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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	
FOSAMAX PRODUCTS LIABILITY LIGATION	MASTER FILE
This Document Relates to All Actions	1:06-MD-1789 (JFK)

PLAINTIFFS STEERING COMMITTEE'S MEMORANDUM OF AUTHORITIES IN OPPOSITION TO DEFENDANT MERCK'S MOTION FOR ENTRY OF *LONE PINE* ORDER

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COMES NOW THE PLAINTIFFS STEERING COMMITTEE, by and through Lead Counsel of Record, and files this Memorandum of Authorities in Opposition to Defendant Merck's Motion for Entry of a *Lone Pine* Order. For the following reasons, this Court should (1) deny Defendant Merck's motion for entry of a *Lone Pine* order, (2) announce a date certain on which the Court will present its suggestion of remand to the Judicial Panel on Multi-District Litigation, and (3) direct the parties' respective negotiating committees to re-engage in global settlement discussions with Special Settlement Master John Feerick for a period of no less than sixty (60) days prior to the date certain on which the Court will present its suggestion of remand to the JPML.

ARGUMENT AND CITATIONS TO AUTHORITY

I. THIS COURT SHOULD REJECT DEFENDANT'S REQUEST FOR THE COURT TO WIELD THE ABERRANT "LONE PINE" CUDGEL IN AN EVEN MORE ABERRANT FASHION.

Defendant Merck has proposed to this Court that it utilize an aberrational procedure in an even more aberrant set of circumstances. Because the Case Management Orders and discovery tools already in place ensure that Defendant and the Court are on notice of who is being sued for what injury and for what medication, and because there is settlement in place or on the near horizon, this Court should reject Defendant's request for a "Lone Pine" order.

A. The "Lone Pine" Procedure Is an Aberration Which, When Utilized, Is Utilized Only in Situations Very Dissimilar to the Fosamax MDL.

Despite Defendant's characterization of a *Lone Pine* order as a valuable and oft-utilized procedure, *Lone Pine* orders are without question the rarest of exceptions in MDLs. Further, there is no MDL *Lone Pine* order that Defendant cited which predated a mass settlement program

through which the majority of the MDL cases were settled. Defendant cites six MDL proceedings (Avandia, Baycol, Bextra/Celebrex, Rezulin, Vioxx, and Zyprexa) in which courts entered a *Lone Pine* order, but the six orders cited by Defendant are dwarfed by the volume of MDL proceedings in which a *Lone Pine* or functionally equivalent case management order did not issue.[1] In all of the cases cited by Defendant in which a *Lone Pine* order was entered, the order was entered only after: (1) the plaintiffs consented to failed to object to the entry of such an order; (2) it became clear the pleadings were deficient in providing notice to the defendants; or (3) a mass settlement program was already underway. *See Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000) ("Neither the [100] defendant[s] nor the court was on notice from plaintiffs' pleadings as to how many instances of which diseases were being claimed as injuries or which facilities were alleged to have caused those injuries."). One or more of these elements is present in all of the cases cited by Defendant, and none is present in the Fosamax MDL.

For ease of reference, the PSC has summarized each of the federal cases cited by Defendant in its memorandum of authorities. This Court can readily see that none of these cases are similar to the Fosamax MDL:

Acuna v. Brown & Root, Inc., 200 F.3d 335 (5th Cir. 2005)

- 1,600 plaintiffs sued over 100 defendants for a range of injuries spanning more than 40 years.
- "Neither the defendants nor the Court was on notice from plaintiffs' pleadings as to how many instances of which diseases were being claimed as injuries of which facilities were alleged to have caused those injuries." Id. at 340.

In re Avandia Mktg., Sales Practices and Prods. Liab. Litig., 2010 WL 4720335 (E.D. Pa. 2010)

- *Lone Pine* order issued only after GlaxoSmithKline initiated its mass settlement program six months earlier. (Jeff Feeley and Trista Kelly, *Glaxo Said to Pay about $60 Million in First Avandia Heart-Risk Settlement*, BLOOMBERG NEWS, May 11, 2010, Exh. A hereto.)

- "Physician Certification" was not a Rule 26 expert report requirement; further, Court specifically exempted from fact or expert discovery any physician completing a physician certification solely because of his or her role in completing the certification.

Baker v. Chevron, USA, Inc., 2007 WL 315346 (S.D. Ohio 2007)

- Plaintiffs filed no opposition to the "Lone Pine" order and, thus, it was entered without opposition. (See partial docket sheet for 1:05-cv-227, S.D. Ohio, Exh. B hereto.)

