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IN THE COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY, PENNSYLVANIA

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<b>IN RE: AVANDIA LITIGATION</b>	:	February Term, 2008
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	:	Case No. 2733
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<b>THIS DOCUMENT RELATES TO ALL</b>	:	
<b>ACTIONS</b>	:	

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**PLAINTIFFS' OPPOSITION TO DEFENDANT GLAXOSMITHKLINE LLC'S  
MOTION FOR A "LONE PINE" CASE MANAGEMENT ORDER**

Plaintiffs file this response to defendant GlaxoSmithKline LLC's ("GSK") "Motion for a Lone Pine Case Management Order," filed on January 3, 2011.

**INTRODUCTION**

GSK filed a motion requesting that the Court require that *all* plaintiffs in *all* filed cases regardless of the injury at issue, file at each plaintiff's expense, a "physician certification" to opine about the case in a fashion similar to the order that was entered in the Avandia Federal MDL Court, Pretrial Order 121. According to GSK's proposal -- which lacks any support in Pennsylvania statutes, rules or case law -- if a plaintiff fails to do so within 60 days, the case is to be dismissed with prejudice.

GSK claims this "case management" scheme is supported by *Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Super Ct. Nov. 18, 1986), an unreported New Jersey trial court decision. GSK's motion should be denied for a host of reasons, including the following:

- A *Lone Pine* order is a rarely utilized and extreme remedy that is not appropriate for this litigation;

- There is no need to resort to a *Lone Pine* order in this case: the system that the Court has fashioned is working;
- A *Lone Pine* order would greatly and unnecessarily increase the costs in this case;
- There is no Pennsylvania Rule of Civil Procedure authorizing such an order. Also, this case is easily distinguishable from those rare instances in other jurisdictions in which a *Lone Pine* order has been entered.

## ARGUMENT

### **I. A *Lone Pine* order is a rarely utilized and extreme remedy that is not appropriate for this litigation.**

GSK's request emanates from the case, *Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Super Ct. Nov. 18, 1986). *Lone Pine* is an unreported New Jersey trial court decision in a toxic tort case that is not even binding precedent in New Jersey. Here, no Pennsylvania Rule of Civil Procedure requires *Lone Pine* orders, or even authorizes them. And GSK cites no Pennsylvania statute or appellate decision allowing such an order.<sup>1</sup> Given the lack of precedent supporting the entry of a *Lone Pine* order, the Court should decline to issue one on this basis alone. The Court should not allow defendants to change the rules, or, more precisely, to create rules and procedures that simply do not exist, even if they seem like a "good idea" from GSK's perspective.

Aside from the lack of supporting rules of civil procedure, the reason courts do not follow *Lone Pine* is clear – rarely is a litigation in such a disastrous state that a court must resort to such drastic measures. The *Lone Pine* court was in a uniquely difficult position. The court faced hundreds of claims against hundreds of defendants alleging injuries for which plaintiffs had failed to show any valid causation. In short, the case was a mess and the court needed some mechanism – any mechanism – to get it under control. This is not such a case.

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<sup>1</sup> Likewise, the concept has garnered little attention from federal appellate courts – the sole officially reported decision being another environmental toxic tort case from the Fifth Circuit. *See Acuna v. Brown & Root, Inc.*, 200 F.3d 335 (5th Cir. 2000). The Third Circuit has never issued an opinion on the use of *Lone Pine* orders.

In *Lone Pine*, plaintiffs claimed that a landfill polluted their properties and caused various physical ailments. *Lone Pine*, 1986 WL 637507, at \*1. There were 464 named defendants and it was unclear what the causes of the plaintiffs' injuries were or which defendants caused them. *Id.* The court found that, after sixteen months of litigation, the plaintiffs had "failed to provide *anything* that resemble[d] a prima facie cause of action," whether for property damage or personal injuries. *Id.* (emphasis added). In addition, during the course of the litigation, the Environmental Protection Agency issued a decision summarizing sixteen studies that had been done on the landfill. *Id.* at \*1. The EPA decision was "completely contrary" to the claims of the plaintiffs, suggesting that there was no groundwater contamination, no transport of pollution, and no contamination beyond the landfill and its immediate vicinity. *Id.* at \*2-3.

