

## **Out of the “Frye – ing” Pan and Into...?**

### **An Overview of Frye, Daubert and the Future of the “General Acceptance” Standard in New York.**

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#### **The Frye Standard**

For decades, in New York State and nearly half of the other fifty states, the admissibility of scientific evidence has been governed by the standard set forth in the case of Frye v. United States, 293 F 1013 (1923). That District of Columbia case involved a dispute concerning the admissibility of results from a forerunner of the polygraph or “lie detector” test. Ultimately, the court in Frye held that such tests were inadmissible. The basis of the Court’s holding was that the proponents of the test had failed to show a “general acceptance”, within the scientific community, that such a test reliably determined veracity.

This idea of “**general acceptance**” of a specific theory, process or technique, lies at the core of the Frye standard. The Frye approach attempts to minimize the odds that triers of fact will consider “pseudo” or “junk-science” in determining the admissibility of novel scientific evidence. Under this standard, the court serves as a “gatekeeper”.

Parties challenging the admissibility of scientific evidence in Frye states may request a pre-trial evidentiary hearing, commonly referred to as a Frye hearing. At these hearings, the court must first determine if the theory is “novel” or “experimental”. If persuaded that the theory is novel and that it merits a Frye hearing, the court then determines whether the theory, technique, etc., has gained “general acceptance” in the relevant scientific field. If the court is satisfied that the novel theory has gained general acceptance in the relevant community; the evidence will be deemed admissible. The Frye test is satisfied. Once the evidence is admitted, the jury must weigh the value of such evidence.

It is important to consider that the trial court’s decision at a Frye hearing can be case determinative. Where the court finds the proponent of challenged scientific evidence has not met

the burden of showing “general acceptance”; the contested evidence (often expert testimony) may be precluded. Where the precluded evidence is necessary to establish a prima facie case, the claim may be dismissed. All of which will transpire, before any expert testimony is presented to the jury.

Importantly, no interlocutory appeal may be made from a ruling at a Frye hearing. Such decisions are merely rulings on the admissibility of evidence. As a result, any party seeking relief from these rulings may appeal only after a final judgment has been entered.

### **The Daubert Standard**

Daubert v. Merrel Dow Pharms. (509 US 113 S.Ct 2786), was a 1993 United States Supreme Court decision that has had a profound influence on cases involving the admissibility of novel scientific evidence. Plaintiff claimed that Bendectin, a common antihistamine and common cough syrup ingredient had caused birth defects. Scientific evidence was proffered by both sides in support of their theories.

Of note, the U.S. Supreme Court specifically rejected both the Frye test regarding the admissibility of novel scientific evidence. Instead, the Court replaced the Frye test with a new standard in accordance with Rules 702 & 703 of The Federal Rules of Evidence. It is important to remember that the Daubert standard is applicable in all Federal courts. However, as Daubert involved statutory and not constitutional law, the Court’s holding was not binding on the states.

In a Daubert analysis, the court must initially assess whether the disputed evidence is **relevant**, **competent** and **material**. Other factors considered in the court’s determination include:

- 1) Whether or not the specific theory, process or technique has been empirically tested.
- 2) Whether or not the theory, process or technique has been subject to peer review and publication in scientific journals.
- 3) What is the known or potential rate of error?
- 4) What are the expert’s qualifications and his/her stature in the scientific community?
- 5) Can the disputed theory, process or technique and results be replicated?
- 6) Can the theory, process, or technique and results be explained clearly and succinctly, so that the court and a jury can readily understand its meaning?
- 7) Has the theory, process, etc., gained general acceptance in the relevant scientific/medical community?

### **Recent Frye Trends**

In the years since Daubert, New York State courts have retained the Frye standard. However, recent cases show a trend away from the “gatekeeper” approach to a more lenient admissibility standard, akin to that outlined in Daubert.

The following is an overview of a few important Frye decisions of the past two decades. The decisions in these cases illustrate the efforts New York courts continue to make in developing a workable standard for determining the admissibility of novel scientific evidence.

**People v. Wesley, (83 N.Y. 2d 417, 183 AD 2d 75)**

This post-Daubert case considered whether a novel forensic DNA testing technique [RFLP] was properly admitted as evidence at a criminal defendant's trial. It was one of the first cases to consider whether forensic DNA analysis had gained general acceptance in the scientific community. The case originated in a brutal rape and murder of a 79 year-old woman in her apartment in Albany, New York. Based chiefly on DNA evidence, the defendant was convicted of murder in the second degree, rape in the first degree, attempted sodomy in the first degree and burglary in the second degree. On appeal, the conviction was affirmed.

