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Important developments in mass torts

GUIDANCE FOR MDLS, CAUTIONS ON RULE 702 AND EXPERT PREPARATION, AND AN UPDATE ON THE TEXAS TWO-STEP

Mass torts are cases with common injuries and typically involve product liability, pharmaceuticals, environmental hazards, or consumer fraud. When multiple lawsuits are filed in federal courts by plaintiffs claiming similar injuries and involving common questions of fact, the Judicial Panel on Multidistrict Litigation (MDL) (https://www.jpml.uscourts.gov/) determines whether transferring these cases to a single district court is appropriate to coordinate discovery and pretrial activities.

Cases filed in the California state court may be coordinated into aggregated state litigation as well. In California, a coordinated litigation is a "Judicial Counsel Coordinated Proceeding, or JCCP." JCCPs are "[c]ases that involve a common issue of fact or law are sometimes filed in more than one California county based on where the parties live, do business, or the incidents occurred. (Cal. Rules of Court, Title Three, Div. IV.) According to the defense-oriented Lawyers for Civil Justice organization, MDLs made up over 70% of the federal civil caseload at the end of the 2023 fiscal year. (Raymond, Nate, "US judicial panel approves first rule to govern federal mass torts," April 9, 2024, available at: https://www.lfcj.com/). As of January 2, 2025 there were 170 total MDL dockets. (https://www.jpml.uscourts.gov/sites/jpml/files.)

This article describes several key developments that may affect California mass-tort practitioners, including the approval of a new rule streamlining MDL practice and procedure, the implications of California's "innovator liability" doctrine on a new mass tort, the impact of recent amendments to Rule 702, and recent efforts by defendants to resolve mass torts in the bankruptcy system through the Texas Two-Step.

New guidance for MDLs

Rule 16.1

In April 2024, the U.S. Judicial Conference's Advisory Committee on Civil Rules approved rule 16.1 (Fed. R. Civ. P. 16.1) addressing MDL Practice and Procedure. (https://www.uscourts.gov/sites/default/files/2024-10_civil_rules_agenda_book_final_10-6.pdf, at p. 81.) A judicial conference subcommittee was first formed to study the issue of mass tort case management in 2017. The final version of the rule provides guidelines on early case management for judges overseeing hundreds of lawsuits consolidated in MDLs. The final version of the rule was approved in June 2024 and is expected to go into effect in late 2025. (https://www.americanbar.org/groups/litigation/resources/newsletters/mass-torts/proposed-frcp-rule-161/?login).

The new rule includes suggestions for the early exchange of factual information for filed cases, the scheduling of initial case-management hearings, and encouragement of the appointment of the plaintiffs' leadership counsel. Although not yet required, some mass torts are already employing these strategies. As an example, case-management orders in the Bard Implanted Port Catheter Products Liability Litigation (*IN RE: Bard Implanted Port Catheter Products Liability Litigation*, MDL 3081, https://www.azd.uscourts.gov/re-bard-implanted-port-catheter-products-liability-litigation) require plaintiff fact sheets along with medical-record substantiation to be submitted *within only 30 days of case filing*. The *Bard* litigation involves defect allegations concerning certain port catheters implanted under the skin and used to deliver medical IV therapy, chemotherapy, and other drugs to patients. The allegations regarding the product are that when the device failed, it caused blood clots, infections and bleeding.

Accelerating the timing of providing substantiating information is an important change. While many mass torts have a longer timeline for plaintiff fact sheets and supporting materials, for example, 60-90 days, the specific timing of required disclosures is under the full discretion of the MDL judge. Attorneys know that getting fact sheets done timely can be challenging, particularly where medical records have been destroyed or there is a tight statute of limitations deadline. For those who are filing or planning to file lawsuits in the mass-tort arena, the new rule signals that "parking a case in the MDL," without supporting information will not be tolerated.

