johnston, Esquire
James E. Kurack, Esquire
Ryan Leonard, Esquire
Obermayer, Rebmann, Maxwell & Hippel, LLP
One Penn Center, 19th Floor
1617 JFK Blvd
Philadelphia, PA 19103
Counsel for Defendant, Teva Pharmaceuticals USA, Inc.

Arthur B. Keppel, Esquire
Charles A. Fitzpatrick, Esquire
Rawle & Henderson LLP
1339 Chestnut Street
One South Penn Square
The Widener Building, 16th Floor
Philadelphia, PA 19107

Counsel for Defendants, Apotex Corp. and Torpharm Inc.

Sharon Caffrey, Esquire
Alyson B. Walker, Esquire
Duane Morris, LLP
30 South 17th Street
Philadelphia, PA 19103

Counsel for Defendant, Genpharm Inc. a/k/a Genpharm General Partner Inc. and Mylan Laboratories, Inc. a/k/a Mylan Pharmaceuticals, Inc.

Terry Henry, Esquire
Scott Reid, Esquire
Cozen O'Connor
1900 Market Street
Philadelphia, Pennsylvania 19103

Counsel for Defendant, Andrx Pharmaceuticals, Inc.

LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO

BY: _____ /s/

Carolyn McCormack, Esquire
Counsel for Defendant,
GlaxoSmithKline LLC, formerly
SmithKline Beecham Corporation,
d/b/a GlaxoSmithKline