dri
The Voice of the Defense Bar

RX for the Defense
The Newsletter of the Drug and Medical Device Committee

April 15, 2016 Volume 24 Issue 2

Recent Case Law Applying the Arsenal of Powerful and Strategic Defense Mechanisms for Avoiding Protracted Litigation

by Carole W. Nimaroff and Jonathan N. Misk

Counsel defending complex pharmaceutical and medical device lawsuits should immediately evaluate the merits of the plaintiffs' claims in order to develop a definition of success and a preliminary strategy to achieve it. Defense counsel have access to a stockpile of munitions to discourage further filings, to narrow the scope of complex litigations, or even to end them entirely, early in the process, but they must consider how best to lay the groundwork for them and how best to deploy them. Recent and interesting cases that have used these tools— including a successful summary judgment motion based on the learned intermediary doctrine in *In re Accutane Litigation* that disposed of thirty-one cases in New Jersey's state coordinated proceedings, *Lone Pine* orders, and a unique and detailed case management order in the propoxyphene litigation in the Eastern District of Kentucky—remind defense counsel to set the stage early and often for the proper use of these pretrial devices. As these recent cases demonstrate, the aggressive assertion of the learned intermediary doctrine, *Lone Pine* discovery orders, and CMOs are three of the best-established mechanisms in defense counsel's arsenal, and they have played a significant role in winnowing plaintiffs' claims. The utility of these strategies in complex drug and device litigations (whether multidistrict litigations or coordinated state proceedings) cannot be minimized: one potent and well-timed pretrial ruling can knock huge swaths of claims out of a case or strip plaintiffs' claims of any substantive support. The trick, of course, is knowing when and how to deploy these mechanisms efficiently and effectively.

This article examines the successful and strategic use of such pretrial tools in several recent cases, which should remind defense counsel to take advantage of these winnowing practices or face protracted and costly litigation.

***Summary Judgment and the Learned Intermediary Doctrine*: In re Accutane Litigation**

Defense counsel must carefully examine plaintiffs' prescribing physicians' depositions to develop strong defenses to failure to warn claims that can determine the trajectory of a case. Prescribing physicians' testimony that they would not have altered their decision to prescribe a drug, even if they had received a different warning, is a death knell for plaintiffs' claims in every learned intermediary jurisdiction, as such admissions lay the groundwork for summary judgment motions based on that doctrine. (As of this writing, all fifty states and two other jurisdictions have adopted the learned intermediary doctrine in some way—either by statute or by a ruling of a state or federal court. In the seven states (plus Puerto Rico) in which the legislatures and state courts have been silent on the application of the learned intermediary rule in prescription medical product cases, federal courts have predicted that the state or its courts would adopt the rule.) Although these motions are nothing new, federal and state courts throughout the country continue to show that they are not shy to grant them where plaintiffs cannot demonstrate that defendants failed to warn the plaintiffs' *prescribing physicians*. Furthermore, summary judgment motions based on the learned

intermediary doctrine can be made as soon as defendants obtain favorable deposition testimony from a plaintiff's treating physician; accordingly, they can often be deployed before lengthy and costly discovery becomes necessary.

A recent decision of the New Jersey Superior Court presiding over the *In re Accutane Litigation* coordinated proceeding that dismissed 31 of 32 cases (the prescribing physician's deposition had not yet been taken in the thirty-second case) in which the plaintiffs could not satisfy their burden under the learned intermediary doctrine, which obligates prescription drug manufacturers to warn only prescribing physicians—not patients—about the risks of prescription drugs, is particularly instructive. Order Granting Mot. Summ. J. Based on Lack of Proximate Cause in Certain Texas Ingestion Cases, *In re Accutane Litig.*, Case No. 271 (N.J. Super. Law Div. Jan. 29, 2016). Relying on deposition testimony from the plaintiffs' prescribing physicians, Hoffmann-La Roche moved for summary judgment, arguing that relevant evidence and deposition testimony demonstrated that the plaintiffs' prescribing physicians would still have prescribed Accutane to the plaintiffs even if the drug's label had included additional information proposed by the plaintiffs. *Id.* at 3. Namely, the plaintiffs' physicians testified that they would have prescribed Accutane to plaintiffs even if (1) the word "temporally" had not been on the label; (2) the label stated the drug had been associated with IBD; and (3) the label had said that the drug "can cause" IBD. The physicians also testified that they still would have prescribed Accutane to the plaintiffs even today, knowing what they know now, had the plaintiffs presented in the same manner.

