Flipping the Script

Managing Consolidated Trial Risk in Drug and Device Litigation

By Patrick H. Reilly, Tarifa B. Laddon, and Theodore E. O'Reilly

Individual cases affect each other and have the power to influence mass tort litigation outcomes.

Consolidated, multi-plaintiff trials cast a long shadow over the defense in mass tort drug and device litigation. In the current environment, they seem to be an inherent risk—an important source of leverage for plaintiffs' counsel.

For that reason, defense counsel may sometimes find themselves resigned to the possibility that trial could involve a multi-plaintiff cacophony with a potentially outsized verdict from a confused jury. But if consolidated trials mean leverage for plaintiffs in mass tort drug and device litigation, then in a very real sense, that means *single-plaintiff trials* are leverage for defendants. How can you flip the script and make plaintiffs' counsel worry about single-plaintiff trials for a change? We don't want to suggest there is any one-size-fits-all strategy here. There isn't. But we believe that any defense-side litigator in this area—from first-year associate to partner—can benefit from a few guiding principles that consider how individual cases affect each other and can be leveraged from the outset of mass tort litigation.

Consolidation Chaos in the World of Mass Tort Drug and Device Litigation

Consolidated trials are a growing risk in mass tort drug and device litigation. By some measures, mass tort litigation is

■ Patrick H. Reilly is a partner in Faegre Drinker Biddle & Reath LLP's Indianapolis office. He is a member of the product liability and mass torts team and co-chair of the medical device practice. His focus is on complex litigation involving drugs, medical devices, and sports. He is also a member of the DRI Drug and Medical Device Committee. Tarifa B. Laddon is a partner in Faegre Drinker Biddle & Reath LLP's Los Angeles office. She is a member of the product liability and mass torts team and life sciences industry team. Ms. Laddon focuses her practice on representing manufacturers of pharmaceuticals and medical devices, with an emphasis on mass torts and jury trials. Ms. Laddon is a member of the DRI Women in the Law and Drug and Medical Device Committees. Theodore E. O'Reilly is an associate in Faegre Drinker Biddle & Reath LLP's Los Angeles office. He is a member of the firm's product liability and mass torts group. Mr. O'Reilly represents manufacturers in complex product liability matters, with a particular emphasis on medical devices and mass torts. Mr. O'Reilly is also a member of DRI. Associates Katie M. Jackson and David P. Koller assisted in the research and preparation of this article.



becoming more prevalent. In 2019, more than 50 percent of the federal docket consisted of multidistrict litigation (MDL) proceedings. Over a third of those MDL proceedings were product liability matters. And as of 2019, most of those product liability MDLs involved pharmaceutical products or medical devices, according to a separate study. A. Vickery et al., *The Trend Toward MDLs in Products Cases*, Aug. 6. 2019.

Consolidated trials pose a significant risk in this environment. To some judges, consolidated trials may seem to offer an efficient case-management tool at the bellwether stage that leads to the resolution of numerous claims and helps determine settlement values. Some judges may also view consolidated trials as a useful tool later in the litigation because they raise the stakes of trial and incentivize settlement. But there is little agreement on whether consolidated trials actually further the goals of global settlement. Some commentators—and virtually all defense counsel—do not believe that multi-plaintiff trials assist settlement efforts at all, at any stage in the litigation. For instance, the 2018 edition of the Bolch Judicial Institute, Duke Law School, *Guidelines and Best Practices for Large and Mass-Tort MDLs* (2d ed.) takes the view that "[c]onsolidation can tilt the playing field, undermining the goal of producing representative verdicts." Consolidated bellwether trials, the guidelines add, "may confuse juries."

