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BLOG

In re Acetaminophen MDL Court Highlights the Significance of Regulator and Medical Organization Conclusions on Causation in Assessing Expert Methodologies

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The December 18, 2023, Southern District of New York opinion *In re Acetaminophen – ASD-ADHD Products Liability Litigation*, notable for excluding all five of plaintiffs' general causation experts under Federal Rule of Evidence 702, reaffirms the importance of the FDA's conclusions on causation, along with those of other research and medical organizations.[1]

The multi-district litigation (MDL) was brought by more than 600 plaintiffs who alleged defendant manufacturers and retailers of acetaminophen products' labeling practices were deficient because they failed to warn that children may develop autism spectrum disorder (ASD) or attention-deficit hyperactivity disorder (ADHD) from in utero exposure to the drug.[2] Judge Denis Cote granted motions by the defendants to exclude the opinions of all five of plaintiffs' general causation experts—an epidemiologist, a toxicologist, a teratologist and geneticist, a pharmacologist, and a psychiatrist—despite the court deeming each "eminently qualified."[3] The experts' exclusion thus turned on the reliability of their opinions. Judge Cote's 49-page decision offers guidance on various Rule 702 issues, which Winston's Product Liability & Mass Tort Digest has covered here, here, and here.

In analyzing the reliability of the opinions offered by plaintiffs' experts, the *In re Acetaminophen* court focused heavily on the FDA's conclusions on causality and the state of the scientific evidence, along with the conclusions of other medical and government organizations. By way of background, the court requested that plaintiffs submit proposed language for a label change for the acetaminophen products at issue.[4] Plaintiffs' proposed warning stated in part that "[s]ome studies show that frequent use of this product during pregnancy may increase your child's risk of autism and attention deficit hyperactivity disorder."[5] Given the "important issues related to public health and drug safety for pregnant women and their offspring" raised by the MDL, the court invited the United States, including the FDA, to submit its views on the plaintiffs' proposed language.[6] While the United States declined to submit a Statement of Interest, it noted in its response that the FDA reached an independent conclusion in 2023 that the scientific evidence on the topic was "unable to support a determination of causality."[7]

In its opinion, the court noted that beginning in 2014, the FDA started conducting periodic reviews on the published safety literature related to acetaminophen use in pregnancy and adverse neurodevelopmental outcomes.[8] After each of these reviews, the FDA concluded that the scientific evidence precluded a causal determination. In 2015, the FDA concluded that "[w]hether the association is causal in nature remains uncertain" and that "the weight of evidence is inconclusive regarding a possible connection[.]"[9] In 2016, the FDA similarly found that "a causal relation

is not certain because of the possibility of confounding," and that published animal studies "were not adequately designed to address the question of causation."[10] A 2017 review noted that "all of the observational studies reviewed had significant limitations" and that the FDA "was unable to draw any conclusion about the causal association" between prenatal acetaminophen and neurodevelopmental outcomes.[11] In 2022, the FDA reviewed an additional 24 studies, and still concluded that "study limitations and inconsistent study findings . . . prohibit causal interpretations." And in 2023, the FDA stated that three additional studies reviewed did not change its conclusions that "the limitations and inconsistent findings of current observational studies of [acetaminophen] and neurobehavioral and urogenital outcomes are unable to support a determination of causality."[12]

The court also focused on the conclusions reached by medical societies, both in this country and in Europe, such as the Society for Maternal-Fetal Medicine, the Royal College of Obstetricians and Gynaecologists, the Organization of Teratology Information Specialists, the American College of Obstetricians and Gynecologists, and the Society of Obstetricians and Gynaecologists of Canada, among others.[13] The court observed that these organizations' conclusions were consistent with the FDA's conclusions—namely 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."[14]

Citing the FDA, which it noted "has been following this research closely for almost a decade," and the international medical associations, the court concluded that "there is no generally accepted scientific conclusion that in utero exposure to acetaminophen causes either ASD or ADHD."[15] As our previous analyses on the Product Liability & Mass Tort Digest have made clear, recent decisions have reinforced the important role of the general acceptance of an expert's conclusions to a court's Rule 702 admissibility analysis, and 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."[16] The *In re Acetaminophen* court considered this fact and ultimately excluded all of plaintiffs' general causation experts for having "not reliably opined so either."[17]

STRATEGIC TAKEAWAYS

In litigation where the issues have great public health significance, the *In re Acetaminophen* court aptly concluded, "[i]t matters to get this right." 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, all of whom the court ultimately excluded.[18] As with other recent decisions, the *In re Acetaminophen* decision reaffirms the importance of considering the conclusions of regulators, such as the FDA, and other reputable medical organizations under a Rule 702 inquiry.

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[1] *In re Acetaminophen – ASD-ADHD Prods. Liab. Liti*g., No. 22MD3043 (DLC), 2023 WL 8711617 (S.D.N.Y. Dec. 18, 2023).

[2] *Id*.

[3] *Id.* at *1.

[4] *Id*.

[5] *Id*. at *2.

[6] *Id.*

[7] *Id.*

[8] *Id.* at *12.

[9] *Id*. at *12–13.

[10] *Id*.

[11] *Id*. at *13.

[12] *Id*.

[13] *Id*. at *13–15.

[14] *Id*.

[15] *Id*. at *15.

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

[17] *In re Acetaminophen*, 2023 WL 8711617 at *15.

[18] *Id*.

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