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SOUTHERN DISTRICT OF NEW YORK

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IN RE: :

FOSAMAX PRODUCTS LIABILITY LITIGATION :  
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No. 06 MD 1789 (JFK)

This document relates to all actions. :  
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OPINION & ORDER

APPEARANCES:

FOR THE PLAINTIFF'S STEERING COMMITTEE:

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**John F. Keenan, United States District Judge:**

Before the Court is Defendant's motion for the Court to enter an order pursuant to Lore v. Lone Pine Corp., 1986 WL 637507 (N.J. Sup. Ct. Law Div. Nov. 18, 1986), requiring all plaintiffs in this MDL to provide facts and materials in support of their claims through expert reports. For the reasons that follow, the motion is granted, with limitations.

## I. Background

Merck has written to the Court on two prior occasions seeking a Lone Pine order. On February 1, 2010, Merck asked the Court to consider entering the order with respect to all "non-ONJ [and non-osteomyellitis] cases," meaning those cases in which Plaintiffs allege a variety of maladies (such as sore and swollen gums, lost and broken teeth, and jaw pain), but not osteonecrosis of the jaw ("ONJ"). In its second request, dated January 3, 2011, Merck reiterated its grounds for a Lone Pine order. Merck again suggested that the order should pertain to all plaintiffs who do not allege ONJ or osteomyellitis, which represented 40% of the docket as of January 2011. Until now, the Court has declined to entertain a motion for a Lone Pine order.

By letter dated September 20, 2012, Merck made its third request for a Lone Pine order. Merck no longer limits its proposed order to plaintiffs who do not allege ONJ or osteomyellitis, but suggests that the Court require every plaintiff to provide (1) a completed Plaintiff Profile Form along with records and an execution of release of medical records; (2) a case-specific expert discovery report from a qualified medical expert attesting that the injury Plaintiff suffered was caused by Fosamax; and (3) a signed statement from

Plaintiff that he or she is willing to proceed with the case upon remand.

Merck argues that given the fact that cases in this MDL are more likely to be dismissed by Plaintiff as they undergo closer scrutiny, a Lone Pine order will ensure that only those cases with qualified plaintiffs remain in this MDL. Merck notes that of the 1,094 cases in this MDL, 138 (13%) have been dismissed. Merck further represents that 11 (31%) of the 35 cases set for case-specific discovery have been dismissed. Finally, Merck states that of the cases that were set for trial, 7 of 12 (58%) were dismissed. (Def. Mem. at 10-11.)

In opposing Merck's motion, the Plaintiff's Steering Committee ("PSC") responds that the Court has fulfilled its mission in this MDL, and rather than initiating "ceaseless adjudication of case-specific issues" through entering a Lone Pine order, the Court should conclude this MDL. (Pl. Opp. at 14.) The PSC urges that this Court should adopt an "exit plan," since the pre-trial proceedings are complete and Merck "has made it clear that it will not fund adequately a global resolution." (Pl. Opp. at 15.)

## **II. Discussion**

### **A. Applicable Law**

Lone Pine orders derive from a 1986 decision of the New Jersey Superior Court in Lore v. Lone Pine Corp., 1986 WL 637507

(N.J. Sup. Ct. Law Div. Nov. 18, 1986). In Lone Pine, the New Jersey court entered a pretrial order that required the plaintiffs to provide facts in support of their claims through expert reports, or risk having their case dismissed. Id., 1986 WL 637507, at \*1-\*3. As one federal court of appeals has noted, "Lone Pine orders are designed to handle the complex issues and potential burdens of defendants and the court in mass tort litigation." Acuna v. Brown & Root Inc., 200 F.3d 335, 340 (5th Cir. 2000).

With increasing frequency, courts overseeing complex pharmaceutical MDLs are using Lone Pine orders to streamline the docket. See In re Avandia Mktg., Sales Practices and Prods. Liab. Litig., MDL No. 1871 (E.D. Pa. Nov. 15, 2010); In re Zyprexa Prods. Liab. Litig., MDL No. 1596 (E.D.N.Y. June 2, 2010); In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab. Litig., MDL No. 1699 (N.D. Cal. Aug. 1, 2008); In re Vioxx Prods. Liab. Litig., MDL No. 1657 (E.D. La. Nov. 9, 2007, July 6, 2009); In re Rezulin Prods. Liab. Litig., MDL No. 1348 (S.D.N.Y. May 9, 2005); In re Baycol Prods. Liab. Litig., MDL No. 1431 (D. Minn. Mar. 18, 2004).