The plaintiffs argued in response that, despite this testimony: (1) their prescribing physicians would have had different discussions with patients that included information about the risks of inflammatory bowel disease ("IBD") associated with Accutane; (2) some prescribing physicians misunderstood the label; (3) the physicians would not have prescribed Accutane had they known that it was "scientifically proven" to cause IBD; (4) the physicians would want to know if a cause-and-effect relationship existed between Accutane and IBD; and (5) the physicians would not have prescribed Accutane to a patient who refused it. *Id.* at 3-4.

The Court credited Hoffmann-La Roche's characterization of the prescribing physicians' testimony and applied the learned intermediary doctrine, noting that it was not sufficient that a different label would likely have changed the physicians' prescribing *discussions* with their patients because the physicians still would have prescribed Accutane to willing patients. *Id.* at 9. Because the doctors *in every instance* testified that they still would have prescribed Accutane even with a different warning, the plaintiffs' claims failed as a matter of law.

While *In re Accutane* is the most recent complex litigation applying the learned intermediary doctrine to grant summary judgment in the defendants' favor, state and federal courts routinely grant similar motions where plaintiffs fail to meet their burden under that doctrine. *See, e.g.*, *Buckley v. Align Tech.*, No. 5:13-cv-02812-EJD, 2015 WL 5698751 (N.D. Cal. Sept. 29, 2015) (Northern District of California granting Align's motion to dismiss because, in pertinent part, the plaintiff did not allege that Align had failed to warn her dentist and Invisalign is only available via a dentist's prescription); *Aubin v. Union Carbide Corp.*, 177 So. 3d 489 (Fla. 2015) (applying the learned intermediary doctrine).

Lone Pine *Orders*

Another tool at defendants' disposal in both federal and state courts to filter out non-viable claims is the *Lone Pine* order, which defense counsel can seek either before, during, or after discovery. Frequently used in product liability and toxic tort actions, such orders require plaintiffs to produce some *prima facie* evidence that their claims are viable. This type of case management order is named for the eponymous New Jersey toxic tort case, in which the trial court required plaintiffs asserting claims for personal injury and property damage to provide: (1) the facts of each

plaintiff's alleged exposure; (2) reports of medical experts or doctors regarding each plaintiff's alleged injuries and that the injuries could be caused by exposure to toxic substances; (3) identification of property affected; and (4) proof of property damage. *See Lore v. Lone Pine Corp.*, No. L-33606-85, 1986 WL 637507 (N.J. Super. Law. Div. Nov. 18, 1986). The Fifth Circuit has explained that such orders allow district courts "to handle the complex issues and potential burdens on defendants and the court in mass tort litigation by requiring plaintiffs to produce some evidence to support a credible claim." *Steering Committee v. Exxon Mobil Corp.*, 461 F.3d 598, 604, n.2 (5th Cir. 2006) (citing *Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000)); *see also Baker v. Chevron USA, Inc.*, No. 1:05-CV-227, 2007 WL 315346, at *1 (S.D. Ohio Jan. 30, 2007) (*Lone Pine* orders are an effective tool in product liability and toxic tort cases to "identify and cull potentially meritless claims and streamline litigation in complex cases involving numerous claimants"). Federal courts have recognized that, as a general matter, *Lone Pine* orders are appropriate if (1) there are multiple parties in a class action or recurring parties in similar suits; (2) the veracity of the plaintiff's allegations is questionable; (3) the case involves complex and fact-intensive issues; and (4) the case involves potentially massive discovery. *See, e.g.*, *Steering Comm.*, 461 F.3d at 604, n.2; *Acuna*, 200 F.3d at 340; *Baker*, 2007 WL 315346, at *1.