For plaintiffs, however, the mere *threat* of consolidated trials provides leverage against the defense. It does so for a few basic reasons. Many of these are similar to the concerns raised in class certification of mass tort claims: aggregation "magnifies and strengthens the number of unmeritorious claims," "makes it more likely that a defendant will be found liable," "results in significantly higher damage awards," and "creates insurmountable pressure on defendants to settle," which is akin to "judicial blackmail," as one court put it. *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 746 (5th Cir. 1996). Regarding consolidated trials specifically, a recent October 2019 study by the Institute for Legal Reform (ILR) found that consolidated trials in MDL proceedings "substantially increase[ed] the likelihood and size of each plaintiff's verdict." John Beisner et al., U.S. Chamber Inst. for Legal Reform, *Trials and Tribulations: Contending with Bellwether and Multi-Plaintiff Trials in MDL Proceedings* (Oct. 2019). Statistically, consolidated trials resulted in plaintiff verdicts almost 80 percent of the time. No consolidated trials identified in the ILR study ended in split verdicts. Conversely, single-plaintiff trials in MDL proceedings favored plaintiffs less than 40 percent of the time.

Although the significant delta between verdicts in consolidated and single-plaintiff trials is shocking, the reasons behind it are not. By their very framework, consolidated trials prejudice the defense. As the ILR study points out, juries often have a hard time distinguishing the facts and evidence among each plaintiff's claims, which can cause substantial "prejudicial juror confusion." When they are presented with a trial in which defendants are facing multiple similar claims at once, juries also tend to develop a negative view of those defendants, which can lead the jury to attempt to "punish defendants based on the multiplicity of claims." Moreover, when one plaintiff in a multi-plaintiff trial is particularly sympathetic, the jurors may apply their sympathy to all plaintiffs and may hold the defendants "liable to all plaintiffs based on factors that do not apply to all of them." This prejudicial framework, in turn, contributes to damages awards that are significantly higher than they are for those in single-plaintiff trials. Thus, instead of helping both sides come to an agreement on *reasonable* case valuations, multi-plaintiff trials instead "artificially skew[] the perceived 'trend' of the litigation in the plaintiffs' favor."

Commentators have pointed out that due to the high prevalence of error, many consolidated trials may turn out to be "hollow victories" for plaintiffs that simply lead to years of appellate litigation before the verdict is reduced or reversed. Every single one of the pro-plaintiff verdicts identified by the ILR study was ultimately appealed, for instance. Even if some appellate courts reverse nuclear, consolidated verdicts for error, it may be cold comfort. Companies likely do not want to face that disruption and stress in the interim. And again, to the extent that these verdicts are subject to change on appeal, it can be difficult for either side to have confidence that the verdicts provide information reliable enough to set values for the other cases in the MDL.

Given these issues, plaintiffs may use the threat of consolidated trials to increase settlement value, regardless of whether a consolidated trial ever occurs in the litigation. This risk seems nearly unavoidable in *any* consolidated trial involving pharmaceutical products or medical devices, given that liability heavily depends on plaintiff-specific facts, including their individual medical histories, how physicians treated and communicated with specific plaintiffs, how warnings differed based on when the plaintiffs filed their specific actions, and the unique experiences that each plaintiff had with the product at issue.

What's the Worry?

If defense counsel approach mass tort pharmaceutical or medical device litigation without properly focusing on the risk of consolidated trials, they may face a difficult position later. At the outset of what will become a mass tort litigation, the parties' and courts' initial decisions lay the foundation for the later course of events.

It is similar to pouring new concrete. If the concrete dries in the wrong way, structural defects and cracks may be difficult to fix. You may not be able to install that outdoor grill because your concrete pour did not allow for gas and electric on the patio. In much the same way, without diligent efforts at the outset of litigation, defense counsel may later find that they have created a structurally deficient foundation that leaves them opposing a multi-plaintiff trial on less than firm footing. Certain factors that courts have found to favor consolidation may have been built into the litigation's foundations at earlier points, before counsel actively began taking the risk into consideration.

For instance, if the court is considering whether to consolidate apparently uniform claims for trial from a bellwether pool, the court may have already developed the (wrong) impression that the claims of the entire mass tort litigation are fairly well defined. As a result, the court may be more susceptible to consolidation. When the litigation reaches that point, however, it may be very difficult for the defense to argue—for the first time—that the pool actually is

not representative of the broader litigation. That fight should have occurred long before.

