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THE SCIENCE OF STORYTELLING IN THE STORYTELLING OF SCIENCE

EPIDEMIOLOGY AND THE NFL COLLIDE

DAUBERT AND FRYE AND ANYTHING GOES, OH MY!

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LAW ELEVATED

DEAR CLIENT,

The Winter 2017 issue of Pro Te focuses on experts, the use of and standards for admission of scientific evidence at trial, and the effect of scientific studies on issues for trial.

The Science of Storytelling in the Storytelling of Science explores how to tell a successful story when dealing with complex issues in science. This article addresses considerations for making the most of your scientific data when presenting dense, complicated material to a judge or jury.

The impact of epidemiological studies is the issue in *Epidemiology and the NFL Collide.* This article digests how scientific studies, even when the studies are not conclusive, can affect litigation by analyzing the effect of such studies in the NFL concussion litigation.

Control of expert testimony via a court's gatekeeping duties—and the frustrating lack of consistency among gatekeepers—are pondered in *Daubert and Frye and Anything Goes, Oh My!* Is a universal standard applying the Daubert factors a better approach or does the standard even make a difference?

As experts drive so many issues in pharmaceutical litigation, we hope that this issue is interesting, topical and informative.

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TABLE OF CONTENTS

THE SCIENCE OF STORYTELLING IN THE STORYTELLING OF SCIENCE

The author acknowledges with gratitude the contribution of Laura Dooley, Professor of Law, Valparaiso University, Visiting Professor of Law, Touro Law Center.

In pharmaceutical litigation, understanding the science involved in the efficacy or safety of a drug or device is essential to obtaining favorable outcomes. But the medical literature is notoriously opaque and difficult to parse. Judges have crammed dockets and often do not spend much time in the scientific world, and the trial setting is not an ideal forum for explaining complex science to juries. An attorney's hard work in unpacking the scientific literature, and digging into the data on which it is based, can make all the difference. Even more importantly, an attorney's ability to translate technical data and medical jargon into language accessible to those responsible for litigation of a case, and ultimately to lay decision makers like judges and juries, is more than an essential skill. It is a science in itself—the science of storytelling.

Here we explore the component steps for preparing to tell a successful scientific story in pharmaceutical product liability litigation. Take, for instance, a litigation in which a large number of plaintiffs allege that a drug has produced a disease temporally related to ingestion of the drug. A successful defense depends directly on the assimilation of what is likely to be an avalanche of data and medical literature, much of which may be conflicting—alongside important strategic calculations about when, where, why, how and to whom the information is optimally presented. These decisions are paramount at two key junctures: the pretrial or "*Daubert*" stage[1] (to the judge) and at trial (sometimes, again, to the judge, and ultimately to the jury).

CONSIDERATIONS WHEN PRESENTING TO THE COURT

Courts use the *Daubert* "gatekeeping" process to decide whether expert opinions are unreliable and therefore inadmissible; astute science counsel use this process to expose scientific flaws in their opponents' cases. The highly structured *Daubert* proceedings require the judge to adjudicate science, particularly when the court holds a pretrial

evidentiary hearing. The judge will have the opportunity to review the parties' briefing, read the expert testimony, and even study scientific articles, textbooks, and other sources of science. In some instances, she may even consult her own experts.[2] At such an evidentiary hearing, the judge metaphorically takes off her robe and becomes a student of science. Rather than parsing procedural rules or regulatory statutes or common law doctrine—the day-to-day fodder of a judge—she must immerse herself in a highly-specialized terrain. An attorney who understands the science and can function as an engaged and interesting educator is best-equipped to convey the salient data in a way that both informs the judge's decision and helps her to write an opinion that captures the sophistication of the science.

CONSIDERATIONS WHEN PRESENTING TO THE JURY

When science is presented at trial, the strategy changes. Juries do not read written briefs setting forth logical arguments based upon scientific data; nor do they have the time or even the opportunity to study the original source documents themselves. Juries are instead asked to absorb science through courtroom testimony elicited on direct and cross-examinations of expert witnesses. The task of building a persuasive scientific story is further complicated by several realities: that expert testimony is dependent on expert availability (making it more difficult for trial counsel to build their story); that expert testimony cannot be unduly repetitive (depriving jurors of rehearing important points); and that testimony is often interrupted by objections and lengthy sidebar arguments (breaking juror concentration).

