Litigation Strategies for Debunking *Daubert* Expert Testimony
# Table of Contents

- **Mastery in the MDL: Maximizing the MDL Daubert Process**  
  Andrew K. Solow, Alan E. Rothman, Ari B. Fontecchio ................................................................. 4

- **Excluding Expert Opinion Impugning Corporate Ethics, Motive and State of Mind**  
  Sheila S. Boston, Bert L. Slonim, Daniel Meyers ................................................................. 10

- **Deconstructing Plaintiffs’ Peer-Reviewed Scientific Literature**  
  Jeffrey H. Horowitz, Bert L. Slonim ........................................................................................................ 14

- **Excluding or Limiting FDA Regulatory Expert Opinion**  
  James D. Herschlein, Bert L. Slonim, David Giroux ............................................................................. 28

- **Taking a Science Expert Deposition to Set Up a Daubert Motion**  
  Pamela J. Yates, Bert L. Slonim, Aaron H. Levine ................................................................. 34
Experts play an essential role in product liability litigation. No matter the product, the injury or the state of the science, the defense of products claims will inevitably focus on the testimony of experts on both sides of the case. Since the Supreme Court’s landmark decision in *Daubert v. Merrell Dow Pharmaceuticals* in 1993, and indeed even before the Court laid out these standards governing the admissibility of expert opinion, litigators have wrestled with issues surrounding their testimony. As plaintiffs increasingly hire “expert” witnesses who advocate rather than present the fact-finder specialized knowledge or expertise necessary to resolve the issues presented by the lawsuit, knowing how and when to identify, discredit or outright exclude questionable expert testimony is more valuable than ever.

This report, *Litigation Strategies for Debunking Daubert Expert Testimony*, explores several key legal techniques for evaluating expert witnesses and the credibility of their testimony as well as the tools available in a defendant’s arsenal to challenge such testimony. Kaye Scholer’s Product Liability team is at the forefront of developing and applying *Daubert* law in product liability litigations across the country. Indeed, Kaye Scholer attorneys have been involved in many of the leading cases discussed throughout this report. The five articles that follow include ways to:

- Use the intersection between the worlds of multidistrict litigation (MDL) and *Daubert* expert testimony in product liability litigation to secure favorable *Daubert* rulings early in proceedings, which can then be applied to large swaths of cases;
- Distinguish an expert witness from a “story teller” and then successfully bar the storyteller from testifying;
- Understand that the phrase “peer reviewed” is not synonymous with “high quality” or even “scientifically accurate,” and how to undermine or limit the sum and substance of peer-reviewed articles and related testimony;
- Identify the issues regarding admissibility of regulatory-expert opinion and the bases for excluding or limiting such opinion; and
- Prevail on a *Daubert* motion by showing not that the expert reached a wrong conclusion, but flawed methods to reach those conclusions.

The authors of these timely articles, members of Kaye Scholer’s nationally recognized Product Liability Litigation team, draw from their extensive experience as trial and national counsel across many types of product liability cases and consultations, including MDL proceedings. Recognized in the top-tier of every legal publication and named by Law360 as the “Product Liability Group of the Year” across multiple years, Kaye Scholer knows how to present at trial complex scientific testimony in a manner understandable to judges and jurors, devise sophisticated defenses, advise on the defensibility of specific claims and assess claims demands.

Our unparalleled combination of deep knowledge and a long track record of success is the reason leading national and international consumer goods, tobacco and life sciences companies rely on us as the “brain trust” responsible for their litigation strategy for complex product liability problems and high-stakes trials.

We hope that this report provides insight into the ever-evolving and increasingly important role that expert testimony plays in product liability litigation. As always, we welcome the opportunity to continue our discussion of these issues in greater depth.
Imagine having the ability to defeat dozens, if not hundreds or even thousands of cases, with a single motion. From a defendant’s perspective, finding the tool to accomplish that goal would be a dream come true. The process of multidistrict litigation (MDL), whereby federal cases from around the country are centralized in a single federal district court for coordinated pretrial proceedings, provides such an opportunity.

One of the most important features of product liability litigation is the role of the expert. Products cases often rise and fall upon whether a court will accept the methodology and testimony of an expert, particularly one who espouses an opinion as to whether the product at issue could cause, and in fact caused, the alleged injury. Under well-enshrined case law, the trial court plays an essential “gatekeeping” role in determining whether expert testimony is admissible in a particular case, commonly referred to in the federal system as “Daubert.”

This article explores the interplay (or intersection) between the worlds of MDLs and Daubert in product liability litigation. In particular, this article addresses:

- The import of Daubert to the MDL process
- The timing of Daubert motions in an MDL proceeding
- The use of “Science Days”
- Favorable MDL Daubert rulings
- Overcoming an adverse Daubert ruling
- Federal-state coordination of the expert process

I. The MDL Process

Before exploring the vital role of expert testimony and Daubert motions, a brief primer on MDLs is in order. 28 U.S.C. § 1407 provides for the coordination of cases into a single MDL proceeding for purposes of pretrial motions and discovery. Under Section 1407, “[w]hen civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings.” The Judicial Panel on Multidistrict Litigation (JPML), a panel of seven district court and Circuit Court judges appointed by the Chief Justice of the United States Supreme Court, makes the decision as to whether to create an MDL and before which district court judge the MDL will proceed. That MDL judge has full discretion to decide which issues to address and how long to keep the cases before sending them back to the respective transferor courts for trial. Under the US Supreme Court’s Lexecon precedent, the MDL judge generally cannot try cases that did not originate in the MDL district, unless the parties agree.
II. The Import of Daubert to the MDL Process

Essential to the MDL process is the goal of consistency, particularly with respect to expert and Daubert issues. As the JPML has repeatedly held in several recent decisions: “Centralization will eliminate duplicative discovery, avoid inconsistent pretrial rulings (including with respect to discovery, privilege and Daubert motion practice), and conserve the resources of the parties, their counsel and the judiciary.”

In the context of an MDL, Daubert rulings can have a magnified impact, largely avoiding the litigation of a string of non-meritorious actions because they can apply to large swaths of cases.

Issues ripe for Daubert consideration include general and specific causation. A ruling on general causation (whether the product at issue could cause plaintiff’s injury in any case) could determine whether any of the cases in the MDL go forward. Similarly, a ruling on specific causation (whether the product caused a particular injury to a particular plaintiff), could impact whether the cases of similarly situated plaintiffs advance.

Because of their applicability to such a wide range of cases in the MDL, successful Daubert motions can have a significant impact on the trajectory of the MDL, including by teeing up dispositive summary judgment motions based on a favorable Daubert ruling, narrowing key issues for trial and reducing case values for settlement purposes. Even where the MDL judge defers ruling on a dispositive summary judgment motion following a favorable Daubert ruling, Daubert motions can still affect the disposition of the individual cases on remand because the MDL judge can couple the Daubert ruling with a Suggestion of Remand to the JPML to remand the cases to transferor courts. This enables transferor courts to be knowledgeable of favorable rulings and avoid re-litigation of the same complicated issues.

III. Timing

In light of the importance of Daubert motions, timing is everything. Daubert motions can come earlier or later in the MDL process. The Human Tissue MDL proceeding serves as a good example of where an early Daubert ruling created efficiency down the line. In that case, there were five months between the creation of the MDL and the first science-based motion, which was before the completion of fact discovery in any of the cases. Based on its rejection of plaintiffs’ experts, the court found a lack of general causation.

Sequenced discovery is one means of moving toward an early ruling on general causation. For example, in the Viagra litigation, Judge Magnuson ordered that the “first phase of discovery for all cases shall be focused on the sole issue of general causation—whether Viagra® is capable of causing” the alleged optical injuries. Because Judge Magnuson granted defendant’s motions to exclude plaintiffs’ general causation experts at the end of the limited discovery period, defendant was spared unnecessary time and expense.

The Daubert case itself—in which plaintiffs’ cases lingered for far longer than the science warranted—demonstrates why early expert determinations can be crucial to testing the strength of plaintiffs’ cases. There, based on scientific studies that were later discredited, plaintiffs dragged out litigation until defendant’s legal costs (that is, the fees for litigating the case; not for damages) became so prohibitive that the company chose to pull its drug from the shelves rather than continue the litigation. In its summary judgment decision, the Supreme Court recognized the importance of addressing scientific issues early in the MDL process by noting the importance of the “gatekeeping role for the judge.” As a practical matter, most MDL judges defer Daubert rulings until some cases have been worked up for trial. But whether Daubert issues are addressed sooner or later in the MDL process, the MDL judge’s “gatekeeping” role is critical.

IV. Science Days

MDL judges have developed a number of ways to achieve their gatekeeping role even short of an early Daubert motion. For example, when an MDL involves complicated scientific issues, courts often permit the use of tutorials called “Science Days” to explain the science involved. The ABA’s Civil Trial Practice Standards suggest that once the court agrees to permit a Science Day and the parties agree on the content, the court should establish the structure of the presentations. The court could ask for pre-recorded or live presentations by one or more experts, and the court could permit the parties to conduct cross examination. Generally, those Science Days are presented in a neutral fashion, with courts encouraging the parties to avoid overt advocacy in their presentation of the relevant science.
V. Examples of Successful MDL Daubert Motions

Recent examples of successful MDL Daubert motions illustrate the MDL judge’s gatekeeping role.

