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IN THIS ISSUE

Jay M. Mattappally, Claire A. Noonan, and Quentin F. Urquhart Jr. report on a potentially problematic judicial trend regarding the admissibility of expert testimony and call for amendments to the Federal Rules of Evidence to curb this trend.

Expert Qualifications Held to be Self-Validating: A Call for Amendments to the Federal Rules of Evidence on the Admissibility of Expert Testimony

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I. Introduction

In recent litigation, particularly in non-*Daubert* jurisdictions, judges have allowed experts to testify at trial based on their qualifications alone without performing an intensive examination into whether these experts have applied the correct scientific methodology under *Daubert* or related local rules.[1] For example, in the recent Accutane litigation in New Jersey, a state appeals court revived more than 2000 consolidated cases that were dismissed when the trial court barred testimony from the plaintiffs' experts.[2] Reversing the trial court's decision, the appeals court adopted a more lax standard for determining the admissibility of expert testimony from a decision handed down by the New Jersey Supreme Court in 1991.[3] In finding the experts' testimony admissible, the appeals court placed great deference on the experts being "extremely well-qualified." However, the New Jersey Supreme Court rejected the lax standard adopted by the appeals court and reinstated the trial court's decision excluding the plaintiffs' experts from testifying.[4] Notably, the Supreme Court affirmed the trial court's analysis that focused solely on the experts' methodology, adding that the "experts' ***credentials were not in issue at any point***."[5]

The following sections of this article provide: (1) a brief overview of the legal standard under the FRE and *Daubert*; (2) a summary of relevant case law where well-qualified experts were excluded from testifying due to a lack of underlying scientific methodology; and finally, (3) a discussion of the need to amend the FRE to emphasize examination of an expert's scientific methodology, not just credentials, when determining admissibility of the expert's testimony.

II. Legal Standard and Relevant Case Law

A. Federal Rules of Evidence and *Daubert*

Rule 702 of the Federal Rules of Evidence ("Rule 702") governs the admissibility of expert witness testimony. In relevant part, Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to

[1] *See, e.g., In re Accutane Litig.*, 165 A.3d 832 (N.J. Super. App. Div. 2017), rev'd, 079958, 2018 WL 3636867 (N.J. Aug. 1, 2018); *see also Kemp ex rel. Wright v. State*, 174 N.J. 412, 425 (2002) ("[The New Jersey Supreme Court] relaxed the standard for admissibility of scientific evidence due to the 'extraordinary and unique burdens' plaintiffs faced when they sought to prove medical causation in toxic tort cases."); *State v. Hernandez*, 707 N.W.2d 449, 453 ("This Court has a formal process for adopting procedural rules after appropriate study and recommendation by the Joint Procedure Committee, and we decline [Defendant]'s invitation to adopt Daubert by judicial decision.").

[2] *See id.*

[3] *Rubanick v. Witco Chem. Corp.*, 593 A.2d 733 (N.J. 1991).

[4] *In re Accutane Litig.*, 2018 WL 3636867 (N.J. Aug. 1, 2018) ("Accutane Supreme Court"). This case will be discussed in more detail *infra*.

[5] *Id.* at *18, fn. 23.

understand the evidence or to determine a fact in issue;
(b) the testimony is based on sufficient facts or data;
(c) the testimony is the product of reliable principles and methods; and
(d) the expert has reliably applied the principles and methods to the facts of the case.[6]

The United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), provided the analytical framework for determining whether expert testimony is admissible under Rule 702. *Daubert* charged trial judges with the responsibility of acting as gatekeepers to exclude unreliable expert testimony, and also provided some general non-exclusive factors that trial judges must use to assess the reliability and helpfulness of scientific expert testimony.[7] These factors include: (1) whether the expert's technique or theory can be or has been tested, that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community.[8]

In 2000, Rule 702 was amended to adopt *Daubert*. Applying the *Daubert* standard, subsequent courts have listed additional non-exclusive factors to evaluate in determining the reliability of expert testimony, including "[w]hether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give."[9] As part of its gatekeeping function, the "trial judge, faced with a proffer of expert scientific testimony, must conduct a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."[10] In doing so, a court may properly preclude an expert's testimony on the grounds that "there is simply too great an analytical gap between the data and the opinion proffered."[11] The goal of any *Daubert* inquiry must be "scientific validity and thus the evidentiary relevance and reliability – of the principles that underlie" a proposed expert's testimony.[12] The focus "must be solely on principles and methodology, not on the conclusions that they generate."[13]

[6] Fed. R. Evid. 702 (emphasis added).
[7] *See* Advisory Committee Notes, Fed. R. Evid. 702.
[8] *Id*.
[9] *Id*.
[10] *Cooper v. Smith & Nephew Inc*., 259 F.3d 194, 203 (4th Cir. 2001) (internal quotations omitted).
[11] *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997).
[12] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594-595 (1993) ("Daubert I").
[13] Daubert I, at 595.

