The Mass Tort Litigation Early Vetting Gap: Addressing the Issue with Administrative Dockets

by

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i. *Introduction*

The nationwide federal civil caseload, according to one study, is 70% comprised of cases in MDL dockets. *See 70% of Federal Civil Cases Are in MDLs as of Year End, FY21*, RULES4MDLS (Apr. 13, 2022), https://www.rules4mdls.com/copy-of-mdl-cases-surge-to-majorty-of (noting that 391,953 cases out of 559,653 federal civil cases reside in MDL dockets and that the MDL caseload concentration has increased 142% in the past decade). This undercuts, according to some, tenets of fairness and justice because in setting standards for MDL courts, the Federal Rules of Civil Procedure (FRCP) are all hat and no cattle.

The Rules do not mention MDLs. *Id.* Oft nicknamed the "wild west" by scholars, the MDL landscape is likened by one writer to "the baroque Holy Roman Empire – an agglomeration of hundreds of feudal principalities, feigning allegiance to one set of laws, but, operating more or less independently – with some of those margraves and palatine counts wielding rather despotic power." James M. Beck, *The Need for Real MDL Rules Will Only Grow More Acute*, DRUG & DEVICE LAW BLOG (Apr. 15, 2019), https://www.druganddevicelawblog.com/2019/04/the-need-for-real-mdl-rules-will-only-grow-more-acute.html.

One such power eliminates – early in the litigation – meritless cases, *i.e.*, those in which the claimant, *in fact*, cannot prove exposure to the alleged harm or that she suffered injuries.

Absent early vetting, corporate defendants face only harm and expense by defending lingering but meritless cases. Aptly descripting this plight is a letter from 45 corporate general counsel: "Allowing thousands of claims that have no relationship to the case (the plaintiff had no exposure to the alleged cause of harm and/or did not suffer any injury from exposure to the alleged cause of harm) to remain on the docket unexamined causes significant harm to the judicial process." *See* Letter from 45 Companies on Need for FRCP Amendments Concerning MDL Cases to Comm. on Rs. of Pract. & Proc. at *2 (Oct. 3, 2019), http://www.lfcj.com/uploads/1/1/2/0/112061707/letter_from_45_companies_urging_frcp_amendments_for_mdl_cases_10-3-19.pdf (hereinafter "Letter from 45 Companies"). "Such claims convey false information to the judge, the parties, and other stakeholders; they complicate rather than clarify the risk assessments needed to understand the value of cases for settlement purposes; and they make it difficult, if not impossible, to select meaningful bellwether cases for trial." *Id.*; *see also* Hannah R. Anderson & Andrew G. Jackson, *The Case for MDL Reform: Addressing the Flaws in a Critical System*, 77-MAR BENCH & B. MINN. 13, 13 (2020) (noting "meritless claims convey false information, making it difficult to evaluate settlement and select meaningful bellwether cases for trial"). Lawyers for Civil Justice (LCJ), an advocacy organization fighting for revising the FRCP to make early vetting mandatory, has coined this phenomenon the "early vetting gap." *Fixing the Imbalance: Two Proposals for FRCP Amendments that Would Solve the Early Vetting Gap and Remedy the Appellate Review Roadblock in MDL Proceedings*, LCJ, at *1 (Sept. 9, 2020), https://6c49d6b3-c5c6-477f-a3c6-cfaa1fd41c48.usrfiles.com/ugd/6c49d6_d760bf1182ed4fe486451a9c1bb54695.pdf (hereinafter "LCJ Comment"). This gap "allows hundreds of thousands of cases to circumvent procedures that protect dockets and defendants from meritless claims in non-MDL cases." *Id.*

MDL courts have discretion to implement early vetting processes. If a court elects to undertake early vetting, it typically works with defense counsel and plaintiffs' counsel to create a case-specific, *ad hoc* approach. In solving the early vetting gap, two schools of thought have emerged as possible solutions: (1) revise the FRCP (argued by "rulemaking advocates"); and (2) implement censuses in MDL proceedings without changing the Rules (argued by "census advocates").[2] This paper briefly reviews both approaches.

