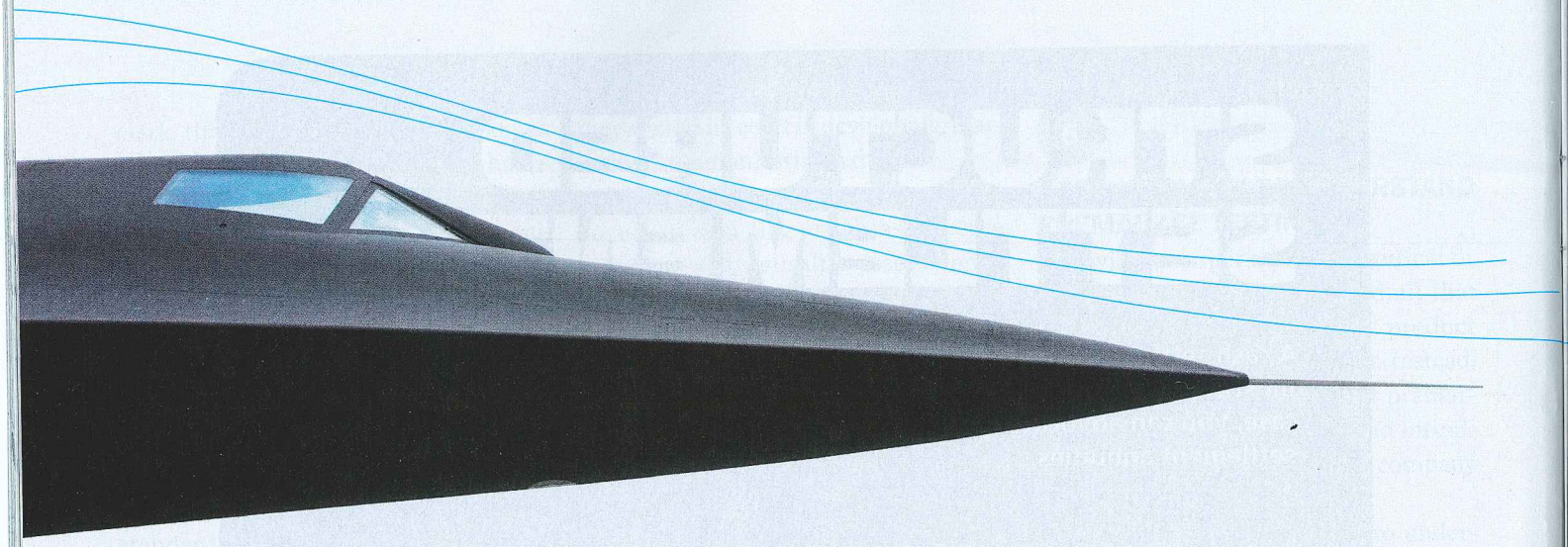

STREAMLINING MDLs

In the Benicar litigation, early and proactive court intervention has streamlined the process and is a model for other plaintiff attorneys to follow. *By* || ADAM M. SLATER

In 2002, Japanese drugmaker Daiichi Sankyo, Inc., began to market Benicar, a new hypertension medication.[1] In the 2014 fiscal year, Benicar's sales exceeded 2 billion dollars.[2] But postmarket surveillance revealed a side effect not foreseen when the drug was launched: small-intestine inflammatory damage that develops over time—sometimes years—and presents as a celiac-like syndrome. It can cause chronic diarrhea, severe weight loss, and other gastrointestinal problems.[3] Despite signals of this side effect soon after the drug came on the market, no warning was included in the label until the FDA forced Daiichi to add one in July 2013.[4]

In April 2015, the U.S. Judicial Panel on Multidistrict Litigation consolidated Benicar cases into a multidistrict litigation (MDL) and assigned it to Judge Robert Kugler in the District of New Jersey.[5] About 1,300 cases have been filed to date. This MDL's process has been an exemplar of current trends in mass tort discovery, offering solutions to the inevitable defense-orchestrated roadblocks present in most mass tort cases.

Early on, the court recognized that many disputes were impeding the pace of discovery, including the language in the protective order and electronically stored information protocol and the defendant's failure to comply with agreements and court orders to produce documents, such as adverse-event source files.

In response, the court scheduled discovery conferences, usually in court, nearly every two weeks. The court's aggressive oversight changed the litigation's entire dynamic, and it has produced swift decisions and relentless progress. This system should be followed in any case when discovery is repeatedly blocked by defendants.

Streamlining and expediting discovery. Early on, the court focused discovery on general causation to achieve a quick resolution of the litigation. The judge concentrated on swiftly reaching the *Daubert* stage on issues of general causation, pinpointing this as the fundamental bellwether issue in the litigation. This approach is innovative, and mass tort leadership should expect more judges to focus on general causation early.

By taking this approach in the Benicar litigation, discovery has been structured through a "macro" framework—focusing on distinct, big-picture issues essential to the plaintiffs' proof of general causation, such as gaining access to adverse event reports and source files, key databases in native format, and raw clinical trial data. This broad focus has made it harder for the defense to evade reasonable discovery requests.

