Exposure Is Not Causation: 
*The Importance of Expert Diligence and Challenges*

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Table of Contents

I. Introduction—Wins and Losses ........................................................................................................... 5
II. Starting with Losses—Rost v. Ford and Acosta .................................................................................. 5
   A. Rost ..................................................................................................................................................... 5
   B. Acosta ................................................................................................................................................ 6
III. Wins—Carl and Lipitor ....................................................................................................................... 7
   A. Carl ....................................................................................................................................................... 7
   B. Lipitor ................................................................................................................................................ 8
IV. Lessons and Strategies .......................................................................................................................... 9
   A. Creativity Matters—One Case at a Time ......................................................................................... 9
   B. General or Specific .......................................................................................................................... 9
   C. Getting Past Semantics to Dose and Methodology ..................................................................... 9
   D. Call a Professional .........................................................................................................................10
   E. Research Theirs ............................................................................................................................10
   F. Use the Deposition .......................................................................................................................11
   G. Know Your Audience ...................................................................................................................11
   H. Paper Your Challenge and Preserve ..........................................................................................11
V. Conclusion—Increase the Odds ..............................................................................................................12

Endnote .......................................................................................................................................................12
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I. Introduction—Wins and Losses

As "degenerates" often say after a bad run at the gaming tables, you win some and you lose some. Product liability litigators have had some significant victories recently, as well as some stunning losses. But as toxic tort, mass tort, and class action litigation will continue to challenge all of us, reviewing these wins and losses should prove instructive.

One of the most critical areas is how to deal with expert opinions and testimony. A solid plan of attack, guided by recent decisions and diligent examination of each case, should increase the chances of a positive result.

II. Starting with Losses—*Rost v. Ford* and *Acosta*

Although there are certainly many other cases that could be the subject of additional discussion, we will discuss the facts and holdings on a couple of recent losses and wins.

A. *Rost*

In 2005, Judge Robert Colville (in Pittsburgh, Pennsylvania) conducted a multi-day evidentiary *Frye* hearing regarding expert testimony in asbestos matters. What perplexed him was the contention by Plaintiff’s experts that every exposure to asbestos was a factual cause of asbestos-related diseases. He struck the experts relying on this theory, and a unanimous Supreme Court affirmed his ruling in *Betz v. Pneumo Abex LLC*, 615 Pa. 504, 44 A.3d 27 (2012).

While *Betz* was finalizing its trip through the Pennsylvania appellate courts, trial in *Rost v. Ford Motor Co.*, --- A.3d ---, No. 56 EAP 2014, 2016 Pa. LEXIS 2638 (Nov. 22, 2016) was taking place. In *Rost*, Plaintiff’s expert Dr. Frank’s causation opinion was that “it is not scientifically possible to identify the particular exposure or exposures that caused a patient’s mesothelioma, and instead the causative agent is ‘the series of exposures.’ All exposures to asbestos contribute to the cumulative dose of asbestos, and the cumulative dose causes mesothelioma. Accordingly, Dr. Frank testified that ‘[a]ll of the exposures that can be documented should all be considered as contributory to [Rost’s] developing his disease.’” *Rost* at *9*. Ultimately, Dr. Frank was willing to conclude that three months at the auto shop alone was sufficient to cause disease, even apart from the decade plus working in a power plant. *Rost* at *9-*13.

Confronted with what was seemingly a mere semantic difference—“each and every exposure” versus “each in the series of exposures,” the Pennsylvania Supreme Court essentially reversed course. Relying on an *amicus* by 58 physicians and scientists, the Court concluded that “cumulative exposure is ‘merely an extension of the ancient concept of dose-response, which is the ‘oldest maxim in the field.’” *Rost* at *26. Since Dr. Frank considered actual exposure, and opined that three months at Smith Motors was itself sufficient to cause disease, his testimony was sufficient:

[T]his Court adopted the “frequency, regularity, and proximity” test as a refinement to the substantial factor requirement for proving causation in mesothelioma cases. In the context of expert testimony on substantial factor causation, [Frequency, regularity, and proximity] provides the legal test, not an additional legal test, for proving substantial factor causation in cases involving disease resulting from asbestos exposure.
Rost at *30-*31 (internal references omitted). If a Plaintiff has met the frequency, regularity, and proximity standard, then causation is a jury question, which could have the effect of barring challenges in the future. The possible result, therefore, is that at trial, exposure equals causation (as all exposures contribute to a total exposure), especially since plaintiffs “have no obligation to eliminate every other potential cause of the development of disease through a ranking of different exposures by type and duration.” Rost at *48.

B. Acosta

In Acosta v. Shell W. Exploration & Prod., 370 P.3d 761 (N.M. 2016). The New Mexico Supreme Court was faced with allegations regarding two hundred residents of Hobbs, New Mexico developing autoimmune disorders (including lupus) purportedly as the result of benzene and pristane exposures from a crude oil storage pit.

As part of a modified Daubert analysis, the New Mexico Supreme Court reversed the trial court’s ruling striking plaintiffs’ expert. Plaintiffs sought to offer the expert testimony of Dr. James Dahlgren that Plaintiffs’ lupus and other autoimmune disorders were caused by exposure to a mixture of benzene, pristane, phytane, and mercury found in crude oil. Dahlgren relied upon numerous animal and human studies to support his opinion that these substances cause immune system disruption, autoimmune diseases, and lupus. Dr. Dahlgren also conducted what he described as an epidemiological study by comparing Hobbs to “unexposed” populations:

Dahlgren asserted that his study was conducted pursuant to the methodological standards set by the Federal Judicial Center’s Reference Manual on Scientific Evidence (2d ed. 2000). Dahlgren’s study included (1) an analysis of Plaintiffs’ medical conditions through patient history, medical records, physical examination, and diagnostic testing, (2) an analysis of exposure information and the temporal relationship between exposure and illness, (3) a review of the medical and scientific evidence to determine whether the exposure can cause the illness (“general causation”), and (4) an application of the general knowledge to the specific circumstances of the case to determine whether the exposure did cause the illness, including consideration of other possible causes (“specific causation”).

Acosta at 764. The trial court excluded Dr. Dahlgren’s opinions, particularly his own study, noting that there were no other studies that made the same showing or that showed a general link between the substances and lupus; Dahlgren’s study failed to “bridge the gap” from association to causation. Acosta at 765.

The New Mexico Supreme Court began its analysis by refuting the trial court’s analysis of the “gap:”

New Mexico has never adopted the Joiner rule that a judge may reject expert testimony where the “analytical gap” between the underlying evidence and the expert’s conclusions is “too great,” and we refuse to do so in this case. Historically, this Court has placed great value on allowing a jury to hear evidence and decide a case on the merits. Joiner is inconsistent with longstanding New Mexico law that leaves credibility determinations and weighing of the evidence to the trier of fact.

Acosta at 767. Further, the New Mexico Court refused to deprive plaintiffs of their “day in court” simply because of a lack of studies:

[D]emonstrating that a chemical is capable of causing a particular injury in the general population is often difficult in first-exposure cases where it has not been the subject of extensive scientific analysis.
We agree with other jurisdictions that “[t]he first several victims of a new toxic tort should not be barred from having their day in court” simply because scientific analysis on a particular chemical cause has not yet been fully developed. Acosta at 768. The Court also appeared to approve of the use of the Bradford Hill criteria\(^1\) in the absence of epidemiological studies with a citation to the Reference Manual on Scientific Evidence, even though that manual states that “[w]e emphasize that these guidelines are employed only after a study finds an association to determine whether that association reflects a true causal relationship.” Michael D. Green, D. Michal Freedman, & Leon Gordis, Reference Guide on Epidemiology, in Fed. Jud. Ctr., Reference Manual on Scientific Evidence, 598-599 (3d ed. 2011); see also n. 141 (“In a number of cases, experts attempted to use these guidelines to support the existence of causation in the absence of any epidemiologic studies finding an association. There may be some logic to that effort, but it does not reflect accepted epidemiologic methodology”) (references omitted)). Concluding that the trial court “improperly blurred the line between the district court’s province to evaluate the reliability of Dahlgren’s methodology and the jury’s province to weigh the strength of Dahlgren’s conclusions,” the Supreme Court reversed.