By the same token, defense counsel should take advantage of every opportunity they have to flip the script on plaintiffs' counsel by pushing for single-plaintiff trials that are more favorable for defendants. As the ILR study mentioned above, plaintiffs prevailed in well less than half of single-plaintiff trials held in MDL litigation over the past decade. Simply put, single-plaintiff trials are a countervailing leverage opportunity.

Flipping the Script

We intend these basic guidelines to help you come up with a defense strategy for addressing consolidated trial risk. While this article focuses mainly on MDL mass tort litigation, the general approach—flipping the script—can be applied to mass tort drug or device litigation in any context, including in the (at least) fifteen states that provide MDL-like procedural tools at the state level. This is meant to be an adaptable approach, not a rigid prescription, because almost every mass tort litigation is different, and the risk of consolidated trials cannot be eliminated completely. Put another way, these points are meant to prompt thought, not to become a plug-in strategy. In some circumstances, these guidelines may be more or less relevant, and it may not always prove possible to achieve the goals suggested below.

Dynamic Case Management

From the beginning, defense counsel should approach case management purposefully. Consider how each decision affects the later fight over consolidated versus single-plaintiff trials. These decisions arise constantly, and sometimes in unexpected ways.

At the outset, defense counsel should lean into any potential initial advantage by pushing for early, single-plaintiff trials, as long as the client is on board. Generally, commentators favor single-plaintiff bellwether trials due to their superiority when it comes to setting value for the other claims in the mass litigation. For instance, the 2018 edition of the *Guidelines and Best Practices for Large and Mass-Tort MDLs* flatly states: "Cases should generally not be consolidated for trial" at the bellwether stage because "[c]onsolidation can tilt the playing field, undermining the goal of producing representative verdicts." Bolch Jud. Inst., *supra*. Thus, defense counsel should approach the bellwether process from a position of confidence: *single-plaintiff bellwethers are simply the way it should be done*. Plaintiffs are the ones who should be fighting an uphill battle here.

Early single-plaintiff bellwethers not only provide more information for evaluating the other claims but can also apply pressure to plaintiffs' counsel if the defense can prevail at a reasonable rate (and the numbers suggest that this is possible). Suddenly, plaintiffs' counsel's investment in the mass tort litigation, and perhaps even their rationale for investing time and resources in taking a case to verdict, looks shakier. Pushing for trial aggressively may not always make sense, of course. It may be possible for the parties to reach agreement on valuation without trying bellwethers, for instance. But if plaintiffs' counsel make noise about consolidated trials from the proverbial get-go, an aggressive response might be the best option.

This may require sustained negotiations to achieve favorable case-management orders. During the negotiations, defense counsel may need to balance various considerations against the need to insulate their clients from consolidated trial risk. *Lexecon* waivers are one decision point in this regard, if cases have been transferred to an MDL, or there is a direct filing order. Conceivably, a defendant *might not want* to pursue trial in the MDL court. In that case, refusing to waive *Lexecon* would largely reserve the question of multi-plaintiff trials for plaintiffs' home courts on remand, which may or may not be desirable.

If a defendant *does* want the MDL court to oversee trials, the defendant might instead explore the possibility of limiting *Lexecon* waivers to single-plaintiff trials only. That solution sounds straightforward on paper. But it may not prove so simple in practice. It might undermine other goals. For instance, limited waiver might make it harder, or even impossible, for the parties to agree on a bellwether process in the MDL. Or the MDL court simply might be more likely to remand cases for trial in their home courts. Remanded cases in particular may be incredibly burdensome for defendants, who may be forced to prepare for dozens of trials simultaneously, in transferee courts across the country, presided over by judges who may follow their own views of the best way to manage the case in front of them (potentially without much regard for the effect on the rest of the mass tort litigation). And even if a defendant does not specifically limit *Lexecon* to single-plaintiff trials, jurisdictional issues may still weigh against joint trials. Choice-of-law problems may be daunting for plaintiffs seeking consolidated trials in an MDL. All things being equal, MDL courts should be hesitant about a consolidated trial that would require a court to apply two or more different states' product liability laws. Where cases are direct filed, defense counsel may be able to argue that the plaintiffs should not get the benefit of a joint trial in the MDL that they would not have had if they filed in their home courts. Bottom line, consolidated trial risk should be a major factor in making the *Lexecon* waiver decision.