Lone Pine orders are particularly appropriate in pharmaceutical MDLs because plaintiffs in these coordinated proceedings are afforded an opportunity to "park" their cases with minimal risk that they will receive individual attention. In the absence of a *Lone Pine* order, an individual case's lack of merit will only be exposed if the case is one of the few selected for discovery and trial. Indeed, some commentators observe that the entry of *Lone Pine* orders by courts in coordinated pharmaceutical proceedings has increased such that they are now "widely used in mass torts to isolate spurious claims." David F. Herr, ANN. MANUAL FOR COMPLEX LIT. § 11.34 (4th ed).

In October 2015, a Kentucky district judge upheld a magistrate judge's entry of a *Lone Pine* order in a mass toxic torts case involving allegations of groundwater contamination by a glass manufacturing plant. *Modern Holdings, LLC v. Corning Inc.*, No. 13-405-GFVT-EBA, 2015 WL 6482374 (E.D. Ky. Oct. 27, 2015). During pretrial discovery, the parties disagreed on several issues, and the Court had "considered motions for restraining orders, multiple motions to dismiss, two amendments to the complaint, and more." *Id.* at *1. After the Court entered a scheduling order mirroring the parties' proposed pretrial schedule, Corning (and co-defendants) moved for a *Lone Pine* order, a mechanism the Court had recognized was available to federal courts under their broad discretion to manage discovery. *Id.* (citing *Lone Pine*, 1986 WL 637507).

The magistrate judge managing discovery agreed with Corning's position and entered a *Lone Pine* order that required each personal injury plaintiff to submit an affidavit identifying: (1) the specific illness sustained; (2) the date of diagnosis and information about the medical provider who diagnosed the illness; (3) the toxic chemical that allegedly caused the illness, including the manner, pathway, dates, duration, and dose; and (4) the scientific literature supporting causation. *Id.* The magistrate judge reasoned that the *Lone Pine* order served several purposes, including: (1) disposing of meritless claims before parties expend substantial resources on discovery and trial preparation; (2) narrowing the issues and allowing the remaining parties to focus on dispute resolution while avoiding the time-consuming, expensive discovery process of filtering meritless issues and claims on a plaintiff-by-plaintiff basis; and (3) promoting speedy settlements by identifying meritorious claims and assessing their values before discovery begins. *Id.* at *4-5.

The plaintiffs moved for reconsideration, which the Court denied. *Id.* The Court reasoned that, *inter alia*, the order sought to "facilitat[e] case management going forward," and it emphasized "its interest in efficient case management and the preservation of resources—for all Plaintiffs, Defendants, and the Court." *Id.* at *3. The Court also noted, in rejecting the plaintiffs' argument that the *Lone Pine* order was unduly prejudicial, that the *Lone Pine* affidavits

required the plaintiffs only to supply general information similar to information contained in a complaint and that the *Lone Pine* order would not deprive the plaintiffs of discovery, but would instead "focus the issues for all parties before full discovery proceeds." *Id.* at *4 ("Like the Fifth Circuit Court of Appeals expressed in the well-cited case *Acuna v. Brown & Root Inc.*, '[e]ach plaintiff should have had at least some information regarding the nature of his injuries, the circumstances under which he could have been exposed to harmful substances, and the basis for believing that the named defendants were responsible for his injuries' in order to join in the suit in the first place. 200 F.3d 335, 340 (5th Cir. 2000).").