ii. *Spreading The Wealth [i.e., The Work]: Shifting The Burden of Screening Cases From Plaintiffs' Firms To MDL Courts And Defendants*

The birth of a looming MDL docket, full of cases both meritorious and non-meritorious, is often formulaic. Publication of some science or regulatory statement tending facially to favor general causation (whether germane or tenuous) will provoke plaintiffs' firms to turn on their machines. Amplifying the radius of mass advertising is social media and ad targeting.[3] With an eventual critical mass of retained claimants, the obvious problem for plaintiffs' firms is the time, expense, and opportunity cost required simply to sift through the records and vet the cases.

Parking a case – the merits of which are unknown even to plaintiffs' counsel – in an MDL parking lot offers plaintiffs' firms special opportunities for burden-tempering and cost-saving. Instead of screening the merits of their cases before filing, plaintiffs' firms can use the MDL as an intake department of sorts. As noted in one article, "estimates indicate more than 40 percent of claimants in an MDL are unable to show any evidence of exposure to the alleged harm." Hannah R. Anderson & Andrew G. Jackson, *The Case for MDL Reform: Addressing the Flaws in a Critical System*, 77-MAR BENCH & B. MINN. 13, 13 (2020). With an unknowable number of meritless claims clogging a docket, with no downside to signing up claimants, and, because lingering meritless claims harm defendants, *see supra* at 2, the defendant is the one with an incentive to sift through the records and screen cases itself. In large cases without *any* form of early vetting, including no census, the defendant's expense in amassing and processing the records of all claimants, many of whom cannot establish some requirement to pursue a claim, is an aimless exercise with a hefty price tag.

iii. *Censuses*

Censuses, according to census advocates, resolve the early vetting gap without the need for rulemaking. Unlike federal censuses of another species, MDL censuses are *ad hoc* creatures that can be made to accomplish a whole host of goals. They could, for example, be designed to require proof of a claimant's exposure to the alleged harm and their injuries allegedly caused by such exposure.

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[2] The authors recognize that those opposing rulemaking as a solution may not necessarily advocate for censusing as a solution. But this paper looks at the two most relevant solutions to the early vetting gap (indeed, others may not even perceive that an early vetting gap issue exists).

[3] Doing double-duty, current marketing campaigns by plaintiffs' firms work not only to sign up new claimants but also might be crafted to mold the minds of future jurors. Daniel Fisher, *How Plaintiff Counsel Ads Create A Mass Tort Fiasco*, CHIEF EXECUTIVE, https://chiefexecutive.net/court-campaigns-ads-mass-tort-fiasco/.

One adopter of the census is the U.S. District Court for the Southern District of Florida, in the (recently newsworthy) Zantac MDL. *See In Re: Zantac (Ranitidine) Prods. Liab. Litig.*, MDL No. 2924 (S.D. Fla.) (hereinafter "Zantac MDL"). There, the parties worked together, with the assistance of a special master and the input of the court, to create a census process "to assist in overall effective case management and the orderly and efficient progression" of the case. Pretrial Order No. 15, Zantac MDL, at *1 (Apr. 2, 2020).

The census forms themselves were straightforward. Plaintiffs who had already filed their cases were tasked with completing two forms: (1) an initial census form (ICF); and (2) a subsequent "census plus form" (CPF). ICFs were due within 30 days of the order, *id.* at *2, and CPFs were due within 60 days of a forthcoming order appointing plaintiffs' leadership counsel, *id.* at *9 (with exceptions for later-filed cases). Plaintiffs' firms applying for leadership positions also were required to submit ICFs for their retained clients who had not yet filed their cases. *Id.* at *3.

