WINSTON & STRAWN LLP

ARTICLE

Tylenol MDL Highlights Expert Admissibility Headaches

MAY 3, 2024

This article was originally published in Law360. Reprinted with permission. Any opinions in this article are not those of Winston & Strawn or its clients. The opinions in this article are the authors' opinions only.

The *In re: Acetaminophen — ASD-ADHD Products Liability Litigation*[1] in the U.S. District Court for the Southern District of New York was brought by more than 600 plaintiffs who alleged that the labeling practices of the defendant manufacturers and retailers of acetaminophen products were deficient because they failed to warn that children may develop autism spectrum disorder or attention-deficit hyperactivity disorder from in utero exposure to the drug.[2]

On Dec. 18, 2023, U.S. District Judge Denise Cote granted the defendants' motions to exclude the opinions of all five of the plaintiffs' general causation experts — an epidemiologist, a toxicologist, a teratologist/geneticist,[3] a pharmacologist and a psychiatrist — despite the court deeming each to be eminently qualified.[4]

After excluding all the plaintiffs' experts, the court entered an order on Jan. 16 directing the plaintiffs to explain why final judgments in favor of the defendants were not warranted.

On Feb. 1, a group of plaintiffs responded and sought to introduce new expert testimony based on the fact that the court's exclusion order predated their entry into the MDL. The defendants have opposed those efforts for reasons including that the plaintiffs' new expert suffers from the "same fundamental methodological defects that led to the Court's exclusion of Plaintiffs' prior experts' opinions."

While the court identified many such so-called methodological defects in its underlying exclusion order, several key rulings are discussed below that are broadly applicable to other product liability and mass tort proceedings.

First, in analyzing the reliability of the opinions offered by the plaintiffs' experts, the court stressed the U.S. Food and Drug Administration's conclusions on causality and the state of the scientific evidence, along with the conclusions of other medical and government organizations.

It noted that beginning in 2014, the FDA conducted periodic reviews on the published safety literature related to acetaminophen, or Tylenol, use in pregnancy and adverse neurodevelopmental outcomes.[5]

After each of these reviews, the FDA concluded that the scientific evidence precluded a causal determination, ending with a 2023 review stating that "the limitations and inconsistent findings of current observational studies" were "unable to support a determination of causality."[6]

The court also focused on the conclusions reached by several medical societies.[7]

As it observed, these organizations' conclusions mirrored the FDA's conclusions that "the weight of the evidence is inconclusive regarding the possible causal relationship between acetaminophen use and neurobehavioral disorders," and that the underlying studies were "limited by serious methodological problems" including "confounding," "elements of bias," and "severe issues with external and internal validity."[8]

Citing to the FDA, which it noted "has been following this research closely for almost a decade," and various medical associations, the court ultimately concluded that "there is no generally accepted scientific conclusion that in utero exposure to acetaminophen causes either ASD or ADHD."[9]

Second, the court underscored the importance of an expert's objective review of the scientific literature.

As many other courts — including the U.S. District Court for the Southern District of Florida in In re: Zantac (Ranitidine) Product Liability Litigation in 2022 — have observed, it explained that "an expert must not cherry-pick from the scientific landscape and present the [c]ourt with what he believes the final picture looks like," and that "exclusion of the proffered testimony is warranted where the expert fails to address evidence that is highly relevant to his or her conclusion."[10]

Here, the court repeatedly noted examples of the plaintiffs' experts' "cherrypick[ing] those findings that support [their] conclusions" and disregarding those that did not.[11]

Such examples include failing to even mention relevant studies, disregarding studies employing the same methodology as the plaintiffs' preferred studies but reaching unsupportive conclusions, relying on isolated and unreplicated findings within a given study, and ignoring subsequent — and relevant — publications by the same authors of a cited study.[12]

Third, the court heavily criticized the plaintiffs' experts for ignoring — or even contradicting — the authors' conclusions of the very studies they cited. It faulted one of the plaintiffs' experts for his continued "willing[ness] to press conclusions that study authors are not willing to make," explaining that this "willingness creates an 'analytical gap' between the conclusions reached by the authors and the conclusions he draws from their work."[13]

As an example, it pointed out that this same expert "repeatedly ignore[d] [study] authors' cautions that familial or genetic confounding may explain, at least in part, the observed association" between acetaminophen and ADHD or ASD.[14] The court similarly faulted other experts for "dismiss[ing] the express limitations of study authors"[15] and ignoring the authors' conclusions that "additional investigations on this subject are needed."[16]

Fourth, the court questioned the failure of one of the plaintiffs' experts to critically engage with known confounders in his report — a deficiency the court noted that "[b]y itself ... requires the exclusion of his opinion."[17]

Here, much of the scientific literature noted the issue of genetic confounding and that "there could be genetic factors that make pregnant people more likely to take acetaminophen during pregnancy, and also make it more likely that their offspring will have ADHD or ASD."[18]

The court noted that both the FDA and many studies relied on by the plaintiffs' expert "acknowledge the need for more work to account for the confounding effect of genetics."[19]

Yet the plaintiffs' expert "repeatedly ignore[d] authors' cautions that familial or genetic confounding may explain, at least in part, the observed association."[20] The court concluded that such a result-driven analysis does not reflect a reliable application of scientific methods.[21]

Fifth, and lastly, the court rejected use by the plaintiffs' experts of a so-called transdiagnostic Bradford Hill analysis[22] that included scientific literature on not just ASD and ADHD, but neurodevelopmental disorders more

broadly.