In re Baycol Prods. Liab. Litig., 2004 WL 626866 (D. Minn. 2004)

- At time of entry of "Lone Pine" order, Bayer had previously announced to the MDL and to its shareholders that it had engaged in a mass settlement program, spending at that time approximately $872 million, in its effort to "agree on fair compensation for anyone who experienced serious side effects from Lipobay/Baycol on its own initiative and without acknowledging any legal liability." (Bayer Group Stockholders' Newsletter 2004, Interim Report for the First Quarter of 2004, p. 7, Exh. C hereto.)

- Further, the PSC and the Defendant submitted the subject case management order to the Court as unopposed. See MDL No. 1431, Pretrial Order 102 and Exhibit, at: http://www.mnd.uscourts.gov/MDL-Baycol/orders-minutes.shtml, Exh. D hereto.)

In re Bextra and Celebrex Mktg. Sales Practices and Prods. Liab. Litig., Pretrial Order No. 29 (N.D. Cal. 2008)

- Several months before the "Lone Pine" order was put in place by the MDL Court, Pfizer had already commenced its massive settlement program. Beginning in May 2008, Pfizer began paying approximately $200,000.00 per Bextra case and $40,000.00 to $50,000.00 per Celebrex case. Pfizer then began a mass settlement program which, by October 2008, resulted in settlement of approximately 90% of the known personal injury claims involving Bextra and Celebrex. (Nathan Koppel and Heather Won Tesorio, *Pfizer Settles Lawsuits Over Two Pain Killers*, WSJ.Com, May 3, 2008, Exhibit E hereto; Pfizer, *Pfizer Reaches Agreements in Principle to Resolve Litigation Involving Its NSAID Pain Medications*, BUSINESS WIRE, October 17, 2008, Exhibit F hereto.)

Jorgensen v. Cassiday, 320 F.3d 906 (9th Cir. 2003)

- Did not involve "Lone Pine" at all

Landry v. Air Line Pilots Ass'n Int'l AFL-CIO, 901 F.2d 404 (5th Cir. 1990)

- Did not involve "Lone Pine" at all

In re Rezulin Prods. Liab. Litig., MDL No. 1348 (S.D.N.Y. April 7, 2005)

- By the time of the April 2005 case management order referenced by Defendant, Pfizer had already been engaged in a mass settlement program with respect to its drug, Rezulin. The mass settlement program began at the end of 2003 and continued into 2004. (Pfizer, Inc., 2004 Financial Report, pp. 19, 24, attached hereto as. Exh. G.)

- Thus, the resulting pretrial order attached to Defendant's memorandum concerned certain non-settling plaintiffs, and plaintiffs with cases involving "silent" liver injury, or non-liver injury cases.

Steering Comm. v. Exxon Mobil Corp., 461 F.3d 598 (5th Cir. 2006)

- Did not hold anything with regard to *Lone Pine* orders Rather, the court merely mentioned in passing a *Lone Pine* order in a footnote to an order affirming the denial of class certification. Id. at 604 fn. 2.

In re Vioxx Prods. Liab. Litig., MDL No. 1657 (E.D. La. November 3, 2007, May 30, 2008, and July 6, 2009)

- The 2008 and 2009 orders referenced by Defendant were issued only after it was jointly announced on November 9, 2007, that Merck had agreed to pay $4.85 billion to resolve Vioxx-related claims in which a claimant has suffered a heart attack, sudden cardiac death, or stroke. (Nov. 9, 2007, Press Release: *Merck Settles Thousands of Vioxx Claims for $4.85 Billion*, Exh. H hereto.)

- The November 9, 2007, Pretrial Order No. 28 issued by District Judge Eldon Fallon was issued on the same day and in concert with the parties' announcement concerning the $4.85 billion settlement.

In re Zyprexa Prods. Liab. Litig., MDL No. 1596 (E.D.N.Y. June 2, 2010)

- On June 9, 2005, Eli Lilly announced the beginning compensation of approximately $700 million to settle three-quarters of the liability claims concerning its drug, Zyprexa. (PRWEB: *Eli Lilly Agrees to Pay Approximately $700M in Zyprexa Settlement*, June 15, 2005, Exh. I hereto.) Through 2005 and the end of 2006, Eli Lilly ultimately agreed to pay at least $1.2 billion to 28,500 people who were injured by the drug. (Alex Berenson, *Lilly Settles with 18,000 Over Zyprexa*, NEW YORK TIMES, January 5, 2007, Exh. J hereto.)

- This 2010 mop-up order specifically identified certain cases that were straggling in the Zyprexa MDL some five years after the mass settlement program was announced in the Zyprexa MDL.