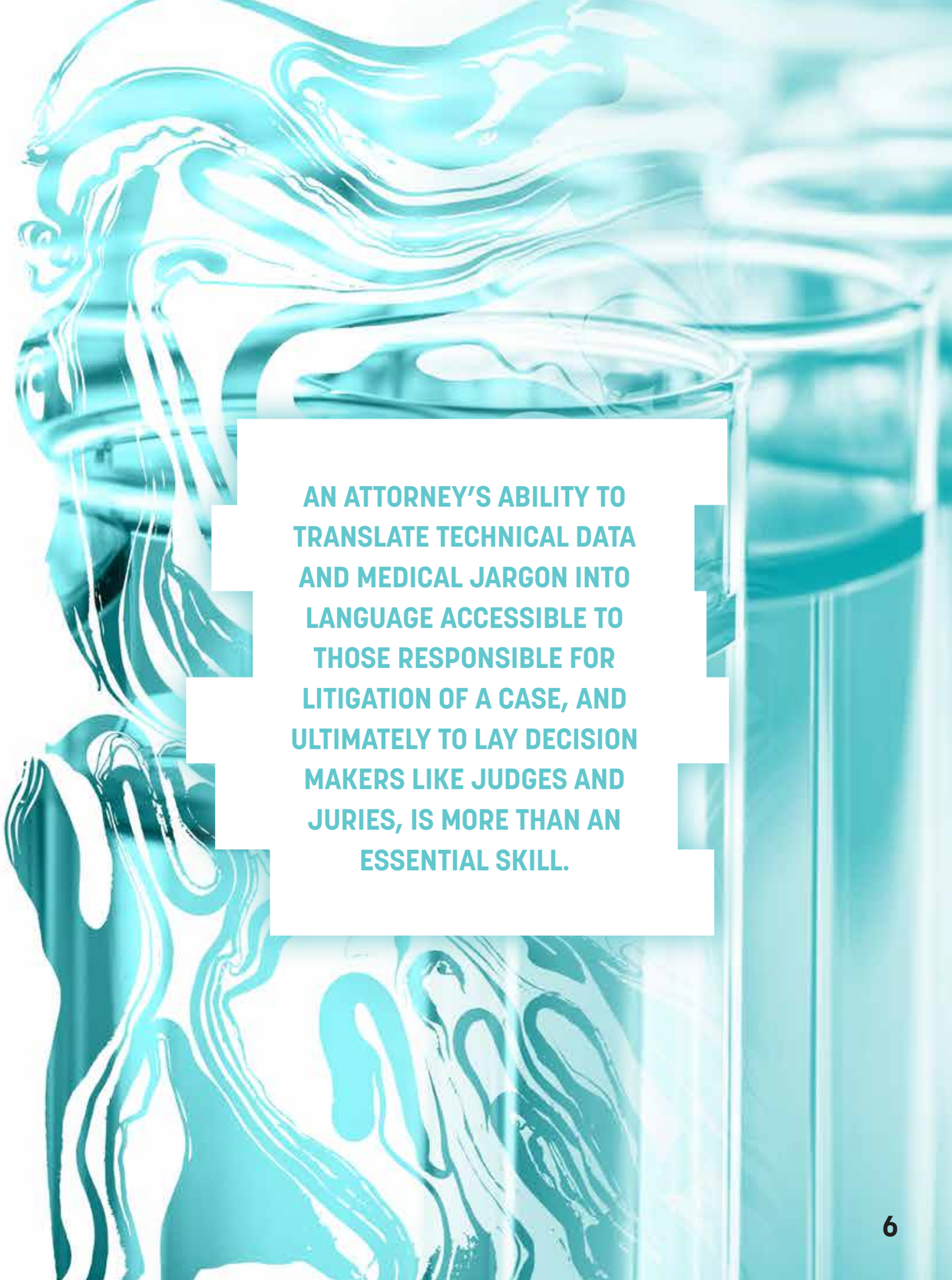
Most lay people understand instinctively that announcements of scientific breakthroughs may be premature, and even wrong. When physicists claimed to have performed nuclear fusion in a bottle, or when researchers linked daily coffee drinking to elevated rates of pancreatic cancer, suspicions abounded in the public consciousness. The news report that binging on chocolate is good for us generated as much skepticism as it did satisfaction. But in the fast-moving world of pharmaceutical litigation, there can be a temptation (particularly among lay decision makers) to defer, without close inspection of the empirical data, to conclusions conveyed by others.