The Court of Appeals reiterated the rule of Frye v. United States, namely, that expert testimony based on a novel scientific principle was admissible "only after a principle or procedure has gained general acceptance in its specified field."

In a thorough examination of the admissibility standard; Chief Justice Judith Kaye noted: "The Frye test emphasizes **"counting scientists' votes rather than on verifying the soundness of a scientific conclusion."** In other words, the court's role was to determine whether there was a consensus in the scientific community as to the reliability of the evidence.

Chief Judge Kaye noted, that in the six years since the original Frye hearing in the case and the review by the Court of Appeals (1994), the RFLP forensic DNA technique had gained general acceptance in the scientific community and was admissible.

**Beck v. Warner-Lambert, (2002 WL 31107923, N.Y. Sup.)**

This case involved an allegation that Rezulin, (a type II diabetes drug), caused cirrhosis of the liver. A Frye hearing was held to determine the admissibility of certain scientific expert testimony.

Defendants sought to preclude plaintiff from offering expert testimony that the drug resulted in cirrhosis. They argued that plaintiff offered no definitive studies or articles demonstrating a causal relationship between Rezulin and cirrhosis. They further argued that there was no evidence that the plaintiff's cirrhosis resulted from exposure to Rezulin.

Plaintiff's expert's countered that there was a reasonable probability that Rezulin contributed to the plaintiff's cirrhosis. They noted that it was undisputed that the drug had caused liver toxicity and failure in some instances.

Defendant's experts' replied that as a Type II diabetic, it would not be unusual for the plaintiff to develop a liver disease, commonly known as "fatty liver", even without any exposure to Rezulin. They also emphasized that the plaintiff's cirrhosis developed five months after Rezulin was discontinued. Lastly, defendants argued that in studies where Rezulin had been associated with liver injury, patients had AST and ALT levels which were three times greater than normal and

exhibited other signs of liver disease, such as high bilirubin counts and jaundice. Defendants noted, that the plaintiff had no comparable test results and that plaintiff exhibited no symptoms of liver disease during the three year period she used Rezulin for her diabetes.

The trial court determined that the causation theory was sufficiently novel to warrant a Frye hearing. As for admissibility, the Court held that the general acceptance standard did not require a showing that a majority of scientists subscribed to the theory proffered by the plaintiff's experts. The court noted that the Frye test was satisfied, where experts espousing a novel theory, or opinion: **“followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions.”**

That decision contained a subtle, yet profound change in emphasis. Previously, a proponent of novel scientific evidence had the burden of showing a general acceptance of the novel theory. In Beck, the Court was more concerned with the soundness of the scientific principles supporting that theory. Subsequent cases have frequently utilized this same logic in favor of admitting a wide range of sometimes questionable scientific evidence or testimony.

**Marsh v. Smyth, (12 A.D. 23d 307, 785 N.Y.S. 2d 440)**

This case involved injury to a nerve in the patient's right arm, allegedly sustained as a result of improper positioning of the patient while under anesthesia for a hysterectomy.

The plaintiff sought to introduce the testimony of two medical experts regarding the causal nexus between the positioning of her arm during the surgery and her injury. Defendant's moved to preclude such testimony based on the fact there was no documented support for plaintiff's theory of causation.

The motion court deemed a Frye hearing necessary. Ultimately, the trial court precluded the testimony of plaintiff's two experts, as not generally accepted by the medical community.

The Appellate Division reversed, holding that a Frye hearing was unnecessary, as expert testimony involving whether the asserted conduct of the defendants was a causative agent for the plaintiff's injury was neither novel, nor experimental.

Specifically, the court stated:

**“The focus of the inquiry...should not be upon how widespread the theory's acceptance is, but should instead consider whether a reasonable quantum of legitimate support exists in the literature for the expert's views. Nor is it necessary, ... that the underlying support for the theory of causation consist of cases or studies considering circumstances exactly parallel to those under consideration in the litigation. It is sufficient if a synthesis of various studies or cases reasonably permits the conclusion reached by the plaintiff's expert.” (Emphasis added).**

**Parker v. Mobil Oil Corp., (16 A.D. 3d 648, 793 N.Y.S. 2d 434)**

This toxic tort case involved a claim by a gas station attendant that his exposure to benzene led to his development of leukemia.