Although no federal rule expressly authorizes the use of Lone Pine orders, federal courts have interpreted Rule 16 of the Federal Rules of Civil Procedure to give the authority to enter Lone Pine orders in complex litigation. See McManaway v. KBR,

Inc., 265 F.R.D. 384, 385 (S.D. Ind. 2009) ("Lone Pine orders are permitted by Rule 16(c)(2)(L) of the Federal Rules of Civil Procedure which provides that a court may take several actions during a pretrial conference, including 'adopting special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems.'" (quoting Fed. R. Civ. P. 16(c)(2)(L))); 35B C.J.S. Federal Civil Procedure § 911 (2009) ("So-called 'Lone Pine orders' are . . . issued under the wide discretion afforded district judges over the management of discovery."); 6A Charles A. Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1525 (2d ed. 1990). Additionally, the Manual for Complex Litigation notes that these orders are "widely used." David F. Herr, Ann. Manual for Complex Lit. § 11.34 (4th ed. 2012).

In evaluating requests for Lone Pine or modified case management orders, courts have found that a number of factors may be relevant, including (1) the posture of the litigation, (2) the case management needs presented, (3) external agency decisions that may bear on the case, (4) the availability of other procedures that have been specifically provided for by rule or statute, and (5) the type of injury alleged and its cause. See In re Digitek Prod. Liability Litig., 264 F.R.D. 249, 256 (S.D. W.Va. 2010).

## B. Application

Upon consideration of the above-listed factors, and mindful of the need to maintain safeguards for plaintiffs, the Court finds that entering a Lone Pine order is appropriate at this stage of the MDL.

First, during its six years in this Court, this MDL has comprised some 1,000 cases. During targeted discovery, Merck produced over 11 million pages of documents and submitted 24 company witnesses to deposition. Additionally, the parties have conducted extensive fact discovery on the 12 cases that were selected for trial. The parties - and the Court - are intimately familiar with the discovery in this MDL.

Accordingly, a Lone Pine order would impose a minimal burden on plaintiffs, as it merely asks them to produce information they should already have. See In re Vioxx Prods. Liab. Litig., 557 F. Supp. 2d 741, 744 (E.D. La. 2008) ("The Court finds that 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.").

Second, given that cases are more likely to result in dismissal once discovery focuses on issues related to causation, the Court has reason to believe that spurious or meritless cases are lurking in the some 1,000 cases on the MDL docket. As Merck points out, more than 50% of the cases set for trial have been

dismissed, and some 31% of cases that have been selected for discovery have been dismissed. Plaintiffs' habit of dismissing cases after both parties have expended time and money on case-specific discovery demonstrates that this MDL is ripe for a Lone Pine order.

Third, whether this MDL culminates in a global or partial settlement, or the remand of cases back to their home districts, a Lone Pine order will boost efficiency. In the event the parties reach a settlement, the elimination of spurious claims will ensure that only plaintiffs with meritorious cases are compensated. If the MDL concludes without settlement, and cases are transferred back to their home districts, Lone Pine will ensure that the home districts receive only viable cases.

The PSC's main argument against entering a Lone Pine order is that it would be aberrational, largely because the parties have not reached a mass settlement. This argument mistakenly assumes that settlement is a necessary predicate for the issuance of Lone Pine orders. The Court can discern no rationale for requiring parties to have reached a settlement - or be on the brink of it - before considering a Lone Pine order. Indeed, the primary purpose of Lone Pine orders is to eliminate meritless cases, which is at best tangentially related to the status of settlement negotiations.

Moreover, the rationale set forth in Lone Pine and its progeny does not militate against entering the order in the absence of a settlement plan. Although settlements had been reached in some of the recent pharmaceutical MDLs in which Lone Pine orders were entered, it has not been deemed a condition precedent. In fact, when the Celebrex court entered the Lone Pine order, it noted, "In terms of the settlement, I don't care. In other words, the fact of the matter is that this order . . . identifies cases that ought to be tried and separates out the cases that ought not to be tried." (Def. Reply at 7.)

### **C. Limitations**

"In crafting a Lone Pine order, a court should strive to strike a balance between efficiency and equity," Vioxx, 557 F. Supp. 2d 741, 744 (E.D. La. 2008). While a Lone Pine order would certainly advance efficiency within this MDL, limiting the scope of the order will effectively safeguard plaintiffs' rights.

As Merck noted in its 2010 letter requesting that the Court consider a Lone Pine order, "It is Merck's position that there is no medical or scientific evidence or opinion that Fosamax® may cause jaw injuries other than ONJ." (Letter of Jan. 27, 2010 at 1.) In its letter dated January 3, 2011, Merck reiterated its position: "[U]nlike the cases involving alleged ONJ or osteomyelitis, the Non-ONJ Jaw Cases . . . have not been

subject to the same level of scrutiny . . . regarding the medical and scientific basis [for their claims.]” (Letter of Jan 3, 2011 at 2.)