Disclosure of third-party financing

Another issue discussed at the Judicial Conference Advisory Committee meeting on October 10, 2024, was third-party litigation financing (https://www.uscourts.gov/sites/default/files/ 2024-10_civil_rules_agenda_book_final_ 10-6.pdf, at p. 417.). The Committee agreed that a subcommittee should be formed to explore new federal rules governing the disclosure of third-party financing. Plaintiff firms that manage mass torts may use third-party funding to assist with costs, especially where litigation stretches on for years, as is common in mass torts. Analyst reports estimate $15.2 billion in managed assets for litigation funding firms in 2023. (Merken, Sara. *US litigation funding in 'state of flux' as deal commitments dip, says report*. Reuters (March 27, 2024), at https://www.reuters.com/legal/transactional/us-litigation-funding-state-flux-deal-commitments-dip-says-report-2024-03-27/).

Proponents of these disclosures claim that greater transparency in funding arrangements is material in

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the management of mass torts, as the funding entities may introduce additional pressure on case management. Proponents of these disclosures include the U.S. Chamber of Commerce, Lawyers for Civil Justice, and the defense bar. Plaintiff attorneys generally oppose additional financing disclosure rules. If you are using third-party funding sources, this may be an issue to consider and discuss with your client and partners.

The proposed new subcommittee should meet for the first time in 2025. Look for new developments in this area in the year to come.

California innovator-liability law impacts on a new mass tort

New developments in the adequacy of label warnings are presenting themselves through matters pending in the Depo-Provera litigation. To appreciate those impacts, here is a summary of why California law in this area is significant.

A key issue in evaluating any pharmaceutical products-liability case is whether the label adequately warns the consumer. Brand-name drugs are subject to the Food & Drug Administration (FDA)'s review and approval of proposed product labels, including the drug's usage, warnings, precautions, and adverse reactions. Generic drug manufacturers generally must use the same FDA-approved label and information from the brand name drug.

The U.S. Supreme Court in *PLIVA v. Mensing* explained: "A brand name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of the labeling, whereas a manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." (*PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613.)

Because generic manufacturers must use the same label as the brand-name drug, generic drug manufacturers are generally protected from failure-to-warn claims due to federal preemption. (In 2011, the U.S. Supreme Court's decision in *PLIVA v. Mensing* held that federal laws on drug labeling conflicted directly with state failure-to-warn claims and, therefore, were preempted against manufacturers of generics.) This is significant because generics make up the vast majority of prescription drugs. In 2011, generics accounted for 70% of prescriptions nationwide. (*Demahy v. Actavis, Inc.*, 593 F.3d at 432 (citing Susan Okie, Multinat'l Medicines-Ensuring Drug Quality in an Era of Global Mfg., 361 New Eng. J. Med. 737, 738 (2009).) Estimates as of November of 2024 show that generics now make up 90% of all prescriptions. (See, Mikulic, Matej, *Branded vs. generic U.S. drug prescriptions dispensed 2020-2023*, Nov 25, 2024 available at: https://www.statista.com/statistics/205042/proportion-of-brand-to-generic-prescriptions-dispensed/.) For purposes of this article, we will not delve into the differences between "authorized generics" and what are commonly referred to as simply generics, however, that information is available on the FDA website at: https://www.fda.gov/drugs/abbreviate-new-drug-application-anda/fda-list-authorized-generic-drugs.

When dealing with a mass tort with injuries and claims of failure to warn when a plaintiff has taken a generic drug, a critical question is, is there a viable case? This is where the innovator-liability doctrine comes into play in California and might provide a path forward in one new mass tort involving a popular contraceptive drug.

California's innovator-liability doctrine arose from two cases. The first case was *Conte v. Wyeth* (2008) 168 Cal.App.4th 89, which held that brand-name manufacturers owed a duty of care to patients using generic versions of their drugs. The second case was *T.H. v. Novartis Pharms. Corp.* (2017) 4 Cal.5th 145, where the California Supreme Court found that brand-name manufacturers could be held responsible for warnings related to both brand-name and generic drugs. This means the brand-name manufacturer could be held liable even if the innovator/brand-name manufacturer did not sell or manufacture the generic drug. California is one of only two states that recognize this innovator liability.