A juror's temptation to rely on the conclusions of witnesses cloaked with the imprimatur of "expert" is a well-recognized phenomenon. Litigation experts have the power to persuade not because they are necessarily right, but because they have pedigrees, experience, and authority. *Daubert* erected the gatekeeper apparatus to help judges keep the junkiest of expert opinions out of earshot of the jury, but even adherence to the *Daubert* standard does not preclude admission of opinions relying upon shaky science, science that has been misinterpreted, or no science at all.

BREAKING DOWN AN EXPERT'S OPINIONS

Let's consider the plaintiffs' expert who presents the opinion that your drug caused a rare disease in a multi-plaintiff litigation. Assume this expert has issued a Rule 26 report explaining the rarity of the condition, how it is diagnosed, and detailing the "lines of evidence" supporting this opinion. One line of evidence consists of case reports where authors have investigated but "ruled out" other causes, leaving your drug as the "culprit." Another line consists of laboratory studies performed in animal models which report features of the disease and suggesting a biologically plausible mechanism of injury. A third line of evidence consists of human population studies using various methodological designs and reporting associations of different strengths and statistical significance.

Decision makers may be tempted to evaluate these sources collectively: *i.e.*, they may, even unconsciously, determine that the aggregation of different types of scientific data presents a



AN ATTORNEY'S ABILITY TO TRANSLATE TECHNICAL DATA AND MEDICAL JARGON INTO LANGUAGE ACCESSIBLE TO THOSE RESPONSIBLE FOR LITIGATION OF A CASE, AND ULTIMATELY TO LAY DECISION MAKERS LIKE JUDGES AND JURIES, IS MORE THAN AN ESSENTIAL SKILL.

compelling, maybe even foolproof, scientific story. But by digging into the empiricism that underlies the reports or studies, science counsel can convey to those decision makers that the data are not as robust as they seem to be. This, in turn, can establish the groundwork for telling successful stories at both the *Daubert* stage and trial. Let's examine an approach that science counsel, when faced with such a daunting task, might use to capture and convey the scientific information.

The process consists of four components: *First*, all the relevant data must be collected and organized into the hierarchy of scientific evidence, a process which lays the foundation for critical analysis. *Second*, a narrative must be developed that enables laypeople to understand complicated data, forcing them beyond facile anecdotal conclusions. *Third*, knowledge of the science must be used to elicit important concessions about the weaknesses of their competing stories from opposing experts at deposition. *Fourth*, science counsel must work as a conduit between the experts and trial counsel in the team effort of marshaling the key information and presenting it at trial in a comprehensible and persuasive way.

To begin, the relevant data must be collected, classified, and ranked in accordance with the hierarchy of scientific evidence. This process culminates in the development of a figurative pyramid depicting the highest-value, most robust scientific data at the top, with layers of less robust (but still essential) data through the middle, with the least robust data at the bottom.

This hierarchy becomes a valuable tool, indeed *the* most valuable tool, in the development of the scientific narrative for the litigation. It helps science counsel identify the data (and categories of experts) that your adversaries are likely to use, evaluate how to structure a *Daubert* strategy, and craft the approach for that strategy from the outset of the case. It also provides a foundation

for assessing whether scientific studies should be undertaken to help answer vital questions necessary to defend the litigation.

In developing the narrative, science counsel is forced to take a deep dive into the empiricism of the dataset as a whole. This critical analysis is often undertaken with the crucial input of retained expert witnesses who can identify lurking problems in study design, identify data points that do not make sense, and question the validity of reported results. By fully understanding the strengths and weaknesses of the studies, science counsel can separate opinion from data and then can begin the arduous process of constructing a scientific narrative for the litigation founded on a bedrock of knowledge.