The *Modern Holdings* decision is critical for defendants seeking to narrow issues prior to litigation and to avoid unnecessary, complex, and inefficient discovery. The decision explains why such orders benefit all parties and why courts, in the interests of judicial efficiency, should consider entering them.

Prior to *Modern Holdings*, a *Lone Pine* order was most recently entered in a prescription drug or device case in late 2012, when the Southern District of New York entered such an order in *In re Fosamax Products Liability Litigation* to "target potentially spurious claims without imposing undue obligations upon other Plaintiffs." *In re Fosamax Prods. Liab. Litig.*, No. 06-MD-1789-JFK, 2012 WL 5877418, at *4 (S.D.N.Y. Nov. 20, 2012). In comparison to the *Modern Holdings* order, the *Fosamax* order is an example of a *Lone Pine* order that came after the completion of significant discovery. Merck twice moved for the entry of a *Lone Pine* order—first on February 1, 2010 and then on January 3, 2011—but the Court declined to entertain either of those motions. *See id.* at *1. More than a year later, Merck again moved for entry of a *Lone Pine* order; the Court granted the motion on November 20, 2012, holding that "the Court has reason to believe that spurious or meritless cases are lurking in some 1,000 cases on the MDL docket . . . 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." *Id.* at *3.

In its third motion for a *Lone Pine* order, Merck argued that the order would "promote the just and efficient conduct of . . . proceedings by ensuring that a process is put in place to eliminate meritless cases." *See* Def. Merck Sharp & Dohme Corp.'s Mem. Supp. Mot. Entry Lone Pine Order at 1, ECF No. 1205, No. 06-MD-1789-JFK, 2012 WL 5877418 (S.D.N.Y. Oct. 15, 2012). The *Lone Pine* order, Merck argued, would "compel each Plaintiff to confirm, by appropriate means, that she has sufficient basis to claim that Fosamax caused the injury she has . . . alleged." *Id.* The Court granted the order, with some limitations, because it was convinced that a *Lone Pine* order would speed up the prospect of a global or partial settlement, result in the remand of cases back to their home districts, and eliminate spurious claims so that only meritorious cases reached the settlement stage and home districts only received viable cases; furthermore, the Court determined that plaintiffs would not suffer any unfair prejudice from the entry of the order. *In re Fosamax Prods. Liab. Litig.*, 2012 WL 5877418, at *3 (The Court specifically highlighted Merck's citation of statistics on rates of dismissal of cases once they're given attention, which convinced the Court that "spurious or meritless cases are lurking in the some 1,000 cases on the MDL docket.").

Defense counsel should recognize the potential opportunity that comes with the entry of a *Lone Pine* order, but they must also be cognizant of appropriately timing any motion seeking such an order. Generally, defense counsel can deploy this strategy before, during, or after discovery; however, counsel should be aware that one state—Colorado—has held that pre-discovery *Lone Pine* orders are *per se* impermissible. *Antero Res. Corp. v. Strudley*, 347 P.3d 149, 151 (Colo. 2015) ("We hold that Colorado's Rules of Civil Procedure do not allow a trial court to issue a modified case management order, such as a *Lone Pine* order, that requires a plaintiff to present prima facie evidence in support of a claim before a plaintiff can exercise its full rights of discovery under the Colorado Rules. Although the comments to C.R.C.P. 16 promote active judicial case management, the rule does not provide a trial court with authority to fashion its own summary judgment-like filter and dismiss claims during the early stages of litigation."). Other jurisdictions may

