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MDL Decisions Demonstrate The Need For Rule 702 Reform

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There is ample evidence that some courts misunderstand their gatekeeping function in screening the reliability of expert opinion testimony. Numerous decisions have held — contrary to the text of Federal Rule of Evidence 702 — that problems with the basis of an expert's testimony or the application of an expert's methodology are issues of weight rather than admissibility.

This problem has been noted by the Advisory Committee on Evidence Rules, which is considering an amendment to Rule 702 and an accompanying committee note. We submitted a letter to the advisory committee recently with our analysis of whether recent decisions in multidistrict litigation cases are properly applying Rule 702.

Our analysis shows that MDL courts frequently misstate the Rule 702 standard, and fail to apply the rule as intended, leading to divisions on important legal questions. The advisory committee should act to stem the tide of unreliable opinion testimony and further the important goal of uniformity.

The Problem of Weight and Admissibility

Rule 702 provides that an expert may testify in the form of an opinion if, among other things, "the testimony is based on sufficient facts or data," it "is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case."[1]

The proponent of expert testimony "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence" under Rule 104(a).[2] Accordingly, the court, not the jury, is charged with deciding whether these reliability tests have been satisfied.

Despite these clear mandates, several circuits have held that courts cannot review the factual basis of an expert's testimony.[3] Others have concluded that the misapplication of an expert's methodology is an issue for the jury.[4]

The advisory committee has taken note of these decisions in which "courts appear to have not read the Rule as it is intended," and is considering an amendment to the introductory language of Rule 702 clarifying that "the court must find the [reliability] requirements to be established by a preponderance of the evidence."[5]

The MDL Perspective on Rule 702

As attorneys who frequently deal with Rule 702-related issues in mass tort MDLs, we analyzed 27 recent decisions from MDLs in the pharmaceutical, medical device and chemical exposure fields concerning the admissibility of general causation expert opinion testimony.

We elected to focus on MDLs for several reasons. The first is sheer volume. MDLs make up a large percentage of pending cases on the federal docket, some containing hundreds or even thousands of individual cases.

Because of the importance of MDL decisions, Rule 702 issues are more likely to be capably presented and argued by both sides. Similarly, courts are more likely to focus on these matters and provide thorough analyses. If courts are failing to properly apply Rule 702 in MDLs, they are likely failing to do so elsewhere.

We also focused on the portions of MDL decisions concerning general causation testimony — that is, the question of whether a product is capable of causing a medical problem, as opposed to the specific causation question of whether a product caused the problem in a particular plaintiff. General causation issues typically have a much larger impact, and because experts providing such testimony tend to employ similar methodologies, cases considering that issue are easier to compare.

MDL Decisions Misapplying Rule 702

Our review of these important MDL decisions revealed some troubling trends.

Many courts flatly mischaracterize the Rule 702 standard. For example, in the Nexium MDL, the district court announced that under Rule 702, "[t]he factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination."[6]

In the recent Talcum Powder MDL decision, the court stated that it could not assess whether an expert reliably applied methodology, relying on case law holding that "disagreement with the methods used by an expert is a question that goes more to the weight of the evidence than to reliability for Daubert purposes."[7]

Other courts fail to apply the Rule 702 standard as intended, dismissing legitimate problems in an expert's factual basis or applied methodology as issues of weight rather than admissibility. In the Taxotere MDL, for example, the court simply accepted an expert's "personal judgment in deciding what articles to review and include in her analysis," and held that additional problems, such as the expert's consideration of studies evaluating medical problems other than the one at issue in the case and lack of statistically significant results in individual studies, were matters that went to weight rather than admissibility.[8]

Similarly, in the Testosterone Replacement Therapy MDL, the court declined to engage with the epidemiological literature underlying experts' opinions, summarily concluding that larger, more recent studies that undercut the experts' conclusions were "no more authoritative than plaintiffs' argument" and thus "the studies' 'merits and demerits ... can be explored at trial.'"[9]

These examples are just a few of many that we brought to the attention of the advisory committee in our letter.

MDL Courts Divided on Important Recurring Questions

Because some MDL decisions fail to apply Rule 702 as intended, courts addressing general causation issues are split on key legal questions that repeatedly arise. For example, MDL courts are divided on the reliability of using statistically insignificant "trends" in data as a basis for an expert's conclusions.[10]

They have also disagreed as to whether proposed experts may reinterpret studies conducted by others to reach conclusions opposite of those reached by the studies' authors.[11] And they have differed on the extent to which experts may analogize across different exposures and different injuries.[12]

The inability of courts to reach consensus on these common questions undermines confidence in the courts and diminishes the value of the MDL process by reducing uniformity. These problems are especially problematic in the context of MDLs, because there is no practical mechanism for appealing Rule 702 issues on an interlocutory basis.[13]

Why the Advisory Committee Should Act on Rule 702

Our review of recent MDL decisions strongly suggests the need for Rule 702 reform. The advisory committee should adopt its proposal to add introductory language specifically instructing courts that Rule 702 reliability factors must be established by a preponderance of the evidence.

