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NEWSLETTERS

Court Excludes Expert's Opinion As Unreliable For Failure To Properly Consider Statistical Significance, But Plaintiffs Get Daubert Do-Over Anyway

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Note: This article appears in the Summer 2015 edition of Barnes & Thornburg LLP's Toxic Tort Practice Update e-newsletter.

Toxic tort cases, similar to product liability actions, are often won or lost based on the strength of expert testimony. Thus, keeping plaintiffs' questionable and over-reaching expert testimony out of the litigation is key. In such cases, judge as gatekeeper is especially important. Earlier this year in a pharmaceutical mass tort action involving the antidepressant Zoloft, a Pennsylvania federal judge ruled that hundreds of people who sued Pfizer over the drug's alleged link to birth defects will be allowed to present another expert. *In re Zoloft (Sertraline Hydrochloride) Products Liab. Litig*. No. 12-MD-2342, 2015 WL 115486 (E.D. Pa. Jan. 7, 2015). The court had excluded or limited all four general causation experts offered by plaintiffs after extensive *Daubert* hearings.

After the first *Daubert* hearing, the court disqualified a general causation expert, an epidemiologist. *In re Zoloft (Sertraline Hydrochloride) Products Liab. Litig*., 26 F.Supp.3d 449 (E.D. Pa. 2014), reconsideration denied sub nom. No. 12-MD-2342, 2015 WL 314149 (E.D. Pa. Jan. 23, 2015). The expert opined that Zoloft, when used at therapeutic dose levels during human pregnancy, is capable of causing a range of birth defects. Pfizer challenged the reliability of the expert's methods and principles.

Under the Third Circuit's 702 framework with respect to reliability, the focus of the court's inquiry is on the expert's methods, not the expert's conclusions. *In re Zoloft*, 26 F.Supp.3d at 452. In the field of epidemiology, the generally accepted method for determining whether a substance is a potential teratogen is to look for statistically significant associations between medication exposure and a pattern of birth defects, which are consistent and replicated across epidemiological studies, and to then apply the Bradford-Hill criteria. *In re Zoloft*, 26 F.Supp.3d at 455. In this case, the expert derived her conclusions about causation, in large part, by charting published findings from various studies on a "forest plot" and drawing conclusions from trends in odds ratios depicted on the forest plot. *Id*. The expert failed to consider whether the underlying published findings were statistically significant and failed to perform any further statistical analysis. *Id*. at 455. In support of this proposition, she cited a single source, a textbook by epidemiologist Kenneth Rothman. *Id*. at 455-56.

The court found that reliance on trends in non-statistically significant data to draw conclusions about teratogenicity, rather than on replicated statistically significant findings, was a novel methodology. *Id*. at 456. The court cited *Wade-Greaux v. Whitehall Labs, Inc*., 874 F. Supp. 1441, 1453

(D.V.I. 1994), aff'd 46 F.3d 1120 (3d Cir. 1994), which excluded the expert's testimony when it found that the opinion was not based upon repeated, consistent epidemiological studies showing statistically significant increased risks). Like the expert in *Wade-Greaux*, the court found that the expert failed to demonstrate that her reliance on non-statistically significant findings is accepted within her scientific community and that she drew her conclusions "by ignoring the basic requirements of the relevant scientific community's methodology." *Id*. at 457. The expert did not address her reasons for relying upon her novel method, rather than relying upon the well-established principle generally relied upon by epidemiologist – the principle of statistical significance. *Id*. at 456.

On reconsideration, the MDL court noted that it had not created a legal standard requiring statistical significance, but rather had made a factual finding that an epidemiologist would use some measure of statistical significance in reaching a conclusion in her discipline of epidemiology. 2015 WL 314149, at *2. In their motion for reconsideration, the plaintiffs asserted that the court failed to credit the expert's reliance on the Rothman Approach. The Rothman Approach was discussed in Bendectin litigation, where plaintiffs sought to be excused from their failure to show statistically significant associations when claiming causation between maternal use of Bendectin and infant birth defects. *DeLuca v. Merrell Dow Pharms., Inc*., 911 F.2d 941 (3d Cir. 1990). The court pointed out that the Third Circuit never affirmatively endorsed the Rothman Approach, but had reversed and remanded the case for a hearing under Rule 702. *In re Zoloft*, 2015 WL 314149 at *4.

In this case, the court found that the plaintiffs failed to show that the Rothman Approach had become generally accepted in the over two decades since *DeLuca*. *Id*. Further, the court found that although Professor Rothman has criticized the overemphasis upon p-values and significance testing, he has never suggested that researchers and scientists should ignore random error in interpreting research data. The court ultimately held that the Rothman Approach, as applied by the expert, did not satisfy Rule 702. The court found that the expert "departed from well-established epidemiological principles and methods . . ." *In re Zoloft*, 2015 WL 314149, at *5.

The court excluded the expert's testimony for several reasons, including her inattention to the principles of replication and statistical significance, her use of certain principles and methods without demonstrating either that they are recognized by her scientific community or that they should otherwise be considered scientifically valid, and the expert's failure to reconcile her currently expressed opinions with her prior opinions and her published, peer-reviewed research. *See In re Zoloft*, 26 F.Supp.3d at 465. Additionally, the court noted that the expert's opinions were unreliable because they were supported by a "cherry-picked" subset of research selected because it was supportive of her opinions (without adequately addressing non-supporting findings). *In re Zoloft*, 2015 WL 314149 at *1. To reach this conclusion, the court examined a large number of studies and found that the expert failed to examine the literature as a whole to reach her causal conclusion. In denying plaintiffs' motion for reconsideration, the MDL court reiterated its holding excluding the expert's testimony as unreliable under the Daubert standard. *Id*. at *5.

Although *In re Zoloft* is a pharmaceutical products liability action, it

provides insight into a broad array of litigation practice areas involving scientific and technical fields, including toxic tort. Where accepted science can be distorted, the court's adherence to its gatekeeping duties is paramount. Here, the court discharged its duty with painstaking precision. It peered beyond the reported p-value and looked to the methodology actually employed in the study to reach its result. The plaintiffs in this case were fortunate – the MDL court has allowed a *Daubert* do-over. This, however, does not diminish the MDL court's favorable findings, which are applicable to toxic tort defendants. Vigilance is required to look beyond the results, and toxic tort defendants should be prepared to point out shortcomings of expert witness opinions when they depart from generally accepted principles and methodology recognized by the relevant scientific community.

For more information about this topic and the issues in this article, please contact Oni Harton in our Indianapolis office at (317) 231-7419 or oni.harton@btlaw.com.

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