In determining whether such a causation theory was scientifically sound, the Court in Parker devised a **three part test**. The test required the following:

- 1) **A determination of the plaintiff's level of exposure to the toxin in question;**
- 2) **Ascertaining whether the scientific literature offered proof that the toxin was capable of producing the specific illness (what the Court called a "dose-response" relationship); and**
- 3) **Establishing specific causation by demonstrating the probability that the specific toxin caused the plaintiff's illness/injury. (This step involved weighing the possibilities of other causes for the plaintiff's illness).**

Of note, the plaintiff presented no evidence of his level of exposure to benzene. As a result, even if plaintiff had been able to establish the second part of the test (i.e. that a particular exposure to benzene caused leukemia), the third component of the test could not be satisfied (ie. That plaintiff's illness resulted from exposure to benzene).

In rejecting the reliability of plaintiff's evidence, the Court stated: **"Of course, stating that any exposure to benzene is "unsafe" is not tantamount to stating that any exposure to benzene causes AML [leukemia]."**

The Appellate Division reversed the trial court's decision denying motions to preclude the plaintiff's expert testimony and dismissed the complaint in its entirety.

**Zito v. Zabarsky (28 A.D.2d 42, 812 N.Y.S. 2d 535)**

This case involved expert testimony concerning an alleged causal connection between an excessive dose of Zocor (a statin class cholesterol drug) and the plaintiff's subsequent development of polymyositis, a muscle disorder.

A Frye hearing was held to determine the admissibility of plaintiff's theory of causation. The trial court held that plaintiff failed to produce any medical literature indicating a causal nexus between an excessive dose of Zocor and the development of polymyositis. As a result, the trial court held that the "general acceptance" test of Frye had not been satisfied. At the conclusion of the trial the Court granted defendant's motion for judgment as a matter of law (pursuant to CPLR 4401). An appeal of that decision ensued.

The Appellate Division agreed with the trial court that the expert theory was novel and required a Frye hearing. However, the Court stated that the Frye test was applied too restrictively. The Court indicated that the preclusion of such expert testimony was improper.

In its' decision, the Appellate Division utilized virtually the same language used by the First Department in Marsh v. Smyth, supra. The Court noted that:

**“...it is not necessary that the underlying support for the theory of causation consist of cases or studies considering circumstances exactly parallel to those under consideration in this litigation. It is sufficient if a synthesis of various studies or cases reasonably permits the conclusion reached by the plaintiff’s expert.” see Zito v. Zabarsky, supra.**

In support of its decision to admit the plaintiff’s novel causation theory, the Court pointed to the reliability of CPK enzyme levels in measuring muscle inflammation.

However, while a CPK blood test is reliable in showing muscle inflammation, it offers no specific information as to the cause or location of the inflammation. Importantly, elevated CPK levels can be attributed to everything from a strenuous workout to a heart attack. The Court indicated that, “It was undisputed that after the plaintiff’s onset of symptoms, her CPK levels were extremely elevated”. However, one would expect a person with an active inflammatory muscle disorder to have a high CPK level. Such a result does not constitute compelling evidence of a relationship between Zocor and polymyositis.

Lastly, the Zito decision failed to address whether or not evidence was offered to show that other causes of the plaintiff’s muscle inflammation had been ruled out. Objective scientific evidence of that sort would appear to be both relevant and necessary to either a Frye or Daubert analysis.

While there is no question that juries are empowered to assign little or no weight to a questionable scientific theory, surely this type of analysis could prove confusing to the average person. Historically, it was the court’s duty, as gatekeeper, to avoid this scenario.

### Analysis

The Beck, Marsh, & Zito approaches to Frye can be contrasted with the standard articulated by the Court of Appeals in People v. Wesley and Parker v. Mobil Oil.

Wesley emphasized that unanimity of expert opinion was unnecessary to show general acceptance. However, Judge Kaye specifically noted that the approach was concerned with “counting scientist’s votes”. If a tally of scientist’s votes is the primary concern of a Frye analysis, then broad acceptance of the disputed theory would appear to be a prerequisite to the admission of novel scientific evidence. If such consensus exists in the scientific community, then support for the theory should exist in the scientific literature.

Beck, Marsh, & Zito are all concerned primarily with a “synthesis of studies” approach. Marsh held that the “focus should not be on how widespread a theory’s acceptance was, but on there being a “reasonable quantum of legitimate support” for the theory. Thus far, no New York court has clearly articulated what constitutes a “reasonable quantum of legitimate support”. In any event, an approach that unconcerned with “widespread acceptance” of a theory or procedure appears to be moving in a different direction than the “counting scientists” approach in Wesley.