It found that a transdiagnostic Bradford Hill analysis raises a question of relevance, as the litigation was "brought to obtain recovery on behalf of those who have been diagnosed with ASD or ADHD,"[23] not anyone with a neurodevelopmental disorder.

And it noted that a transdiagnostic Bradford Hill analysis "obscured limitations in the scientific literature,"[24] as there "was no separate analysis of, for instance, the consistency among the findings [of] ... the strengths of any association, or any other relevant Bradford Hill factor, before the results of [NDD] studies were combined with the conclusions they drew from the studies of ASD and ADHD."[25]

The court further observed that the diagnostic criteria for these conditions were undeniably distinct, and that the mere fact that "ASD and ADHD are both categorized as NDDs does not suffice" to justify the use of a transdiagnostic Bradford Hill analysis.[26] And importantly, it also found that a transdiagnostic Bradford Hill analysis "is not a methodology that has been subjected to peer review and publication either generally or as applied to ASD or ADHD."[27]

STRATEGIC TAKEAWAYS FOR PRACTITIONERS

While the preceding discussion touches on just a handful of the broader rulings within the court's decision, those rulings highlight key principles on the admissibility of expert testimony in product liability and mass tort matters that counsel should be aware of, including:

1. When possible, expert opinions should be aligned with regulator assessments or the established medical consensus.

Here, the court juxtaposed the position of "major medical organizations and regulators," which have "cautioned against drawing causal inferences from the existing body of scientific literature," against the plaintiffs' experts who drew that very conclusion, and all of whom the court ultimately excluded.[28]

Other courts have similarly noted that "if an expert makes an analytical leap from available data that no other scientist outside of the litigation has made, a court may consider that fact."[29]

An expert's alignment — or an opposing expert's lack of alignment — with an established consensus in the scientific community can be a powerful tool in a Rule 702 inquiry into the admissibility of that expert's opinion.

2. Experts must undertake an objective review of relevant scientific literature and meaningfully address any contrary findings.

By admonishing the practice of cherry-picking only supportive studies or findings, the court reaffirmed the general principle that a reliable expert methodology entails an objective review of scientific literature — not just those studies that are supportive of an expert's opinions.

The ruling also emphasizes the need for experts to avoid relying on isolated findings within studies while disregarding conflicting or unreplicated outcomes within those same studies or elsewhere. A failure to do so risks exclusion of that expert's opinions.

3. Experts cannot ignore the conclusions or limitations placed on data by study authors.

The ruling also places importance on not just the data reported in a given study, but the conclusions and limitations the study authors place on the interpretation of that data.

Ignoring those conclusions or limitations creates an analytical gap between an expert and the authors of a study on which that expert relies. Experts should thus take care not to exceed the conclusions and limitations placed on any particular findings by a study's authors.

4. A failure to address potential confounders is relevant to the admissibility of an expert's opinions.

Litigants often argue that consideration of confounding factors goes to the weight of an expert's opinion, not its admissibility. But the court's ruling confirms that the failure to account for confounding factors can represent an unreliable application of scientific methods — especially when the body of scientific literature or the findings of other reputable organizations note a high likelihood of confounding.

5. The court's rationale regarding exclusion of transdiagnostic Bradford Hill analyses may apply to other causation methodologies.

The court determined that a transdiagnostic Bradford Hill analysis "is not a methodology that has been subjected to peer review and publication either generally or as applied to ASD or ADHD."[30]

It also added that such a methodology raised "a question of relevance" regarding its use of outcomes not at issue in the litigation,[31] and that the use by the plaintiffs' experts "obscured limitations in the scientific literature."[32]

These and other rationales for exclusion may be relevant for other causation methodologies as well, such as a weight-of-the-evidence approach. If multiple exposures or outcomes are included in a single causation analysis — even outside the Bradford Hill criteria — a challenge to the admissibility of that causation analysis may be appropriate.

---

[1] In re Acetaminophen – ASD-ADHD Prod. Liab. Litig. , No. 22MC3043 (DLC), 2023 WL 8711617 (S.D.N.Y. Dec.18, 2023).

[2] Id.

[3] Teratology is the study of birth defects.

[4] In re Acetaminophen, 2023 WL 8711617, at *1.

[5] Id. at *12.

[6] Id. at *13.

[7] Id. at *13-15.

[8] Id.

[9] Id. at *16.

[10] Id. at *18.

[11] Id. at *39; see also id. at *36 (noting one of plaintiffs' experts "ignore[d] inconsistent results," rendering his methodology unreliable).

[12] See id. at *26, *37, *40, *44.

[13] Id. at *33.

[14] Id.

[15] Id. at *36.

[16] Id. at *42.

[17] Id. at *31.

[18] Id. at *6.

[19] Id. at *31.

[20] Id. at *32–33.

[21] Id. at *33.

[22] A Bradford Hill analysis is a commonly used expert methodology in product liability and mass tort matters to assess causality based on a set of nine criteria first proposed by Sir Austin Bradford Hill in 1965.

[23] In re Acetaminophen, 2023 WL 8711617, at *20.

[24] Id. at *21.

[25] Id. at *42.

[26] Id. at *21.

[27] Id. at *42.

[28] Id. at *18.

[29] In re Zantac (Ranitidine) Prod. Liab. Litig. , 644 F. Supp. 3d 1075, 1187 (S.D. Fla. 2022).

[30] In re Acetaminophen, 2023 WL 8711617, at *42.

[31] Id. at *16.

[32] Id. at *21.

8 Min Read

Related Topics

Multi-District Litigation (MDL)

Related Capabilities

Product Liability & Mass Torts

Life Sciences

Related Professionals

Rand Brothers

Courtney Block