

CALL FOR PUBLIC COMMENT

**STANDARDS AND BEST PRACTICES
FOR LARGE AND MASS-TORT MDLS
BOLCH JUDICIAL INSTITUTE, DUKE LAW SCHOOL
(UPDATING DECEMBER 19, 2014, REPORT)**

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STANDARDS AND BEST PRACTICES FOR LARGE AND MASS-TORT MDLS

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(Updating and Revising December 2014 MDL
Standards and Best Practices)

CHAPTER 1

MANAGEMENT OF TRANSFERRED CASES

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MDL STANDARD 1: The transferee court, in consultation with the parties, should articulate clear objectives for the MDL proceeding and a plan for pursuing them. The objectives of an MDL proceeding should usually include: (1) the elimination of duplicative discovery; (2) avoiding conflicting rulings and schedules among courts; (3) reducing litigation costs; (4) saving the time and effort of the parties, attorneys, witnesses, and courts; (5) streamlining key issues; and (6) moving cases toward resolution (by trial, motion practice, or settlement).

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BEST PRACTICE 1C: At an early juncture, the parties and the transferee judge should collaboratively develop a discovery plan.

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BEST PRACTICE 1C(IV): Individual claimants should be required to produce information about their claims.

In non-MDL cases, plaintiffs are required to produce information about their claims from the outset, and that practice should not change simply because a claim has been transferred into an MDL proceeding. Such a balanced approach will ensure that both sides obtain information critical to claims or defenses. Moreover, development of plaintiffs' individual claims is vital to the establishment of a fair and informative bellwether trial process and is indispensable to any settlement discussions in which the parties may engage. In fact, settlement talks are often delayed because the parties have not anticipated the need to assemble information necessary to assess the strengths and weaknesses of the global litigation and examine the potential value of individual claims. Finally, requiring plaintiffs to produce information verifying their basic factual allegations should allay concerns that MDL proceedings invite unsubstantiated claims.

Of course, until determinations are made about the process by which cases might be selected for bellwether trials (if any) in the MDL proceeding (as discussed

below) or early remand to transferor courts for trials, there is no need to delve into full case development of all cases (e.g., plaintiff depositions, case-specific expert discovery). Rather, each claimant should initially be required to engage in streamlined, cost-effective paper discovery to the maximum extent possible.

BEST PRACTICE 1C(v): In large mass-tort MDLs, a court should, on the parties' request, consider issuing a case management order approving plaintiff and defendant fact sheets, which can provide useful case-management information for purposes of selecting bellwether trials and conducting settlement negotiations. Fact sheets also help to uncover cases that should not have been centralized in the first instance.

One of the most useful and efficient initial mechanisms for obtaining individual discovery in large mass-tort MDLs is the use of fact sheets. Fact sheets are court-approved, standardized forms that seek basic information about plaintiffs' claims and defendants' knowledge about aspects of those claims — for example, what injury the plaintiff sustained as a result of using the product and defendant's representative's contacts with providers of allegedly harmful pharmaceuticals. Plaintiff fact sheets spare defendants the expense of tailoring countless interrogatories to individual claimants¹ while allowing plaintiffs' attorneys to fulfill early discovery obligations with relative ease. It is also common in mass-tort MDL proceedings for the parties to negotiate (and for the court to approve) defendant fact sheets.² However, fact sheets will be meaningful only if plaintiffs, defendants, and their counsel devote appropriate time and attention to this project. The fact sheets should be deemed a form of discovery governed by the relevant Federal Rules of Civil Procedure, requiring the same level of completeness and verification.

Fact sheets can serve multiple purposes. The parties and court should give careful consideration to the purpose of plaintiff and defense fact sheets in their MDL, given the needs of the litigation. Fact sheets can provide an efficient mechanism to assist the parties and the court in assessing whether certain claims may be candidates for expedited resolution through voluntary withdrawal, dispositive motions, or through a settlement process. Moreover, fact sheets sharpen assessments of the propriety and focus of a bellwether process.