In the Zoloft birth defects litigation, the MDL issued three Daubert opinions over the course of 18 months, excluding all of plaintiffs’ experts from opining that Zoloft causes various types of birth defects in humans. In June 2014, Judge Cynthia Rufe initially excluded plaintiffs’ expert epidemiologist, stating that the epidemiologist “takes a position in this litigation which is contrary to the opinion she has expressed to her peers in the past, relies upon research which her peers do not recognize as supportive of her litigation opinion, and uses principles and methods which are not recognized by the relevant scientific community and are not subject to scientific verification.” That opinion was followed by an opinion prohibiting plaintiffs’ biological mechanism experts from using their reliance on animal and in vitro studies to opine that “Zoloft, when used by pregnant women at conventional doses, causes an increased risk of congenital malformations in human babies.” Following those decisions, the MDL court allowed plaintiffs a do-over by granting their motion for leave to submit a new expert report. Most recently, the court struck that new expert’s testimony, concluding that a biostatistician “failed to consistently apply the scientific methods he articulates, has deviated from or downplayed certain well-established principles of his field, and has inconsistently applied methods and standards to the data so as to support his a priori opinion.”

In the Denture Cream litigation, the MDL court rejected plaintiffs’ attempt to introduce new evidence in an effort to come back from a previous exclusion of their general causation experts. The court found that plaintiffs’ new evidence—a new study, expert analysis, epidemiological evidence, evidence of a dose-repose relationship and case reports—failed to satisfy Daubert because the evidence was riddled with methodological flaws. In light of the “factually inaccurate data and unsupported assumptions,” the court found that plaintiffs’ experts’ theory “generally lacks the sound scientific basis and intellectual rigor required by Daubert.”

In a series of Daubert decisions in the Boston Scientific Pelvic Mesh litigation, the MDL court found that plaintiffs’ many experts committed a number of Daubert violations, including summarizing corporate documents instead of providing expert analysis, using unreliable methods, failing to provide a rationale for rejecting contrary evidence, providing common sense analysis for which an expert’s opinion was unnecessary, and failing to rule out alternative causes.

In the Prempro hormone therapy proceeding, the MDL court excluded plaintiffs’ experts’ testimony that estrogen-only form of hormone replacement therapy caused breast cancer. Interestingly, that decision was issued jointly by the MDL judge and another federal judge who had a number of hormone therapy cases that could not be transferred to the MDL proceeding because those cases had been removed to federal court under the Class Action Fairness Act’s “mass action” provision. That provision precluded MDL transfer absent the consent of a majority of the plaintiffs. In their Daubert decision, the judges rejected the testimony because the experts discounted data that undermined their opinions, relied on statistically insignificant data and did not understand the differences among the various drugs involved in the case. The judges found that the experts’ opinions were not sufficiently reliable to undercut a decade-long study from the Department of Health and Human Services demonstrating that estrogen-only hormone replacement did not increase the risk of breast cancer. This decision moved a large swath of cases closer to settlement or dismissal.

Similarly, in the Viagra proceeding, the MDL judge granted defendant’s motions to exclude plaintiffs’ general and specific causation experts. Effectively ending the MDL, the judge held, “[b]ecause Plaintiffs have failed to produce admissible expert testimony that Viagra caused their [faint] [non-arteritic anterior ischemic optic neuropathy], [defendant’s] motion for summary judgment must be granted.”

VI. Strategies to Fight the Unsuccessful Daubert Ruling

Of course, not every Daubert motion is successful, so defendants have developed various methods of appealing an adverse decision. Upon receiving an unfavorable Daubert ruling, defendants can ask the MDL court’s permission to take interlocutory appeal to the MDL district’s Circuit Court of Appeals under 28 U.S.C. § 1292. If the district court and the Circuit Court both permit it, the interlocutory appeal can proceed. Defendants also can appeal upon the conclusion of an MDL trial (often referred to as a “bellwether trial”) that was subject to the adverse Daubert ruling. The US Supreme Court recently held that a party need not wait for the conclusion of the entire MDL proceeding before appealing a final decision in an individual case within the MDL.

Another option is for defendants to appeal after remand to the transferor courts, but the “law of the case” doctrine can limit this strategy. The Manual on Complex Litigation (§ 20.133) provides that “[a]lthough the transferor judge has the power to vacate or modify rulings made by the transferee judge, subject to comity and ‘law of the case’
considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings.”

In practice, the “law of the case” doctrine can take the form of an elevated “clear error” standard of review by the transferor court. Alternatively, as some courts have held, the review could entail the same standard applicable to a motion for reconsideration. Although there is a high hurdle in overturning a decision of the MDL court, the law does not foreclose such a challenge after remand and presenting those arguments to the transferor court.

VII. Federal-State Coordination

MDLs often involve similar cases pending in state court arising from use of the same product. To boost efficiency, federal and state courts have the option of cooperating. The courts can hold a joint Science Day, pursue joint expert discovery or have coordinated Daubert hearings. Similarly, federal courts could invite state court judges to sit in on federal Daubert hearings. Although a federal court’s proceedings cannot bind state court judges, such coordination could educate state court judges on key issues in the case, develop relationships between federal and state court judges, and avoid end-runs in state courts around rulings of MDL judges.

Thus, the Daubert process is an essential element of litigating any product liability action. But its power is particularly pronounced in the context of an MDL proceeding. Understanding its impact and how to use the process to best position your company will place you one step ahead in both mastering and maximizing the MDL Daubert process.

6. Daubert, 509 U.S. at 597.
7. BA – Civil Trial Practice Standards, Section 7.
13. 28 U.S.C. § 1332(d)(11)(C)(i) (“[a]ny action(s) removed to Federal court pursuant to this subsection shall not thereafter be transferred to any other court pursuant to section 1407, or the rules promulgated thereunder, unless a majority of the plaintiffs in the action request transfer pursuant to section 1407”).
17. Motorola Mobility, Inc. v. AU Optronics Corp., No. 09 C 6610, 2014 WL 258154, at *5 (N.D. Ill. Jan. 23, 2014) (citations omitted) (“the ‘clear error’ standard of review to the MDL court’s denial of summary judgment, while being mindful of the fact that ‘[i]t would vitiate most of the purposes of consolidating litigation if, after remand, parties could simply re-visit the transforee court’s pre-trial rulings’”).
The US Supreme Court recently held that a party need not wait for the conclusion of the entire MDL proceeding before appealing a final decision in an individual case within the MDL.
Excluding Expert Opinion
Impugning Corporate Ethics, Motive and State of Mind

Sheila S. Boston
Partner

Bert L. Slonim
Counsel

Daniel Meyers
Associate

In product liability litigations there has been an increasing trend for plaintiffs to hire “expert” witnesses whose intended role is more to argue the client’s cause from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit.” Plaintiffs typically offer these types of witnesses to: (1) impugn a company’s motive, intent, or state of mind; (2) question a company’s ethical or moral decisions; and/or (3) provide an advocacy-based historical or factual narrative of the product by summarizing the company’s internal documents. This article focuses on how a defendant can successfully bar an expert “storyteller” from improperly lending “their credentials and reputations to the party who calls them without bringing much if any relevant knowledge to bear on the facts actually at issue.”

Motion to Bar Testimony Under Daubert and Federal Rules of Evidence 702 and 403

When faced with an expert who intends to argue plaintiff’s case from the witness stand, a defendant should file a Daubert motion to exclude such testimony. The motion should advance four main arguments:

1. Unreliable: Defendant should argue that plaintiff’s expert’s opinion is unreliable and therefore fails to satisfy Federal Rule of Evidence (FRE) 702. Under FRE 702, courts exclude testimony as unreliable if the expert is not qualified by knowledge, skill, experience, training or education to offer the purported opinion; if the expert’s methodology is unreliable; or if the expert has not reliably applied the methodology to the facts in the case.

2. Irrelevant: Defendant should argue that plaintiff’s expert’s subjective, advocacy-based, opinions related to the company’s motive, intent, state of mind, and ethics are irrelevant and would not “help the trier of fact understand the evidence” or “determine a fact in issue” as required by FRE 702.

3. Invade the Province of the Jury: Defendant should argue that plaintiff’s expert’s “storytelling” testimony is inadmissible under FRE 702 because the jury is capable of interpreting and understanding the documents on their own without the expert’s advocacy-based narrative.

4. Unduly Prejudicial: Defendant should argue that even if such testimony were reliable and marginally relevant under FRE 702, the court should preclude such testimony under FRE 403 because the testimony will unfairly prejudice and confuse the jury because of the...
In 2004, in the Rezulin (diabetes medication) multidistrict litigation, Judge Lewis A. Kaplan of the Southern District of New York issued a landmark decision wherein he granted, in part, defendants’ motion in limine and excluded plaintiffs’ experts from offering opinions about: (1) the motive, intent, and state of mind of defendant and others; (2) defendant’s ethical behavior; and (3) the history of Rezulin. Since Judge Kaplan’s Rezulin decision in 2004, defendants around the country have successfully argued that such testimony should be excluded. Although this article primarily focuses on excluding expert testimony in federal courts, most states have laws that closely resemble FRE 702 and 403 and, thus, defendants should consider filing a similar motion when faced with a “storytelling” expert in state court.

Testimony Regarding a Company’s Motive, Intent, and State of Mind Is Inadmissible

It is common for plaintiff’s experts to include in their expert reports conclusory statements about a defendant’s motive, intent and state of mind. For example, these experts often purport to offer opinions such as: “defendant was motivated by profits and therefore . . .”; “defendant intentionally. . .”; “defendant was aware of. . .”; and “defendant concluded.” These opinions are inadmissible for several reasons.

