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PERSPECTIVE

Federal court: Expert's testimony doomed by misuse of data

By Jonathan Tam and Mary Kim

A recent decision from the U.S. District Court for the Northern District of California serves as a helpful reminder of the importance of expert testimony in products liability cases; the need for experts to apply reliable methods when forming their opinions; and the vital gatekeeping role that courts have to ensure that unfounded expert evidence does not reach juries.

In *Rodman v. Otsuka America Pharmaceutical, Inc.*, 18-cv-03732-WHO (N.D. Cal. May 18, 2020), the plaintiff alleged that she developed tardive dyskinesia, an involuntary movement disorder, as a result of taking Abilify, an antipsychotic medication approved by the U.S. Food and Drug Administration. The plaintiff asserted product liability claims against the defendant pharmaceutical manufacturer, including the claim that the defendant failed to adequately warn of the risk of tardive dyskinesia.

In an attempt to support that claim, the plaintiff proffered Laura Plunkett, Ph.D., as an expert in pharmacology, toxicology, and FDA regulations. The defendant moved to exclude Dr. Plunkett's testimony, arguing that Dr. Plunkett was not qualified to offer an opinion on the inadequacy of a medication label, and that her opinions were methodologically unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals., Inc.*, 509 U.S. 579 (1993).

Rule 702 provides that in order for an expert's opinion to be admissible, the expert must be "qualified," the opinion must be "based on sufficient facts or data" and "the product of reliable principles and methods," and the expert must "reliably appl[y] the principles and methods to the facts of the case." In the landmark *Daubert* decision, the United States Supreme Court held that trial courts are to serve as gatekeepers and must ensure that experts have reliably applied their methodologies in reaching their opinions.

In Rodman, Judge William H. Orrick rejected the defendant's argument that Dr. Plunkett lacked the necessary qualifications. Although Dr. Plunkett could not prescribe Abilify or diagnose tardive dyskinesia, the court held that "those skills are not necessary prerequisites to testifying about the adequacy of Abilify's label." Dr. Plunkett's "experience and expertise as a toxicologist and pharmacologist qualify her to opine" on the adequacy of the label.

However, turning to Dr. Plunkett's opinion that the Abilify label did not include an adequate warning of the risk of tardive dyskinesia, the court found that Dr. Plunkett's methodology was "problematic." Dr. Plunkett asserted in her report that two scientific sources showed that the incidence rate of tardive dyskinesia was higher than that which was disclosed in the Abilify label. The court found that the sources Dr. Plunkett relied on did not actually provide "true incidence rates."

Indeed, the sources "cautioned" that they "cannot be used to calculate an incidence rate." For example, the first source disclaimed: "The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events." The second source disclaimed that the true incidence rate was "not known." Perhaps most devastating was the fact that Dr. Plunkett conceded at her deposition that the sources did not provide a true incidence rate.

Judge Orrick ultimately held that Dr. Plunkett's opinion was unreliable because it "exceeds the boundaries of the sources she relies on by going beyond what the sources concluded." As the court concluded in excluding her opinion under *Daubert*: "Because Dr. Plunkett extrapolated conclusions beyond the scope of her sources, I find that her opinion on label inadequacy is not the product of reliable principles or methods."

> The *Rodman* case serves as yet another cautionary tale that even if an expert is well qualified to offer an opinion, that does not necessarily mean that her opinion will satisfy *Daubert*'s exacting standards of reliability.

Notably, in so holding, Judge Orrick recognized that another federal court had excluded Dr. Plunkett's opinions on analogous grounds in another unrelated litigation. In *In re Mirena Ius Levonorgestrel-Related Product Liability Litigation (No. II)*, 341 F. Supp. 3d 213 (S.D.N.Y. 2018), *appeal pending*, 19-2155 (2d Cir.), the court found that Dr. Plunkett's "handling" of a study was "problematic" because she cited the study for a proposition not found in the study. Indeed, the study authors noted the limitations of their study and Dr. Plunkett ignored them. For this and other reasons, the court in *Mirena* held that her opinions were "beset by methodological deficiencies" and thus inadmissible.

In *Rodman*, the exclusion of Dr. Plunkett's testimony under *Daubert* was "ultimately fatal" to the plaintiff's "failure to warn claim on the theory that the Abilify label underreported the risk" of tardive dyskinesia, and the court granted the defendant's motion for summary judgment.

The *Rodman* case serves as yet another cautionary tale that even if an expert is well qualified to offer an opinion, that does not necessarily mean that her opinion will satisfy *Daubert*'s exacting standards of reliability. The qualifications and reliability inquiries are analytically distinct. Lawyers working with experts should take care to ensure that their experts apply reliable methods when analyzing scientific data. Failure to do so may result in the exclusion of your expert. ■

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