¹ See JOHN H. BEISNER & JESSICA D. MILLER, *ELIMINATE THE TORT, NOT THE MASS: A MODEST PROPOSAL FOR REFORMING HOW MASS TORTS ARE ADJUDICATED* 4 (Wash. Legal Found. 2009), <http://www.wlf.org/upload/beisner09.pdf> (expressing concern about the quality of mass-tort claims filed in MDL proceedings, noting that “[t]his problem is compounded by the fact that many of the claims are not developed by the filing counsel — they effectively were purchased from other attorneys who advertised to attract claimants in their home markets with no intention of ever litigating the claims themselves”); MCL § 22.83; see also Elizabeth J. Cabraser & Katherine Lehe, *Uncovering Discovery*, 12 SEDONA CONF. J. 1, 8 n.40 (2011) (“The use of ‘fact sheets’ to streamline discovery by replacing formal interrogatories with supposedly less onerous, more fact-oriented formats is now a common practice in mass tort multidistrict litigation.”).

² See, e.g., Pretrial Order No. 6: Plaintiff Fact Sheets and Defendant Fact Sheets at ¶ 12, *Bextra & Celebrex Marketing Sales Practices & Prod. Liab. Litig.*, MDL No. 1699 (N.D. Cal. Feb. 13, 2006).

Streamlined plaintiff fact sheets (one to two pages) can be used in some MDLs to quickly identify cases that should not have been added to the cases centralized in the MDL in the first instance. In other MDLs, including large mass torts, more extensive plaintiff fact sheets (five to twenty pages) can serve a broader purpose, providing some useful information to the court and parties to inform selection of bellwether trials and settlement negotiations. If only a few core questions are required to be completed, the same fact sheet can serve both purposes.

Targeted plaintiff fact sheets can be particularly useful in the largest mass-tort MDLs, which involve personal injury claims allegedly caused by a pharmaceutical drug. In such cases, the plaintiff fact sheet should provide sufficient information to permit the parties and the court to determine: (1) product identity (if not covered in a preliminary product identification disclosure); (2) exposure, alleged injury, and any adverse consequences; (3) date of injury and of notice or discovery of defendant(s)' alleged wrongful conduct; and (4) authorizations for the release of relevant medical and pharmacy records and other relevant fact sources (such as employers, where wage-related claims are asserted).

Similarly, requiring the collection of plaintiffs' medical records (in personal injury cases) or employment histories (in employment cases) is another straightforward way that a transferee judge can encourage a robust exchange of key information at a relatively early stage. This information can help defendants verify the answers provided in the fact sheets and can shed light on the potential causes of the plaintiffs' injuries.

As part of the parties' preparation and negotiation of proposed fact sheets, they should work on protocols or proposed orders governing the form and scope of authorizations and records-collection procedures. Parties should work to reach agreement on and obtain court endorsement of authorization forms, when and how they may be used, the timeframe and subject-matter scope of permissible records collection, how records will be collected and made available, and how collection costs will be divided.³ Addressing these issues early in an MDL facilitates uniformity and efficiency during this important early information-gathering phase and obviates unnecessary disputes and delay.

BEST PRACTICE 1C(vi): When plaintiff fact sheets are used, defendant fact sheets may serve a similarly important purpose.

In MDLs employing a plaintiff fact sheet, the defendant may also be directed to reciprocate by providing the plaintiff with a defendant fact sheet after an agreed upon period of time. Like the content of the plaintiff fact sheet, the content of a defendant fact sheet will vary based on the claims involved in the MDL and should

³ See, e.g., Pretrial Order No. 22, Service of Plaintiff Fact Sheets and Defendant Fact Sheets at ¶¶ 6–7, *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 2740 (E.D. La. Mar. 10, 2017).

be negotiated by the parties to facilitate the early exchange of information. For example, if streamlined plaintiff fact sheets are agreed upon by the parties, the defendant's fact sheet should be equally streamlined. Conversely, some large mass-tort MDLs will likely call for more extensive defendant fact sheets. The parties should also discuss the content and timing of defendant fact sheets concurrently with their discussion of plaintiff fact sheets.

The parties thus should consider to what extent the defendant should be required to produce fact sheets for individual plaintiffs, providing basic information the defendant may have about the claimant, her physicians (in product liability injury cases), or her claim. The utility and practicability of individualized information in defendant fact sheets depends upon a number of factors, including the nature of plaintiffs' allegations and the pre-suit relationship (if any) between plaintiffs and defendant, or, in a personal injury case, the contacts or relationship between defendant and plaintiffs' physicians.

The extent to which defendants are required to provide individualized, patient-specific information should be considered on a case-by-case basis. Factors to consider include the likelihood of defendant possessing any plaintiff-specific documents or information and the accessibility and potential relevance of any such documents or information.