Importantly, qualifications alone do not suffice to render an expert's opinion admissible.[14]

It "is axiomatic that an expert, no matter how good his credentials, is not permitted to speculate."[15] The trial court's gatekeeping function requires more than simply "taking the expert's word for it."[16] Indeed, even a "supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant under the test set forth by the Supreme Court in *Daubert.*"[17]

B. Cases Excluding Opinions of Well-Qualified Experts Due to a Lack of Underlying Scientific Methodology

1. *In re Accutane Litig*., 079958, 2018 WL 3636867 (N.J. Aug. 1, 2018).

As discussed above, this case presented the most recent (and egregious) example of an appeals court placing too much emphasis on certain experts' qualifications, rather than the substance of the experts' underlying scientific methodology. The litigation arose when over two thousand plaintiffs brought products liability actions against the developers of Accutane, a prescription acne drug, alleging that they developed Crohn's disease as a result of taking Accutane. Since the filing of these actions in 2005, several epidemiological studies were published concluding there is no causal relationship between Accutane and Crohn's disease. The plaintiffs' experts in gastroenterology and statistics disputed the findings and conclusions of these epidemiological studies, and instead relied on case reports, animal studies, causality assessments, and a biological mechanism hypothesis in asserting the contrary view that Accutane can in fact cause Crohn's disease. The defendants challenged the methodology and evidence used by the plaintiffs' experts as unreliable and sought the exclusion of their testimony. Specifically, the defendants argued that the epidemiological studies "effectively disproved any general causal association between Accutane and Crohn's disease," and that these studies were "'the most important and reliable data that exist[ed] on Accutane and Crohn's disease' and [were] superior to other forms of evidence previously used in the [] litigation such as case reports, animal studies, and theories on biological mechanisms."[18]

After a pretrial evidentiary hearing, the trial court excluded the plaintiffs' experts' testimony, holding that the experts' respective methodologies were unsound because they did not interpret the relevant data and apply them to the facts of the case as would other experts in the field.[19] Further, the court held that there was no rational basis for the plaintiffs to ignore the findings

[14] *Clark v. Takata Corp*., 192 F.3d 750 (7th Cir. 1999).
[15] *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1088 (10th Cir. 2000) (emphasis added).
[16] Advisory Committee Notes, Fed. R. Evid. 702 (emphasis added).
[17] *Clark*, 192 F.3d at 759 fn. 5 (emphasis added).
[18] Accutane Supreme Court, at *7.
[19] *Id.*, at *5.

in all the epidemiological studies, and instead rely on case reports and animal studies when the latter was a "seriously flawed and a less reliable form of evidence" than the former.[20] Notably, the trial court concluded that the plaintiffs' experts were "exceptionally learned and accomplished professionals," and that their "credentials [were] impressive and each [expert was] a leader in his/her profession,"[21] but the court did not perform any additional analysis of, or give any special deference to, these credentials while examining the substance and/or methodology underlying the experts' testimony. In fact, the trial court proceeded to refer to them as "self-validating expert[s]" and "hired gun[s]" who wanted to "have it both ways" by rejecting the best available evidence as flawed while also relying on inferior evidence.[22] The trial court subsequently issued an order dismissing all the plaintiffs' claims with prejudice.

On appeal, the appeals court reversed the trial court's decision and concluded that the plaintiffs' experts had employed a "sound methodology and simply interpreted the data differently than defendants' experts."[23] In doing so, the appeals court found that the plaintiffs' experts were "***extremely well-qualified***" experts who "considered all of the relevant data and information, applied appropriate methodology in analyzing the epidemiological studies, and expressed valid reasons for rejecting the conclusions of some of the epidemiological studies and in accepting other studies as supportive of their opinion."[24] The appeals court also disagreed with the trial court's characterization of the experts as hired guns.

