Strategic Considerations

Exposing Meritless Claims in Drug and Medical Device Product Liability MDLs

By Christopher J. Kaufman, Jason R. Harmon, and Torrey Peterson

Defendants should develop pretrial procedures early in litigation to expose meritless filings and noncompliant plaintiffs and force plaintiffs to demonstrate that individual cases meet some threshold of merit.

Federal multidistrict litigation (MDL) has become a common and familiar procedural setting for pharmaceutical and medical device manufacturers facing mass tort product liability litigation. As of May 2019, fifty-one of the sixty-nine active product liability MDLs (74 percent) involved pharmaceutical drugs or medical devices, many of which include hundreds, if not thousands, of plaintiffs. *See* J.P.M.L., MDL Statistics Report–Docket Type Summary (May 15, 2019).

Multidistrict litigation is intended to promote the just and efficient resolution of a large number of similar cases involving one or more common questions of fact that are pending in different district courts across the country. In these circumstances, cases are consolidated into a single MDL court for pretrial coordination—meaning the MDL becomes a procedural tool for coordinating discovery, minimizing the risk of competing rulings by different courts on the same issues, and encouraging the broad resolution of similar claims.

But MDLs can also incentivize mass filings of meritless cases, making them arguably less efficient and just than intended. In an ordinary "one-off" case, procedural safeguards exist to protect defendants

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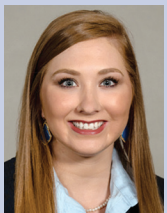

from litigating claims that lack merit. For instance, a defendant in federal court may seek dismissal of a complaint that fails to satisfy federal pleading standards. *See* Fed. R. Civ. P. 12(b)(6). But courts may not apply those standards with the same rigor in an MDL as in an individual case—ironically justified by concerns of "efficiency." *See, e.g.*, *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, No. 11 C 5468, 2012 WL 3582708, at *4 (N.D. Ill. Aug. 16, 2012) (deciding not to consider 12(b)(6) challenges on case-specific issues in an MDL). The result of such leniency is that plaintiffs can file their claims in an MDL "without the individual merit of their case being scrutinized as closely as it would if it proceeded as a separate individual action." *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, 4:08-MD-2004, 2016 WL 4705827, at *1 (M.D. Ga. Sept. 7, 2016). The *Obtape* MDL court noted:

> This phenomenon produces the perverse result that an MDL, which was established in part to manage cases more efficiently to achieve judicial economy, becomes populated with many non-meritorious cases that must nevertheless be managed by the transferee judge—cases that likely would never have entered the federal court system without the MDL.

Id.

In litigation involving pharmaceutical drugs and medical devices, this problem is particularly acute, especially where large case inventories (regardless of merit) may be perceived by plaintiffs' counsel as a driver of increased overall settlement valuations. Aggressive plaintiffs' attorney advertising can deliver hundreds—if not thousands—of claimants who are willing to file suit. Seemingly unrestricted by the traditional processes that require a reasonable pre-suit investigation, plaintiffs' counsel are now able to file MDL product liability actions in bulk. It is no wonder that MDL filings now take up more than *half* of the federal civil docket.

To counter these problems effectively, defendant manufacturers and their counsel should understand where weaknesses exist in the case inventories to expose meritless cases and target them for dismissal. In doing so, defendants should develop pretrial procedures early in the litigation that (1) incorporate traditional safeguards against meritless filings and noncompliant plaintiffs and (2) put the onus on individual plaintiffs to demonstrate their cases have some threshold degree of merit.

Enforce Federal Pleading Standards

The first opportunity to expose meritless filings exists at the pleading stage, but as noted above, MDL courts may not necessarily require strict compliance with federal pleading standards. This is because MDL plaintiffs commonly file "master" complaints that assert general allegations on behalf of each plaintiff who, in turn, separately file "short-form" complaints. *See* Manual for Complex Litigation (Fourth) §40.52 (2004). The master complaint must be general enough to apply to all plaintiffs, but when considered in tandem with the short-form complaint, should contain facts sufficient to satisfy the minimum pleading requirements. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007) (a complaint does not suffice if it makes "naked assertion[s]" devoid of "further factual enhancement"); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (the Federal Rules of Civil Procedure "do not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.").

Plaintiffs have had success in MDLs leveraging the tension that exists between the factual specificity required by the pleading standards and the generality necessitated by the MDL model. In some circumstances, courts have given plaintiffs "substantial leniency" in pleading their cases. *See, e.g.*, *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-1928, 2009 WL 577726, at *8 (S.D. Fla. Mar. 5, 2009) (assessing the "sufficiency of plaintiffs' claims with substantial leniency."). The result is that often MDLs "require nothing more of claimants than the pleading equivalent of 'count me in.'" Advisory Comm. on Civ. Rules, *MDL Subcommittee Report*, at 148.

