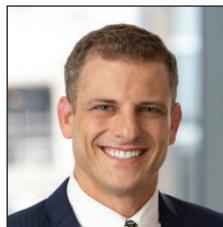


What Defense Litigators Need to Know About the New Federal Rule of Civil Procedure 16.1 on Multidistrict Litigation

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Since their creation by the Multidistrict Litigation Act of 1968, federal multidistrict litigations (MDLs) have become necessary to the functioning of the U.S. court system. At the end of FY2024, more than 60 percent of pending federal civil cases were housed in MDLs, down only slightly from the high-water mark of around 70 percent set the preceding year.¹ MDLs are intended to promote convenience and “the just and efficient conduct” of factually related claims, which often include mass tort claims, by centralizing at least a portion of the claims’ pretrial proceedings before a single district court.² The unique challenges of managing these centralized cases have led many MDLs to become sprawling and unmanageable.

The problems endemic to MDLs are at least partially attributable to the lack of specific guidance under the Federal Rules of Civil Procedure. That changed when Rule 16.1 went into effect on Dec. 1, 2025. While the other “Rules of Civil Procedure … continue to apply in all MDL proceedings,” Rule 16.1 encourages courts to consider MDLs’ unique case management issues from the outset of the litigation and recognizes appropriate tools to address those issues. As a result, the new Rule may represent an inflection point in courts’ management of MDLs, leading to a more just and efficient system.

What Rule 16.1 Provides

Rule 16.1 establishes a process by which courts and parties can (and should) engage on key MDL case management issues from the outset of litigation. Pursuant to Rule 16.1(a), the MDL court initiates the process by issuing an order setting an initial case management conference. The MDL court also orders the parties to submit a joint preconference report governed by Rule 16.1(b). Following the conference, the MDL court issues an initial case management order under Rule 16.1(c) that will govern the MDL, subject to possible later amendment.³

Rule 16.1’s Committee Note emphasizes that, although the court retains discretion over the matters

to be addressed, “early attention” to the important case management matters listed in the Rule “should be of great value to the transferee judge and the parties.”⁴ The substance of the new Rule 16.1 comes primarily from paragraphs (b)(2) and (b)(3), which lists case management matters for the parties to include in their preconference report and that the MDL court may wish to include in its initial case management order. Paragraph (b)(4) additionally permits parties to include in their preconference report “any other matter that the parties wish to bring to the court’s attention,” allowing them to identify any MDL-specific case management challenges and propose procedures to address them from the outset.⁵

Rule 16.1(b)(2) provides the presumptive list of case management matters as to which the parties must provide their final views in the preconference report. These matters are: (A) “whether leadership counsel should be appointed” and, if so, the details of leadership arrangements; (B) any pending orders that may need to be revisited; (C) “a schedule for additional management conferences with the court”; (D) “how to manage the direct filing of new actions in the MDL proceedings”; and (E) “whether related actions have been—or are expected to be—filed in other courts, and whether to adopt methods for coordinating with them.”⁶

Rule 16.1(b)(3) provides the presumptive list of matters as to which the parties are to provide only their initial views because their final positions may need to wait until after appointment of leadership counsel.⁷ These matters include: (A) consolidated pleadings; (B) early exchanges of information between the parties; (C) discovery; (D) “any likely pretrial motions”; (E) potential actions by the court “to facilitate resolving some or all actions”; (F) whether any matters should be referred to a magistrate judge or a master; and (G) the “principal factual and legal issues likely to be presented.”

In short, Rule 16.1(b) gives the parties the opportunity to raise case management matters at the outset

of litigation and recognizes various case management tools that MDL courts can and should use. However, the Rule makes it incumbent on individual MDL judges to decide whether and how to use those tools—and others not included in or referenced by Rule 16.1—to promote just and efficient MDL case management.

How to Use Rule 16.1

Rule 16.1(b)(3)(B) - Early Exchanges of Information and Expedited Procedures: From the defense perspective, Rule 16.1(b)(3)(B) is among the most important provisions of the new Rule because it formally recognizes two longstanding case management practices that courts can employ to combat some of MDLs' most pervasive problems.

Individual work-up of bellwether cases and potential bellwether cases is common in MDLs. Bellwethers are a handful of cases intended to be representative of the overall MDL case inventory, and the process of moving them toward trial through case-specific litigation is intended to help the parties to value the remaining claims.⁸ Pretrial proceedings may include trials of bellwether cases if jurisdictional prerequisites are met. Cases not selected as bellwethers may languish without any merits-based work-up, with the non-bellwether plaintiffs obligated to provide only minimal information about their claims through plaintiff fact sheets or similar case management tools.