Bellwether-pool selection is another decision point. If the pool is not purely randomly selected, then defense counsel should attempt to limit the extent to which it is stacked (intentionally or not) with ostensibly "identical" plaintiffs. The goal is to avoid a situation where bellwether plaintiffs appear to be clones who will be able to point to superficial similarities in support of joint trials. All the early information that counsel was able to collect will be crucial. To be clear, this is not a call for gamesmanship, which is sometimes a concern of MDL courts in this area. Just the opposite. A diverse pool furthers the goals of the bellwether process better by making it more likely that the parties will test a broader range of claims. Consolidated trials undercut the value of this process.

Motion practice may also provide opportunities to lay a solid foundation, well before the parties actually brief consolidation. For example, if the defense can foreclose certain claims or punitive damages allegations through Rule 12 motions, that may provide another barrier to joint trials by further differentiating tranches of cases. It may even make trial less attractive for plaintiffs in general. Defense counsel can also potentially use another much-discussed tool: *Lone Pine* orders. Even if such an order does not lead to case dismissals, it may be worth pursuing at the appropri-

ate point because it can help make clear the depth of the dispute over "no injury" cases. For instance, if a litigation team achieves a screening order that categorizes cases into multiple categories of claim type, it will decrease the likelihood of later consolidation.

Drill Down on Individual Issues

Defense counsel's trial preparation workup for single-plaintiff trials should serve double duty: it should also be the basis for opposing consolidation. The exact legal formulation varies by jurisdiction, but a key factor in the consolidation analysis is whether "individual issues outnumber common issues." *In re Dalkon Shield IUD Prods. Liab. Litig.*, 693 F.2d 847, 853 (9th Cir. 1982). There are two types of discovery here: case-specific discovery, such as plaintiffs' individual medical histories; and generic or company discovery that is common across groups of cases, to a greater or lesser degree. Defense counsel should actively leverage both types of information in the fight against consolidated trials.

The more case-specific information that defense counsel can obtain early on, the better. Depending on the circumstances and the court, potential sources of individualized information include the basics: plaintiff fact sheets; written discovery; medical records, and depositions of plaintiffs, their family members, and their treating physicians. Often, this discovery occurs in stages or waves, particularly in actively managed MDL proceedings. That puts the onus on defense counsel to seek wider latitude actively for early discovery, which may often require careful negotiation. Even if all that will be forthcoming early on is a fact sheet, defense counsel should make the most of it. They might press for as detailed a form as possible, even if the defendant will need to reciprocate with a detailed fact sheet.

While collecting as much detailed, case-specific information as possible is crucial, it is not sufficient. The information needs purpose. Defense counsel must have a plan to make this information actionable for opposing consolidation. Again, there are many ways to do this, from assigning paralegals to perform comprehensive deep dives into medical histories, to working with case-specific experts to understand individual plaintiffs' conditions, to assigning associates to evaluate key criteria and create matrices or grids. This process does not have to be one-size-fits-all, of course. For instance, it can be relatively substantive: what did each treating physician know regarding risks, and when did he or she know it? Or it may be more basic: associates may be able to differentiate cases into different groups based on a few indicators, and then a paralegal team might prioritize higher concern categories over others in the process of preparing chronological summaries of individual plaintiffs' medical histories. The litigation team will then be able to focus on those higher concern cases earlier, and plan accordingly for how best to pitch single-plaintiff trial plans and oppose consolidation, if necessary.

Company discovery may be equally as important because individualized issues may boil down to differences among various iterations of pharmaceutical products and medical devices, and the related regulatory, design, and testing histories of each product. Defense counsel should work closely with defendants to understand the universe of products at issue, their history, and how they are intended to perform and/or differ. Key differences to highlight might concern warnings and labels on pharmaceuticals or the history of the design and development of ostensibly similar medical devices within product groups. For instance, if different plaintiffs were implanted in different years with different iterations of a product, then there may be very little "common" discovery. To the extent that products differ, plaintiffs' arguments for efficient presentation of company discovery at trial become even less persuasive.

