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Expert Testimony in Zoloft Lawsuit Ruled Inadmissible

Written on Friday, September 5th, 2014 by Colin Holloway, Attorney at Law
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Plaintiffs suing drug manufacturer Pfizer over alleged birth defects caused by its antidepressant Zoloft suffered a defeat last week when a [federal judge rejected key portions of testimony](#) from three medical expert witnesses. Experts for the plaintiffs were prepared to testify that Zoloft caused birth defects in humans, but US District Judge Cynthia Rufe found the scientific opinion supporting the connection to be unreliable and inadmissible during trial.

Judge Excludes Zoloft Plaintiffs' Expert Testimony

Judge Rufe held a special hearing to analyze the proposed testimony of three scientific expert witnesses: Thomas Sadler, an embryologist; Robert Cabrera, a teratologist; and Michael Levin, a molecular developmental biologist. The three experts were called upon by plaintiffs to connect Zoloft use by pregnant mothers to infant defects, but, after reviewing their expert opinions, Judge Rufe determined

that all three doctors fell short of connecting Zolofit to birth defects with imperfect scientific methodology, and thus could not testify to the jury.

Central to Judge Rufe's opinion was the failure to reconcile existing studies on Zolofit, which did not find it was related to birth defects, with the proposed testimony in the upcoming trial. Zolofit has been prescribed to pregnant women for the entire duration of its 20 years on the drug market, and as such there is a significant amount of research available on the potential impact it has on pre-natal development. Some of the existing research has produced results that indicate Zolofit *does not* cause birth defects, but none of the plaintiffs' doctors addressed the discrepancy in findings.

The rules of trial evidence, as interpreted by the Supreme Court case *Daubert v Merrill Dow*, require that all expert witness testimony be reliable – a standard that is typically measured by the quality of the scientific methods used to form an expert opinion. Taking that guidance into account, Judge Rufe found that, “The experts’ failure to reconcile inconsistent epidemiological research with their opinions regarding human causation is a significant methodological flaw, undermining their reliability under *Daubert*,” and the court was therefore forced to exclude portions of the testimony that claimed Zolofit causes birth defects.

Latest Expert Witness Ruling Consistent with Previous Decision

In April, Judge Rufe also denied testimony from a plaintiff expert witness, Dr. Anick Berard, who was prepared to claim that Zolofit could be affirmatively linked to birth defects. Dr. Berard is a professor specializing in teratology, the study of congenital abnormalities, whose testimony was determined to be unreliable for similar reasons. In her finding on Berard, Judge Rufe wrote, “The court finds that the expert report prepared by Dr. Bérard does selectively discuss studies most supportive of her conclusions, as Dr. Bérard admitted in her deposition, and fails to account adequately for contrary evidence, and that this methodology is not reliable or scientifically sound.”

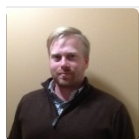
Drs. Cabrera, Sadler, and Levin, whose expertise did not directly pertain to congenital defects, faltered without Dr. Berard's contribution. Connecting the recent ruling with the similarly reasoned decision to exclude Dr. Berard as a plaintiff expert witness, Judge Rufe wrote, “The court notes that Drs. Cabrera, Sadler, and Levin were retained for their expertise on biological mechanisms, and although they each reviewed the epidemiological literature, it was Dr. Bérard who was retained for her expertise in that field. Had the court found Dr. Bérard's methodology was sound, they would have been justified in relying upon her report as evidence in support of their own human causation opinions. However, without Dr. Bérard's opinion to rely upon, the court must examine whether each of these experts adequately addressed the epidemiological evidence in forming their opinions on human causation.”

Zolofit Plaintiffs' Expert Witnesses May Limit Testimony

Unlike her decision with Dr. Berard, Judge Rufe did not fully exclude testimony from Drs. Sadler, Cabrera, and Levin. All three doctors are experts in biological mechanisms, which is a field that can support a relationship between Zoloft and birth defects without making the argument that the drug definitely caused them. Because all three experts are able to support the opinion that it is *plausible* that Zoloft alters biological mechanisms necessary to fetal development, plaintiffs are able to use limited portions of their testimony.

All three plaintiffs' expert witnesses used in the Zoloft lawsuit have conducted extensive research on animals, but none can definitively say the results carry through to humans – further preventing them from linking Zoloft to human birth defects. Pfizer attorneys expressed satisfaction in the ruling, and noted that the lack of [expert witnesses](#) capable of offering reliable evidence that Zoloft causes birth defects is a hurdle that plaintiffs will not be able to overcome.

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About Colin Holloway, Attorney at Law

[LinkedIn](#) Colin Holloway is an attorney operating in the Washington DC area. He is a graduate of Carnegie Mellon University and Emory University School of law, and has practice experience in criminal defense, personal injury litigation, mediation, and employment law.

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