First, it is highly unlikely that a plaintiff’s expert ever worked at (or with) defendant’s company and therefore plaintiff’s expert has no firsthand knowledge to support her conclusions. Second, no matter how credentialed plaintiff’s expert may be, she lacks the “crystal-ball-like insight into another’s mental state” and therefore is unqualified to testify to defendant’s motive, intent and state of mind. Third, because a jury is capable of drawing their own conclusions from defendant’s internal documents, permitting an expert to interpret these documents for the jury would invade the province of the jury.

When faced with plaintiff’s expert’s purported state-of-mind opinions in the Rezulin litigation, Judge Kaplan excluded such testimony and explained that “[i]nferences about the intent or motive of parties or others lie outside the bounds of expert testimony.” In the Viagra litigation, the court barred plaintiff’s expert from offering testimony on defendant’s motive, intent and state of mind because “there [was] no indication in the record that the jury [] would require special assistance to interpret the documents” plaintiff’s expert intended to interpret for the jury. Similarly, in the Nevada state court Actos litigation, the court explained that it did “not see how motive relates to any of the Plaintiffs[’] causes of action” and thus the court barred such testimony.

Testimony Questioning a Company’s Ethics and Morality Is Inadmissible

Similarly, plaintiff’s experts often attempt to offer opinions that defendant acted “unethically” or “immorally” by taking, or not taking, a certain action related to the product at issue. These opinions are inadmissible because they are merely the expert’s subjective belief, they will not assist the jury, and such testimony will unfairly prejudice the jury.

In Rezulin, Judge Kaplan excluded plaintiff’s expert’s opinions that defendant acted unethically, explaining that such testimony was unreliable under FRE 702 because the opinions were: (a) based on the expert’s personal, subjective views; (b) irrelevant under FRE 702; and (c) unfairly prejudicial and confusing under FRE 403.

Judge Kaplan aptly noted that “[w]hile the defendants may be liable in the court of public opinion, or before a divine authority for any ethical lapses, expert opinion as to the ethical character of their actions simply is not relevant to these lawsuits.” Even if an expert tries to circumvent the decisions excluding opinions regarding a defendant’s ethics by couching her opinion in terms of how a “responsible” or “reasonable” company would conduct itself without using
the word “ethical” or “unethical,” courts have ruled that this testimony is inadmissible for exactly the same reasons.12

**An Expert’s Advocacy-Based History/Factual Lesson on a Product Is Inadmissible**

Plaintiff’s experts frequently include lengthy historical narratives in their expert reports wherein they purport to offer “expert” opinions based on their review of company and regulatory documents related to the product at issue. In reality, plaintiff’s expert’s “intended role is more to argue the client’s cause from the witness stand.”13 For this reason, Judge Kaplan excluded plaintiff’s expert’s testimony about the history of Rezulin—explaining that the expert did “no more than counsel for plaintiff will do in argument, i.e., propound a particular interpretation of [defendant]’s conduct.”14 The court in the Viagra litigation excluded similar testimony, explaining that the expert’s report “simply summarizes and states her advocacy-based interpretation of documents in the record concerning regulatory activity related to Viagra” and that the jury could interpret the documents without the expert’s assistance.15

**Conclusion**

It has become common practice for plaintiffs in product liability cases to proffer highly credentialed experts to opine on the defendant’s mental state, ethical decisions and company documents. A defendant facing such testimony should recognize that these opinions do not pass muster under FRE 702 and 403 and should move to exclude the testimony. Because of the clout “experts” carry with juries, having a court bar plaintiff’s expert from “storytelling” can go a long way in helping to secure a defense verdict.

2. Id.
11. Id. at 544.
14. Id. at 551 (quotation omitted).
Deconstructing Plaintiffs’ Peer-Reviewed Scientific Literature

Jeffrey H. Horowitz
Partner

Bert L. Slonim
Counsel

I. Introduction

Although peer-reviewed scientific evidence is central to most mass tort and product liability litigations, peer review is not foolproof and the fact that an article has been peer reviewed does not guarantee high quality or even scientific accuracy.

As an editor of the Journal of the American Medical Association explained, there is “no study too fragmented, no hypothesis too trivial, no literature too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate, too obscure, and too contradictory, no analysis too self-serving, no argument too circular, no conclusions too trifling or too unjustified, and no grammar and syntax too offensive for a paper to end up in print.”

Accordingly, it is important for counsel to consider the potential weaknesses of peer-reviewed studies relied on by plaintiffs’ experts. This article discusses the substance and procedure of how such studies may be undermined or limited.

II. Peer-Review Failure

There have been some spectacular failures of peer review, including articles published in JAMA and other leading medical journals:

Lumpectomy/breast cancer—Prior to 1985, most patients diagnosed with breast cancer underwent a mastectomy, a disfiguring surgical removal of the entire breast. Treatment was revolutionized when a study was published in the New England Journal of Medicine reporting that breast-conserving lumpectomy was just as effective as mastectomy for early-stage breast cancer. Unknown at the time was that one of the investigators had falsified surgical and laboratory study data. Even after the fraud was uncovered in the early 1990s, it was not disclosed to physicians, patients or the public. Although subsequent reanalysis of the data (excluding the falsified data) confirmed the study’s key finding, for many patients, life-and-death decisions were made on the basis of fraudulent peer-reviewed data.

MMR vaccine-autism—In 1998, Lancet published a peer-reviewed study linking the measles-mumps-rubella
vaccine to autism. The study was the opening shot in a decades-long controversy that endangered the public health as parents agonized over whether to immunize their children and the plaintiffs’ trial bar pressed a litigation assault on vaccine manufacturers. Undisclosed was the fact that the lead author of the study had received payments from a plaintiff’s attorney, that the methods purported to have been used were not followed, and that required ethics approvals for pediatric subjects had not been obtained. In 2010, the lead author was sanctioned and *Lancet* “fully retract[ed] this statement from the published record.”

**Viagra/blindness**—In 2006, a study published in the *British Journal of Ophthalmology* purportedly linked Viagra to NAION, a condition that can cause blindness. That article fueled multidistrict product liability litigation and the lead author became plaintiffs’ key expert witness. The court initially denied a *Daubert* challenge seeking to exclude the expert, principally because the study was published in a peer-reviewed journal, but did permit discovery regarding the study. The discovery revealed substantial inaccuracies in the study data, errors in the statistical methods, and mistakes in the computer programming as well as other flaws, leading the court to reconsider and reverse its initial decision. The court concluded that “Almost every indicia of reliability the Court relied on in its previous *Daubert* Order regarding the McGwin Study has been shown now to be unreliable. Peer review and publication mean little if a study is not based on accurate underlying data.”

**Accutane/depression & suicide**—In 2005, the *American Journal of Psychiatry* published a study linking Accutane to changes in brain function implicated with depression. Although the article did note that funding had been provided by lawyers involved with Accutane litigation and acknowledged some limitations, undisclosed and undetected by peer review were flaws in the data and methodology that rendered the study scientifically worthless. Similar to the Viagra NAION case, a court decision found that while the study “was peer reviewed, [the researcher] admitted that he did not in fact follow the steps described in the article.”

The researcher “could not document much of the data on which his published results were based.” “[H]e admitted that some of the statistical analysis was inaccurate,” and “he admitted that some of the [data] he used in his calculations were inaccurate, [but] could not check the accuracy of the remaining numbers because the original data could not be retrieved.” Based on these flaws, the court ruled that the expert could not rely on the study.

### III. Challenging Scientific Literature—Substance

#### A. Did the Researcher Actually Utilize the Methods Represented to Have Been Used?

Manuscripts reporting original scientific research are generally divided into four sections: Introduction, Methods, Results and Discussion. The “methods” section is crucial because it permits readers to assess precisely how the investigator conducted the experiment and to replicate the experiment, which is the hallmark of true peer review.

Recent cases have revealed instances where the researchers have not followed the methodology represented to have been used in their studies. In the Viagra case, the researcher represented in the published paper that he counted subjects as “exposed” to Viagra only if they used the medication before they developed NAION; the court found that the researcher did not adhere to this methodology and that a number of subjects who were counted as exposed had been diagnosed with NAION before they first used the medication (obviously the medication could not have caused the condition in that circumstance).

Similarly, in the Accutane case, the Court found that the researcher “did not actually use the methodology he claimed to have used,” and that “contrary to representations made in the article, he did not get before-and-after . . . questionnaires from many of the subjects.” Likewise, in the MMR vaccine case, the *Lancet* retraction reports that the investigator did not adhere to the methods claimed in the study: “In particular, the claims in the original paper that children were ‘consecutively referred’ and that investigations were ‘approved’ by the local ethics committee have been proven to be false.”
B. Were the Statistical Calculations Done Properly?

Statistical analysis is crucial to interpreting the results of a study. Statistics help to determine whether the observed results of an experiment are a function of chance or whether there is a causal relationship. Guidelines issued by the International Committee of Medical Journal Editors specify that a biomedical study should provide sufficient statistical detail so an independent researcher can verify the claimed results.\(^{12}\)

Biomedical journal peer reviewers do not ordinarily check the statistical calculations to verify the results reported in a study.\(^{13}\) That omission leaves room for error. Recent cases show that it is not safe to assume that statistical calculations in published studies are valid.