In an effort to determine whether *any* of the claims were valid, the New Jersey trial court resorted to extreme measures and ordered plaintiffs to produce: "[r]eports of treating physicians and medical or other experts, supporting each individual plaintiff's claim of injury and causation." *Id.* at \*2. Failure to do so led to dismissal of the claim with prejudice.

Clearly, the *Lone Pine* court issued the order because: (1) a governmental agency had issued a report in direct contravention of the plaintiffs' claims; (2) the plaintiffs had put forth *no* independent evidence in support of their claims; and (3) the plaintiffs were unable to identify which of hundreds of defendants allegedly caused an injury and how that injury was caused. This fact pattern could not be further from this case.

First, all of the governmental agencies reviewing Avandia's cardiovascular safety have been very clear: Avandia increases the incidence of adverse cardiovascular events, the very events that are the subject of the plaintiffs' claims in this litigation. This includes the following governmental actions:

2007 FDA Advisory Committee: In a vote of twenty-three to three, members of the Committee agreed: "Avandia increases the risk of ischemic cardiovascular disease."

2007 FDA: FDA requires GSK to add a black box to its label discussing an increased incidence of myocardial ischemic events.

2010 FDA Advisory Committee: In a vote of twenty-one to three, members agreed: “there are significant safety concerns that Avandia increases cardiovascular risk compared to [Actos].” Seventeen members voted to require additional warnings or restricted sales. Twelve members voted to remove Avandia from the market altogether.

FDA 2010: FDA halts enrollment in the TIDE trial due to concerns of cardiovascular risk and ethical considerations of continuing the trial with Avandia.

FDA 2010: FDA significantly restricts the use of Avandia due to the increased risk of cardiovascular events.

MHRA statement 2010: The United Kingdom’s FDA equivalent voted unanimously to recommend removal of Avandia from the European market due to increased cardiovascular events. Specifically, their review found “the risks of rosiglitazone outweigh its benefits and that it no longer has a place on the UK market.”

European Union 2010: Avandia sales have been suspended due to increased cardiovascular risk.

Hence, unlike *Lone Pine*, plaintiffs’ claims in this litigation are not in anyway contrary to those of regulatory authorities – they mirror these findings. And indeed, these findings are consistent with the numerous studies that now have been published that show the clear and consistent cardiovascular risk of Avandia, the same injuries that are alleged in this litigation.

This likewise is not a case in which plaintiffs have failed to pinpoint what their injuries are, who caused those injuries and how those injuries were caused. Here, the vast majority of plaintiffs in the *Avandia* MTP allege a finite type of injury – myocardial ischemic injuries, CHF and stroke. Plaintiffs

know what caused those injuries – Avandia. Plaintiffs also know who made the drug – GSK, the sole defendant.

In addition, in connection with the trial-set cases, plaintiffs have produced expert witnesses who are leaders in their fields to support that these injuries are caused by GSK’s drug Avandia. Their opinions are shared by governmental agencies and independent scientists from across the globe, including many at the FDA. (And, in fact, recently, the MDL Court denied GSK’s *Daubert* motions on both general and specific causation.) Accordingly, this proceeding is readily distinguishable from *Lone Pine* or other cases where such orders have been deemed appropriate.

**II. There is no need for the exception of a *Lone Pine* order in this case: the system that the Court has fashioned is working.**

The system that the Court has established to manage the cases in this MTP is accomplishing these goals, and doing it well. By contrast, GSK’s proposed *Lone Pine* order would do just the opposite.

**A. The Court’s current system is not broken.**

“Resorting to crafting and applying a *Lone Pine* order should only occur where existing procedural devices explicitly at the disposal of the parties by statute and federal rule have been exhausted or where they cannot accommodate the unique issues of th[e] litigation.” *Digitek*, 264 F.R.D. at 259. The reason for this: *Lone Pine* orders increase the risk that the procedural rules and safeguards set forth in the rules of civil procedure will be ignored. *See McManaway*, 265 F.R.D. at 386 (citing *Simeone v. Girard City Bd. of Educ.*, 872 N.E. 2d 344, 350 (Ohio Ct. App. 2007)); *see also Digitek*, 264 F.R.D. at 257. Indeed, GSK’s proposed order in this case blatantly ignores and bypasses the well-established Pennsylvania rules of discovery and summary judgment.