The limited information available about non-bellwether claims often makes it difficult for the parties to value the overall MDL case inventory. In particular, MDLs without effective mechanisms for culling meritless claims from the outset often attract plaintiffs that lack even *prima facie* claims. The best available data show that between 30 percent and 75 percent of claims in some MDLs are ultimately found to be unsupported.⁹ If parties are considering settlement, it is not possible to accurately value the overall inventory without knowing roughly how many claims will ultimately turn out to be unsupportable. Discussions before a reasonable valuation are unlikely to be productive, and any settlements reached without an understanding of the number of claims with genuine merit can be skewed in plaintiffs' favor by the sheer size of the MDL inventory. Defense counsel must be diligent in advocating for the court to institute effective procedures to cull meritless claims from the outset and throughout the MDL.

Rule 16.1(b)(3)(B) endorses courts' use of early exchanges of information (e.g., plaintiff fact sheets) and procedures to dismiss unsupported claims (e.g., *Lone Pine* orders), case management tools not explicitly provided for by other Federal Rules.¹⁰ Together, collecting information about all plaintiffs' claims and establishing expedited procedures to dispose of unsupported claims can make a major difference in the progression and resolution of MDLs. While individual work-up of bellwether cases can help value potentially meritorious claims, the information developed in those work-ups will rarely help identify the number of unmeritorious claims lurking in the MDL inventory. Individual work-up also entails significant monetary expense and investment of time by the parties and the MDL court. Rule 16.1's endorsement of courts establishing methods to address unsupportable claims at the outset of litigation is critical to move MDLs efficiently toward a fair resolution, whether that resolution is agreed upon by the parties or ordered by a court.

Whether early exchanges of information under Rule 16.1(b)(3)(B) can meaningfully advance the MDL will depend both on the information required and on how readily it can be verified. Plain-

tiff fact sheets and other forms of early information exchanges are much more likely to identify unsupported claims when they require plaintiffs to provide evidence, rather than just their own say-so. As the Rule's Committee Note provides, “[t]he level of detail called for ... should be carefully considered to meet the purpose to be served and avoid undue burdens.”¹¹ The MDL court should also consider whether plaintiffs have “reasonable access” to information when establishing procedures for expedited resolution of claims.¹² Thus, defense counsel should be diligent in identifying from the MDL's beginning which factual issues may potentially be relevant to a plaintiff's *prima facie* claim, particularly those that turn on evidence to which plaintiffs have reasonable access.

Rule 16.1(b)(3)(E) – Measures to Facilitate Resolution: Under Rule 16.1(b)(3)(E), the parties should address “whether the court should consider any measures to facilitate resolving some or all actions before the court.” This stands in contrast to an earlier proposed version of the Rule, which framed this provision as “measures to facilitate settlement.” The defense bar strongly objected to the implication that settlement should be considered from the outset of the litigation, before defendants have a genuine opportunity to value the MDL case inventory. These objections led the Rule's drafters to adopt “resolving” to reflect a broader role for the MDL court than just encouraging settlement.

The Committee Note makes clear that “whether parties reach a settlement is just that—a decision to be made by the parties.”¹³ Rather than simply push “mediation and other dispute resolution alternatives,” MDL courts should also facilitate resolution through “focused discovery orders, timely adjudication of legal issues, selection of representative bellwether trials, and coordination with state courts.”¹⁴ In other words, courts should engage on the merits early in the MDL, helping the parties gain the information necessary to fairly value the MDL claims to efficiently promote a fair resolution.

Presented properly in the preconference report, defendants' views on Rule 16(b)(3)(E) may help forestall or resist any judicial pressure toward premature settlement. Defendants should identify the legal issues and discovery orders required to meaningfully address potentially dispositive legal issues, such as federal preemption or a failure of proof due to an exclusion of expert testimony under Federal Rule of Evidence 702. It is incumbent on defense counsel to communicate that “timely adjudication” of these matters nearly always means that the MDL court should give them early consideration. Unnecessarily prolonging the litigation wastes the resources of the parties and the MDL court, and settlement is unlikely until the parties know if defendants will succeed on their dispositive legal arguments. Defendants should also identify factual issues central to the value of plaintiffs' claims that may warrant early discovery or, more likely, early exchanges of information under Rule 16.1(b)(2)(B).

Rule 16.1(b)(3)(C) – Discovery: “A major task for the MDL transferee judge is to supervise discovery in an efficient manner.”¹⁵ In mass torts, discovery is frequently a major part of defendants' litigation costs. Including discovery as a case management matter to be addressed at the MDL's outset gives defense counsel the opportunity to help define the relevant issues before discovery is served. Under Rule 16.1(b)(3)(G), the parties should identify their initial views on “the principal factual and legal issues likely to be presented” in the preconference report. The Committee Note then advises that “[t]he principal issues in the MDL proceeding may help guide the discovery plan and avoid inefficiencies and unnecessary duplication.”¹⁶

Having the parties identify the principal legal issues and the discovery necessary to evaluate those issues educates the court from the MDL's outset on the appropriate scope of discovery and may provide support for later challenges to overbroad discovery requests. Defense counsel should be prepared to frame the issues appropriately to limit plaintiffs' discovery into irrelevant topics and to articulate what defendants need from plaintiffs to support their defenses, including that plaintiffs' claims lack *prima facie* support. While some discovery will be relevant in virtually any case—*e.g.*, discovery into compliance with statutes of limitations—other issues for discovery will be unique to a given MDL. In products liability MDLs, for instance, discovery may be needed to develop a factual record to support alternative causes or a defense under the learned intermediary doctrine.

