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'Accutane' Appeal Presents Opportunity for NJ to Adopt 'Daubert'

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Causation is an essential element needed to prove a products liability claim and which often involves scientific and medical complexities. In such instances, expert testimony is required.

It has been the position of many products liability lawyers that the New Jersey standard for admissibility of expert testimony needs to be more stringent and consistent with the federal standard set forth in *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993). Applying a strict standard to judicial gatekeeping of scientific evidence, Daubert is intended to ensure that "junk science" is not permitted to reach the jury.

New Jersey, however, adheres to the Kemp standard, which, in practice, provides for less scrutiny of an expert witness's methodology than the approach followed in other courts. New Jersey's adherence to *Kemp* incentivizes litigation where the plaintiff's medical/scientific theory of the case may be less than sound—and results in many of these cases being filed in New Jersey because of the more lenient standard of admissibility.

Most recently, in *In re Accutane Litig.*, 451 N.J. Super. 153 (App. Div. 2017), the Appellate Division applied an even more "relaxed standard," which accepted the arguments of plaintiffs' experts without addressing whether they employed a coherent methodology. As a result, the Accutane defendants have filed a petition for certification to the New Jersey Supreme Court, which seeks clarification of the New Jersey standard for expert admissibility and advocates for more stringent judicial gatekeeping. As a result, the New Jersey Supreme Court has been presented with the perfect opportunity to adopt *Daubert* and ensure that there are robust checks on the expert testimony presented in New Jersey courts, as well as to stop the proliferation of cases filed in New Jersey by out-of-state plaintiffs, who seek to take advantage of this less rigid standard.

Expert Testimony in Pharma Products Liability Litigation

As stated above, expert testimony is critical in pharmaceutical products liability cases. In fact, every jurisdiction requires expert testimony to prove medical causation—that is proof that a

medicine can cause a disease and that the medicine was the cause of plaintiff's disease. *See, e.g., In re Accutane Litig*., 451 N.J. Super at 191-92. Ultimately, a significant portion of products liability cases are won and lost based on proof (or lack thereof) of causation. Indeed, the admissibility of expert testimony on causation often means the difference between costly and protracted litigation and resolution at the summary judgment stage.

Federal and State Standards

At the federal level and in most states, the admissibility of expert testimony is governed by *Daubert v. Merrell Dow Pharm*., 509 U.S. 579 (1993), and Federal Rule of Evidence 702. Under *Daubert*, a party must show: (1) that the reasoning and methodology underlying their expert's testimony is scientifically valid; and (2) that the proffered opinion assists the trier of fact in understanding the evidence or determining a fact at issue. *Daubert*, 509 U.S. at 592-93; *see also In re: Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig*., 858 F.3d 787, 792-93 (3d Cir. 2017).

Under *Daubert*, trial courts "serve as gatekeepers for expert witness testimony." *In re: Zoloft*, 858 F.3d at 792. In that role, the court must first determine if a witness is qualified "by knowledge, skill, experience, training, or education," and then determine whether the offered testimony "is the product of reliable principles and methods[] and … the expert has reliably applied the principles and methods to the facts of the case." *Daubert*, 509 U.S. at 579. Under *Daubert*, courts conduct a robust review of an expert's opinion, considering "the testability of the hypothesis, whether it has been peer reviewed or published, the error rate, whether standards controlling the technique's operation exist, and whether the methodology is generally accepted." *In re Zoloft*, 858 F.3d at 792. The *Daubert* standard is codified in Federal Rule of Evidence 702, which permits expert opinion where:

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

The *Daubert* standard applies in federal courts and 37 state courts.

A minority of states, including New Jersey, apply what is referred to as the *Frye* standard—named for *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). While called a standard, in practice, the states that do not apply *Daubert* apply a varying set of "relaxed" principles to the admissibility of expert testimony. The *Kemp* standard is New Jersey's articulation of *Frye*. These inconsistent and relaxed standards invite forum shopping and lead to inconsistent outcomes in cases involving similar products and plaintiffs. The Accutane appeal presents an opportunity for the New Jersey Supreme Court to adopt *Daubert*, and join the majority of states applying a uniform standard to the admissibility of expert testimony. This approach would bring New Jersey in line with the majority of courts and discourage forum shopping.

The 'Kemp' Standard

The New Jersey Supreme Court first enunciated a less rigorous standard for expert admissibility in toxic tort cases in *Rubanick v. Witco Chem. Corp*., 125 N.J. 421, 449 (1991). Expanding on *Rubanick*, the New Jersey standard for the admissibility of expert testimony in pharmaceutical products liability cases was announced in *Kemp ex rel. Wright*, 174 N.J. 412 (2002). In *Kemp*, the court acknowledged that it "relaxed the standard for admissibility of scientific evidence," due to what it called the "'extraordinary and unique burdens' plaintiffs faced when they sought to prove medical causation." *Id*. at 425 (quoting *Rubanick*, 125 N.J. at 433). Despite articulating a "relaxed" standard, the court cited *Daubert* favorably, acknowledging that "the inquiry is a 'flexible one,' and that its focus must be 'solely on principles and methodology, not on the conclusions that they generate.'" *Id*. at 426 (quoting *Daubert*, 509 U.S. at 594-95).