The non-binding cases cited by Defendant are exceptional and unlike the case before this Court. The source case for the order Defendant proposes, *Lore v. Lone Pine Corp.*, No. L. 33606-85, 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986), is not binding on this Court, and has absolutely no precedential value, even in the state court system from which it issued. This is because unpublished New Jersey decisions are, by formal rule, bereft of precedential value. N.J. RULES OF COURT § 1:36-3.

Notwithstanding the fact that the original *Lone Pine* order has no precedential value, it was rendered under completely different and extreme circumstances. Plaintiffs sued "some 464 defendants," including the operator of a landfill and generators and haulers of toxic materials. *Lone Pine*, 1986 WL 637507, at *2. Plaintiffs, some of whom lived 20 miles from the landfill, alleged a variety of injuries including depreciation in property value and personal injuries ranging from allergies to skin rashes. *Id.* at *2-3. Likewise, *Acuna*, the only federal court of appeals case to embrace the entry of a *Lone Pine* order, involved similarly exceptional circumstances. In *Acuna* "approximately one thousand six hundred plaintiffs su[ed] over one hundred defendants for a range of injuries [related to uranium mining at a number of different locations and] occurring over

the span of up to forty years." *Acuna*, 200 F.3d at 340. "Some plaintiffs worked in uranium mines and processing plants, while others alleged exposure to radiation or uranium dust or tailings through contact with family members who worked in the mines or through environmental factors such as wind and groundwater." *Id.* at 338. Due to the exceedingly diverse theories of recovery and the huge number of defendants, the court was concerned that the pleadings did not provide sufficient notice to defendants or the court. *Id.* at 340. Quite obviously that is not the case here. Rather, the JPML's charge to this Court involved one product (Fosamax) and one Defendant (Merck). Thus, insofar as Defendant is concerned, Plaintiffs' claims are based on a single product, Fosamax, and chiefly one Defendant: Merck.

Further, each and every one of the MDL orders which Defendant cites as authority for issuance of a "Lone Pine" order already had in place a mass settlement program.

In *In re Baycol Products Liability Litigation*, MDL No. 1431 (D. Minn. Mar. 18, 2004), Bayer had settled thousands of plaintiffs' cases prior to the entry of the *Lone Pine* order; therefore, the order served as a device at the ***end*** of the litigation to cull through the remaining cases. The same is true for *In re Bextra & Celebrex Marketing Sales Practices & Products Liability Litigation*, MDL No. 1699 (N.D. Cal. Aug. 1, 2008). When the *Lone Pine* order was entered in *Bextra*, Pfizer had already settled with many individual plaintiffs, significant discovery had occurred, including expert and scientific testimony, and the remaining litigants were engaged in settlement negotiations and pretrial preparation. In *In re Rezulin Products. Liability Litigation*, 441 F.Supp. 2d 567, 569-570 (S.D.N.Y. 2006), a *Lone Pine* order was entered after the initiation of a massive settlement program and after one theory of general causation relied on by some plaintiffs had been excluded under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579,

113 S. Ct. 2786 (1993). The *Lone Pine* order in *Rezulin*, again occurring well into the litigation and discovery process, was intended to determine whether plaintiffs who had relied on "the silent injury" theory still had "good grounds . . . to continue prosecuting [their] claim[s] in light of the *Silent Injury* and other decisions." 441 F. Supp. 2d at 570.

In *In re Vioxx Products Liability Litigation*, 557 F. Supp. 2d 741, 744 (E.D. La. 2008), the case had been "in state courts for over seven years and [the MDL court] for over three years" and "much discovery [had] taken place" prior to the entry of the *Lone Pine* order. The court in *Vioxx* stressed that "*Lone Pine* orders may not be appropriate in every case and, even when appropriate, may not be suitable at every stage of litigation. . . . [I]n the present case, a *Lone Pine* order may not have been appropriate at an earlier stage before any discovery had taken place . . . ." *Id.* Further, as the initial "Lone Pine" order in the Vioxx MDL was issued - - not coincidentally - - on the same day the $4.85 billion settlement was jointly announced, the "Lone Pine" order in Vioxx was implemented to ensure that the very few remaining cases that did not participate in the MDL settlement were handled in a pre-stated fashion.