Further, we urge the committee to adopt a committee note expressly stating that the sufficiency of an expert's basis and the application of an expert's methodology are threshold questions of admissibility and not matters of weight.

In light of the widely acknowledged power of expert testimony and its ability to mislead the finder of fact, these reforms are urgently needed.

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[1] Fed. R. Evid. 702(b), (c), (d).

[2] Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing Bourjaily v. United States, 483 U.S. 171 (1987)).

[3] See, e.g., Manpower Inc. v. Ins. Co. of Pa., 732 F.3d 796, 806 (7th Cir. 2013) ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, on summary judgment" (quoting Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000))); Milward v.

Acuity Specialty Prods. Grp., 639 F.3d 11, 22 (1st Cir. 2011) (same).

[4] See, e.g., City of Pomona v. SQM N. Am. Corp., 750 F.3d 1036, 1048 (9th Cir. 2014) ("[O]nly a faulty methodology or theory, as opposed to imperfect execution of laboratory techniques, is a valid basis to exclude expert testimony"); U.S. v. Shea, 211 F.3d 658, 668 (1st Cir. 2000) ("[A]ny flaws in [an expert]'s application of an otherwise reliable methodology went to weight and credibility and not to admissibility").

[5] See Daniel Capra, Memorandum to Rule 702 Subcommittee re: Rule 702(b) and (d) — weight and admissibility questions, at 1, 26 (Oct. 1, 2018) (Agenda Book, Advisory Committee on Evidence Rules Oct. 19, 2018, meeting) at 171 (italics omitted).

[6] In re Nexium (Esomeprazole) Prods. Liab. Litig., 2014 WL 5313871, at *1 (C.D. Cal. Sept. 30, 2014) (quoting Hangarter v. Provident Life & Accident Ins. Co., 373 F.3d 998, 1017 n.14 (9th Cir. 2004), aff'd sub nom. In re Nexium Esomeprazole, 662 F. App'x 528 (9th Cir. 2016).

[7] In re Johnson & Johnson Talcum Powder Prods. Marketing, Sales Practices & Prods. Litig., No. 3:16-MD-2738(FLW), slip op. at 46 (D.N.J. April 27, 2020) (quoting In re Diet Drugs Prods. Liab. Litig., 2000 WL 962545, at *13 (E.D. Pa. June 28, 2000)).

[8] In re Taxotere (Docetaxel) Prods. Liab. Litig., 2019 WL 3997122, at -*6 (E.D. La. Aug. 23, 2019).

[9] In re Testosterone Replacement Therapy Prods. Liab. Litig., 2018 WL 4030585, at *2 (N.D. Ill. Aug. 23, 2018) (quoting Schultz v. Akzo Nobel Paints LLC, 721 F.3d 426, 433 (7th Cir. 2013)).

[10] Compare In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig., 26 F. Supp. 3d 449, 465 (E.D. Pa. 2014) (rejecting such reliance) and In re Abilify (Aripiprazole) Prods. Liab. Litig., 299 F. Supp. 3d 1291, 1367 (N.D. Fla. 2018) (same), with In re Testosterone Replacement Therapy, 2018 WL 4030585, at *3 (permitting reliance on trends) and In re Prempro, 2012 WL 13033298, at *3 (same).

[11] Compare In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II), 341 F. Supp. 3d 213, 241 (S.D.N.Y. 2018) (rejecting reinterpretation) and In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig., 145 F. Supp. 3d 573, 593 (D.S.C. 2015) (same), with In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig., 858 F.3d 787, 800 (3d Cir. 2017) (permitting reanalysis) and In re Celexa & Lexapro Prods. Liab. Litig., 927 F. Supp. 2d 758, 765 (E.D. Mo. 2013) (same).

[12] Compare In re Mirena (No. II), 341 F. Supp. 3d at 288 (questioning analogy to other drugs) and In re Abilify (Aripiprazole) Prods. Liab. Litig., 299 F. Supp. 3d at 1311 (same), with In re Celexa & Lexapro, 927 F. Supp. 2d at 762-63 (permitting lumping of different agents) and In re Prempro Prods. Liab. Litig., 2012 WL 13033302, at *4 (E.D. Ark. April 19, 2012) (same).

[13] See U.S. Chamber, Institute for Legal Reform, MDL Imbalance: Why Defendants Need Timely Access to Interlocutory Review 9 (April 2019).