In the Viagra case, the court found that the statistical “methodologies described in the study were not the actual methodologies used.”\(^{14}\) In addition, the court found that the statistical computer programming “code that the [the researcher] wrote to produce the numbers in the McGwin Study contained errors that would affect the odds ratios and confidence intervals.”\(^{15}\) Similarly, in the Accutane case, the investigator “admitted that some of the statistical analysis was inaccurate.”\(^{16}\)

Recently, in the Zoloft birth defects litigation, a defense expert epidemiologist noticed a subtle anomaly in the odds ratio and confidence interval of a key finding. (The upper and lower bounds of the confidence interval should be symmetric around the odds ratio; in this case, the expert observed that when the data were graphed they appeared asymmetric.) The authors of the paper were contacted and they promptly published a correction in the New England Journal of Medicine.\(^{17}\) The correction played an important role in the Court’s decision to exclude plaintiffs’ biostatistician expert because the corrected odds ratio was no longer statistically significant. The court found that the expert “re[l]ied upon replication of statistically significant (and borderline significant) results . . . [but] did not reconcile this [new] information with his opinions.”\(^{18}\)

The takeaway message: defense counsel should have their experts carefully scrutinize, and attempt to replicate (to the extent possible), any key finding relied upon by plaintiffs’ experts.\(^{19}\)

C. Does the Dataset That Was Analyzed Accurately Reflect the Condition of the Subjects?

Before any statistical analysis can be performed, data needs to be collected and recorded. There is considerable opportunity for error in that process. Initial data collection often involves making entries on paper forms; such entries may be ambiguous or inconsistent (recall the highly contentious 2000 presidential election where hanging chads and other ambiguities made it difficult or impossible to assign certain ballots to a candidate). If the initial data is collected on paper forms, it will need to be entered into an electronic dataset and errors may be made in key punching.

A well-done study will, of course, utilize procedures, including quality control procedures, to minimize and correct data entry errors. Indeed, the International Society for Pharmacoepidemiology has promulgated good practice guidelines to insure data quality and integrity.\(^{20}\)

Nevertheless, peer review does not guarantee that good practices have been observed or that the electronic dataset accurately represents the study population. Even apart from intentional falsification of data—such as occurred in the breast cancer lumpectomy trials—recent cases demonstrate that studies published in peer-reviewed publications may contain serious data errors. In the Viagra case, the court found that there were “miscodings” in the electronic dataset and that “the discrepancies between the dates of first use on the original survey forms and in the electronic dataset raise serious concerns about the reliability of the McGwin Study as originally published.”\(^{21}\) Similarly, in the Accutane case, the court found that the researcher “admitted that some of the [data] he used in his calculations were inaccurate, [but] could not check the accuracy of the remaining numbers because the original data could not be retrieved.”\(^{22}\)

In testing the validity of a study, it is important to obtain the original data collection forms if possible so they can be compared to the electronic dataset.

D. Does the Study Properly Address Confounding, Bias and Chance?

Chance—“A study may find a positive association (relative risk greater than 1.0) when there is no true association.”\(^{23}\) A chance finding attributable to random error is called a false-positive. Requiring that a finding be statistically significant
Biomedical journal peer reviewers do not ordinarily check the statistical calculations to verify the results reported in a study. Recent cases show that it is not safe to assume that statistical calculations in published studies are valid.
reduces the play of chance, but does not eliminate it. Indeed, under the conventional definition of statistical significance, 1 in 20 statistically significant findings will be the result of chance. If the investigators perform multiple comparisons—by conducting numerous statistical tests on the same dataset—the likelihood of spurious associations increases. In the Zoloft birth defects litigation, the court excluded plaintiffs’ expert epidemiologist in part because she relied on findings that might have been “statistical artifacts of multiple comparisons.”

Bias—Bias is “anything that results in a systematic (nonrandom) error in a study result and thereby compromises its validity.” There are many types of bias that may creep into a study, such as selection bias (where there is some intrinsic difference between cases and controls) or detection bias (where cases routinely undergo more frequent medical testing than controls).

Confounding —“The third major reason for error in epidemiologic studies is confounding.” That is, what may appear to be a relationship between an exposure and an outcome is actually due to the fact that both the exposure and outcome are related to another variable that was overlooked or could not be accounted for in the analysis. For example, the studies investigating whether there may be a relationship between maternal use of antidepressant medications and birth defects note that depression is associated with co-morbidities that increase the risk of birth defects and that it is difficult to ascertain whether an observed risk is attributable to the medication or to the underlying indication for which the medication is prescribed (this is called “confounding by indication”).

All studies should be carefully scrutinized for weaknesses and limitations attributable to confounding, bias and chance.

E. Are the Findings Based on Post-Hoc Subgroups?

A well-designed study has a clearly articulated hypothesis that is being investigated, and in the case of biomedical studies, in a specifically defined population. Thus, the International Committee of Medical Journal Editors specifies that the introduction of a study should:

State the specific purpose or research objective of, or hypothesis tested by, the study or observation. . . . Both the main and secondary objectives should be clear, and any prespecified subgroup analyses should be described.

The notion that subgroup analyses should be limited to subgroups that are pre-defined as part of the hypothesis under investigation, and before data collection, is critical. Subgroups defined after the data has been collected are inherently suspect because if any set of data is partitioned into small subsets it is likely (or inevitable, if there are enough subgroups) that some subset will show a statistically significant difference, even if there is no real underlying difference between the groups.

In other words, “subgroup analyses are problematic because as you do multiple comparisons, you may get statistically significant results purely as a function of the subgroup and chance.” For that reason, post hoc subgroup analysis “smacks of betting on a horse after the race is over.” As an example, if one examines each of the Zodiac signs separately in a trial of aspirin to treat heart attacks (a therapy that has been proven to be effective), one would conclude that most Zodiac signs derive benefit from aspirin, but those born under the signs Libra and Gemini are actually harmed by aspirin. Thus, even if there is no intentional manipulation, data dredging subgroups after the fact will often yield a statistically significant result and a creative researcher can find a scientifically plausible explanation to fit virtually any observed result.

Accordingly, counsel should be wary of studies that report results that are statistically significant only as to select subgroups. It is worth investigating the underlying study protocol to determine whether the subgroup was pre-specified or defined after the data was collected. As one court stated, “[i]t is not good scientific methodology to highlight certain elevated subgroups as significant findings without having earlier enunciated a hypothesis to look for or explain particular patterns.”

F. Did Matrixx v. Siracusano Eliminate the Legal Requirement of Statistical Significance?

In General Electric Co. v. Joiner, 522 U.S. 136, 145–47 (1997), the Supreme Court affirmed exclusion of expert testimony as unreliable because, among other things, it was predicated on studies whose findings were statistically insignificant. Accordingly, federal courts generally require statistically significant epidemiological proof of causation under Daubert.

Plaintiffs have attempted to chip away at the statistical significance requirement citing a dictum in Matrixx
Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309 (2011). However, Matrixx is not a case about the standard for reliable expert testimony under Federal Rule of Evidence 702; it is a securities fraud case about the standard for materiality concerning information that would be significant to an investor. The defendant argued that adverse event reports were not material information because the number of such reports did not establish a statistically significant risk that the product was causing the adverse events. The Supreme Court rejected this argument and held that adverse event reports can be material to securities disclosure obligations even absent statistical significance. In its opinion, the Supreme Court made clear that it was not even considering—much less ruling—that a scientific expert may reliably conclude that causation exists predicated on findings that are not statistically significant:

We note that courts frequently permit expert testimony on causation based on evidence other than statistical significance. We need not consider whether the expert testimony was properly admitted in those cases, and we do not attempt to define here what constitutes reliable evidence of causation.

131 S. Ct. at 1319 (internal citations omitted) (emphasis added). In the Zoloft birth defects litigation, the Court explained that Matrixx was inapplicable and held that statistical significance remained a requirement, rejecting the so-called “Rothman approach” that places diminished weight on statistical significance.

G. Has the Author Disclosed Her Litigation Consulting Work?

Virtually all journals require that authors disclose conflicting financial interests. Thus, where an author has been retained by a party as a litigation expert, and for that reason has a financial interest in the outcome of the litigation, there is a disclosure obligation.

The “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,” promulgated by the International Committee of Medical Journal Editors specify that “Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself,” and place responsibility on the author/litigation expert “for disclosing all financial and personal relationships that might bias their work.” Nevertheless, litigation experts have been known to fail to provide the required disclosure.

In July 2008, Lancet Oncology published an article regarding smokeless tobacco and cancer in which the conflict disclosure stated: “The authors declare no conflicts of interest.” Shortly after publication, the journal learned that one of the authors, Dr. Steven Hecht, had been working as a plaintiffs’ litigation expert, and promptly published a correction: “During the immediate months preceding submission of the review [Dr. Hecht] was acting in the capacity of an expert witness for the plaintiff in a future court case against a smokeless tobacco company. [Dr. Hecht] declares his participation in this case in no way influenced his writing or involvement in the review.”

The Committee on Publication Ethics, which promulgates guidelines adopted by many scientific journals, has found instances of nondisclosure of litigation consulting, which it characterizes as “a major conflict” of interest. COPE recommends that journal editors investigate any alleged failure to disclose expert litigation work and that they either require disclosure or refuse to publish the manuscript.

Thus, where a litigation expert has published on a topic pertinent to a case, the timing of the expert’s retention and disclosure to the publication should be explored.

IV. Confronting Peer-Reviewed Articles—Procedure

A. Are the Underlying Raw Data, Protocols and Statistical Calculations Discoverable?

As noted previously, even absent a litigation in which an expert is relying on a scientific study, peer reviewed medical journals are increasingly requiring authors to make available upon request their original unprocessed data, including the study protocol, the electronic dataset used in the analysis, and the computer code used to analyze the
data and generate the statistical results. Thus, the American College of Epidemiology has published a policy statement encouraging data sharing; the Annals of Internal Medicine has adopted a "reproducible research" initiative that "require[s] authors to state whether they are willing to share the protocol, data or statistical code;" the National Institutes of Health require data sharing for all grants with funding in excess of $500,000; and federal regulations provide that research data collected with federal funds must be made available under the Freedom of Information Act. Procedures have been devised for researchers to prepare their underlying data in a format suitable for sharing that protects confidentiality and medical privacy (including compliance with the Health Insurance Portability and Accountability Act).