While Defendant cited the Vioxx MDL proceedings as good precedent for the imposition of the *Lone Pine* procedure, it neglects to stress to the Court that the *Lone Pine* order in the Vioxx MDL came **after** a global resolution was instituted which ensured the settlement and disposition of 95% of the cases in that MDL. Thus, the Vioxx MDL's *Lone Pine* procedure was a post-settlement mop-up procedure utilized to address those cases which either were not eligible for compensation through the MDL settlement program or which had opted out of participation in the MDL settlement program. There is no MDL settlement program in Fosamax. Thus, this MDL is not ripe for the entry of a *Lone Pine* order. If there were an MDL settlement in Fosamax, then the

Lone Pine procedure which would have much more utility for addressing those cases which did not fit within the settlement or chose to opt out of the settlement program. However, no such settlement is on the horizon and, thus, there is no compelling reason to consider the imposition of a *Lone Pine* order on patients who have not had the option of participating in the MDL settlement program.

Ultimately, the cases cited by Defendant establish only that a tiny fraction of courts have sometimes issued *Lone Pine* orders where (a) plaintiffs had sued dozens, if not hundreds, of unrelated defendants based on disparate theories of injury; (b) plaintiffs agreed to or did not oppose the entry of a case management order; or (c) where the mass settlement program had been agreed to and instituted. This litigation falls into none of those categories.

In the six MDL cases cited by Defendant, it bears mentioning that in all of those (*Rezulin, Bextra/Celebrex, Vioxx, Avandia, Zyprexa*, and *Baycol*), there had already transpired mass settlement plans and the *Lone Pine* orders were addressed to those cases that had opted out or otherwise not participated in the settlement procedure. This is not the situation before this Court. There is no settlement plan in place. The MDL settlement discussions have impassed and there are no MDL settlement discussions ongoing. There is no basis for this Court to create an extraordinary procedure as suggested by Defendant.

B. "Lone Pine" Departs from the Federal Rules of Civil Procedure and Should Be Used Sparingly, If at All.

While Defendants identifies the six MDLs for which mass settlements had been announced as its most persuasive authority for this Court, it neglects to mention that the

overwhelming majority of presiding MDL transferee courts[1] do not issue *Lone Pine* orders. It cannot be overlooked that the *Lone Pine* decision was not premised upon federal procedure. Rather, it was a New Jersey state trial court order[2] which has not been adopted by the Second Circuit Court of Appeals. Further, a "*Lone Pine* order should issue only in an exceptional case and after the defendant has made a clear showing of significant evidence calling into question the plaintiffs' ability to bring forward necessary medical causation and other scientific information." *In re Digitek Prod. Liab. Litig.*, 264 F.R.D. 249, 258 (S.D.W.Va. 2010) (cit. and internal quot. omit). Accordingly, as no case-specific discovery (other than plaintiff fact sheets) has taken place in the hundreds of cases outside the trial pool, it would be fundamentally unfair to require the litigants to operate outside the normal federal procedures and acquire and produce case-specific expert reports before the commencement (and close) of fact discovery in their individual cases. "Resorting to crafting and applying a *Lone Pine* order should occur only 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 this litigation." *Id.* at 259.

Tellingly, Defendant does not seek to conduct any case-specific discovery beyond the case-specific fact discovery that has already taken place in the trial pool cases. Rather, it asks this Court to ignore the Rules of Federal Procedure for discovery and dispositive adjudication and short-circuit the discovery and pre-trial process. Additionally, and perhaps most surprisingly, Defendant asks this Court to have Special Master John Feerick - - who was consented to by the

[1] By this author's count, more than 99.9% of MDL transferee courts have not implemented *Lone Pine* orders.

[2] *Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Superior Ct. Law Div. 1986).

parties as the Special Settlement Master - - to serve as the "Lone Pine" referee. The appointment was made pursuant to Federal Rule of Civil Procedure 53(a): i.e., consent of the parties. Rule 53(a) permits the Special Master to perform duties consented to by the parties. The refereeing of Merck's "Lone Pine" cudgel by the Special Master - - or any Special Master - - was and is not consented to by the Plaintiffs Steering Committee. The efforts of Dean Feerick should be directed to settlement, not summary case disposition.

The fundamental problem with *Lone Pine* orders is that they emanate from procedural rules that do not specifically grant the authority for courts to issue such orders. It is not surprising, then, that Defendant cites not a single case from the Second Circuit Court of Appeals in support of tits Motion. That is because no such case exists. Indeed, despite Defendant's arguments to the contrary, *Lone Pine* orders are very much the exception, rather than the rule.

Instead of resorting to amorphous concepts such as inherent case management authority to justify a *Lone Pine* order, the Court should first look to existing procedural devices to address the issues raised, and should not ignore existing procedural rules and safeguards merely because mass tort cases are "different" from typical tort cases. Indeed, with no real guidelines to control the parameters and scope of *Lone Pine* orders, they are fertile ground for inconsistency, prejudice, and *ultra vires* action. *See* John T. Burnett, Lone Pine *Orders: A Wolf in Sheep's Clothing for Environmental and Toxic Tort Litigation*, 14 J. Land Use & Envtl. L. 53, 75-76 (1998).