Under *Kemp* and its progeny, and like *Daubert*, in exercising their gatekeeping function, trial courts are supposed to focus on the reliability of an expert's methodology. *Id* at 427. However, unlike *Daubert*, in *Kemp*, the Supreme Court specifically declined to adopt concrete guidelines, including fit, testability and error rate, which were adopted in *Daubert*. The failure to adopt these concrete guidelines ultimately results in a situation where parties litigating nearly identical cases can present tenuous and often misleading expert testimony in one courtroom, whereas the same testimony would never be permitted in a federal court just across the street.

'Kemp' as Applied in Accutane

In *In re Accutane*, plaintiffs alleged that they developed Crohn's disease as a result of taking Accutane.

Plaintiffs proffered the opinions of two experts, who both testified, inter alia, on the basis of epidemiological studies. *In re Accutane Litig*., 451 N.J. Super. at 162. Even though (1) plaintiff's experts acknowledged that none of the six studies was able to demonstrate statistically significant evidence of a correlation between Accutane and Crohn's disease; (2) plaintiff's experts relied on statistically insignificant evidence of a positive association between Accutane and Crohn's disease, while ignoring evidence of a negative association; and (3) plaintiffs relied on studies that reached opposite conclusions to support their opinion. Despite these flaws, the Appellate Division permitted the testimony because, in its words, it is the "jury's core function to weigh the credibility of expert witnesses, and the trial court should not use a *Kemp* hearing as a vehicle to dismiss a case the court perceives as weak." Id. at 212.

Based on the Appellate Division's holding in *In re Accutane*, it is the jury's responsibility to identify and discredit junk science, a position contrary to *Daubert*, and *Kemp* for that matter. The Appellate Division usurped *any* gatekeeper role. Instead, it chose to relax the standard so far that the only meaningful considerations for a court are whether the expert is "qualified," employs the correct terminology, and looks at the right evidence, not whether the expert employed a methodology accepted by the scientific community. The result of that approach is that pharmaceutical companies must litigate cases whenever an expert can cabin a theory of causation into the words of the trade, regardless of whether their methodology is actually scientifically reliable.

Why the More Stringent 'Daubert' Standard is Necessary in NJ

There are three compelling reasons why New Jersey needs to adopt the more stringent standard articulated in *Daubert*. *Daubert* would ensure that: (1) juries are only presented with real and reliable science; (2) cases litigated in New Jersey are consistent with other courts; and (3) New Jersey courts are not a magnet for litigation based on dubious science.

The essential holding of the Appellate Division in *Accutane* is that plaintiff's experts are permitted to disagree with the entire body of science, including not only the pharmaceutical companies themselves, but independent researchers and the FDA. At its most simple level, in New Jersey, the jury can credit an opinion that no scientist other than a litigation-hired expert agrees with.

Daubert does not permit this sort of junk science. Courts that follow *Daubert* acknowledge that "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp*., 78 F.3d 316, 319 (7th Cir. 1996). In fact, federal and state courts have rejected the exact same evidence presented to the Appellate Division because *Daubert* requires courts to consider the particular degree of acceptance within a scientific community. *Daubert*, 509 U.S. at 594. Where the scientific and medical community does not agree that a medicine can cause an injury, *Daubert* ensures that a litigation-driven opinion that is, at best, ahead of that science is not permitted to reach the jury.

The consequences of failing to adopt *Daubert* are profound. New Jersey is home to many of the largest pharmaceutical companies in the world. This fact is of particular importance given a recent U.S. Supreme Court precedent limiting where companies are subject to personal jurisdiction. New Jersey is a potential forum for major percentages of pharmaceutical products liability litigation. In fact, as it stands now approximately 93 percent of all cases filed against New Jersey-based pharmaceutical manufacturers are filed by non-New Jersey plaintiffs. 2013-2015 Report of the Supreme Court Committee on Rules of Evidence, Part II, at 15, 108 (Jan. 15, 2015).

The failure to adopt a more vigorous approach to expert testimony that is in line with the majority of jurisdictions will incentivize plaintiffs to continue to inundate New Jersey courts with cases that may be based on dubious scientific evidence. As it stands now, large plaintiffs firms have actually urged plaintiffs to file cases in New Jersey state court to take advantage of the more relaxed standards for expert testimony. *Id*. at 107. Adopting *Daubert* would help stem that tide. ■

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