decline to enter *Lone Pine* orders depending on the timing of the motion, the stage of the litigation, or any of the other factual circumstances of the case. *See, e.g.*, *Adinolfe v. United Techs. Corp.*, 768 F.3d 1161, 1167-69, 1175-76 (11th Cir. 2014) (finding that it is both legally inappropriate and unwise for trial courts to issue *Lone Pine* orders before determining whether plaintiffs' claims could survive a motion to dismiss); *In re Digitek Prod. Liab. Litig.*, 264 F.R.D. 249, 259 (S.D. W.Va. 2010) (declining to enter *Lone Pine* order at relatively early stage in litigation, favoring instead "available procedural devices such as summary judgment, motions to dismiss, motions for sanctions and similar rules" to achieve the goals of efficiency, elimination of frivolous claims, and fairness); *McManaway v. KBR, Inc.*, 265 F.R.D. 384, 388 (S.D. Ind. 2009) (granting in part and denying in part a request for a *Lone Pine* order and noting that "[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"); *Simeone v. Girard City Bd. of Educ*., 872 N.E.2d 344, 350 (Ohio Ct. App. 2007) (reversing and remanding trial court's entry of *Lone Pine* order and noting that "[t]he *Lone Pine* order has faced harsh criticism because it gives courts the means to ignore existing procedural rules and safeguards," including when the order "cuts off or severely limits the litigant's right to discovery, [thereby] closely resembling summary judgment, albeit without the safeguards that the Civil Rules of Procedure supply"); *see also cf. In re Vioxx Prods. Liab. Litig.*, 557 F. Supp. 2d 741, 744 (E.D. La. 2008) (affirming *Lone Pine* order, but noting that "*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").

Accordingly, before seeking a *Lone Pine* order, it is critical that defense counsel research carefully the historical treatment of *Lone Pine* orders in the particular jurisdiction and assess the procedural history of the case in question to ensure that a *Lone Pine* order would serve the interests of efficiency and judicial economy.

Modern Holdings and *Fosamax* underscore another technique that defendants can deploy to nip protracted discovery in the bud. A *Lone Pine* order can help ensure that only legitimate claims are subject to comprehensive discovery and have a chance to reach trial. This strategy may not only eliminate distractions and assist counsel in preparing cases for trial, but it may also satisfy clients by stemming expense and delay.

Unique and Detailed Case Management Orders: **Romo v. McKesson Corp.**

Approximately three months after the entry of the *Lone Pine* order in *Modern Holdings*, another Eastern District of Kentucky court entered a unique and detailed case management order in a prescription drug case. Case Management Order No. 5, *Romo v. McKesson Corp.*, No. 2:l5-cv-00089-DCR (E.D. Ky. Jan. 26, 2016). Notably, the CMO had the flavor and effect of a *Lone Pine* order, demonstrating courts' willingness to employ their broad discretion in managing pretrial discovery to promote efficiency and judicial economy.

On November 13, 2012, fifty individual plaintiffs filed a complaint against more than 25 brand name and generic manufacturers of drugs containing the active ingredient propoxyphene. Compl. ¶ 1, *Romo v. McKesson Corp.*, No. 2:l5-cv-00089-DCR (E.D. Ky. Nov. 13, 2012). Each plaintiff had ingested a prescription medication containing propoxyphene to treat mild to moderate pain. Plaintiffs alleged claims of strict liability in defective design, strict liability in failure to warn, strict liability in tort, negligent design, negligence, negligent failure to warn, fraudulent non-disclosure, negligent misrepresentation, fraudulent misrepresentation and concealment, negligence per se, breach of express warranty, breach of implied warranty, deceit by concealment, and violations of provisions of the California Business and Professions Code and California Civil Code, all arising out of the defendants' alleged mislabeling of the product and alleged concealment of the limited benefit and true risks associated with the product. *Id.* ¶¶ 230-523.

On November 20, 2012, defendants removed the action to the United States District Court for the Central District of California, and an *en banc* panel of the Ninth Circuit Court of Appeals upheld the removal. *See* Notice of Removal, ECF No. 1, *Romo v. McKesson Corp.*, No. 2:15-cv-00089-DCR (C.D. Cal. Nov. 20, 2012); *Romo v. Teva Pharm. USA, Inc.*, 742 F.3d 909 (9th Cir. 2014). The California federal court then transferred the case to the Eastern District of Kentucky, where it was consolidated into an MDL. *See* Order Granting Def.'s Mot. Transfer This Action to E.D. Ky. and Finding that Def.'s Mot. To Sever Has Been Rendered Moot, *Romo v. McKesson Corp.*, No. 2:15-cv-00089-DCR (C.D. Cal. June 9, 2015).