More specifically, such *Lone Pine* orders are inherently unfair and prejudicial to Plaintiffs for at least two reasons: (1) they serve as improper, untimely substitutes for summary judgment motions, and (2) they ignore other existing procedural safeguards and rules.

First, Defendant's *Lone Pine* request is the functional equivalent of the Defendant's filing a "no evidence" summary judgment motion long before discovery is complete in this litigation. In other words, little difference would result from Defendant filing a summary judgment motion, asserting that Plaintiffs have no evidence of injury, instead of their *Lone Pine* motion.

As with the grant of a *Lone Pine* order, such a summary judgment motion would put Plaintiffs to their proof, forcing them to obtain expert and physician reports posthaste to overcome the motion. However, with a *Lone Pine* Motion, Defendant would not be required to further participate in discovery at all, much less produce their own expert reports. *See Morgan v. Ford Motor Co.*, 2007 WL 1456154 at *7-8 (D.N.J. 2007). In *Morgan*, the court refused to grant defendants' *Lone Pine* motion because "[a]ny discovery must not be one-sided. . . . Defendants are not entitled to file what amounts to a summary judgment motion without first allowing the party opposing the motion a chance to conduct discovery." *Id.*

As Defendant know, significant due process concerns prohibit such summary judgment practice, which is why summary judgment is appropriate only "after adequate time for discovery." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Contrary to the self-serving procedure Defendant proposes, summary judgment motions under Federal Rule of Civil Procedure 56 are intended to impose procedural safeguards that adequately protect the interests of ***all*** parties, while still addressing alleged factual deficiencies that *Lone Pine* orders are thought to remedy. In the ordinary course of pharmaceutical litigation, defendants typically move for summary judgment under Rule 56 after all discovery has been conducted. At that point, plaintiffs are required to offer evidence, expert witness testimony, and set forth specific facts that show a genuine triable issue of fact. Issuing a *Lone Pine* order, on the other hand, shortcuts the summary judgment process by

demanding that Plaintiffs prove their *prima facie* cases prematurely and without the benefit of full or even reciprocal discovery by Defendant.

The Supreme Court of the United States has addressed the overall benefits of the existing procedural rules in *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002). The Court held that "under a notice pleading system, it is not appropriate to require a plaintiff to plead facts establishing a prima facie case." *Id.* at 511. "This simplified notice pleading standard relies on liberal discovery rules and summary judgment motions to define disputed facts and issues and to dispose of unmeritorious claims." *Id.* at 512. The Court held that, with the limited exception of the kinds of cases described in Rule 9(b), requiring prima facie evidence at the pleadings stage would conflict with the notice pleading standard of Rule 8(a). *Id.* at 512-13.

Second, Federal Rule of Civil Procedure 26(a)(2) mandates reciprocal discovery. After pretrial disclosures, all parties are automatically mandated to disclose additional information, including expert witnesses. Although the timing of the disclosures is ultimately within the discretion of the courts, the spirit and letter of the rule requires the parties to exchange expert information simultaneously at least 90 days before the trial date. Fed. R. Civ. P. 26(a)(2) (c). If the evidence is intended solely to contradict or rebut testimony disclosed by another party, then the disclosure must be made within 30 days after the initial disclosure. *Id.* Rule 26 provides that one side should not be accorded the palpable procedural advantage gained by unilateral production of expert reports by its adversary.

All parties are entitled to due process. Appellate courts have held time and again that summary judgment cannot be granted without first affording the party against whom judgment is entered an opportunity to conduct discovery. As a general matter, federal litigation revolves

around the generous and wide-ranging discovery provided by the Federal Rules of Civil Procedure and the Federal Rules of Evidence, which in turn operate from the basic underlying principle that court procedures should be fair to ***both*** sides.

Despite Defendant's claims to the contrary, Plaintiffs have already provided significant case-specific discovery to Defendant in this litigation. Plaintiffs have been required to unilaterally provide and verify extensive medical and non-medical information within a very compressed time period in the form of Plaintiffs' Fact Sheets and records authorizations. The PPF already obligates Plaintiffs to provide great detail regarding the nature of the claims pursued against Defendant. The information in the PPF (and from medical records available to Defendant[2]) establishes the foundational basis for Plaintiffs' prima facie case. As discovery proceeds, Defendant will garner additional case-specific information regarding Plaintiffs in due course.