When litigation is involved, it is a bedrock legal principal that a litigant ‘has a right to every man’s evidence,’ except for those persons protected by a constitutional, common-law, or statutory privilege. Where a scientific study is central to the opinion of an expert in a product liability litigation, the law is well settled that the underlying study data is obtainable by subpoena. The seminal case is Deitchman v. E.R. Squibb & Sons, Inc. In that case, Squibb and other pharmaceutical companies were defendants in actions alleging that diethylstilbestrol (DES) caused vaginal adenocarcinoma in the daughters of women who used the medication. Squibb served a document subpoena upon Dr. Arthur Herbst, a researcher who maintained a registry of vaginal adenocarcinoma cases and published more than a dozen articles regarding DES and adenocarcinoma.

Although Dr. Herbst was not engaged as an expert in the litigation, plaintiffs’ experts relied on his studies in support of their product liability claims. Dr. Herbst moved to quash the subpoena on the grounds that it was burdensome and oppressive, and more importantly, that it would jeopardize patient confidentiality and deter patients and physicians from supplying the registry with data in the future. The Seventh Circuit reversed the trial court decision quashing the subpoena. The court found that Squibb had a compelling need to examine the underlying data in order to test the validity of the studies:

In testing the validity of a study, it is important to obtain the original data collection forms if possible so they can be compared to the electronic dataset.

The value of the conclusions turns on the quality of the data and the methods used by the researcher. . . . So if the conclusions or end product of a research effort is to be fairly tested, the underlying data must be available to others equally skilled and perceptive. . . . [A] study of this sort may have a number of different but inadvertent, biases present. . . . For Squibb to prepare properly a defense on the causation issue, access to the Registry data to analyze its accuracy and methodology is absolutely essential.

The court ruled that a protective order could be fashioned to compensate Dr. Herbst for his time and to protect medical privacy.

A similar result was obtained in the multidistrict phenylpropanolamine (PPA) products liability litigation. Plaintiffs, claiming to have suffered strokes as a result of using over-the-counter cough and cold medications that contained PPA, relied on an epidemiologic study, the Yale Hemorrhagic Stroke Project (HSP). Defendant pharmaceutical manufacturers served “a series of subpoenas on hospitals possessing medical records for participants” so they could “verify the accuracy of the data underlying the HSP and to clarify the extent to which the HSP participants were scrutinized for ‘potential stroke risk confounders.’” The court denied a motion to quash the subpoenas and directed the parties to work with the hospitals to establish a redaction protocol so the underlying data could be produced.

In the multidistrict hormone replacement therapy (HRT) litigation, defendants subpoenaed and obtained underlying data from the Women’s Health Initiative study, which is the cornerstone of plaintiffs’ claims that their use of HRT caused breast cancer. As in the DES and PPA cases, the MDL court supervising the HRT litigation entered orders directing the Fred Hutchinson Cancer Research Center to produce underlying data, subject to certain restrictions.

Thus, it is clear that researchers who publish studies relevant to product liability litigation can be compelled to produce their underlying data, protocols and statistical calculations, subject to a suitable protective order.
Daubert charges trial courts with the gatekeeping responsibility of keeping outside of the courtroom scientific evidence that is unreliable. If the crux of an expert’s opinion is based on a peer-reviewed study that is found to be unreliable, the expert’s opinion will be excluded.
B. Are Peer-Reviewed Comments, Criticisms and Related Documents Discoverable from Scientific Journals?

The International Committee of Medical Journal Editors obligates medical journals to hold peer-review communications confidential and to oppose requests for discovery:

Editors must not disclose information about manuscripts (including their receipt, content, status in the reviewing process, criticism by reviewers, or ultimate fate) to anyone other than the authors and reviewers. This includes requests to use the materials for legal proceedings.50

In two recent decisions, both involving the arthritis medications Bextra and Celebrex, district courts in Massachusetts and Illinois have sided with medical journals and held that peer-review communications are not discoverable. In May 2007, Pfizer, which was a defendant in multidistrict product liability litigation involving the medications, served the New England Journal of Medicine with a subpoena seeking peer-review documents concerning 11 articles the journal had published about the drugs, as well as peer-review documents relating to manuscripts that the journal had rejected. Pfizer subsequently limited its requests to “(1) the complete record of communications between the NEJM editors and the authors of any articles (published or unpublished) concerning Celebrex or Bextra and (2) copies of any documents produced, voluntarily or otherwise, in connection with any dispute concerning Celebrex or Bextra.”51 The journal advised that it had no documents responsive to request (2), and it moved in the District of Massachusetts to quash the subpoena as to request (1).

Granting the journal’s motion to quash, the court found that editors and peer reviewers were entitled to the same type of confidentiality as journalists and that “the batch or wholesale disclosure by the NEJM of the peer reviewer comments communicated to authors will be harmful to the NEJM’s ability to fulfill both its journalistic and scholarly missions.”52

Pfizer also served the Journal of the American Medical Association with a subpoena that was virtually identical to the one served on the New England Journal of Medicine, and when JAMA objected, Pfizer filed a motion to compel in the Northern District of Illinois. Reaching a result similar to the one involving the NEJM, the court denied Pfizer’s motion to compel, holding that “any probative value would be outweighed by the burden imposed on the Journals in invading the sanctity” of the peer-review process, and that “it is not unreasonable to believe that compelling production of peer review documents would compromise the process.”53

Thus, the case law disfavors subpoenas to scientific journals seeking discovery of documents concerning peer review of articles that are relied on by experts in product liability litigations.

V. Remedies

A. Exclusion of the Study and/or the Expert

Daubert charges trial courts with the gatekeeping responsibility of keeping outside of the courtroom scientific evidence that is unreliable. If the crux of an expert’s opinion is based on a peer-reviewed study that is found to be unreliable, the expert’s opinion will be excluded.

In the Viagra case, in its initial decision, the court ruled that plaintiffs’ general causation evidence was admissible, finding it to be reliable principally because of a study published in a peer-reviewed journal. However, after discovery demonstrated that the study was critically flawed notwithstanding peer review, the court reconsidered the earlier decision and concluded the study was fatally flawed:

In its previous Daubert ruling, the Court placed great weight on the fact that the McGwin Study had been peer reviewed and published by the Journal, and that the study had not been produced using post-litigation data. As noted above, however, numerous miscodings and errors have rendered the McGwin Study as published unreliable.54

The court then considered whether there was a sufficient basis for the expert’s opinion absent that particular study and concluded there was not.55 In a companion opinion, the court granted summary judgment dismissing the cases holding that “[b]ecause Plaintiffs have failed to produce admissible expert testimony that Viagra caused their NAION, Pfizer’s motion for summary judgment must be granted.”56
On the other hand, if there is a reliable basis for the expert’s opinion that is independent of the flawed study, then the opinion may be admissible even without the study. Thus, in the Accutane case, the appellate court affirmed the lower court decision excluding the expert’s study, finding it to be “not soundly and reliably generated,” but nevertheless remanded the matter to the trial court “to consider whether [the expert] should be permitted to testify as an expert on general causation without reference to the PET study.”

B. Correction or Retraction of the Study

Many scientific journals are members of the Committee on Publication Ethics, an organization “concerned with integrity of peer-reviewed publications in science, particularly biomedicine.” COPE has promulgated a Code of Conduct that provides for correction or retraction of flawed studies:

> Whenever it is recognised that a significant inaccuracy, misleading statement or distorted report has been published, it must be corrected promptly and with due prominence.

If, after an appropriate investigation, an item proves to be fraudulent, it should be retracted. The retraction should be clearly identifiable to readers and indexing systems.

Consistent with the COPE guidelines, Lancet published a retraction of the MMR vaccine autism article, and Lancet Oncology published a correction of the smokeless tobacco article to disclose the author’s work as a litigation expert. Similarly, in the Viagra NAION litigation, the medical journal retracted the article, and in the Zoloft birth defects litigation the medical journal published a correction.

Thus, if discovery reveals significant flaws in a published study, the journal may be willing to correct or retract the publication.

C. Scientific Integrity Investigations

The Office of Research Integrity (ORI), part of the Department of Health and Human Services, promotes integrity in biomedical and behavioral research supported by the U.S. Public Health Service by defining research misconduct and overseeing institutional investigations of misconduct. Prior to June 2005, ORI regulations specified that

Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

This provision was controversial because the phrase “or other practices that seriously deviate from those that are commonly accepted within the scientific community” is vague and because it could be construed to encompass non-intentional misconduct. The regulation was amended effective June 2005. ORI’s current definition of “research misconduct” is limited to three specific acts (fabrication, falsification and plagiarism), each of which requires intent as a necessary element of the offense:

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

Besides federal regulations, individual institutions may have their own policies regarding scientific integrity and research misconduct that govern researchers affiliated with the institution.

Thus, depending upon the degree of culpability, the source of funding, and the institutional affiliation of the researcher, a scientific integrity investigation may be initiated if there is serious misconduct in a study. Federal regulations and institutional policies have established procedures for a party to file a scientific misconduct complaint.