Innovator liability in California – a chance for users of Depo-Provera (and generic versions) for recovery?

A new matter seeking Judicial Panel on Multi-District Litigation (JPML) MDL status is the Depo-Provera litigation. Depo-Provera is a contraceptive injection manufactured by Pfizer, Inc. and by Pfizer's authorized generic affiliates. Generic manufacturers have also made and sold the drug, depot medroxyprogesterone acetate (DMPA), for more than 20 years. Injured plaintiffs in the recent litigation claim that the injections cause meningiomas or brain tumors. A recent study in the *British Medical Journal* showed a 555% increase in the incidence of meningioma among users of Depo-Provera and generic versions of the drug. (Roland, et al., "Use of progestogens and the risk of intracranial meningioma: national case-control study," British Medical Journal, Vol. 384, published online March 27, 2024 at https://doi.org/10.1136/bmj-2023-078078.) According to the recently filed complaints, several of the plaintiffs have undergone intracranial surgery and have experienced vision loss, seizures, and neurological issues due to the meningiomas. (Memo in Support of Motion for Transfer of Actions to the Northern District of California Pursuant to 28 USC section 1407 for Coordinated or Consolidated Pre-Trial Proceedings, Nov. 26, 2024.)

As with all MDLs, the ultimate location of the District Court where the Depo-Provera MDL is assigned will be based on multiple factors. These include the convenience of the parties, the conservation of judicial resources and the prevention of duplicative rulings. A group of plaintiffs in the Depo-Provera litigation are advocating for California to be selected for the MDL transferee forum, because California is the most populous state and one of only two states in the country with innovator liability.

Support for a California-based MDL includes that, between 2011 and 2015, an

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estimated 25% of all women in the U.S. (18-44 years old) received Depo-Provera, and that California is the most populous state and home to the highest percentage of people of color (45% of its population). (See, Daniels K, Abma JC. *Contraceptive methods women have ever used: United States, 2015-2019*. National Health Statistics Reports; no 195. Hyattsville, MD: National Center for Health Statistics. 2023. DOI: https://doi.org/10.15620/cdc:134502; see https://www.census.gov/library/visualizations/interactive/race-and-ethnicity-in-the-united-state-2010-and-2020-census; https://www.cdc.gov/nchs//data/nhsr/nhsr195.pdf.) Some plaintiffs have alleged that the drug was primarily marketed to Black and Latina women. (See, Memo in Support of Motion for Transfer of Actions to the Northern District of California Pursuant to 28 USC section 1407 for Coordinated or Consolidated Pre-Trial Proceedings, Nov. 26, 2024; and Daniels, K et al., "Contraceptive Methods Women Have Ever Used: United States, 2015-2019", Nat'l Health Statistics Report, No. 195, Dec.14, 2023 at https://www.cdc.gov.nchs//data/nhsr/nhsr195.pdf.)

Because Depo-Provera's exclusivity patent expired some 20 years ago, the majority of women who were administered Depo-Provera will have received generic versions of the drug, making California's innovator-liability their only hope for recovery. (See generally, https://www.fda.gov/drugs/abbreviated-new- drug-application-anda/fds-list-authorized- generic-drugs, excluding authorized generic, there were more than a dozen generic manufacturers of depot medroxyprogesterone acetate.)

At the time of writing this article, Pfizer has provided information in court filings that it sought approval of a label change to include the risk of meningiomas and the FDA rejected it. So, as is true with all litigation at this stage, the outcome is unclear. California's innovator-liability doctrine is a big part of the discussion regarding where this case should be coordinated, because, if applied, most of the plaintiffs with viable claims will likely be California plaintiffs.