In large mass-tort MDLs involving alleged harmful pharmaceuticals or medical devices, the defendant fact sheet typically would provide sufficient information regarding contacts and communications with the plaintiff's medical provider(s), including: (1) identification of the representatives who met with or called upon such provider(s); (2) the dates of contact; (3) existence of "call notes" or similar documents that summarize the contacts with the physician(s); and (4) payments, honoraria, reimbursements, or other financial arrangements with such provider(s).

BEST PRACTICE 1C(vii): In large mass-tort MDLs, particularly those involving competing brands or versions of a similar pharmaceutical drug, the court should consider issuing a case management order requiring a product identification disclosure sheet to quickly identify cases that should not have been centralized in the first instance.

Within mature large mass-tort MDLs, a variety of case management techniques have identified individual cases that should not have been centralized in the first instance because the plaintiff did not use the product at issue in the litigation. A streamlined "product identification" verification (one to two pages) can be used in large mass-tort MDLs to quickly identify cases that do not belong. The order would require early verification of whether and when plaintiff used the product at issue, though the verification should be relatively streamlined and not

burdensome. The purpose of such a verification is not to replace a fact sheet or impose any undue document burden on the plaintiff but to ensure that the individual case is properly centralized in the MDL. This technique may be especially useful in large pharmaceutical product MDLs in which multiple manufacturers may have produced different versions of the drug. The court should consider dismissing or remanding to the transferor court those cases in which claimants are unable to provide adequate, timely verification of product usage.

BEST PRACTICE 1C(viii): Standardized interrogatories may serve as an alternative to fact sheets.

An alternative to fact sheets is standardized interrogatories or document requests, which are less costly and onerous than individually-tailored interrogatories and document requests. Standard document requests can also be included within or annexed to a form fact sheet. In personal injury product liability MDLs, requiring plaintiffs to produce documents that demonstrate proof of product use and injury can help the parties and court focus resources on viable cases.⁴

Especially as a proceeding matures, the transferee judge may consider the entry of *Lone Pine* orders requiring all plaintiffs to submit an affidavit of support from an independent physician.⁵ These orders are particularly important in an MDL proceeding involving disparate theories of causation — or where multiple alternative potential causes of the alleged injuries exist. In some MDL proceedings, courts have required defendants to prepare fact sheets for each plaintiff that provide basic information they may have about the claimant or their claim. Typically, this step is required only after a plaintiff has completed a fact sheet.

⁴ See, e.g., Pretrial Order No. 18, Plaintiff Fact Sheet and Defendant Fact Sheet & Ex. A (Plaintiff Fact Sheet) at 6, *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 2740 (E.D. La. Feb. 14, 2017); MDL Order No. 10 [Dkt. 251], Order Concerning Early Disclosure of Product Identification Information, *In re Zofran (Ondansetron) Prods. Liab. Litig.*, MDL No. 2657 (D. Mass. May 26, 2016) (“The Court has concluded that production of [product identification] information at a relatively early stage in the litigation may assist in the preservation and collection of additional evidence; is not likely to be unduly burdensome; is not likely to result in unfairness to any party; and may help resolve certain issues in this litigation in a timely manner.”); Pre-Trial Order No. 27, Plaintiff Fact Sheets and Defendant Fact Sheets at ¶ 2, *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, MDL No. 2592 (E.D. La. Apr. 22, 2016) (requiring “records of proof of use and proof of injury within 90 days from the date Plaintiff’s complaint was filed”).

⁵ Byron G. Stier, *Resolving the Class Action Crisis: Mass Tort Litigation as Network*, 2005 UTAH L. REV. 863, 927–28; see McGovern, *supra* note xxii, at 1888–89 (“[In the Fen/Phen litigation, the parties] cooperated extensively with each other in the discovery process in order to reduce their transaction costs. Innovative processes, including the MDL-standardized fact sheets . . . provided models for discovery”); see also Order # 12, Case Management (PFS) at ¶ A.2, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100 (S.D. Ill. Mar. 3, 2010) (“A completed PFS, which requires that each Plaintiff sign the Declaration in Section XIII, shall be considered to be interrogatory answers and responses to requests for production under the Federal Rules of Civil Procedure, and will be governed by the standards applicable to written discovery under the Federal Rules of Civil Procedure.”).

BEST PRACTICE 1C(ix): The court should consider enforcing the deadlines for submitting fact sheets, excusing late submissions only on an appropriate showing.