III. Wins—Carl and Lipitor

A. Carl


In Carl, the Plaintiffs claimed that their use of talc products caused their ovarian cancer. The Court allowed a Rule 702 Kemp hearing, and in doing so referred positively to the same Reference Manual the Acosta court cited but then disregarded:

Of particular value to the court in making its analysis is The Reference Manual on Scientific Evidence (3rd Edition, hereinafter, “the Reference Manual”) issued by the Federal Judicial Center and the National Research Council of the National Academies. The Reference Manual is an invaluable tool. Because it is indicative of what the scientific community deems to be reasonable, the Reference Manual provides excellent guidance to trial judges in sifting through and prioritizing the information generated at a Kemp Hearing. At such a hearing, a court is asked to assess whether the experts in the field would reasonably rely on methods and data as Plaintiffs’ experts have done in this case. Through the Reference Manual, the scientific community “speaks” to trial courts, and advises as to what may be considered to be reasonable, from an informed and objective perspective.

Carl at *5. Plaintiffs’ counsel were not challenged on qualification grounds. Instead, the Defendants challenged the methodologies of the experts, with a focus on epidemiology’s value in toxic tort cases.

The Court discussed the various types of epidemiological studies and their relative strengths, lab studies, cancer biology, animal studies, agency statements, and, again, the Bradford Hill criteria. After doing so, the Court expressed frustration due to its impression that “it almost appeared as if [Plaintiffs’] counsel wished the court to wear blinders.” Carl at *34. Particularly, the Court found fault with Plaintiffs’ experts selective reading of epidemiology, while also not being able to explain to the Court’s satisfaction the biological plausibility of talc causing cancer (focusing on tissue inflammation in particular). See Carl at *50 (“[Plaintiffs’ expert] noted candidly, “This is why there’s got to be continuing studies to understand this whole process
better.”). The Court also found strength of association lacking, noted the failure to rule out other causes, and focused on Plaintiffs’ experts’ opinions being litigation-driven as important considerations (especially since one of the experts had noted his lack of certainty of talc causing cancer in publications prior to his becoming a testifying expert).

Finally, the Court concluded:

As is true of most adversarial proceedings, the written reports and testimony of Plaintiffs’ experts are much like a patch-work quilt; individual pieces that when sewn together create a single blanket. If well sewn, the blanket covers the issues required to meet Plaintiffs’ burden of proof. Positioning, for the sake of discussion, that each piece of cloth is sound, the fragments cannot become a quilt without thread. Without a clearly stated, demonstrable hypothesis of specific causation, grounded in a reliable methodology, there is no thread and the pieces of cloth remain disparate.

Accepting, for the sake of discussion, that the case control studies relied upon . . . convey an inference that there is some type of causal association between talc and ovarian cancer, it means nothing without a hypothesis of specific causation . . .

As discussed, the testimony of Plaintiffs’ experts suffers from multiple deficiencies, the most salient of which are the narrowness and shallowness of their scientific inquiries and the evidence upon which they rely. Their peers in the scientific community would not rely upon such limited information.

Carl at *60-*62.

B. Lipitor


Each of these opinions are worth a read, but we will focus on a couple of key issues. The first expert excluded (on general causation) was Dr. Nicholas Jewell, a statistician who, to summarize, tried to show a statistical correlation between Lipitor at certain doses and diabetes, but did so in a manner that the Court viewed as “cherry picking.”