ICFs inquired into the user's exposure to Zantac (including whether it was prescribed or over the counter, generic or name brand, and the dates of use) and the alleged injuries. Claimants were to provide some proof of their exposure and injuries, which could be ticking a box indicating that medical diagnostic records or proof-of-use records were "not yet requested" or a letter from plaintiffs' counsel explaining why no proof yet existed. *Id.* at *18, Ex. A, ICF. CPFs could be supplemented later. *Id.* at *15. According to rulemaking advocates, the plaintiffs' ability to supplement their materials or explain why proof was forthcoming was not as helpful for early vetting.[4]

Additionally, a "voluntary opt-in registry" for unfiled claimants was created "to permit additional transparency for the Court and leadership counsel into the claims that are still being investigated and developed, and thus remain unfiled." *Id.* at *2. Participation was not obligatory (but it was "encouraged"), and it came with certain benefits and duties. *Id.* at 10. For example, unfiled registrants were required to complete CPFs alongside plaintiffs who had filed cases. CPFs included a certification of the claimant's legal representation; the user's general background; the user's Zantac usage (including the dates of use, products and doses, the prescribing physicians, the location, and manner of administration, and whether it was a generic or name brand); and the claimed injuries (including medical diagnoses, dates of diagnoses, and whether the claimant had a handful of certain risk factors). *Id.* at *19-22, Ex. B, CPF.

There were several benefits of registry participation to unfiled registrants. For example, unfiled registrants were relieved of "immediately pay[ing] a filing fee and prosecut[ing] their case." Pretrial Order No 72, Zantac MDL, at *1 (S.D. Fla. Feb. 28, 2022). Instead, "they could wait to do so until a later stage of the litigation." *Id.* For corporate defendants, an administrative docket of unfiled registrants has benefits. For example, unfiled registrants, should they ultimately file their cases, were required to file in federal court and transfer them to the MDL (unless the MDL court lacked subject matter jurisdiction). The defendants benefited "as [they]

[4] Indeed, as the litigation progressed, the court issued various orders directed to claimed deficiencies in CPFs. *See, e.g.*, Pretrial Order No. 59, Zantac MDL, at *1-2 (S.D. Fla. Feb. 12, 2021).

had fewer filed cases to defend against and, relatedly, fewer jurisdictions in which to do so." *Id.* On the other hand, administrative dockets of unfiled registrants may incentivize continued mass advertising by plaintiffs' firms and further encourage parking unvetted claimants within the MDL. The MDL order's solution was to require "good faith." In filing their complaints, claimants committed "to name only those defendants that they have a good faith belief marketed or manufactured Zantac or ranitidine products that such Claimants ingested or that they in good faith believe they may have a valid claim against for other reasons." Pretrial Order No. 15, Zantac MDL, at *11 (Apr. 2, 2020).

Registry participation also tolled the applicable statute of limitations until the first of 90 days after: (1) the date the unfiled registrant exited the registry; or (2) the date the court closed the registry. *Id.* Corporate defendants were accordingly pressed into tolling agreements with an untold number of unfiled claimants represented by any number of plaintiffs' firms. Tolling also was the primary incentive for plaintiffs' firms to get as many unfiled claimants registered with the MDL as fast as possible. But it is important to recall that the defendants were not forced into the census agreement – it was a negotiated process under the guidance of the court. So, the benefits and detriments of a tolling agreement would have been anticipated and bargained for.

Rulemaking advocates criticize censuses because they purportedly are "*ad hoc* or extra-judicial management of MDLs through such practices as waiving filing fees, not requiring the formal filing of claims, and ignoring pleading standards on MDL dockets." *70% of Federal Civil Cases Are in MDLs as of Year End, FY21*, RULES4MDLs (Apr. 13, 2022). LCJ recommends formal studies of the Zantac census to assess whether it furthered "the aims of early vetting by providing incentives for plaintiffs' counsel to conduct basic due diligence into their cases before filing," or whether the census "risk[ed] institutionalizing an unauthorized 'MDL exception' to the FRCP by excusing compliance with the basic requirements of pleading, disclosure, and discovery that apply in all other civil cases." *Id.*