The defendants sought certification with the New Jersey Supreme Court, arguing, *inter alia*, that the appeals court's decision "nullifies the trial court's role as the gatekeeper of expert witness testimony and will '***allow[] any credentialed expert to argue their way to a jury***.'"[25] They further argued that the appeals court failed to apply "methodological scrutiny", and instead applied a more relaxed standard for admissibility despite the existence of "well-developed science."[26] Notably, the Defense Research Institute (DRI) and other industry associations filed amicus briefs on this issue, asserting that:

> robust gatekeeping is necessary because juries struggle to absorb complex scientific concepts and are poorly equipped to assess methodological soundness. . . . ***juries may be misled by highly-qualified experts*** who offer opinions that are not supported by the wider scientific community and that juries faced with complex scientific evidence ***may simply "fall back" on an expert's credentials as a basis for evaluating the testimony at issue***. To guard against that risk, . . . experts should be required to prove not only that their

[20] *Id.*, at *18.
[21] In re Accutane Litigation, 2015 WL 753674, at *2 (N.J. Super. L.).
[22] Accutane Supreme Court, at *18.
[23] *Id.*, at *5.
[24] *Id.*, at *19 (emphasis added).
[25] *Id.*, at *19 (emphasis added).
[26] *Id.*, at *20.

methodology is sound, but that such methodology is reliably applied to the facts of the case.[27]

The New Jersey Supreme Court re-affirmed the trial court's ruling excluding the plaintiffs' experts' testimony. In doing so, the Court stated that the case provided the "appropriate setting for illustrating how courts should evaluate the methodology of a credentialed expert when determining whether an opinion is based on scientifically sound reasoning."[28] The Court noted that when "[p]roperly exercised, the gatekeeping function ***prevents the jury's exposure to unsound science through the compelling voice of an expert***."[29] The Court reiterated that the key to admission of the opinion is the "validity of the expert's reasoning and methodology"[30], and noted that the "experts' ***credentials were not in issue at any point***" in the trial court's analysis.[31] The Court held that plaintiffs' well-credentialed experts employed an unsound methodology whereby they disregarded the relatively large body of epidemiological studies that did not support their position on causation; instead, they selectively relied on inferior forms of evidence such as case reports and animal studies that did support their position.[32]

2. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311 (9th Cir. 1995) ("Daubert II")

After the Supreme Court's decision in *Daubert*, the case was vacated and remanded back to the Ninth Circuit. In *Daubert*, minors brought products liability actions against a drug manufacturer, alleging that their mothers' ingestion of the manufacturer's morning sickness pills caused them to have limb reduction birth defects. On remand, the Ninth Circuit held that the plaintiffs' scientific expert testimony was not admissible to prove that the pills caused the birth defects because the experts, despite their "impressive qualifications," did not provide the Court with an explanation of their methodology.[33]

In so doing, the Court noted that although the "Supreme Court waxed eloquent on the impressive qualifications of plaintiffs' experts," "something doesn't become 'scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive".[34] Rather, the key is to perform an "objective, independent validation of the expert's methodology"[35]. To make a proper showing under Rule 702, the plaintiffs' experts had to explain how

[27] *Id.*, at *22 (emphasis added).
[28] *Id.*, at *6 (emphasis added).
[29] *Id.*, at *27 (emphasis added). *See also* State v. Cavallo, 88 N.J. 508, 518 (1982) ("The danger of prejudice through introduction of unreliable expert evidence is clear. While juries would not always accord excessive weight to unreliable expert testimony, there is substantial danger that they would do so, precisely because the evidence is labeled 'scientific' and 'expert.'").
[30] Accutane Supreme Court, at *27.
[31] *Id.*, at *18, fn. 23 (emphasis added).
[32] *Id.*, at *29-30.
[33] Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311 (9th Cir. 1995) ("Daubert II") (emphasis added).
[34] Daubert II, at 1315-16.
[35] *Id.*, at 1316.

they reached their conclusions and point to an objective source such as a treatise to show that they followed the scientific method, as is practiced by at least a recognized minority of scientists in their field. Instead, the Court held that the plaintiffs made no such showing because the court was "presented with only [their experts'] qualifications, their conclusions and their assurances" that their methodology comported with standard scientific procedures, and not an explanation of what the actual methodology was.[36]

3. *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996)

In *Rosen*, the Seventh Circuit affirmed the exclusion of the deposition testimony of plaintiff's expert, a "distinguished cardiologist" with "sterling credentials," because the expert's testimony that the nicotine patch at issue caused the plaintiff's heart attack was not valid scientific evidence and therefore was not admissible under *Daubert*.[37] The Court noted that under *Daubert*, "a district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist."[38] In doing so, the court must make sure that "when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work."[39] If not, their testimony is inadmissible, "***no matter how imposing their credentials***".[40]