The Court finds that Dr. Jewell’s analysis of [the data] was results driven, that Dr. Jewell’s methodology and selection of relevant evidence changed based on the results they produced, and that Dr. Jewell chose to ignore and exclude from his report his own analyses that did not support his ultimate opinions. It is apparent to the Court that rather than conducting statistical analyses of the data and then drawing a conclusion from these various analyses, Dr. Jewell formed an opinion first, sought statistical evidence that would support his opinion and ignored his own analyses and methods that produced contrary results.

The Court then excluded the specific causation opinions of Dr. Murphy, primarily because her opinions flowed solely from the general conclusion that Lipitor causes diabetes and a temporal relationship to the bellwether plaintiff’s onset, and had failed to rule out the other risk factors for diabetes. *In re Lipitor*, 150 F. Supp. 3d at 661-62. Plaintiff’s second specific causation expert was later excluded on similar grounds. *See Daniels*, 2016 U.S. Dist. LEXIS 68828.

The Court also excluded the general causation opinions of Plaintiffs’ experts for all Lipitor doses other than the highest dose in the MDL (80 mg) because “studies have found a statistically significant increase in the risk of diabetes in patients taking 80 mg of Lipitor” and the expert “applied the Bradford Hill factors.” *In re Lipitor*, 174 F. Supp. 3d at 922. As to the other dosages, the Court’s analysis also took the Bradford Hill criteria into account, noting that:

Plaintiffs argue that while none of this evidence alone might be sufficient for a causation opinion, that taken together, there is “smoke,” and that behind the smoke, “there is, after all a fire.” To be sure, it is possible for the entirety of the evidence to support an opinion even when individual pieces of evidence are not sufficient in isolation, but it is also possible that multiple pieces of insufficient evidence add up to insufficient evidence. *In re Lipitor*, 174 F. Supp. 3d at 924 (internal citations omitted). Simply put, the Court maintained that Plaintiffs’ experts “confuse[d] association and causation.” *In re Lipitor*, 174 F. Supp. 3d at 935.

**IV. Lessons and Strategies**

Many of the suggestions made below will not be overly surprising, but they do reflect the ongoing evolution of exposure cases throughout the United States. Expert challenges should be weighed and carefully constructed in light of the law in each jurisdiction; however, recent trends suggest some “truisms” to consider.

**A. Creativity Matters—One Case at a Time**

Even the most routine case, whether part of a mass filing/class action or not, will have facts of its own that warrant special attention. Efficiency is, of course, a commodity for attorneys who expect to be fairly compensated for their time and effort, but not at the expense of examining those unique facts. Following a set pattern in each case without a fact-based approach could hurt the chances of an expert challenge down the line. This is especially true given that a strong start for a potential challenge will be the attention the expert paid to the facts - so the focus should lie there as well.

**B. General or Specific**

An important initial consideration is what type of causation the expert is addressing. Put simply, general causation addresses whether a particular agent/allegedly toxic substance can cause a particular illness, while specific causation addresses whether that agent/substance in fact caused the particular plaintiff’s illness. *Harris v. CSX Transp., Inc.*, 232 W. Va. 617, 753 S.E.2d 275, 390 n.4 (W.Va. 2013). The analysis set forth below will vary based on the type of causation opinion offered, so try to determine where the expert is headed to appropriately focus efforts.

**C. Getting Past Semantics to Dose and Methodology**

The *Rost* decision discussed above was a direct result of the Pennsylvania Supreme Court choosing to ignore the similarities between the “each and every exposure contributes” opinion held by Dr. Frank in the past, and his rewording of the opinion to “every exposure that is part of the cumulative dose contributes.” At
oral argument in *Rost*, defense counsel went to great pains to make the minor semantic difference plain to that court, but was unsuccessful in winning the day.

However, even when pointing out such trivial differences fails with the court, it is an important part of the challenge. Not only could it have persuasive effect with a jury should a challenge be unsuccessful, it represents a systematic approach to analyzing an expert's opinion.