DEVELOPING A NARRATIVE TO DEBUNK JUNK SCIENCE

One of the frustrating features of mass tort litigation is its failure to quickly end claims predicated on the allegation of disorders and syndromes on the margins of medical acceptance. Alleged "syndromes" are often so poorly defined that plaintiffs with barely cognizable medical problems are squeezed into the "big litigation tent" erected by their lawyers. Sometimes a disease which is rarely diagnosed in the United States is alleged, forcing plaintiffs to claim that the diagnosis has been "overlooked" by the U.S. medical profession because accepted criteria used to diagnose it are inappropriately restrictive. Whatever tactic is pursued, the scientific narrative must always address threshold issues of scientifically reliable disease definitions and diagnostic criteria.

THE MOST COMMONLY CONTESTED SCIENTIFIC ISSUE IN PHARMACEUTICAL PRODUCT LIABILITY CASES IS GENERAL CAUSATION.

The most commonly contested scientific issue in pharmaceutical product liability cases is general causation—*i.e.*, the requirement that the plaintiff establish that the drug or device is, in fact, capable of causing the harm alleged. Science counsel's narrative will address the plaintiff's general causation theory not only by *challenging*

key studies, but also by *explaining* deficiencies in whole classes of evidence. For example, returning to our hypothetical, even if a rare disease has a low background rate in the population, case reports can be challenged because they rarely provide all the information needed to evaluate the authors' conclusions about causation. Such reports also fail to rule out the occurrence of disease in any one person due to random chance. Laboratory experiments performed in animals are fraught with vulnerabilities which make extrapolation of data to humans quite hazardous. Indeed, when the concentration of drug administered to an animal is converted from the milligram per kilogram measurement used in the experiment to the dose in an "average" person of 70 kg, the end result is usually equivalent to a massive overdose that far exceeds the recommended dose. Finally, human population studies need to be critically evaluated for biases and confounding factors, lack of statistical significance, and improper control groups. Defects in study design can make results of even controlled epidemiological studies unreliable.

When the analysis is complete, the narrative pulls together all the data demonstrating that your drug has a remarkable safety record and does not cause the alleged injury, based upon reliable scientific evidence in accordance with the hierarchy of scientific evidence. The narrative also addresses the scientific data propounded by plaintiff experts and systematically evaluates each category of data, each individual study, and any speculative mechanisms of biological plausibility. The narrative then serves as the blueprint for cross-examining plaintiff experts during their depositions for the purpose of obtaining critical admissions or even concessions for use in *Daubert* challenges and at trial.

Obtaining this type of useful testimony at expert depositions is not accidental. It requires the formulation of a methodical game plan that combines many strategies built upon intensive preparation. These include review of the expert's published scientific work, identification of the expert's scientific methods and procedures (e.g., the use of the 95% confidence interval), recognition and exploitation of all the relevant data the expert has ignored in his expert report, and a keen understanding of how that expert approaches the dataset as a whole. Science counsel with this heightened state of preparation is then able to actively listen to the expert's testimony, waiting for clues to exploit. Allowing an opposing expert who values the sound of his own voice to talk endlessly at a deposition can be productive, but only when that expert is prone to providing useful admissions in his monologues. Knowing when to politely interrupt and compel an answer to a specific question requires patience, experience, and a keen sense of when to press the point.

STORYTELLING AT TRIAL

We now can address the trial of the case. Though jury trial in civil cases is often considered a dying phenomenon,[3] it is in front of the jury that the role of science counsel in constructing a cohesive and compelling scientific story becomes even more important. Together with the trial lawyers charged with actually presenting the defense to lay decision makers, science counsel must develop a trial plan. In that process, science counsel serves as an important intermediary between the scientific experts and the trial lawyers. Together as a team, attorneys and expert witnesses are then able to use the special skill sets of each to determine how best to present complicated scientific data.