Modifications to Rule 702 – has it really changed anything?

Some practitioners believe that the 2023 amendments to the Federal Rules of Evidence (FRE) Rule 702 have changed the landscape for expert testimony. The key changes are:

- Expert testimony must not be admitted unless the expert offering evidence demonstrates by a preponderance of the evidence that the evidence and testimony is admissible under all of Rule 702's admissibility requirements. (Behrens, Mark, Jan. 30, 2024, *A Brief Guide to the 2023 Amendments to the Federal Rules of Evidence*. Available at: fedsoc.org/commentaryfedsoc-blog/a-brief-guide-to-the-federal-rules-of-evidence-1.)
- FRE Rule 702(d)'s amended version requires an expert's opinion to stay within the bounds of what he/she can conclude from reliably applying the expert's basis for opinions and his/her methodology in reaching those opinions. (Behrens, Mark & Trask, Andrew, *Federal Rule of Evidence 702: A History And Guide To The 2023 Amendments Governing Expert Evidence*, Texas A&M Law Review, Vol. 12, p. 44 (2024).)
- The amendment reinforced the judge's role as a gatekeeper to prevent unreliable expert testimony from admission. This is especially critical in the evaluation of expert testimony in complex civil cases like mass torts. Experts' testimony should be helpful to the jury, but should avoid assertions of "absolute" certainty, or even "to a reasonable degree of scientific certainty" if, in fact, the methodology is subjective and susceptible to discrepancies. (*Ibid*., see also, FRCP, Rule 702, Committee Notes on Rules – 2023 Amendment; available at: www.law.cornell.edu/rules/fre/rule_702#.)

Key takeaways for ensuring your experts are adequately prepared

Most attorneys who handle mass-tort cases will likely feel that these amendments to rule 702 don't really change much because robust, helpful and reliable testimony from experts has always been required to establish product defects in, for example, pharmaceutical and medical-device cases. On the other hand, many defense counsel feel that these amendments will assist them in preventing expert testimony from being admitted in plaintiff cases. (Bexis, *How are the recent rule 702 amendments faring in court?*, Drug & Device Law, May 13, 2024, available at: www.druganddevicelawblog.com/2024/05/how-are-the-recent-rule-702-amendments- faring-in-court?). Some recent cases highlight how the courts are using 702's amendments to take a closer look at the experts and their specific expertise as well as whether the expert uses demonstrably reliable methodology.

In *Hill v. Medical Device Business Services, Inc*., No. 3:2021cv00440 – Document 84 (M.D. Tenn. 2024) the district court excluded two experts from testifying in a product case involving a hip implant. The plaintiff's first expert, a metallurgist, was excluded because the court found she lacked adequate medical background to opine on the causation of injury and also failed to properly rule out alternative causes of the product's failure. The plaintiff's next expert was excluded because the opinions were reliant upon the now-excluded metallurgy expert and her inadmissible conclusions.

In its opinion in *Hickcox v. Hyster-Yale Grp.* (D. Kan. 2024) 715 F.Supp.3d 1362, 1379-80, the court excluded a licensed mechanical engineer from providing testimony in a forklift-injury case because the expert lacked specific expertise in forklift design. The court further determined that the methodology of the engineer was unreliable because he did not conduct testing on proposed alternative forklift designs to show feasibility. In support, the court cited the advisory notes to rule 702 amendments that the long-standing belief that "the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility" were simply incorrect application of the rule. (*Id*. at 1380.) Although not a mass-tort case, this is a good example of how the amendment to the rules can be used to limit or exclude experts.

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For all these reasons, it is critical for attorneys to 1) understand the issues and obtain specific and helpful expert testimony; 2) communicate clearly with the experts to ensure the testimony meets with 702 and the needs of the case; 3) ensure the methodology is reliable and well-supported in compliance with the amended standards; 4) refrain from overstating conclusions which can be drawn from the expert's analysis; and 5) accept and appreciate what the Court will need to do to uphold their gatekeeping role.