Thus, there is no "exhaustion" of the normal rules of procedure and, this Court should outright reject Defendant's request for case-specific expert affidavits. So-called *Lone Pine* orders circumvent the established Rule 56 procedure for summary adjudication and is a one-side obligation. This Court should not entertain granting any summary judgment in any case that has not been fully discovered on the case-specifics. In a *Lone Pine* scenario, Defendant would not be required to further participate in discovery at all, much less produce expert reports on the case-specifics of those cases to which the putative order would apply. *See Morgan v. Ford Motor Co.*, 2007 WL 1456154, at **7-8). In *Morgan*, the District Court refused to grant the defendant's *Lone Pine* motion because "[a]ny discovery must not be one-sided. . . . Defendants are not entitled to file what amounts to a summary judgment motion without first allowing the party opposing the motion a chance to conduct discovery." *Id.*

II. THE "LONE PINE" PROCEDURE REQUESTED BY DEFENDANT WILL UNDULY PROLONG THIS MDL AND WILL NOT FACILITATE SETTLEMENT.

It cannot be forgotten what this Court's original charge was: to conduct coordinated pretrial proceedings. This Court has fulfilled that mission. Without any settlement plan in place that would streamline the Court's "Lone Pine" involvement, Defendant now seeks to move this Court into the ceaseless adjudication of case-specific issues, rather than addressing the broad charge entrusted to it by the Judicial Panel on Multidistrict Litigation. In addition to the reasons stated in § I, *supra*, in the absence of a mass settlement program, this Court should reject Defendant's attempt to move it beyond its duties under 28 U.S.C. § 1407.

A. This Court Has Fulfilled Its Charge Under 28 U.S.C. § 1407.

On August 16, 2006 - - more than six years ago - - the Judicial Panel on Multi-District Litigation centralized the Fosamax litigation before this Court and charged it with the duty to accomplish the common, centralized litigation issues, per 28 U.S.C. § 1407. As set forth in this Court's CMO No. 17, the parties have: exchanged and reviewed millions of pages of documents; taken dozens of depositions of Merck employees; conducted expert discovery and numerous *Daubert* hearings; and tried several bellwether cases. Deposition discovery against Merck has been closed for more than four years now. The charge of the JPML has been accomplished. All the same, Defendant seeks no end to the MDL.

So what, then, is the end game Defendant envisions? The educational end game already has been achieved from the bellwether trials. Any case can be won, any case can be lost. Both sides have risk through trying cases further. This we now know and this Defendant now knows. Just as with significant overseas military operations, MDLs should have, first, a set of defined

objectives and, second, an exit plan. It is far too easy for "mission-creep" to set in and perpetuate an MDL beyond that which it is set to do: get the pretrial coordinated proceedings completed. The Court and the parties have accomplished what the original CMO's envisioned in this MDL and are now well beyond what the parties and the Court originally envisioned in terms of the length of this MDL. The trial package is fundamentally complete. The Court's exhaustive *Daubert* rulings are established. This MDL is no longer in the phase of coordinated "pretrial proceedings". It is clearly in the phase of plaintiff-specific issues and Defendant seeks to ever-expand that phase.

Through filing its "Lone Pine" motion, Defendant apparently and finally has acknowledged the end of the MDL is nigh. Defendant fails to acknowledge, however, that if this Court were to determine that a *Lone Pine* order is warranted, any such order typically is coupled with the end of the MDL either through a global settlement or the remand of the cases to the several District Courts of proper venue. Through the special master process, Defendant has made it clear that it will not fund adequately a global resolution of the MDL. Therefore, as this MDL is presently postured, a global settlement does not appear to be a likely event on the horizon.

The average age of Fosamax plaintiffs is 71 years old. Dozens of plaintiffs in this MDL have died from natural causes during the pendency of this MDL. This Court should reject any attempt by Defendant to further extend the timespan of this MDL beyond the 6+ years. Accordingly, this Court should reject Defendant's request that this Court engage in the case-specific adjudication procedure that Defendant proposes and which so many MDLs have refused to employ, absent a mass settlement.

B. Defendant Has Grossly Expanded the List of Cases to Which the Proposed

"Lone Pine" Procedure Would Apply.

In its original *Lone Pine* letter to the Court in January 2010, Defendant to funnel out cases that did not identify "osteonecrosis of the jaw" or "osteomyelitis" in their Plaintiff Profile Forms. (Exh. K hereto.) Defendant now seeks to go way beyond that initial approach and request that the Court require expert reports from each and every case pending in this MDL - - before the conduct of any case-specific discovery and with no prospect of a mass settlement in this MDL. This Court should reject Defendant's request, both as originally requested in January 2010 and now as greatly expanded in 2012.