D. Private Civil Action Against Investigator

If an investigator publishes a study that fraudulently or
If there is a reliable basis for the expert’s opinion that is independent of the flawed study, then the opinion may be admissible even without the study.
negligently links a product to a harmful effect, does the manufacturer have a civil remedy against the investigator? For instance, could the manufacturer of the MMR vaccine state a claim against Dr. Wakefield, who was found culpable of misconduct and whose study Lancet retracted?

There are no reported cases on point. In *CSX Transportation v. Gilkison*, the plaintiff railroad company, which had been sued by thousands of plaintiffs alleging asbestos injuries, sued a radiologist and a plaintiffs’ law firm with orchestrating a fraudulent mass x-ray screening process to manufacture cases. Although the district court initially dismissed most of the claims, the Fourth Circuit reversed, and defendant ultimately prevailed at trial.

Clearly, bringing a lawsuit against a researcher should be reserved for extreme cases because it could be construed as an attempt to stifle academic freedom and scientific discussion. In 2007, a Congressional Committee released a staff report describing what it characterized as “intimidation” of an “independent scientist” who had discussed a possible increased cardiovascular risk of the diabetes drug Avandia at scientific meetings of the Endocrine Society and the American Diabetes Association. The staff report asserted that the manufacturer of the medication “silenced [the physician’s] concerns about Avandia by complaining to his superiors and threatening a lawsuit.” The staff report also alleged an attempt to intimidate a researcher who had expressed concerns about Vioxx. In its conclusion, the staff report states “Corporate intimidation, the silencing of scientific dissent, and the suppression of scientific views threaten both the public well-being and the financial health of the federal government, which pays for health care.”

**VI. Conclusion**

Peer-reviewed scientific evidence is central—often outcome determinative—to product liability and mass tort litigation. Because peer review is far from perfect, such evidence can be and should be vigorously challenged. Scientific journals and courts have recognized that true peer review requires replication by independent scientists. Researchers should be willing to provide their underlying data, study protocols and statistical programming. If necessary, the case law indicates that a party can compel such disclosure, subject to a suitable protective order.

This is a revised version of an article previously published by Lori Leskin and Bert L. Slonim.

---

7. Id. at 11.
8. Id. at 11-12.
10. Accutane slip op. at 10-11.
13. Brief for Amici Curiae Daryl E. Chubin et al. at 10, *Daubert v. Merrell Dow Pharms.*, Inc., 509 U.S. 579 (1993) (No. 92-102) (“peer review referees and editors limit their assessment of submitted articles to such matters as style, plausibility, and defensibility; they do not duplicate experiments from scratch or plow through reams of computer-generated data in order to guarantee accuracy or veracity or certainty”).
15. Id.
16. Slip op. at 11.
19. “Many peer reviewed journals now require authors to be prepared to share


22. Slip op. at 12.


32. Id.


34. E.g., Norris v. Baxter Healthcare Corp., 397 F.3d 878, 887 (10th Cir. 2005); Hollander v. Sandoz Pharms. Corp., 289 F.3d 1193, 1215-16 (10th Cir. 2002); Burleson v. Texas Dept’of Criminal Justice, 393 F.3d 577, 585-86 (5th Cir. 2004); Allen v. Pa. En’g Corps, 102 F.3d 194, 195, 197 (5th Cir. 1996).


42. Office of Management and Budget Circular A-110 §.36(d)(1) provides that “in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.”

Excluding or Limiting FDA Regulatory Expert Opinion

James D. Herschlein
Partner

Bert L. Slonim
Counsel

David Giroux
Associate

Introduction

It has become increasingly commonplace in pharmaceutical or medical device product liability litigation—particularly large, centralized mass tort litigations involving hundreds or thousands of plaintiffs—for both plaintiffs and defendants to offer competing FDA regulatory experts. As with all other expert testimony, FDA regulatory experts are permitted to the extent that their scientific, technical, or other specialized knowledge assists the trier of fact to understand the evidence or to determine a fact in issue.

Although FDA regulatory experts are routinely offered and permitted to testify in such cases, there are grounds for opposing such proffered opinions, in whole or in part, particularly if the expert overreaches. In general, such experts are permitted to testify (if qualified) about the FDA regulatory framework, the contents of FDA regulations, and perhaps the defendant company’s interactions with the FDA. Experts cross the line, and are vulnerable to being excluded when they overreach by offering legal conclusions, advocacy-based narratives of facts, or opinions about the state of mind or intent of the agency or of the defendant in a given case.

This article discusses the issues regarding admissibility of regulatory expert opinion and bases for excluding or limiting such opinion.

General Evidentiary Rule: Expert Opinion Interpreting and Applying Domestic Law or FDA Regulations Is Inadmissible

It is a fundamental evidentiary rule that expert testimony on the meaning and applicability of law is inadmissible because it usurps the role of the judge. In a trial setting, the judge alone instructs the jury as to what the law is and what the legal standards applicable to the case are. As the DC Circuit held: “Each courtroom comes equipped with a ‘legal expert,’ called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards.” Burkhart v. WMATA, 112 F.3d 1207, 1213 (D.C. Cir. 1997). FDA regulatory experts are not permitted to testify about domestic law, i.e. the law that governs the case in which they are testifying (such as state tort law or strict products liability law) and may be precluded from offering interpretations of FDA regulations.

Courts have precluded experts, including FDA regulatory experts, from offering opinions about the standards that apply to the case and whether the defendant pharmaceutical or device manufacturer violated duties of care under applicable domestic law (such as expert opinion that a pharmaceutical manufacturer failed to fulfil its duty to warn under state law). The court in In re: Initial Public Offering Securities Litigation summarized the general rule that expert opinion on domestic law is inadmissible: “The rule prohibiting experts from providing their legal opinions or
conclusions is so well established that it is often deemed a basic premise or assumption of evidence law—a kind of axiomatic principle. In fact, every circuit has explicitly held that experts may not invade the court’s province by testifying on issues of law.” 174 F. Supp. 2d 61, 64-65 (S.D.N.Y. 2001) (internal citations and quotations omitted).

In addition to being precluded from offering opinion testimony about domestic law, some cases hold that FDA regulatory experts are precluded from offering opinion testimony regarding the interpretation of FDA regulations, reasoning that such testimony amounts to legal conclusions that are to be made by the court. These cases hold that it is the court’s role to interpret FDA regulations and then instruct the jury as to its interpretations. For example, the court in Livingston v. Wyeth, Inc., 2006 WL 2129794, at *6 (M.D.N.C. July 28, 2006) held that “while the summaries of FDA regulatory practices” offered by a proffered FDA regulatory expert may be helpful, the expert’s “application of law to the facts of this case on an ultimate legal question is not.” Similarly, the court in In re Rezulin Products Liability Litigation, 309 F. Supp. 2d 531, 547-50 (S.D.N.Y. 2004) precluded multiple experts from testifying about FDA procedures or from giving testimony that the defendant failed to adequately disclose material facts to the FDA.

The same holds true in medical device cases as well. For example, the court in United States v. Caputo, 374 F. Supp. 2d 632, 646 (N.D. Ill. 2005) held that “[w]hile an expert may testify regarding industry standards and practices, he may not offer opinions that amount to legal conclusions” and precluded the expert from testifying about whether defendants complied with medical device safety reporting requirements. The court in Steele v. Depuy Orthopaedics, Inc., 295 F. Supp. 2d 439, 446 (D.N.J. 2003) similarly precluded an FDA regulatory expert from offering such opinions.

However, some courts have permitted regulatory experts to offer opinions about FDA regulations. For example, the court in Smith v. Wyeth-Ayerst Laboratories, Inc., 278 F. Supp. 684, 700 (W.D.N.C. 2003) permitted an expert to testify about the standard of care applicable to manufacturers under FDA regulations because his “experience with the

Oftentimes drawing the line between what an FDA regulatory expert may and may not testify about is difficult, and courts often reach different conclusions as to what topics are permissible subjects of expert testimony.

FDA is sufficient to support opinion testimony regarding the applicable standard of care for reporting adverse drug events.”

Sometimes, parties tap former FDA employees as FDA regulatory experts. The FDA has opposed allowing former Agency employees to testify as regulatory experts offering interpretations of Agency regulations on the grounds that it is for the court, and not the jury, to interpret FDA regulations. For example, in Strong v. Am. Cyanamid Co., 261 S.W.3d 493 (Mo. Ct. App. 2007), the Agency submitted an amicus brief arguing that “The trial court should have interpreted the regulations itself and given guidance to the jury, with all appropriate deference to FDA’s interpretation. It should not have allowed the jury to interpret the regulations independently.” FDA Amicus Br. at 20. The Agency continued: “[T]he interpretation of a regulation is a question of law; it is precisely the type of legal question that courts generally are expected to address.” Despite FDA’s protestations, the Missouri Court of Appeals held that the testimony of plaintiff’s regulatory expert was admissible.

Narrowly Tailored FDA Regulatory Expert Testimony May Be Permitted

Although FDA regulatory testimony should be disallowed under the general rule prohibiting experts on issues of domestic law, a number of decisions have permitted at least some expert testimony about FDA regulations. For example, many courts will permit a regulatory expert to testify about the content of FDA regulations, and perhaps even a defendant company’s interactions with the FDA. For example, the court in In re Diet Drugs Prod. Liab. Litig., 2001 WL 454586, at *18 (E.D. Pa. Feb. 1, 2001) allowed a former FDA employee to testify regarding “how information should be communicated to the FDA and what information should be reflected in labels, as mandated by applicable regulations,” but precluded the expert from offering personal opinions regarding pharmaceutical company standards that were not set forth in FDA regulations.