There are “orderly processes provided by the civil rules, which are designed both to bring the meritorious case to a conclusion and to derail the meritless case.” *Simeone*, 872 N.E.2d at 644. Where effective procedural mechanisms are already being (or can be) successfully employed, courts have

declined to enter *Lone Pine* orders. See, e.g., *Abrams v. Ciba Specialty Chems. Corp.*, No. 08-00068-WS-B, at \*4-5 (S.D. Ala. Oct. 23, 2008) (entry of a *Lone Pine* Order was unwarranted where the plaintiffs produced basic factual evidence about their claims, that much of the evidence and arguments on causation would be substantially the same for all plaintiffs, that the case should instead proceed with a test group, and that the use of a *Lone Pine* order would not advance the goal of focusing the parties' attention and efforts on the efficient resolution of the test case); *Morgan v. Ford Motor Co.*, No. 06-1080 (JAP), 2007 WL 1456154, at \*9-10 (D. N.J. May 17, 2007) (holding that a *Lone Pine* order requiring more than 700 plaintiffs to produce affidavits from qualified environmental experts and licensed physicians would be inappropriate, and that a phased discovery process, employing an initial round of bellwether trials, would be followed instead); *In re 2004 DuPont Litig.*, 2006 WL 5097316, at \*2 (E.D. Ky. Mar. 8, 2006) (adoption of a *Lone Pine* order would be premature where the information that the defendants sought could be obtained through the ordinary process of written discovery).

The procedures already put in place *by this Court* are effectively managing this proceeding. Indeed, there are less than 300 cases currently on the docket, there are existing fact sheet requirements,<sup>2</sup> and GSK can point to no significant problem here that would even come close to necessitating the use of a *Lone Pine* order.

The current system has effectively managed this litigation by requiring plaintiffs to substantiate their claims through production of threshold information, fact sheets and key medical records. When plaintiffs are unable to meet these requirements, GSK can and has taken advantage of these mechanisms

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<sup>2</sup> Plaintiffs who file a case are required to complete a detailed Fact Sheet. The Fact Sheet requires plaintiffs to provide information about their claim, Avandia prescription history, medical background, history of medication use, personal and family information. In addition, the Fact Sheet requires plaintiffs to produce medical records and provide executed authorizations that allow GSK to collect plaintiffs' medical records and bills, employment records, and other records.

to achieve dismissals of cases. Contrary to GSK's assertions, these dismissals are not evidence of a system that is broken, but one that is working.

If plaintiffs were each required, under GSK's proposal, to obtain and provide individualized expert reports, GSK would still need to "analyze" those reports and the medical records on which they are based. There is absolutely no need here to require plaintiffs to go to the expense of providing a physician report in addition to the existing discovery requirements – this report adds nothing other than an additional hurdle of burden and expense on each plaintiff. This is not to mention the inevitable challenges to these reports that GSK would muster and the time and costs (including additional expert fees) that would be needed to deal with those challenges, all at a premature juncture in the litigation. That some plaintiffs have not provided fact sheets is an entirely different issue and can be addressed as such without having to deviate from the rules.

Moreover, as the Court is aware, as these cases proceed toward trial, both parties have been and will be required to issue expert reports. There is no legitimate reason to depart from the ordinary process and frontload that requirement, effectively and unfairly modifying the ordinary rules and sequence governing discovery, expert reports, and summary judgment to plaintiffs' disadvantage. *See In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, Order at p.2 (M.D. Fla. Nov. 16, 2007) (denying motion for entry of *Lone Pine* order as "premature"). *Lone Pine* orders are the very rare exception, not the rule.

Given the above, the "balance between efficiency and equity" that *Lone Pine* orders purportedly are intended to restore, *see In re Vioxx Prods. Liab. Litig.*, 557 F. Supp. 2d 741, 744 (E.D. La. 2008), is already being attained at this stage of the litigation.

As GSK has pointed out repeatedly to the Court, GSK has resolved many, many cases, incidentally without the need for any *Lone Pine* order. Finally, there has not been an Avandia trial to date, rendering GSK's request highly premature.