Defense counsel should not assume that this discovery can wait. Although it is true to some extent that substantial time will often pass before it is clear which cases are resistant to settlement and will need to be worked up in discovery for potential remand and trial, the earlier counsel can drill down to individualized issues and begin highlighting them for the court, the better. That information may help make single-plaintiff trials a foregone conclusion. Even if it doesn't, however, it will help mitigate the risk of consolidation at every step of the way, even if the question of joint trial is not briefed until much later.

Deal with the Difficult Cases

Every mass tort litigation is different and flipping the script may not always be possible. In some circumstances it may be exceedingly hard to avoid consolidated trials. For example, the judge overseeing the current MDL may have previously handled consolidated trials and may feel confident in doing so again. An MDL court that oversaw single-plaintiff bellwethers may conclude that such trials no longer serve the purpose of settlement, the issues are sufficiently well-defined, and consolidated trials are appropriate. Transferee courts may also consolidate cases for similar reasons, regardless of whether those reasons are well-founded. These are relatively common scenarios.

In these potentially more difficult circumstances, defense counsel must be realistic. It will be important to create a record for the inevitable appeal, and defense counsel should be making a conscious effort to do so throughout the litigation. Counsel should not wait until the last round of pretrial motions and trial objections. For instance, in an initial status conference after remand, a transferee court might foreclose remaining discovery that was not feasible or reasonable for the defendant to complete in the MDL. If that discovery is necessary to oppose consolidation, it may not be enough for counsel to argue the issue briefly at the status conference, which may or may not be recorded. It might be important for the defendant to make clear, via a noticed motion to reopen discovery or some other means, which information is and is not available, and how it negatively affects the consolidation analysis.

With tough cases, defense counsel must also keep the right mindset. Making a record should not eclipse the other aspects of being a good trial lawyer. For instance, defense counsel might consider front-loading objections via motions in limine as much as possible, so that they can take a targeted approach to live objections at trial, which may positively influence juror perceptions.

Be Direct with Clients

Given the stakes, it bears emphasizing that client communication is essential for success. The clearer and more direct the

communication, the better. When defense counsel and in-house counsel are squarely on the same page, defense counsel can confidently be more aggressive about pushing for earlier, single-plaintiff trials, which we believe is the best counter to the threat of consolidated trials. Likewise, in-house counsel answer to others at their company, and they need to be comfortable trusting defense counsel because consolidated-trial risk can be significant. Accordingly, be on the same page: defense counsel should make sure that their in-house counterparts know what is being done about the risk and why. They should not assume that in-house counsel—who are often very busy—are thinking through what consolidated trials mean at each stage of the litigation. Be realistic about the risks: there is no surefire way to eliminate the risk of consolidated trials, and in some circumstances, the likelihood of consolidated trials may be quite high. Be clear about that. And be open to changes in strategy: as the litigation progresses, goals may need to be adjusted and different tactics employed. Defense counsel should reevaluate the situation with in-house counsel as needed. At bottom, communication will help in-house counsel set expectations internally. They will be armed with the information that they need to do their job better.

The Risk Is Here to Stay

The risk of consolidated trials will probably be with defense counsel and their clients for the foreseeable future in mass tort litigation involving pharmaceutical products or medical devices. The MDL Subcommittee of the Advisory Committee on Civil Rules Judicial Conference of the United States continues to discuss a number of proposed rules or reforms that would affect mass tort litigation, but none of the reforms look likely to affect consolidated trial risk significantly. The related October 3, 2019, letter from forty-five general counsel to the Judicial Conference of the United States Committee on Rules of Practice and Procedure also did not specifically address consolidated trials, although it did raise MDL parties' concern over "an uncertain legal environment" in which they may not know, among other things, "what motions the court will entertain…." Perhaps, in the future, there will be some room to consider limitations on consolidated trials.

For the time being, the risk is here to stay. As long as that is the reality of mass tort litigation in this area, the flip-the-script attitude advocated here should help defense counsel approach this difficult issue with the right strategic mindset. FD