Similarly, the court in In re Heparin Prod. Liab. Litig., 2011 WL 1059660, at *8 (N.D. Ohio Mar. 21, 2011) permitted an expert to testify about what FDA regulations require, but precluded the expert from offering ultimate question testimony.
By identifying and challenging inappropriate opinions, parties may be able to exclude FDA regulatory expert opinions either in part or entirely.
Issues arise, however, when a regulatory expert overreaches by purporting to assess the motive, intent, state of mind or ethics of a company, the FDA or others; by offering legal conclusions regarding whether the pharmaceutical company complied with or violated FDA regulations; or by merely providing a narrative recitation of facts. Courts take a dim view of such proffered testimony and may either exclude it in whole, or at least limit it. For example, the court in In re Fosamax Products Liability Litigation, 645 F. Supp. 2d 164, 191-92 (S.D.N.Y. 2009) precluded an expert from offering a narrative history of Fosamax, permitting the expert to only comment on company documents to explain their regulatory context, define specialized terminology or draw inferences that would not be apparent without the benefit of specialized knowledge. The Fosamax court also precluded knowledge, intent or state of mind expert testimony. The court in In re Gadolinium-Based Contrast Agents Prod. Liab. Litig., 2010 WL 1796334, at *13 (N.D. Ohio May 4, 2010) excluded similar testimony. For a more detailed discussion of court decisions excluding state of mind testimony, see “Excluding Expert Opinion Impugning Corporate Ethics, Motive and State of Mind” earlier in this report.

Oftentimes it is difficult to draw the line between acceptable and inadmissible FDA regulatory expert testimony, and courts often reach different conclusions regarding what topics are permissible subjects of expert testimony. For example, the court in In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig., 2007 WL 1964337 at *5 permitted plaintiffs’ expert to testify concerning whether the defendant’s actions were “reasonable and appropriate,” while the court in Hines v. Wyeth, 2011 WL 2730908 (S.D. W. Va. July 13, 2011) excluded the proffered testimony of an FDA regulatory expert “concerning the reasonableness of defendants’ testing procedures or the intent, motives, or knowledge of defendants or their employees” and barred the expert from “simply [constructing] a factual narrative based upon recorded evidence.” While the Guidant court permitted the expert to testify about certain discrete FDA regulatory issues, it excluded “her general opinion regarding how a responsible or ethical drug manufacturer should act.”

In the same vein, the court in In re Gadolinium-Based Contrast Agents Prod. Liab. Litig., 2010 WL 1796334 (N.D. Ohio May 4, 2010) permitted an expert (a former FDA employee) to testify about “regulatory requirements relating to the development, testing, marketing and post-marketing surveillance of prescription drugs” and the defendants “compliance therewith based only on the documents and exhibits in evidence;” the court precluded narrative history testimony and testimony related to the knowledge, intent, motivations, or purposes of the defendant or the FDA.

In other words, even courts that are inclined to permit some FDA regulatory testimony generally exclude opinions regarding the state of mind or intentions of FDA officials or projection of how the Agency would have reacted had the defendant acted differently. For example, the court in In re Fosamax Prod. Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) precluded such expert testimony, stating the expert “conceded at the hearing that her regulatory expertise does not give her the ability to read minds. Nevertheless, her report is replete with such conjecture. This is not a proper subject for expert or even lay testimony.” Similarly, in Kruszka v. Novartis Pharm. Corp., 28 F. Supp. 3d 920, 930-36 (D. Minn. 2014), the court permitted the experts to testify about the FDA regulatory process, FDA regulations, the defendant’s interactions with the FDA and compliance with FDA regulations, but precluded the experts from giving testimony about motive, intent, corporate state of mind, industry standards, monitoring of clinical trials and ghostwriting.
Conclusion

FDA regulatory experts have become increasingly commonplace in pharmaceutical and medical device products liability litigation, and there is no reason to expect that their involvement in such cases will cease in the foreseeable future. Such experts can, and sometimes do, serve a valuable purpose: they can help a jury of laypersons understand the complicated world of FDA regulations and how industry interfaces with the Agency. However, parties—frequently plaintiffs—proffer regulatory experts for purposes that invade the province of the judge and the jury. Legally impermissible or problematic subjects include the knowledge, motive, intent or state of mind of a party (or, as it is often put, to offer mind-reading testimony); whether a company complied with FDA regulations; whether a company adhered to certain standards of care; the meaning of FDA regulations; whether a company complied with state tort or products liability law; or simply to provide a narrative of facts (frequently advocacy-based narrations or regurgitations of a party’s factual theories).

When proffered, such expert testimony can be quite intimidating; oftentimes it might appear that, if a jury were to buy all of such testimony, the case would be over and done with. That said, the proposed testimony and reports of such experts must be examined with great scrutiny and a keen eye. By identifying and challenging inappropriate opinions, parties may be able to exclude FDA regulatory expert opinions either in part or entirely. When appropriately cabined, FDA regulatory expert opinions are manageable and can frequently be rebutted with competing expert testimony.
Taking a Science Expert Deposition to Set Up a Daubert Motion

Pamela J. Yates
Partner

Bert L. Slonim
Counsel

Aaron H. Levine
Associate

In any deposition, counsel wants to get the jury-friendly admission from a plaintiff’s medical expert that will be the key to a defense verdict—whether it is a causation admission that something other than your client’s product could have caused the injury or a credibility admission that casts doubt on the expert’s testimony. In some cases, however, there may be an opportunity to get something more than the admissions that will sway a jury. There may be an opportunity to exclude the expert from testifying at all or to substantially limit the scope of the expert’s testimony. Here, we discuss strategies and techniques for deposing an expert to set up a Daubert motion aimed at excluding plaintiff’s expert from testifying at trial.

Federal Rule of Evidence 702, which sets forth the requirements for the admissibility of expert testimony, provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Thus, the primary requirements for an expert to offer opinion testimony at trial are: (1) the expert possesses knowledge beyond that of a lay person that will assist the jury; (2) the expert must be qualified; and (3) the methodology must be reliable and must fit the case. An expert deposition should probe each of these requirements, particularly the reliability of the experts’ methodology.

In many ways, a Daubert challenge is like a high-school math test. You may get the right answer to the question, but if you don’t show that you got the answer the right way, you won’t pass the test. The same applies here. A Daubert challenge does not go to the expert’s conclusion, but rather the methodology. It bears repeating that a Daubert motion is not fundamentally about whether the plaintiffs’ expert is right or wrong because that is a jury question. Thus, a common rebuttal to any Daubert motion is that defendants are merely challenging the conclusions of the expert, not the expert’s actual methodology. The proponent of the expert will portray the issue as a legitimate scientific debate where reasonable experts merely disagree. In order to prevail on a Daubert motion, the aim is not to show that the expert reached a conclusion that is wrong, but that the experts used flawed methods to reach those conclusions.

Is the Expert Qualified?

Although it is rare that a party will put forth an expert that is simply unqualified to bring some special knowledge or
skill beyond that of a layperson, setting up an appropriate attack on qualifications as an initial matter can ultimately alert the court to any limitations or biases that may raise skepticism about the expert’s methods. Further, even if the attack on an expert’s qualifications does not play directly into the Daubert challenge, it may provide useful material for cross examination at trial. Therefore, when preparing for any expert deposition, counsel should start by thoroughly vetting the expert. Items that should be reviewed include: the expert’s CV; testimonial history; IDEX/DRI/Bloomberg reports; prior disciplinary actions; publications; Google searches; Twitter/Facebook and other social media profiles; and any YouTube or other video sources. Regardless of whether these searches turn up any smoking gun, they will inform the strategy for the deposition and counsel will have a feel for the witness before first meeting him or her at the deposition.

Digging into the expert’s background does not end the inquiry into qualifications. As part of the deposition strategy—whether for a Daubert challenge or for trial—it is important to wall off an expert from testifying about subjects and from offering opinions that go beyond his or her expertise. Consider asking a series of “you are not . . .” questions. For example: You are not a medical doctor? You are not a cardiologist? You are not an epidemiologist? You are not a biologist? You are not a toxicologist? You are not board certified in psychiatry? You are not a PhD in statistics? Just because a witness is an expert in one field does not give him or her license to offer opinions across the spectrum of medical or scientific disciplines.

Moreover, once the expert’s field has been suitably defined and narrowed, it is worth exploring whether there are guidelines about expert testimony that have been established by the professional societies related to the expert’s specialty. Some examples include the AMA Code of Medical Ethics Opinion 9.07, “Medical Testimony”; American Academy of Neurology Qualifications and Guidelines for the Physician Expert Witness; and The Teratology Society’s 2005 position paper regarding “Causation in Teratology-Related Litigation.” In particular, it may be possible to show that the expert’s methodology deviates from the standards promulgated by the professional society. In any event, these sources are useful for providing standards set forth by the expert’s peers in the relevant field.

The most important question that must be answered in any Daubert inquiry is why is this expert’s methodology unreliable?

Of course, there also are many other areas to explore with respect to the expert’s background and bias—how much money the expert has made testifying, whether the testimony is always on behalf of plaintiffs, whether the expert has published on the subject matter, whether the expert teaches the subject, etc.—but again, these attacks simply lay the foundation for casting doubt about the expert. The true Daubert attack must be on the methodology.

The Core Daubert Factors

While there is no single factor or group of factors that is determinative of a reliable methodology, courts have set forth a variety of factors that should be considered. These factors are aimed at drawing the distinction between an expert who properly employs an established method versus one who engages in junk science, speculation and inappropriate extrapolation. In Daubert, the Supreme Court set forth the following non-exhaustive list of core factors:

• Whether the expert’s theory or technique can be (and has been) tested
• Whether the expert’s theory or technique has been subjected to peer review and publication
• Whether there is a known or potential rate of error and/or standards that control the technique’s operation
• Whether the assessment or technique is generally accepted in the scientific community

Daubert at 2796-97.