Court’s focusing on the general acceptance of scientific principles and not on the overall theory utilizing those principles risk abdicating their role as gatekeeper. Where the courts no longer

play that essential role, the burden of ascertaining the reliability of scientific evidence may be placed upon lay jurors lacking the skills essential in making that complex determination.

### **Points to Consider**

Attorneys seeking to introduce novel scientific evidence, or challenging the admissibility of such evidence must recognize the importance of the type of Frye analysis used by the court in determining their dispute.

Courts adhering to a “synthesis of studies” analysis frequently deny motions to preclude and admit the contested evidence or testimony. This approach finds reliability in the scientific principles utilized by the expert. Eg. An elevated CPK blood test is a reliable and generally accepted test for determining muscle inflammation. Although this principle is perfectly sound and logical, the conclusion drawn from such a principle may be devoid of any scientific foundation (Eg. Use of Zocor can result in elevated CPK levels; therefore this patient’s use of Zocor resulted in her development of polymyositis [muscle inflammation]. Unfortunately, correlation does not equal causation. Sound scientific principles are the foundation of any credible theory. However, where courts find reliability of a theory in mere principles, an important part of the analysis may be neglected. Often, the result is a liberalization of the standard for admitting novel scientific evidence and an increased likelihood that jurors will be evaluating what courts in this jurisdiction formerly considered “junk science”.

Courts adhering to a “counting scientists” approach appear to be concerned more with the general acceptance of a scientific theory than with mere principles. These courts frequently grant motions to preclude novel scientific evidence. Where the proponent of the contested evidence was unable to introduce relevant scientific data or studies to support their theory of causation, the expert’s opinion was deemed unreliable and the evidence is excluded. In effect, the court is exercising its historical role of “gatekeeper” in shielding jurors from “pseudo-science”. The verification code for this document is 886360.

### **What to do**

It is incumbent on those seeking to preclude novel scientific evidence or testimony to assume that the court will be utilizing a Zito (synthesis of studies) analysis in determining whether a Frye hearing is warranted. In such cases, the court’s primary focus will be on the reliability of the scientific principles involved in the procedure, or technique. Here, criticism of the proffered evidence must focus on:

- 1) a challenge of the reliability of the evidence with a version of the Three Part Test in Parker v. Mobil Oil (also see Wills v. Amerada-Hess, 2002 WL 140542, 2002 US Dist LEXIS 1546.
- 2) flaws in the proponent’s scientific principles, process or technique;
- 3) case law supporting the historical “gatekeeper” role of the court;
- 4) cases emphasizing the value of an aggregate of scientific opinion;
- 5) criticism of cobbling together of distinct theories or studies; and

- 6) whether the proffered evidence or testimony is sufficiently linked with the facts of the case, so that it aids the jury in resolving the dispute;

### **Conclusion**

In the last several decades, we have witnessed an unparalleled acceleration in the pace of scientific learning and technical complexity. Moreover, the exponential growth of technology experienced in the last generation may pale in comparison to what the future holds. Undoubtedly, this increasing technological complexity will influence all aspects of our society, particularly the law.

It is entirely reasonable to assume that litigation involving novel scientific theories, processes, or techniques will experience extraordinary growth in the next decade. Undoubtedly, expert testimony and scientific evidence involving these new technologies will increasingly be subject to Frye and Daubert challenges.

Legal practitioners not having encountered a Frye or Daubert challenge, may be surprised to discover that an increasing number of their cases require a Frye and/or Daubert analysis. Furthermore, a failure to make a timely Frye, or Daubert challenge can result in a waiver of that right.

Among the issues which have been, or are likely to be subject to Frye/Daubert challenges are:

- DNA and Epigenetic evidence
- Voice and facial recognition technologies
- Mold litigation
- Automobile accident reconstruction and biomechanics
- Psychiatric/psychological testimony and evidence
- Experimental medical techniques and/or medications
- Diagnostic testing for mental disorders, such as autism
- Evidence of racial or sex based bias in employment, education, etc.
- Ballistics
- HIV Prophylaxis
- Toxic Torts
- Litigation resulting from large scale vaccination programs
- Fractal geometry – utilized for finance, image compression, demographics Surveillance technologies
- Forensic sciences
- Chemical analysis
- Environmental degradation, or remediation

These and many other evidentiary issues will continue to be affected by advancing technologies. For those litigating such claims, a familiarity with the Frye and Daubert standards governing the admissibility of novel scientific evidence will be a valuable asset.