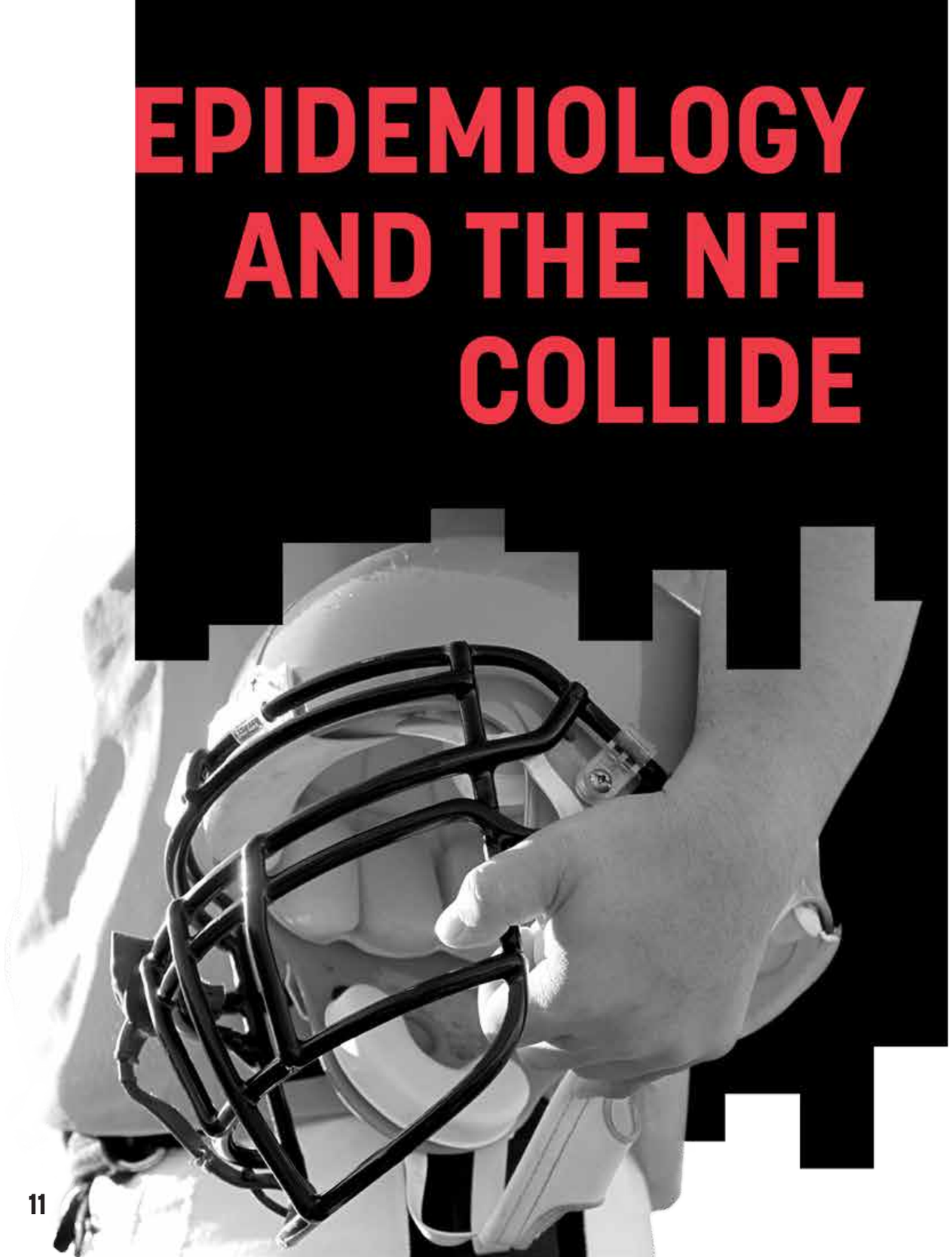
Trial lawyers are adept at seeing the overarching structure of a case and figuring out how to use evidence within that landscape to paint a detailed picture of their client's story. Scientific evidence presents a special challenge, however; trial lawyers must both employ that evidence strategically and translate it successfully to lay decision makers. Science counsel plays an essential role in that process. At this point in the litigation, science counsel has been immersed in the medical data and literature, and has become adroit at identifying the most salient (in terms of both relevance and reliability) data. And because science counsel has also gained a fluency in the lingua franca of the scientific world, he is able to serve as a conduit between the medical experts and trial counsel, translating the jargon to make it more accessible without losing its important nuances. Science counsel also forms important relationships with the scientific experts, usually medical doctors, establishing trust and assimilating the experts into the trial team.