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The court also has eschewed formal discovery protocols in favor of informal requests and is willing to rule quickly on almost all disputes, resulting in a constant flow of important documents and data. From March to July, 40 key "causation-related" defense witnesses will have been deposed, to be followed by pinpointed Rule 30(b)(6) depositions related to general causation, expert discovery, and *Daubert* motions on general causation. As plaintiff attorneys, we should embrace this opportunity, since the alternative often is aimless battles at a plodding pace over tangential discovery requests and minutiae with no real endgame.

Active court management. The court has issued other important decisions that are instructive across all MDLs. For example, it denied Daiichi's motion to seal documents, strongly disapproving of over-designation and offering a roadmap for challenging confidentiality designations in general.[6] The court found: "The fact that a party may not want the public to view its potentially damaging documents is not determinative as to whether a document should be sealed."[7]

Plaintiffs also instituted a weekly meet-and-confer process on the typically oversized privilege log. As a result, documents have been systematically removed from the log by consent, without the need for court intervention.

The court developed a detailed protocol for defense depositions after a contested hearing.[8] In part, the attorney defending the deposition is prohibited from explaining a form objection, unless requested by the questioning attorney. Over objection, Daiichi must produce each deponent's work performance evaluations, because it will streamline questioning.[9] Performance evaluations can be substantive and should be used when available in any litigation.

The court also denied Daiichi's request to depose Japanese witnesses in Japan and selected Hawaii as a compromise. The plaintiffs argued that depositions in Japan would be extremely burdensome, in part because of restrictions that Japanese law imposes on the permissible scope of questions, and they argued that conducting the depositions in the United States would offer significant efficiencies for the court and the parties.

Bellwether considerations. The court randomly selected bellwether cases—a recent trend.[10] The court balanced this by randomly selecting the cases to replace bellwethers that were voluntarily dismissed and by denying Daiichi's request for extra strikes to balance the dismissals, finding no evidence that the pool was rendered less representative.

In the context of bellwether discovery, the court denied Daiichi's motion to preclude the plaintiffs' counsel from speaking with prescribing and treating doctors about anything other than the case-specific medical treatment before their depositions. The court rejected this motion as overstated and unworkable.[11] This decision is consistent with recent decisions in other MDLs, and it likely signals that such motions are not viable in federal courts in the absence of unique factors.[12]

Ultimately, as with most pharmaceutical MDLs, these cases will rise and fall largely based on discovery, as well as the scientific evidence and literature supporting causation. However, the court's aggressive, results-oriented approach will continue to be an important factor in this litigation, and it offers a blueprint for a streamlined approach in future MDLs.

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Notes

1. Benicar is the first hypertension medication sold by Daiichi containing olmesartan medoxomil. Daiichi added Benicar HCT, Azor, and Tribenzor to the line. All are collectively referred to as Benicar.
2. Kanoko Matsuyama, *Growth Concerns Loom for Daiichi Sankyo on Drug Warning: Health*, Bloomberg (Feb. 8, 2015), www.bloomberg.com/news/articles/2015-02-08/growth-concerns-loom-for-daiichi-sankyo-on-drug-warning-health.
3. Eric V. Marietta et al., *Immunopathogenesis of Olmesartan-Associated Enteropathy*, 42 Alimentary Pharmacology & Therapeutics 1303–14 (2015).
4. U.S. Food & Drug Admin., *FDA Drug Safety Communication: FDA Approves Label Changes to Include Intestinal Problems (Sprue-Like Enteropathy) Linked to Blood Pressure Medicine Olmesartan Medoxomil* (July 3, 2013), www.fda.gov/Drugs/DrugSafety/ucm359477.htm.
5. In accordance with New Jersey federal court practice, Judge Kugler's magistrate, Joel Schneider, has overseen the management of discovery.
6. *In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 1:15-md-02906-RBK-JS, MDL No. 2606 (D.N.J. Jan. 21, 2016) (order denying the defendant's motion to seal).
7. *Id.*
8. *In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 1:15-md-02906-RBK-JS, MDL No. 2606 (D.N.J. Mar. 8, 2016) (case management order no. 22 on deposition guidelines).
9. *In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 1:15-md-02906-RBK-JS, MDL No. 2606 (D.N.J. Mar. 24, 2016) (order granting the plaintiffs' request for performance evaluations).
10. *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, No. 2:14-md-02592-EEF-MBN, MDL No. 2592 (E.D. La. Nov. 20, 2015) (case management order no. 3 on the process for selecting bellwether discovery pool).
11. *In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 1:15-md-02906-RBK-JS, MDL No. 2606 (D.N.J. Apr. 6, 2016) (order granting in part and denying in part the defendants' motion to preclude woodshedding).
12. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 2016 WL 929343 (N.D. Ill. Mar. 7, 2016); *In re Xarelto*, 2016 WL 915288 (E.D. La. Mar. 9, 2016).