In support of this, Defendant cites the Avandia MDL *Lone Pine Order* - - which like the others cited in Defendant's January 2010 letter only came after the announcement of a mass settlement of most cases in the MDL. As the Court will see from reviewing the Avandia MDL order, the Avandia MDL did not do what Defendant seeks this Court to do here. Rather, the Avandia MDL had an exhaustive list of symptoms or conditions that a reviewing physician would certify the particular plaintiff had.

As this Court is all too aware, "osteonecrosis of the jaw" had no ICD-9 diagnostic code until 2007 and a multitude of terms described the symptoms now consistent with the condition. For instance, when Defendant was searching its adverse event database for osteonecrosis of the jaw events, it utilized a preferred term "PT" and lower level term "LT" list that included scores of symptoms descriptive of osteonecrosis of the jaw. (See 07/-24-06 Olivero-Vilardo email re "ONJ Query", MRK-FOSMDL-FIO-00002122-00002124, Pl. Exh. 1.2233, Exh. L hereto.) Thus, if this Court were to seriously consider a *Lone Pine* order, the certification should go beyond just "osteomyelitis" and "osteonecrosis of the jaw" and the plaintiff-specific query should include - -

at the very least - - those surrogate terms Defendant itself used, in light of the absence of a diagnostic code for osteonecrosis of the jaw when most of these cases occurred.

In its letter of January 27, 2010, attached hereto as Exhibit K, Defendant proposed a *Lone Pine* procedure only for those cases which allege an injury other than osteonecrosis of the jaw or osteomyelitis of the jaw: "Merck therefore requests that the Court institute a procedure which would require each Non-ONJ Case Plaintiff (*i.e.,* any Plaintiff who does not allege ONJ or osteomyelitis in his or her verified PPF) to file and serve a supporting expert opinion within a reasonable period of time that contains a certification by an appropriate medical expert authenticating that there is a medical/scientific basis for the allegation that Fosamax® caused the injury." (Exh. K, p. 2.) On January 3, 2011, Defendant reiterated its request for a *Lone Pine* order for cases which "involve alleged jaw injuries *other than* ONJ or osteomyelitis." (Exh. M hereto, p. 2.) In Defendant's proposed CMO presently before the Court, Defendant requests this Court to submit each and every MDL Plaintiff to Defendant's now proposed *Lone Pine* procedure of having each plaintiff submit a Rule 26(a)(2) expert report before the first bit of case-specific discovery is done.

This proposed procedure would require each and every plaintiff to provide an expert report before any fact discovery is done in those cases (other than the submission of the written Plaintiff Profile Form and signed medical record authorizations) in contravention of the procedures set forth in the Federal Rules of Civil Procedure. Thus, this Court should outright reject Defendant's request for case-specific expert affidavits.

C. In the Event of the "Lone Pine" Procedure Desired by Defendant, the Plaintiffs Would Be Entitled to Re-Open General Discovery, and Discovery on the Non-ONJ or Non-Osteomyelitis Causation Issues.

To that issue, and accordingly, if Defendant is serious about requiring expert disclosures in specific cases - - which have conducted no case-specific discovery pursuant to this Court's Case Management Orders (most of which were negotiated by the parties) - - then this Court should reopen discovery and let the PSC take additional limited discovery on the science of other jaw bone injury cases.

Defendant has known for several years that Fosamax is inducing jaw injuries short of ONJ. During the trial of the Shirley Boles case, the PSC presented a heavily redacted document in which a Merck scientist admitted the existence of a relationship between Fosamax and non-ONJ dental injuries. In its MK-0822 Executive Summary, marked as Exhibit 1.0702 for the Shirley Boles trial, Defendant admits the following:

> During the course of studying WAES [Worldwide Adverse Event System] narratives, we appear to have detected a new pattern of dental adverse events in the Fosamax program.
> . . .
>
> While doing surveillance of dental adverse events related to osteonecrosis of the jaw (ONJ) in the Fosamax program through the WAES program, CRMSS [Clinical Risk Management and Safety Surveillance] personnel have independently detected a significant new pattern of dental AE's that are not similar to typical ONJ. The pattern is characterized by accelerated jaw deterioration/degradation; extreme jaw bone loss; loosening of teeth, localized jaw pain; occurrence of periodontal problems (dental infection, tooth abscess) in individuals who often previously had no complaints; empty tooth sockets, secondary to spontaneous tooth loss; atraumatic tooth avulsion; and spontaneous implant loss. . . .
>
> It took a long time for this pattern to become quantitatively interesting, but it appears to have doneso [sic]. . . .
> . . .
>
> d) The individuals who stated that the dental AE's were not *thought to be drug-related* could not possibly have known what we know from the Fosamax program.