Defendant manufacturers should seek enforcement of federal pleading standards to ensure that the MDL master and short-form pleadings, together, serve their intended purpose and contain *facts* to substantiate the elements of plaintiffs' state law claims. *See In re Zofran (Ondansetron) Prods. Liab. Litig.*, 1:15-md-2657-FDS, 2017 WL 1458193, at *5 (D. Mass. Apr. 24, 2017) ("The creation of an MDL proceeding does not suspend the requirements of the Federal Rules of Civil Procedure, nor does it change or lower the requirements of those rules."). Otherwise, meritless cases are better able to find their way into an MDL. To do this, manufacturers should move to dismiss deficient master complaints and seek entry of pretrial orders that streamline the dismissal process for deficient short-form complaints. Manufacturers can also draw from two strategies in seeking such orders: the use of model pleadings and requiring factual specificity in the short-form complaints.

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Use Model Pleadings

Using "model pleadings" will allow MDL courts to address pleading issues in individual cases that can later be applied across the MDL. For example, in the *Mirena* MDL, the court issued rulings in one case that served to guide the parties on similar issues moving forward. *See In re Mirena IUD Prods. Liab. Litig.*, No. 13-MD-2434, 2015 WL 144214, at *1 (S.D.N.Y. Jan. 9, 2015) ("Under CMO 22A, Defendants are permitted to submit a letter explaining why each case should be dismissed consistent with this Court's opinion in *Truitt*.... Each Plaintiff against whom Defendants so move must then either voluntarily dismiss her case with prejudice or set forth the specific facts and/or law that distinguish her case from Ms. Truitt's.").

The *Mirena* approach improves efficiency and conserves resources by identifying the viable claims and defining the scope of discovery across the litigation. Ignoring these issues may undermine such efficiency.

Require Factual Specificity in the Short-form Complaint

Even though the master complaint may be pleaded with some generality, plaintiffs can

still satisfy federal pleading standards by asserting the necessary factual specificity in the short-form complaint. But this is not possible if the short-form complaint is nothing more than a check-the-box form that allows plaintiffs to indicate which claims from the master complaint they want to assert. Defendant manufacturers should negotiate short-form complaints that allow—or even prompt—plaintiffs to describe the facts substantiating their claim or claims.

Manufacturers can also expose meritless cases by requiring the production of fundamental evidence that substantiates essential elements of plaintiffs' claims.

Establish Product Identification

Obviously, individual plaintiffs must objectively prove that they actually used the drug or medical device at issue in the litigation. But this may be easier said than done early in the case if the proper checks and balances are not in place to vet filings for product identification and improper parties. Plaintiffs can become susceptible to filing suit against the wrong party where the drug or medical device at issue is among a family of similar, yet different, products that are indicated for the same use but made by other manufacturers, and in the pharmaceutical context, where the prescription drug at issue has gone generic.

To manage MDL case inventories effectively and ferret out baseless filings, manufacturers should develop procedures early in the litigation that require plaintiffs to establish actual use of the drug or device at issue, perhaps by producing a medical billing, or insurance record containing a product identification sticker or NDC (national drug code) identifier. If plaintiffs do not have some objective proof of product identification, defendant manufacturers will be positioned to seek dismissal of cases that lack proper documentation and proof.

Demand a Fully Compliant Plaintiff Fact Sheet

The plaintiff fact sheet—a standardized, negotiated, and judicially adopted questionnaire that each plaintiff is required to complete, often in lieu of interrogatories and requests for production—is a common written discovery tool in product liability MDLs. As such, compliance with plaintiff fact sheet disclosure obligations should be governed by the standards for written discovery obligations under the Federal Rules of Civil Procedure. *See* Manual for Complex Litigation (Fourth) §22.83 (2004).

When strategically designed to solicit relevant, non-privileged information on pertinent issues in the litigation, and the production of documents and electronically stored information (ESI) containing such relevant information, the plaintiff fact sheet becomes a useful tool for efficiently understanding and evaluating the inventory, identifying cases for bellwether consideration, and developing settlement assessments. *See, e.g., In re Zofran (Ondansetron) Prods. Liab. Litig*, MDL No. 2657, MDL Order No. 11 ("The Court has concluded that that the use of [plaintiff fact sheets, document production, and authorized releases] will assist in the just, speedy, and inexpensive determination of these proceedings.").

As part of this process, manufacturers should consider identifying plaintiff fact sheet deficiencies at the outset to hold all plaintiffs accountable for complying with their disclosure obligations, not just the plaintiffs selected as bellwether candidates. If such plaintiffs are not able to cure deficiencies within a reasonable time, a process should exist whereby defendants can seek dismissal of noncompliant plaintiffs. *See In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, CMO No. 12 (S.D. Ill. Mar. 3, 2010) (court order allowing dismissals with prejudice for failure to comply with plaintiff fact sheet obligations).

Require Objective Proof of Injury

Manufacturers can also expose meritless cases by requiring the production of fundamental evidence that substantiates essential elements of plaintiffs' claims. This could be as simple as a medical record demonstrating that the plaintiff has been diagnosed with the alleged injury, or an affidavit from an independent doctor explaining why the product is linked to the plaintiff's condition. Such orders—often called *Lone Pine* orders after *Lore v. Lone Pine Corp.*, 1986 WL 637507 (N.J. Sup. Ct. Nov. 18, 1986), which was the first instance where the court ordered the plaintiffs to offer proof connecting the plaintiff's alleged injury with the defendant's product—are appropriate in an MDL because "it is not too much to ask a Plaintiff to provide some kind of evidence to support their claim that [the drug] caused them personal injury." *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 557 F. Supp.2d 741, 744 (E.D. La. May 30, 2008). This is particularly true given that MDLs can be susceptible to meritless filings.