4. *G.T. Laboratories, Inc. v. Cooper Companies, Inc.*, 92 C 6647, 1998 WL 704302, at *6 (N.D. Ill. Sept. 24, 1998)

In *G.T. Laboratories*, the trial court excluded the testimony of the defendant company's expert witness for failure to demonstrate the reliability of the expert's alternative methodology under the *Daubert* factors; rather, the defendant solely relied on the assertion that its expert was "well-regarded".[41] The court held that simply being "well-regarded" is "not a substitute for analysis of the *Daubert* factors."[42]

5. *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269 (5th Cir. 1998)

In *Moore*, the Fifth Circuit affirmed the exclusion of the testimony of the plaintiff's toxicological causation expert, a "highly qualified" medical doctor/pulmonary specialist with "outstanding" qualifications, because the expert's opinion was not sufficiently grounded in scientific methodology and therefore was not sufficiently reliable for the jury to consider.[43]

6. *Castellow v. Chevron USA*, 97 F. Supp. 2d 780, 798 (S.D. Tex. 2000)

[36] *Id.*, at 1319.
[37] *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316 (7th Cir. 1996) (emphasis added).
[38] *Id.* at 318.
[39] *Id.*
[40] *Id.* at 318-19 (emphasis added).
[41] *G.T. Laboratories, Inc. v. Cooper Companies, Inc.*, 92 C 6647, 1998 WL 704302, at *6 (N.D. Ill. Sept. 24, 1998).
[42] *G.T. Laboratories,* 1998 WL 704302, at *6.
[43] *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 273 fn. 2, 278 (5th Cir. 1998) (emphasis added).

In *Castellow*, the trial court excluded opinions offered by the plaintiffs' "eminently qualified" experts because the opinions were not reliable as they posited a theory that was not generally accepted; their particular hypothesis in this case had not been subjected to testing or peer review; and most importantly that, their result driven methodology (modeling to determine exposure assessment) was rife with error and speculation.[44]

7. *Ocasio v. C.R. Bard, Inc.*, 2015 WL 2062611 (M.D. Fla. May 4, 2015)

In *Ocasio*, the trial court excluded the testimony of the plaintiffs' "clearly qualified" design and testing expert because his opinions were not based on sufficient facts or data, and were not the product of reliable principles and methods.[45] Specifically, the expert had not tested, examined, or even seen the device in person. Rather, his only opinions were "gleaned from documents selected by Plaintiffs' counsel," and completely lacked "*any* independent verification of the data or testing of the device."[46] Further, his methodology was unreliable in that he simply reviewed the facts of the case, the known failure modes of the device and similar devices, and relevant medical literature, after which he subjectively compared the defendants' approach to "what he believed a prudent product manufacturer would have done."[47]

C. A Call to Amend the FRE and/or its Advisory Comments on the Admissibility of Expert Testimony

Despite the final positive result in the Accutane litigation, the appeals court's ruling in that case (including its potentially catastrophic effects on future litigation if it were upheld) raised significant concerns that must be addressed in the federal rules going forward. Specifically, the FRE and/or its Advisory Comments should be amended to include language providing guidance to judges to be cognizant of the distinction between an expert's "qualifications" versus the underlying "methodology" used by the expert in providing his/her expert opinion. The FRE should also be amended to recommend that judges perform an intensive examination at the outset of the case that focuses primarily on the reliability of an expert's methodology, not credentials. If the methodology is not based on sound scientific principles, the expert should not be allowed to testify and potentially influence lay jurors based solely on strong credentials.

This is not a new or radical idea; rather, as shown by the cases summarized above, courts have been excluding highly qualified experts for employing unreliable methodologies in numerous jurisdictions for decades. Thus, these recommended amendments are simply meant to codify these holdings into the federal rules so as to

[44] *Castellow v. Chevron USA*, 97 F. Supp. 2d 780, 798 (S.D. Tex. 2000) (emphasis added).
[45] *Ocasio v. C.R. Bard, Inc.*, 2015 WL 2062611, at *2-3 (M.D. Fla. May 4, 2015) (emphasis added).
[46] *Id.*, at *3.
[47] *Id.*

provide additional guidance to judges when evaluating the admissibility of expert testimony under FRE 702.

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