Other census variations, including those employed by the 3M Earplugs MDL and the Juul MDL, are subject to similar criticisms. Rulemaking advocates argue that the 3M Earplugs census did not require evidence of exposure and injury, but instead simply directed plaintiffs to answer questions under oath and to request audiology reports. LCJ Comment, at *6. Similarly, the Juul census purportedly did not require evidence of product use and instead permitted claimants to certify their exposure. *Id.* Thus: "Even the experiments with a 'census' effort to gather information currently taking place in three MDLs are not designed to require plaintiffs' counsel to conduct basic due diligence before filing or to provide the early vetting that is needed, despite the fact that the census experiments arose from discussions about the lack of early vetting in MDLs." *70% of Federal Civil Cases Are in MDLs as of Year End, FY21*, RULES4MDLS (Apr. 13, 2022). Other rulemaking advocates are satisfied with the use of a census – so long as it requires evidence of exposure to the alleged harm and evidence of injury – and only if it "is a *rule*." *See* Letter from 45 Companies, at *2 (emphasis added).

iv. *Proposed Revisions To The Federal Rules of Civil Procedure*

Rulemaking advocates hope for formalizing many of the benefits realized through censusing via formal changes to the FRCP. According to them, preexisting Rules meant to

govern "the vetting of cases and/or their dismissal at early stages if they are not adequately pled" commonly misfire (*i.e.*, fail to apply) in MDLs. *70% of Federal Civil Cases Are in MDLs as of Year End, FY21*, RULES4MDLS (Apr. 13, 2022).

The LCJ's proposed revision to Rule 26(a)(1) adds language under a new heading, "(F) Multidistrict Initial Limited Disclosure":

> (i) *In General.* In any action alleging personal injury pending in a coordinated or consolidated pretrial proceeding established pursuant to 28 U.S.C. § 1407, each plaintiff shall, without awaiting a discovery request, provide to the other parties documents or electronically stored information evidencing:
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> > (a) that plaintiff used or was exposed to any product, substance or service which allegedly caused injury; and
> >
> > (b) that plaintiff suffered the injury alleged in the action.
>
> (ii) *Timing*. Unless otherwise ordered by the court, a plaintiff must make the initial disclosure referred to in subparagraph (F)(i) within 60 days of:
>
> > (a) the transfer, removal, or assignment of the action to the coordinated or consolidated proceeding; or
> >
> > (b) the filing of the action directly in the district where the coordinated or consolidated pretrial proceeding is pending.

LCJ Comment at *14. These revisions allegedly establish a touchstone for separating meritless cases from claims that satisfy the bare minimum requirements for proceeding, deter the filing of meritless claims, free up judicial resources, and eliminate *ad hoc* procedures. *Id.* at *7. Advocates suggest that these revisions are not controversial, given that the Rules already purport to "govern the procedure in all civil actions and proceedings in the United States district courts." *70% of Federal Civil Cases Are in MDLs as of Year End, FY21*, RULES4MDLS (Apr. 13, 2022). (quoting FED. R. CIV. P. 1).

Some census advocates argue that the common practice of implementing Plaintiff Fact Sheets (PFS) already provide the information sought by the proposed rule. LCJ Comment, at *3. Rulemaking advocates' rebuttal argues the insufficiency of PFSs for two reasons. First, PFSs are not implemented early enough in a case's lifetime to be helpful for *early* vetting. Second, PFSs, often lack "the most basic necessity for vetting: evidence of exposure to the alleged cause and a resultant injury." *Id.* In other words, PFSs are, at most, an interrogatory substitute, not a vetting one. *Id.*

In any event, rulemaking advocates' call for change has hit a snag. That is because the Advisory Committee on Civil Rules, once keen on addressing the early vetting gap through

proposed rulemaking, has redirected its focus. Currently, instead of pursuing rulemaking, the Committee is more interested in monitoring censusing.