Rule 16.1(b)(2)(D) – Direct Filings: As Rule 16.1's Committee Note explains, “some parties have stipulated to ‘direct filing’ orders entered by the court” when large numbers of actions are expected to be filed in or removed to federal court after the MDL is created.¹⁷ As a strategic matter, it will rarely be appropriate for defense counsel to stipulate to direct filings. By obviating the need for plaintiffs to file a complaint in an appropriate venue with jurisdiction over their claims, direct filing may obscure the appropriate state for choice of law questions (including the applicable statute of limitations) and the appropriate legal venue after remand. Defendants considering agreeing to a direct filing order should ensure that any such order contains a provision expressly noting that the defendant retains all of its *Lexecon* rights to eliminate any potential argument by plaintiffs that a waiver occurred.¹⁸ If the parties do stipulate to direct filing, they should reach an agreement detailing the plaintiff-specific information that the complaints must include to identify the state law that applies and the appropriate judicial district for remand in addition to any other information not apparent from a direct filing.

Rule 16.1(b)(3)(A) – Consolidated Pleadings: Some MDLs have used consolidated pleadings, such as master complaints and short form complaints. While it is generally inadvisable for defendants to agree to any form of consolidated pleading, if they are going to be used, it is critical to understand the different types. A master complaint may “supersede prior individual pleadings,” with the legal effect of merging the actions for pretrial proceedings into one complaint, or it may be only an administrative summary of the claims without legal effect or merger.¹⁹ Rule 16.1's Committee Note makes clear that all MDL pleadings, including consolidated pleadings, are subject to the Federal Rules of Civil Procedure.²⁰ Howev-

er, a superseding master complaint may functionally strip away the individualized information courts typically use to evaluate claims at the pleadings stage. Superseding master complaints may also help plaintiffs sidestep pleading requirements imposed by applicable state law. If consolidated pleadings are unavoidable, defendants should seek a case management order clarifying that any consolidated pleadings are for only administrative purposes and have no legal effect on the individual cases within the MDL. Regardless of the type of complaint, defense counsel should be diligent in holding plaintiffs' complaints to the standards that govern all federal pleadings.

What the Future Holds

Although it is hard to yet know the long-term practical impact of Rule 16.1, its enactment may represent an inflection point in how MDLs are managed. The Rule's formal recognition that the Federal Rules of Civil Procedure apply to every case in an MDL proceeding puts to rest any lingering notion that MDLs are “some kind of judicial border country, where the rules are few and the law rarely makes an appearance.”²¹ Moreover, the Rule endorsing and formalizing the early consideration of case management issues may entrench and expand the growing trend of judges effectively employing case management tools to address MDLs' endemic problems.

Very early signs offer some cause for optimism. Even before Rule 16.1 became law, new case management orders in some MDLs suggest that judges may have taken the new Rule's lessons to heart. In May 2025, the court in the *Depo-Provera* MDL entered the parties' agreed-upon order requiring that each complaint include necessary plaintiff-specific allegations, establishing processes to identify deficient complaints, and creating a timeline for plaintiffs to cure any deficiencies or face sanctions, including dismissal.²² The *Aqueous Film-Forming Foam* MDL had been ongoing for almost seven years when the court entered a new case management order in August 2025. That order included deadlines by which every plaintiff would have to provide completed plaintiff fact sheets, provide records proving they were diagnosed with their alleged injuries (and when), and submit proof of their exposure to the allegedly harmful substances at issue in that litigation.²³

While Rule 16.1 becoming law is progress, it is only the next step in a long process of improving how MDLs are managed. It is incumbent on defense counsel to continue advocating for the evolution of case management norms to help promote a fairer and more efficient MDL system that is less subject to abuse. ◉

Endnotes

¹U.S. Courts, Judicial Caseload Indicators - Judicial Business 2024, <https://www.uscourts.gov/data-news/reports/statistical-reports/judicial-business-united-states-courts/judicial-business-2024/judicial-caseload-indicators-judicial-business-2024.>; U.S. Courts, Table S-19, Cases Transferred by Order of the Judicial Panel on Multidistrict Litigation, Cumulative from September 1968 Through September 30, 2024, https://www.uscourts.gov/sites/default/files/2025-01/jb_s19_0930.2024.pdf; Robert Johnston & Gary Feldon, *Federal MDL Rule Benefits From Public Comments*, Law360 (Apr. 10, 2024), <https://www.law360.com/articles/1823645/federal-mdl-rule-benefits-from-public-comments>.

²Multidistrict Litigation Act of 1968, codified at 28 U.S.C. § 1407.

³Fed. R. Civ. P. 16.1 (“Rule 16.1”).

⁴Rule 16.1(a) Committee Note.

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