**D. Call a Professional**

Any such systematic approach will immediately benefit from more sophisticated eyes. To that end, if possible, call in defense experts to be involved as soon as is practicable. Despite anticipated attorney arrogance, experts in the actual disciplines involved in an exposure case will know more about the scientific principles at play than the attorneys will. The defense experts will be able to spot issues attorneys may miss as part of dose construction, causation, and the nature of the exposures allegedly experienced.

Defense experts can help you sort through the other sides’ reports and anticipated testimony. If the result of an expert challenge is an evidentiary hearing, obviously expert testimony on the defense side will be invaluable. Don’t ignore the additional value of affidavits supporting a challenge as well as the experts’ assistance in crafting lines of inquiry for depositions and trial testimony. Note that this is also a good opportunity to shore up any issues with the defense experts’ own presentations. What’s good for the goose is good for the gander, and the other side will likely consider challenges of their own (see, e.g., *Danley v. Bayer*, 169 E.Supp.3d 396 (S.D.N.Y. 2016) (cross *Daubert* motions in an IUD perforation case); *Stults v. Am. Pop Corn Co.*, 815 F.3d 409 (8th Cir. 2015) (challenging defense expert’s experimentation)).

**E. Research Theirs**

As each case is different, each expert is different. In preparing a case and potential expert challenge, it is critically important to research every aspect of the expert you can. Start with something as simple as a search engine. Look for and borrow or purchase any publications the expert has authored or relies upon. Reach out to networks for prior transcripts, reports, and anything else of interest. This will arm you for a challenge and future discovery.

Armed in this fashion, you should be able to detect patterns in how the expert approached each case in which she participates. You may also find some “repeats”—in other words experts who opine in multiple types of expert challenges. For example, Dr. Frank opined on asbestos in Pennsylvania in *Rost*, but has also been excluded challenged and/or had his opinions excluded in the past (including the recent example of *Watkins v. Affinia Grp.*, 54 N.E.3d 174 (Ohio Ct. App. 2016) in which the failure to conduct a *Daubert* hearing on Dr. Frank was grounds for reversal)) and ascribed cancer causation to other products (like diesel exhaust in *Harris, supra* and asbestos, diesel and radiation in *Payne v. CSX Transp.*, Inc., 467 S.W.3d 413 (Tenn. 2015)). While Dr. Dahlgren (of *Erin Brockovich* fame) was creating his own epidemiology study in *Acosta*, he was also being excluded in vinyl chloride (*C.W. v. Textron*, Inc., 807 F.3d 827 (7th Cir. 2015)) and asbestos (*Crane Co. v. Delisle*, Nos. 4D13-4351, 4D14-146, 2016 Fla. App. LEXIS 16761 (Fla. Dist. Ct. App., Nov. 9, 2016)) matters. As noted above, statistician Dr. Nicholas Jewell was excluded in both the Lipitor and Zoloft mass torts.

You may also be able to find instances of “cherry picking”—those useful time in which an expert conducts an inappropriately selective review of the available evidence. An interesting recent example was the exclusion of Dr. Miller’s benzene-related opinions in *Burst v. Shell Oil*, 104 F. Supp. 3d 773 (E.D. La. 2015); the Court pointed out that:
Compounding Miller’s unreasonable and often unfounded assumptions is Miller’s failure to engage in any critical evaluation of his modeling results against empirical scientific literature measuring actual exposure levels. Instead, Miller accepts witness testimony outright and only selectively chooses when to rely on scientific literature.

*Burst*, 104 F. Supp. 3d at 790. Does the opposing expert take his sides’ witnesses at their word, but doubts the scientific literature upon which he purports to rely? Good to know for a challenge of methodology (and to damage credibility at trial).

**F. Use the Deposition**

Many have likely sat through an expert deposition in which only the basics are covered. Resist this tendency to simply “pin” the expert down. There is certainly great value in taking any opportunity narrowing the issues for trial down as much as possible (see *Ivory v. International Bus. Machines Corp.*, 480 S.W.3d 612 (Tex. App. 2015) (narrowing the case to only home exposures to TCE because all other exposures were deemed speculative)), but also consider using the deposition to plow new ground (those in Pennsylvania, Oregon, and other states that do not allow expert depositions are accordingly jealous).