**B. The Paxil Order is Very Different.**

In the Paxil litigation, the very limited *Lone Pine* order issued -- far different than the one GSK seeks here -- was under very different circumstances. For example, two cases actually went to trial (one to verdict), and scores more advanced very close to trial before being settled. Further, and more importantly, the Paxil order only applies to “cases in which the injury claimed is not currently identified or associated with Paxil use.” Here, by contrast, GSK wants the order to apply to all cases, even where the injuries clearly have been associated with Avandia use.

Perhaps when bellwether trials are concluded, and the remaining parties have had the opportunity to consider a more global resolution of the entire litigation, the Court may wish to revisit this issue. But, at this time, no such order is warranted or necessary. Removing the safeguards of the rules of civil procedure and requiring the expenditure of vast sums of money at this point is simply unfair to those plaintiffs who have not had the benefit of rulings and trials to guide their decisions.

**III. This case is distinguishable from those cases in which a *Lone Pine* order has been entered.**

As the *Vioxx* court carefully observed, “*Lone Pine* orders may not be appropriate in every case, and even when appropriate, they may not be suitable at every stage of the litigation.” *Vioxx*, 557 F. Supp. 2d at 744. The *Lone Pine* order in that MDL was issued only after: (1) the case had been litigated in the MDL court for seven years; (2) after twenty bellwether trials had been held (six in the MDL and fourteen others in state courts throughout the country); and, (3) the majority of cases had been resolved via a master settlement plan. *Id.* In fact, the order applied only to cases not participating in that plan. *Id.* at 742.

The order entered in the *Bextra/Celebrex* litigation followed this same pattern. See Paul D. Rheingold, *Litigating Mass Tort Cases* § 8:27.50 (observing that, in entering a *Lone Pine* order in *Bextra/Celebrex*, the district court “was influenced by evidence it already had that these were weak cases

and that their resolution was standing in the way of a global resolution of the remaining Bextra cases that were conjoined in the MDL.”). The cases in this MTP are far from such a procedural posture.

### CONCLUSION

The system has not broken down in this case, and it therefore need not be “fixed” by GSK’s proposed order – one that alters the playing field, intimidates litigants and their counsel, and pointlessly increases the costs and burdens on plaintiffs. This is nowhere near the type of unmanageable circumstance that has existed in the few cases where such orders have been entered. To the contrary, this case is a working model of how mass tort pharmaceutical litigation can be effectively managed using the standard tools and mechanisms available to the parties and the Court, without the need to resort to unconventional, and potentially risky, measures, such as GSK now proposes.

Moreover, even if it seems like a “good idea” from GSK’s perspective, the order is not allowed by any existing Pennsylvania Rule of Civil Procedure. The Court should not allow defendants to change the rules, or, more precisely, to create rules that do not exist.

Respectfully submitted,

/s/Rosemary Pinto  
Rosemary Pinto

DATED: January 20, 2011

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**IN THE COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY, PENNSYLVANIA**

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**IN RE: AVANDIA LITIGATION** : **February Term, 2008**

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**Case No. 2733**

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**THIS DOCUMENT RELATES TO ALL** :  
**ACTIONS** :

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**ORDER**

AND NOW, this                      day of                      , 2011, in consideration of the  
MOTION of Defendant GlaxoSmithKline LLC's Motion for a *Lone Pine* Case Management Order and  
Plaintiff's response hereto it is ORDERED that the Defendant's Motion is DENIED. Failure to comply  
with the terms of this Order will result in dismissal with prejudice.

BY THE COURT:

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Sandra Mazer Moss, J.

**CERTIFICATE OF SERVICE**

I hereby certify that on January 20, 2011, I electronically filed Plaintiff's Opposition to Defendant GlaxoSmithKline LLC's Motion for a "LONE PINE" Case Management Order, and it is being served this day on all counsel of record via transmission of Notices of Electronic Filing generated by the Civil Electronic Filing System on the following Defendant's Liaison Counsel:

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/s/ Rosemary Pinto  
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Rosemary Pinto

Dated: January 20, 2011

VERIFICATION

I, Rosemary Pinto, verify that I am the Attorney in this matter and that upon my knowledge or information and belief the facts set forth in the forgoing Plaintiff's Motion in Opposition to Defendant GlaxoSmithKline LLC's Motion for a "LONE PINE" Case Management Order hereto are true and correct. This statement is made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities.

\s\ Rosemary Pinto  
Rosemary Pinto, Esquire