On January 26, 2016, the Kentucky court entered Case Management Order Number 5, a discovery management order, in the ordinary course of managing the MDL. *See* Case Management Order No. 5, *Romo*, No. 2:l5-cv-00089-DCR. In an effort to identify viable cases, the order required each plaintiff to provide specific information relevant to his or her claims. Specifically, the Court required each plaintiff whose claims had not been dismissed in their entirety as of February 1, 2016, and who alleged ingestion of a propoxyphene-containing pain product along with a "contemporaneous injury," to provide: (1) the dates of ingestion of a relevant product; (2) "[p]rima *facie* evidence of acquisition of a [p]roduct" (i.e., pharmacy records with National Drug Codes; pill bottles with the plaintiff's name, NDC or manufacturer name, and product name clearly visible; or a pharmacist's affidavit stating that the drug was dispensed to the plaintiff; but *not* medical records denoting a prescription, an affidavit from a healthcare provider attesting to prescribing the product to the plaintiff, or an affidavit from the plaintiff attesting that he or she ingested the drug); and (3) *prima facie* evidence of the alleged injury in the form of a medical record containing the date of the injury or a signed affidavit from a physician attesting to the alleged injury and the date. *Id.* at 3. The Court required even more comprehensive evidence from plaintiffs claiming a "cumulative or latent injury." *Id.* at 3-4.

The Court stated that the purpose of the order was "to conserve judicial resources, eliminate duplicative discovery, serve the convenience of the parties and witnesses, and promote the just and efficient conduct of this litigation," but the Court's order also placed the burden of maintaining their claims squarely on the plaintiffs. *Id.* at 1. Accordingly, while masked as an ordinary discovery order, the CMO had the substance and effect of a *Lone Pine* order, affirmatively requiring the plaintiffs to bring forth *prima facie* evidence proving their ingestion of the subject product and connecting their ingestion of that product to their alleged injuries. This development in the propoxyphene litigation should remind defense counsel that district judges have wide discretion to craft how discovery will proceed and to create case management plans to fit the individual circumstances of the litigations before them. Defendants in complex drug and device cases should highlight the *Romo* case in seeking similar discovery orders aimed at managing unwieldy litigations.

As these and other recent cases makes clear, defendants in complex pharmaceutical and medical device litigations have at their disposal myriad mechanisms for narrowing or ending litigations before they become unnecessarily costly and time-consuming. But defense counsel must know what options are available and when to use them.

Carole W. Nimaroff *is a counsel and* ***Jonathan N. Misk*** *is an associate in Hughes Hubbard & Reed LLP's Product Liability and Toxic Torts Practice Group. Ms. Nimaroff has represented a broad spectrum of pharmaceutical and medical device manufacturers in mass tort products liability litigations in both multidistrict and state coordinated proceedings. Mr. Misk's practice similarly focuses on the defense of major product liability actions in both federal and state court. Ms. Nimaroff and Mr. Misk were assisted in the preparation of this article by Kate Aufses, a law clerk at Hughes Hubbard. If you have any questions regarding this article, please contact Ms. Nimaroff at carole.nimaroff@hugheshubbard.com or Mr. Misk at jonathan.misk@hugheshubbard.com.*

Hughes Hubbard assists Merck in its defense of the Fosamax litigation, including in connection with Merck's request for a Lone Pine *order in those cases. This article represents the personal views of the authors, is provided for informational purposes only, and does not constitute legal advice. No representation is made about the accuracy of the information, and no information is being provided in the context of any attorney-client relationship. You should consult with your own lawyer for your legal needs.*