Since the Supreme Court’s decision, Daubert progeny cases have set forth multiple other criteria for courts to consider. See e.g., General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997) (excluding expert testimony where there was “simply too great an analytical gap between the data and the opinion proffered”); In re Paoli R.R. Yard PCB Litig., 35 F3d 717, 765 (3d Cir. 1994) (excluding expert testimony where the expert “place[d] heavy reliance on unreliable . . . data”).

In exploring the core Daubert factors, counsel should ask the expert whether the expert has tested his or her theory; what the error rate is of his or her method; whether the expert has published his or her findings to his or her peers; whether the expert has presented his or her theories at professional
scientific meetings and symposia; and whether the expert can cite any published studies, peer-reviewed papers, text books or scientific authorities that endorse his or her methodology and concur with his or her conclusions.

Of course, the reliability of the method is not revealed simply by asking the expert whether she can answer the questions above. In order to uncover the actual failures in an expert’s method, a thorough exploration of the expert’s analysis is warranted. Counsel should start with the expert’s outlier conclusion and work backwards to dismantle it as only having been attainable through a faulty methodology. Every link in the expert’s chain of reasoning should be explored; if even one link is unreliable the opinion may fall.

**What Are the Methodological Flaws?**

The most important question that must be answered in any Daubert inquiry is why is this expert’s methodology unreliable? The expert will almost always say that he or she reviewed the relevant studies, analyzed the strengths and weaknesses of the data, and applied the proper criteria (e.g., causation experts will often say that they applied the Bradford Hill factors). But paying lip service to the methodology is not the methodology. So it is important to demonstrate where the specific failures lie within the expert’s methods. In preparing to do so, counsel should consider the following:

- Did the expert ignore contrary data?
- Did the expert cherry-pick data?
- Did the expert fail to consider all the relevant data?

If it is discovered that an expert cherry-picked only the most favorable studies or results supporting his or her conclusion, the inquiry does not end there. It still should be explored why the expert cherry-picked. In other words, could the exclusion of unfavorable studies be justified by a reliable methodology? (Maybe the excluded studies were seriously flawed.) To that end, counsel will want to know what inclusion/exclusion criteria the expert used in selecting studies; why some studies were omitted; and what criteria the expert used to determine which results within a particular study were most reliable.

Beyond just cherry-picking, methodological flaws may exist in the type of data relied on by an expert. An expert opining on human causation is usually required to cite human epidemiological studies in support of his or her opinion. But in a case where the epidemiologic data does not support the plaintiff’s case, an expert may look for other support for his or her opinions. To that end, counsel should consider:

- Did the expert inappropriately rely on data based on excessive doses?
- Did the expert inappropriately rely on animal studies?
- Did the expert inappropriately rely on in vitro (test-tube) studies?
- Did the expert inappropriately rely on weak and/or unreplicated statistical associations?

Where these issues occur, you will want to establish the significance of the expert’s reliance on such data. Some approaches to consider here are: Isn’t it true that the dose you cite in support of this finding is 10 times the dose that is given to humans? Isn’t it true that you are extrapolating from this in vitro or animal study to humans? Isn’t it true that the only finding you cite for this proposition is not statistically significant or that it has not been replicated in other studies?

**Where Are the Analytical Gaps?**

It is also important to consider how the expert is using the data to support his or her opinion. Most experts will provide some rationale for the manner in which they weighed or interpreted the data, but at times, uncovering that rationale will expose the flawed methodology. For instance, an expert claiming to consider all of the data, or the totality of the data, may simply be putting together a laundry list and then drawing unsupported conclusions about it. In determining how to uncover the analytical gaps in the expert’s methodology, counsel should consider:

- Is the expert overstating the results of some studies, or drawing conclusions that go beyond what the study authors themselves concluded?
- Is the expert drawing inappropriate extrapolations?
- Is the expert substituting personal opinion as scientific knowledge?
- Is the expert merely offering untested or unproven hypothesis (e.g., biological plausibility)?

To this end, it is often important to ask the expert what support there is for each area where she may be speculating, assuming or overstating the evidence. Questions such as: What is the basis for that statement? Isn’t it true that the study authors offer other explanations for this finding (quote the study)? Did you consider this study’s express qualifications/limitations regarding the results? What criteria did you use for determining how to weigh the results of
different studies? Can you cite any peer-reviewed, published study that supports that statement? Have you tested your theory? Have you ruled out other possible causes?

**Be Creative**

Just because an expert uses an unreliable method doesn’t mean it is easily exposed. A savvy expert will not only know how to find a way to support his or her conclusion, but will also be prepared to defend the method at deposition. Since courts are not as well versed in the science as either the expert or the lawyers are, many judges can only look for the expert to provide a plausible explanation for their departure from standard methods. When an expert is prepared to answer why they did what they did, you may need to consider other options.

The use of hypothetical questions may be helpful in this regard. Of course, these questions vary greatly from case to case and need to be tailored to the specific case, but the following questions may help you decide how to do so in your case: You wouldn’t cite a finding from one study as reliable, but reject other findings from the same study as unreliable? You wouldn’t use one methodology to determine causation in this case, and use a different methodology to determine causation in another case involving a different drug?

Many times, an expert who testifies in one case will be designated in future cases involving the same product. Where an expert is offering case-specific opinions, you will not only want to consider the case at hand, but will also want to lock the expert in for future cases. Hypotheticals can be particularly useful for the “next” case where the expert may testify. For example: You agree that you must rule out “X” risk factor in order to determine that this product caused the injury? If Mr. Smith took drug “A,” drug “B” and drug “C,” how would you know which product caused her injury? If Mrs. Doe only used the medication for less than one month, would that affect your opinion?

Finally, counsel should be prepared to go off script. While it is essential that one is prepared with a detailed outline that attacks the flaws identified in the expert’s methodology, merely moving from one scripted question to another may not yield the necessary testimony. The toughest expert to challenge is a hired gun who will know where the weaknesses in the data are and how to stay on message. However, just because an expert says he/she follows a reliable methodology does not make it so. It is important to prepare for any deposition by working closely with the corresponding defense expert so that counsel is equally, if not better, prepared. So when the expert doesn’t adequately answer a question, don’t just ask it over and over again, and do not just move on. Be prepared to fight. When the science is strong enough to file a Daubert motion, counsel needs to know it and must consider where the expert dug him or herself a new hole with each answer. So, if the expert rejects one finding because the study had a certain flaw, counsel needs to know which of the studies the expert relied on have the same flaw. When an expert relies on a nonsignificant finding in support of his or her opinion, counsel will need to know which nonsignificant findings refute the expert’s opinion. At the end of the day, this may or may not accomplish what is needed for a Daubert motion, but if it doesn’t, it will develop useful material for trial.
Many times, an expert who testifies in one case will be designated in future cases involving the same product. Where an expert is offering case-specific opinions, you will not only want to consider the case at hand, but will also want to lock the expert in for future cases.
About Our Product Liability Practice

Kaye Scholer has led some of the largest and most complicated product litigations of the past 10 years, representing a wide range of companies across a variety of industries in large-scale mass tort actions and individual lawsuits. Whether we are serving as national counsel, brokering innovative settlements or managing multi-front litigation wars, our practice offers a unique blend of strategic litigation counsel and courtroom brilliance. Our robust Life Sciences practice extends beyond state lines, involving cases filed nationwide that have a broad impact and involve significant issues, such as defending pharmaceuticals that remain on the market by way of challenging the admissibility of expert testimony under *Daubert* and related case law. For consumer products companies, we have a proven track record representing some of the world’s biggest and best known brands, enabling us to adapt to the complexities and nuances in a wide range of industries across the consumer products market. Our product liability group and its lawyers are recognized as leaders in the field by many publications and rankings, including *Chambers*, *Legal 500*, *LMG Life Sciences* and *Law360*. 

---

**Contributors**

Sheila S. Boston  
Partner  
sheila.boston@kayescholer.com  
+1 212 836 7197

Arthur E. Brown  
Partner  
arthur.brown@kayescholer.com  
+1 212 836 8592

James D. Herschlein  
Partner  
james.herschlein@kayescholer.com  
+1 212 836 8655

Jeffrey H. Horowitz  
Partner  
jeffrey.horowitz@kayescholer.com  
+1 212 836 7572

Lori B. Leskin  
Partner  
lori.leskin@kayescholer.com  
+1 212 836 8541

Andrew K. Solow  
Partner  
andrew.solow@kayescholer.com  
+1 212 836 7740

Pamela J. Yates  
Partner  
pamela.yates@kayescholer.com  
+1 310 788 1278

Alan E. Rothman  
Counsel  
alan.rothman@kayescholer.com  
+1 212 836 8860

Bert L. Slonim  
Counsel  
bert.slonim@kayescholer.com  
+1 212 836 8897

Ari B. Fontecchio  
Associate  
ari.fontecchio@kayescholer.com  
+1 212 836 8004

David Giroux  
Associate  
david.giroux@kayescholer.com  
+1 212 836 7721

Aaron H. Levine  
Associate  
aaron.levine@kayescholer.com  
+1 212 836 7586

Daniel Meyers  
Associate  
daniel.meyers@kayescholer.com  
+1 312 583 2393

---

Attorney advertising. Prior results do not guarantee future outcomes. ©2015 Kaye Scholer LLP; 250 West 55th Street, New York, NY 10019-9710. (63286016)