Merck now advocates for a Lone Pine order to apply to every case in the MDL, including those that involve allegations of ONJ or osteomyellitis, yet does not provide a sufficient basis for such a drastic expansion in scope. While Merck has certainly demonstrated that specific discovery is likely to eliminate a significant number of meritless claims from this MDL, the evidence also suggests that these meritless claims will be found chiefly among plaintiffs who have not alleged ONJ or osteomyellitis. Therefore, limiting the Lone Pine order to only non-ONJ and non-osteomyellitis plaintiffs will target potentially spurious claims without imposing undue obligations upon other plaintiffs.

**D. Additional Considerations**

Having determined that a Lone Pine order as to the non-ONJ and non-osteomyellitis plaintiffs is appropriate, the Court will now consider the parties’ additional suggestions as to how the Lone Pine process should be tailored to this MDL.

The PSC’s suggestion that discovery should be reopened concurrent with this order is denied. The Lone Pine order only requires information from plaintiffs that they should already have. Reopening discovery would directly contravene the goals

of Lone Pine by delaying the litigation and introducing inefficiencies.

Second, Merck has suggested that the Court require a "substantial number" of cases that pass Lone Pine to undergo extensive discovery. This request is denied as premature; the Court may revisit this suggestion after the Lone Pine process is complete.

Third, the Lone Pine process will be managed in the same manner as discovery productions: incidental disputes are referred to Magistrate Judge Francis and final adjudication of whether Lone Pine has been satisfied will be conducted by this Court.

### **III. Conclusion**

For the foregoing reasons, the Court is satisfied that this order is essential to the fair and efficient administration of this litigation. Accordingly, it is hereby

ORDERED, pursuant to Fed. R. Civ. P. 16 and 26, that all plaintiffs who have not alleged osteonecrosis of the jaw or osteomyelitis shall produce the following documents in accordance with the schedule set below:

1. Completed Plaintiff Profile Forms, records requested therein, and executed Authorizations for Release of Medical Records for each Plaintiff in MDL 1789 pursuant to CMO #3.

2. A Rule 26(a)(2) Expert Report, signed and sworn to by a qualified physician or other medical expert ("the expert") that includes the following:

a. The name, professional address, and curriculum vitae of the expert, including a list of all publications authored by the expert within the preceding ten years;

b. A list of the Plaintiff's medical records reviewed by the expert prior to the preparation of the Expert Report, as well as copies of any such records not posted on the website of MRC, the vendor that has collected various medical records in this litigation and made those records available to plaintiffs pursuant to the terms of paragraph 5 of CMO 13;

c. The dates during which the Plaintiff used Fosamax and references to the evidence relied upon to determine such use (either the actual pages or the Bates stamped numbers);

d. The name(s) of the physician(s) who prescribed Fosamax to the Plaintiff;

e. Whether the expert believes to a reasonable degree of medical certainty that Fosamax caused Plaintiff's alleged injury, and if so, the factual and medical/scientific bases for that opinion; and

f. The date, at least by month and year, when the expert believes to a reasonable degree of medical certainty the Plaintiff first developed the injury alleged to have been caused by Fosamax.

g. Plaintiffs shall send the Expert Reports to counsel for Merck by a manner agreed to by the parties.

3. A signed statement from each Plaintiff affirming that he/she is willing to proceed with the case upon remand.

4. Plaintiffs shall produce the documents and Expert Report required by paragraphs 1 through 3 above pursuant to the following schedule:

a. Plaintiffs in cases in which the surname of the first named Plaintiff begins with the letter A through I shall make their productions by February 20, 2013.

b. Plaintiffs in cases in which the surname of the first named Plaintiff begins with the letter J through R shall make their productions by April 22, 2013.

c. Plaintiffs in cases in which the surname of the first named Plaintiff begins with the letter S through Z shall make their productions by June 20, 2013.

5. The failure to comply with the terms of this Order within the time periods prescribed by this Order may result in the dismissal of the delinquent Plaintiffs' actions with prejudice, as set forth below.

a. For any Plaintiff who fails to comply with this Order in a timely and complete manner, Merck will notify the Plaintiff and the Court of the failure to comply.

b. The Plaintiff will then have 15 days to show cause why the Plaintiff's Complaint should not be dismissed with prejudice.

c. If the Plaintiff fails to demonstrate sufficient cause for the failure to comply with this Order, the Plaintiff's Complaint will be dismissed with prejudice.

d. If the Plaintiff demonstrates sufficient cause for the failure to comply with this Order, the Court will have discretion to determine the relief necessary for Plaintiff to comply reasonably with this Order.

6. Supervision of the above-described productions will be referred to Magistrate Judge Francis.

SO ORDERED.

Dated: New York, New York  
November 20, 2012

  
John F. Keenan  
United States District Judge