The Texas Two-Step in mass torts

Corporations are increasingly looking to the bankruptcy system to resolve mass tort liability. Primary goals of the bankruptcy system include finding ways for companies to reorganize and financially survive. Main goals of the tort system include compensating victims for harms suffered and incentivizing corporations to follow practices that ensure consumer safety. The use of a new tactic, the Texas Two-Step, highlights these differences.

In this controversial strategy allowing for corporate restructuring under Texas law, a financially healthy company may spin off the liabilities for a mass tort into a separate subsidiary, then follow up with a funding agreement from the parent company to cover the creditor liability. Proponents of this tactic claim it assures finality in the resolution of claims and avoids the years of litigation necessary to try and settle cases in the tort system. Plaintiff attorneys' critiques of the Texas Two-Step process include that it largely eliminates tort victim negotiating power and drags out the settlement process.

Tort victims also lose their Seventh Amendment right to a jury trial and the ability to win punitive damages. Finally, because of the particular Texas Two-Step structure, the parent company is not in bankruptcy, so it maintains much of its flexibility and freedom during the process, such as the ability to pay shareholders dividends and pay executive bonuses. The strategy is being scrutinized in the context of the Johnson & Johnson Talcum Powder Litigation. (https://www.njd.uscourts.gov/johnson-johnson-talcum-powder-litigation).

After tens of thousands of lawsuits were filed on behalf of women suffering from ovarian cancer alleging a connection to Johnson & Johnson talcum powder products, Johnson & Johnson, Inc. (J&J) spun off a subsidiary, LTL Management, Inc. (Litigation Talc Liability), and filed bankruptcy on behalf of that entity on October 14, of 2021. This bankruptcy was dismissed by the U.S. Court of Appeals for the Third Circuit on January 30, 2023, in *In re LTL Mgmt., LLC* (3d Cir. 2023) 64 F.4th 84. The court found that "a debtor who does not suffer from financial distress cannot demonstrate its Chapter 11 petition serves a valid bankruptcy purpose supporting good faith." (*Id*. at p. 101.)

Two hours and eleven minutes after the first bankruptcy was dismissed for a lack of financial distress and lack of good faith, J&J filed a second LTL bankruptcy in the United States District Court for the District of New Jersey. This case was dismissed by the trial court on July 28, 2023, and the Third Circuit affirmed the dismissal in July of 2024 (*In re LTL Management LLC* (3d Cir., July 25, 2024) 2024 WL 3540467).

On September 20, 2024, J&J filed a third bankruptcy on behalf of its new subsidiary, Red River Talc, LLC. This bankruptcy was filed in the Southern District of Texas and is before the Honorable Christopher M. Lopez (*In re Red River Talc LLC,* Bankr. S.D. Tex., No. 24-90505), and unlike in the previous filings, is premised on a pre-packaged proposed bankruptcy plan. Whatever the outcome, the decision will likely be appealed to the U.S. Court of Appeals for the Fifth Circuit. If there is a split in authority between the Third and Fifth Circuits, the Supreme Court might accept the case to resolve the split. For now, the tens of thousands of talc claimant cases are stayed.

This case and other bankruptcy cases are relevant for mass-tort practitioners as they signal a commitment by corporations to resolve cases outside the tort system. Mass-tort practitioners should watch for the outcome of the *Red River Talc, LLC* trial which is scheduled for February. It may solidify a new pathway out of the tort system for companies with mass-tort liability.

Conclusion

Whether you are new to mass torts or a seasoned veteran in this practice area, the new federal guidelines for case management and recent use of the bankruptcy system to resolve cases outside the tort system signal significant new developments in the mass-tort arena. Application of the amendments to Rule 702 are important for all plaintiff attorneys working with experts. Finally, impacts of existing California innovator-liability law on the Depo-Provera litigation may affect whether that litigation will find its home in a California federal court.

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