(Exh. 1.0702, italics in original, attached hereto as Exh. N.)

If this MDL is going to proceed for many more months, fact discovery additionally should re-open as new scientific literature on the topic of Fosamax and its relationship to osteonecrosis of the jaw is published each week. Thus, if Defendant is serious about requiring expert disclosures in specific cases - - which have conducted no case-specific discovery pursuant to this Court's Case Management Orders (most of which were negotiated by the parties) - - then this Court should reopen discovery and let the PSC take additional limited discovery on the science of the non-ONJ jaw injury cases, as well as updated liability discovery as no such discovery in this MDL has been permitted for the last four-and-a-half years.

D. If this Court Desires to Enter a "Lone Pine" Order, it Should Do So Only after Announcing Suggestion of Remand of the MDL and Then Only as to Non-Osteonecrosis or Non-Osteomyelitis Cases.

If this Court wishes to enter a "Lone Pine" order, it should (1) limit it to only those cases that do not identify Osteonecrosis of the Jaw or Osteomyelitis of the Jaw in their Plaintiff Profile Form and (2) only in conjunction with the announcement of a date certain for suggestion of remand of all other cases pending in this MDL. The MDL No. 1789, the average age of which is 71 years old, already have been in this MDL for two more years than anyone originally envisioned:

> So this is the first conference since my former colleagues and friends -- or maybe I should say my friends and former colleagues, I hope, is more accurate instead of former colleagues -- assigned to me MDL 1789, which is denominated with the usual in re tricky title, In Re Fosamax Products Liability Litigation. And as I was looking over the papers, I was struck by the docket number, 1789. What was 1789? First Constitution was in 1788. 1789 was the year George Washington became President. And what did he say? I don't want to be President for life. I don't want to be a king. Now, I have a lifetime appointment, but I don't want 1789 to last as long or even as long as President Washington's first term.

(09/14/06 hrg. transcript, page 3, lines 3 through 15, Exh. O hereto.)

It is certainly telling for this Court to consider something that Defendant did not put in its papers. Defendant has settled, for cash payment, two cases, one which was pending in State Court in Escambia County, Florida, and one which was pending in State Court in Montgomery County, Alabama. Defendant has not settled one case in this MDL. The remand of cases to their home districts will help to facilitate settlement as Defendant has yet to try a case of a plaintiff in her hometown. If this Court were to consider the entry of a "Lone Pine" order at all, therefore, it should give Defendant what it originally requested but only if it is coupled with the end of the MDL and remand of those cases for which a diagnosis of osteonecrosis or osteomyelitis of the jaw is identified in their PPFs.

As presented above, Defendant's proposed CMO grossly expands the scope of its prior two requests as Defendant now seeks to have this Court invert expert discovery and impose a unilateral Rule 26(a)(2) expert report requirement on all cases in the MDL. Previously, Defendant argued that only those cases not alleging the onset of osteonecrosis of the jaw or osteomyelitis of the jaw should be subjected to the *Lone Pine* order. As addressed in its most recent letter to the Court pertaining to "Lone Pine", Defendant then would have this Court couple that *Lone Pine* process with a decade long remand process in which cases are trickled back to their proper venues. Defendant knows full well that the current average age of the patients in this MDL is **71 years old, that scores of Fosamax plaintiffs have died during the pendency of this MDL,** and that such a slow remand process would work to the significant detriment of those patients. For a company like Defendant that has existed for a hundred years and will exist for hundreds more, the time element is not a concern. It is a concern, however, for humans for whom time of existence is not an abstraction and is not measured in quarterly and annual reports to stockholders.

. Accordingly, if this Court is to issue any type of "Lone Pine" CMO, it should couple it with the substantial end of the MDL, absent a global settlement. This Court should enter a date certain for the remand of the MDL first. Then, with the Special Master having in hand the knowledge that there is a date certain to the end of the MDL, this Court should order the parties to re-engage with Dean Feerick for a period of sixty (60) days prior to the remand date certain entered by this MDL. Such a date-certain approach to the end of the MDL would, in the estimation of the PSC, do more to facilitate the settlement than any bellwether trial or *Lone Pine* order would.

CONCLUSION

For the foregoing reasons, the Plaintiffs Steering Committee respectfully requests this Court to deny Defendant's Motion for Entry of a "Lone Pine" Order.

* * *

RESPECTFULLY SUBMITTED, this 29th day of October, 2012.

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