A deposition is a valuable method to explore the underlying philosophy, reliance materials, and methods of an expert. It’s a useful form of pretrial “voir dire.” Through dialogue with the expert regarding the basis for their opinions (see *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 477-78 (1st Cir. 2016) (detailing the experts’ reliance on a “no safe level of exposure” theory and weighing of various studies despite being neither an epidemiologist or a researcher)), other possible theories (*Zellars v. NexTech Northeast, LLC*, 895 F. Supp. 2d 734, 737 (E.D. Va. 2012) (noting from deposition testimony that expert failed to take other causes into account)), and/or testing the limits of those opinions (see *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 854 (E.D.N.C. 2015) (noting the flaws in Dr. Mark’s methodologies through excerpts from his deposition testimony)), you can gain intelligence for trial or ammunition for the challenge.

**G. Know Your Audience**

Of course, one cannot pass the gate without accessing the gatekeeper. Research the judge who will be hearing the challenge. As an example: looking up the history of Justice Donohue, the author of the majority opinion in *Rost*, would indicate that she authored a devastating intermediate court opinion in *Betz* (see *Betz v. Pneumo Abex LLC*, 998 A.2d 962 (Pa. Super. Ct. 2010)) that was later overturned by the Pennsylvania Supreme Court as it unanimously rejected “each and every exposure” (*Rost* and *Betz* remain at odds, likely complicating exposure cases in Pennsylvania in the future). Once you know your audience, you can tailor your presentation accordingly. Much like a law school exam, to the extent possible, learn what the “professor” expects to see and give it to them. Even if the result is a loss, you will (hopefully) educate the judge in a way that can help at trial with rulings and jury instructions, and gain insight into any latent biases or other pitfalls to avoid.

**H. Paper Your Challenge and Preserve**

Finally, since we can’t win them all, keep in mind the rules in the given jurisdiction for creating an appellate record. Sometimes the best audience will unfortunately be the appellate judges assigned to review the matter. This means making sure the record is complete and accurate. Even if a challenge is raised on the spur of the moment (during trial, for example), be sure to “paper” the request with a subsequent filing. This ensures avoiding an incomplete picture on appeal or, even worse, some argument in favor of waiver.
V. Conclusion—Increase the Odds

Card counters are barred from casinos throughout Vegas because they use their superior knowledge to lessen the “house advantage.” By knowing how many valuable cards remain in the blackjack shoe, they increase their odds of making the right decision. Although no one can predict with certainty how judges are going to exercise their responsibilities as a gatekeeper, there are steps to take to increase the “edge.” As noted above, the key is extensive preparation to ensure that the defense of a product involves a creative and thorough approach. This includes a complete vetting of the experts on both sides of the case, and a carefully planned attack when one is warranted. There is no need to leave challenges to chance by a roll of the dice; instead, use your skill and resources to take on the “house.”

Endnote

1 The Bradford Hill criteria include a weighing of the following factors: (1) strength of association (i.e., is the association strong and statistically significant?); (2) consistency of the relationship whether it has been repeatedly observed in other persons?; (3) specificity of association (i.e., is there a particular association between the substance and the condition it purportedly causes?); (4) temporality (are the cause and effect bound in time, or as Hill states, “which is the cart and which is the horse?”); (5) biological gradient (does the association reveal a dose-response curve?); (6) plausibility (i.e., whether there exists a biologically plausible mechanism by which the agent could cause the disease?); (7) coherence (does cause-and effect interpretation of the data conflict with the history and biology of the disease?); (8) experiment (is the frequency of the associated events affected by reducing the amount of the suspected substance?); (9) analogy (should science anticipate similar results from a consideration of alternative explanations?).