In 2017, the Advisory Committee created the Subcommittee on Multidistrict Litigation to study various possible changes to the FRCP, including changes to address the early vetting gap. Alison Frankel, *As MDL case surpass 1 million, defense group's push for early vetting heats up*, REUTERS (Mar. 17, 2021), https://www.reuters.com/article/legal-us-otc-mdl/as-mdl-cases-surpass-1-million-defense-groups-push-for-early-vetting-heats-up-idUSKBN2B92UJ.

As phrased by the Advisory Committee, the MDL Subcommittee is currently monitoring developments with the use of the "new simplified method[] called a 'census'" being employed by several MDL courts. *See* Memorandum from the Advisory Comm. on Civil Rs. to Comm. on Rs. of Pract. and Proc. at *7 (Dec. 14, 2021). Censuses are meant "to devise a less burdensome initial fact-gathering method and expedite the early developments of the litigation." *Id.* at *7. It is reported that the MDL Subcommittee is "very happy with how this ["initial census"] has been developing in the big MDLs." *See* Minutes on Rs. of Pract. & Proc. at *22 (Jan. 5, 2021).

Ultimately, the Standing Committee has concluded that rulemaking is potentially unnecessary and will be difficult to accomplish. While "a rule may be helpful," it says, "it is also possible that these [census] practices may just be circulated as best practices and could belong in the Manual on Complex Litigation or spread as a model by discussion at conferences." *Id.* at *22. In other words, "[a] rule may not be necessary." *Id.* Moreover, rulemaking is made difficult considering views that "courts and the plaintiffs' bar think there is little need for change and the defense bar does think there is a need for change." *Id.* at *22-23. But rulemaking advocates argue that "as a [mere] guideline or 'best practice,' [the census] is doomed to failure" because "[p]arties will continue to game the system." Letter from 45 Companies at *2. Parties will moreover remain uncertain as to whether censuses will be employed or enforced. *Id.* Either way, the MDL Subcommittee has shifted its focus from the early vetting gap – being difficult and potentially unnecessary – "to other matters in MDL proceedings, notably appointment of leadership counsel on the plaintiff side and arrangements (often called common benefit fund arrangements) for compensating leadership counsel for their efforts." Memorandum from the Advisory Comm. on Civil Rs. to Comm. on Rs. of Practice & Proc. at *7 (Dec. 14, 2021).

v. *Tips*

As the fight for changing the Rules carries on (or doesn't), corporate defendants would do well to advocate in their cases for implementing early vetting censuses. The use of an administrative docket for unfiled claimants can offer benefits to the parties. But it can also frustrate the goals of early vetting if claimants are permitted to remain there indefinitely. Below are some tips for negotiating censuses in your high-volume cases:

- Defendants should advocate for evidence-based proof of exposure and injuries, steering clear of exceptions whereby plaintiffs' counsel may assure that proof is absent but forthcoming. Attaching documentation should be made an express requirement of the census.

- Negotiate cost-splitting with the plaintiffs in the collecting and processing of medical records.

- The current consensus among rulemaking advocates is that 60 days is a reasonable deadline for completing the census – on the one hand short enough to be helpful for early case vetting, and on the other long enough to permit compliance by the claimants without undue burden.

- There should be penalties for noncompliance with the timing or documentation requirements. For example, negotiate revisiting any tolling agreements at interim intervals with the aim of preventing unregistered claimants who fail to comply from remaining in the registry.

- Negotiate a binding obligation for claimants to file their cases in federal courts and transferring to the MDL. Endeavor to hold unregistered claimants to any Rule 702 orders dismissing the case on general causation.

- Corporate defendants should therefore advocate to hold unfiled claimants on administrative dockets to the same census requirements that apply to filed cases. That way, unfiled claimants still get the myriad benefits of registry participation – whatever they are – while also being compelled to prosecute their cases in a timely, and orderly, fashion.

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