Enforce Plaintiffs' Document Production and ESI Obligations

Under Rule 26(b)(1), all parties, not just defendants, are required to produce non-privileged information that is relevant to the claims or defenses and proportional to the needs of the case. As part of the discovery process, manufacturers should require the production of discoverable documents in each individual plaintiff's possession, custody, or control. In today's world of smartphones, social media, and electronic communication, every plaintiff should be expected to search for relevant and responsive information in these mediums. *See, e.g., Hinostroza v. Denny's, Inc.*, 2018 WL 3212014, at *4–6 (D. Nev. June 29, 2018) (ordering the plaintiff to produce ESI in the form of text messages, email, and social media in a slip-and-fall case). Just as manufacturers spend significant time and resources searching for and reviewing potentially millions of pages of internal responsive documents, plaintiffs should be held accountable for conducting their own due diligence to search for responsive information in social media postings, emails, text messages, photographs, videos, blog posts, and the like. *See, e.g., In re Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 2740, PTO No. 71 (E.D. La. Dec. 15, 2017) (order enforcing the plaintiff fact sheet requirement that every plaintiff produce relevant ESI, including photographs, emails, social media content,

group chat messages, text messages, and blog posts, among others).

By enforcing plaintiffs' compliance with MDL discovery obligations, manufacturers can conduct evaluations across the entire inventory to identify and expose potentially meritless cases on several legal and/or factual bases, such as statute of limitations, proof of use, product identification, lack of injury, causation, etc.

Incentivize Compliance

The key to leveraging the plaintiff fact sheet process, *Lone Pine* orders, or plaintiffs' discovery obligations successfully to expose meritless cases lies in creating an efficient dismissal process for enforcing noncompliance. Many MDL courts enter orders that streamline the dismissal of plaintiffs who fail to comply with their discovery obligations. *See, e.g., In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 460 F.3d 1217, 1226 n. 4 (9th Cir. 2006) ("more than 850 claims were dismissed pursuant to defendants' motions to dismiss for failure to comply with CMO 6"); *In re Abilify (Aripiprazole) Products Liability Litigation*, MDL No. 2734, ECF 1112 (N.D. Fla. Jan. 31, 2019) (ordering 400 plaintiffs to show cause why they failed to comply with their plaintiff fact sheet obligations).

Leverage the Bellwether Process

Outside of an MDL, "one-off" drug or medical device product liability cases will generally proceed through litigation with relative certainty that they will be tried to verdict, unless a defendant succeeds with dispositive motions or settles. In an MDL setting, however, litigants' expectations may be different, depending, in part, on the number of plaintiffs in the coordinated proceeding.

Cases selected for MDL bellwether trial workup are often chosen pursuant to a negotiated procedure whereby the parties each independently identify a subset of cases from the entire inventory that they believe are "representative" of the broader MDL. Absent judicial control over case selections, plaintiffs' counsel typically select cases they deem have the most significant injuries and damages calculations, while the defense is likely to select cases that lack an injury or have strong alternative causation considerations.

When making bellwether case selections in this setting, manufacturers should develop a strategy using relevant, litigation-specific criteria and demographics to ensure that weak, meritless cases do not sit on the sideline while others get ready for trial. This is particularly true when the "weak" cases are demonstrably representative of the broader inventory. All plaintiffs should be prepared to try their case to the jury.

Manufacturers should also remain vigilant for the possibility of "spontaneous" voluntary dismissals of defense-picked bellwether cases, thereby tilting the balance of remaining bellwether cases in favor of plaintiffs. To combat this tactic, manufacturers should seek a protocol for the initial bellwether selection process that permits defendants to select replacement cases and/or strike cases from the bellwether pool that are selected by plaintiffs. *See In Re: Invokana (Canagliflozin) Products Liability Litigation*, MDL No. 2750, CMO No. 20, at 2 (D.N.J. July 27, 2017) (allowing defendants to replace any defense-picked bellwether case voluntarily dismissed by plaintiffs before a cutoff date); *In re Norplant Contraceptive Prod. Litig.*, MDL No. 1038, 1996 WL 571536, at *1 (E.D. Tex. Aug. 13, 1996) (entering a protocol permitting defendants either to strike one plaintiff-selected bellwether for each voluntarily dismissed defense-selected bellwether case or choose which case would be tried first).

Conclusion

Exposing and dismissing meritless cases in a broader sea of MDL filings requires sustained attention, resources, creativity, and commitment by manufacturers and their counsel to an overall strategy that promotes a just and efficient MDL. By doing so, the parties and the court will be better positioned to isolate the legal and factual issues in dispute, define the scope of discovery, and assess the remaining cases for possible resolution. FD