The transferee judge should articulate clear expectations and impose clear timelines for completing plaintiff and defendant fact sheets, together with clear procedures and timelines for addressing deficiencies.⁶ Unless such procedures and deadlines are adhered to and enforced, counsel handling multiple claims may fall far behind in fulfilling that obligation. While the obligation to provide a timely, complete fact sheet falls solely on counsel of record for the individual MDL plaintiff or defendant, the court should expect the PSC and defense counsel to cooperate and share information regarding fact sheet compliance status to enable the PSC to communicate with counsel for individual plaintiffs with the goal of reducing deficiencies and motion practice.

Although deadlines may be extended upon a showing of good cause or agreement of the parties, timely and substantial compliance with fact sheet requirements, including completion of “core criteria,” should be the norm. Case management orders should include procedures for dismissing claims due to substantial noncompliance with fact sheet requirements and deadlines.

BEST PRACTICE 1C(x): The transferee judge should consider, in addition to deadlines for the completion of fact sheets, a case management order detailing the process for handling late or incomplete fact sheets.

The parties should agree on a process that usually should include sending a non-compliance or deficiency notice letter, short (but reasonable) windows for correction of any alleged deficiency (typically ten to thirty days), and a schedule for motion practice for unresolved compliance issues. Several MDL courts have effectively addressed motions to dismiss through a two-tiered process: first, motions to dismiss without prejudice, followed by a short grace period during which the party can re-file; and second, motions to dismiss with prejudice.⁷ While the goal should be to have cases decided on the merits, the fact sheet process is a critical component of the effective management of the litigation. The transferee judge should deal with fact sheet non-compliance directly and promptly, including

⁶ See generally, e.g., Case Management Order 12 (PFS), *supra* note 6; Case Management Order 18 (DFS), *In re* Yasmin and Yaz (Drospirenone) Marketing, Sales Practices & Prods. Liab. Lit., MDL 2100 (S.D. Ill. Mar. 3, 2010).

⁷ See *In re* Ethicon, Inc. Pelvic Repair System Prods. Liab. Litig., No. 2:14-cv-20042, 2015 WL 5786776, at *2 (S.D. W. Va. Sept. 30, 2015); *In re* Cook Medical Inc. Pelvic Repair Sys. Prods. Liab. Litig., No. 2:14-cv-30296, MDL No. 2440, 2015 WL 4458971, at *2 (S.D. W. Va. July 17, 2015); Order No. 7, *In re* Mirena IUD Prods. Liab. Litig., No. 13-MD-2434 (CS) (S.D.N.Y. Aug. 15, 2013); Order No. 7A, *In re* Mirena IUD Prods. Liab. Litig., No. 13-MD-2434 (CS) (S.D.N.Y. Apr. 24, 2014).

through a well-defined process culminating in motions to dismiss.

Because one of the benefits of having court-approved fact sheets is the elimination of disputes as to whether certain questions are appropriate in a particular MDL, courts should consider ways in which the process for enforcement of fact sheet obligations might be streamlined, including modifying typical meet-and-confer requirements for discovery motions in favor of a well-defined procedure for addressing fact sheet compliance issues in the order implementing the fact sheets.

BEST PRACTICE 1C(xi): On a sufficient showing that individual fact sheets have been filed with material, inaccurate information, the court should consider requiring that some minimal amount of evidence supporting the claim or defense in the fact sheets be submitted.

Plaintiff fact sheets, including streamlined fact sheets, in many cases provide sufficient information to support the plaintiffs' claims. However, there have been reported opinions in the largest mass-tort MDLs, usually involving allegedly harmful pharmaceuticals or medical devices, in which large numbers of fact sheets have been submitted with material, inaccurate information. Although the defendant can verify individual claims after receiving release authorizations and conducting discovery, doing so takes substantial time in MDLs that consist of thousands of claims. Meanwhile, the cases remain active.

When a significant number of fact sheets have been submitted with inaccurate information, the court should consider requiring that all individual parties submit some minimum quantum of evidence, for example, pharmaceutical records, receipts from pharmaceutical purchases, and medical records. If no such evidence is available, the court should provide individuals an opportunity to explain the absence of the evidence.

BEST PRACTICE 1D: Class actions may require a different approach to discovery because of the need to resolve class-certification issues as early as practicable.

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BEST PRACTICE 1E: The transferee judge should confer with the parties to determine whether holding bellwether trials would advance the litigation.

The transferee judge should determine as a threshold matter whether bellwether proceedings would be beneficial. But determining whether and which cases should serve as bellwethers is usually devilishly difficult. Counsel must provide the judge with sufficient information describing the nature of claims, extent of injuries, and other pertinent data so that the judge can make an informed