The art of storytelling has long been a key component to effective trial preparation. Successfully using scientific evidence, particularly expert testimony, in that preparation is especially challenging. But complicated scientific data can be captured into a coherent story that fits into an overarching narrative. The collaborative process among science counsel, expert witnesses, and trial lawyers is one that is both art and science. And it is essential for success.

1. Or the *Frye* stage, in those jurisdictions still using the *Frye* standard to assess the admissibility of expert opinion testimony.
2. Under the Federal Rules of Evidence, a federal court may empanel its own experts, as occurred in the silicon gel breast implant litigation.
3. See Laura G. Dooley, *National Juries for National Cases: Preserving Citizen Participation in Large-Scale Litigation*, New York University Law Review.

DAVID M. COHEN

EPIDEMIOLOGY AND THE NFL COLLIDE



"Iron" Mike Webster was one of the greatest centers to ever play professional football. Known for playing sleeveless in freezing temperatures to intimidate his opponents, Webster spent 17 seasons in the NFL and helped lead the Pittsburg Steelers to four Super Bowl Championships in the 1970's. He was later inducted into the Pro Football Hall of Fame and named to the NFL's all-time team—a true football legend.[1]

But the glory of football quickly faded after his retirement. Unable to keep a job and losing his marriage, Webster became homeless, depressed, indebted, drug-addicted, and plagued by chronic pain that made sleep almost impossible. At one point Webster became so desperate for rest that he would shoot himself in the leg with a Taser until he lost consciousness. In 2002, Mike Webster died of a heart attack at age 50.[2]

What happened next would change professional football forever. During Webster's autopsy, forensic pathologist and medical examiner Dr. Bennet Omalu discovered that Webster suffered from Chronic Traumatic Encephalopathy (CTE)—a brain disease never before seen in professional football players.[3] In 2005, Omalu published his findings in the medical journal *Neurosurgery*. CTE was catapulted into the national spotlight. But was football really the cause of Mike Webster's rare brain disease? The answer to that question is an epidemiological one.

EPIDEMIOLOGY DEFINED

"Epidemiology is the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations."[4] Epidemiology attempts to understand the cause and prevention of disease[5] and is considered among "the best evidence of causation in the mass torts context."[6]

Epidemiological evidence is often tendered as evidence of general causation, i.e. whether an agent is capable of causing a particular disease or health outcome. It may also be admitted to prove the safety and efficacy of a product, to explain a defendant's actions, or as the basis for an expert's opinion. Given their general nature and inherent bias, epidemiological studies alone do not answer questions of specific causation, i.e. whether an agent caused a *particular* individual's disease or health outcome.[7]

CATEGORIES OF EPIDEMIOLOGIC STUDIES

There are two categories of epidemiologic studies: experimental and observational. In an experimental study, a researcher selects two groups of individuals from a given population. He then exposes one group to a suspected agent while leaving the second group unexposed. The researcher later evaluates both groups for development of the disease.

Experimental studies include randomized controlled trials and are often double-blinded, making them the "gold standard" of epidemiological evidence. However, experimental studies in humans are ethically prohibited when an agent is known to be potentially harmful. As a result, most epidemiologic studies are observational.

There are two main types of observational studies: cohort and case-control. Both types of studies have a comparison group and determine if there is an association between exposure to an agent and a disease. If an association is present, the study then measures the strength of that association. In a cohort study, a researcher selects a group of individuals who have been exposed to the agent in question and a second group who have not been exposed. The researcher then follows the groups and compares their development of the disease.[8] Behind randomized controlled trials, cohort studies are the strongest form of scientific evidence.[9]

In contrast, case-control studies begin by identifying a group of individuals who actually have the disease and a second group who do not. The researcher then compares the groups' past

exposures to the agent in question. If the agent causes the disease, the researcher should find a higher proportion of past exposures among those who have the disease.[10] Case-control studies fall just below cohort studies in the hierarchy of scientific evidence.[11]

Case reports, like the one regarding Mike Webster, describe clinical events in a single patient and are among the weakest forms of scientific evidence.[12] Alone, case reports cannot establish a causal link between an agent and a disease primarily because there is no comparison group, and they are generally excluded at trial.[13] Even Dr. Omalu conceded that his case report of Mike Webster "by itself [could not] confirm a causal link between professional football and CTE."[14]

PRESENCE OF ASSOCIATION

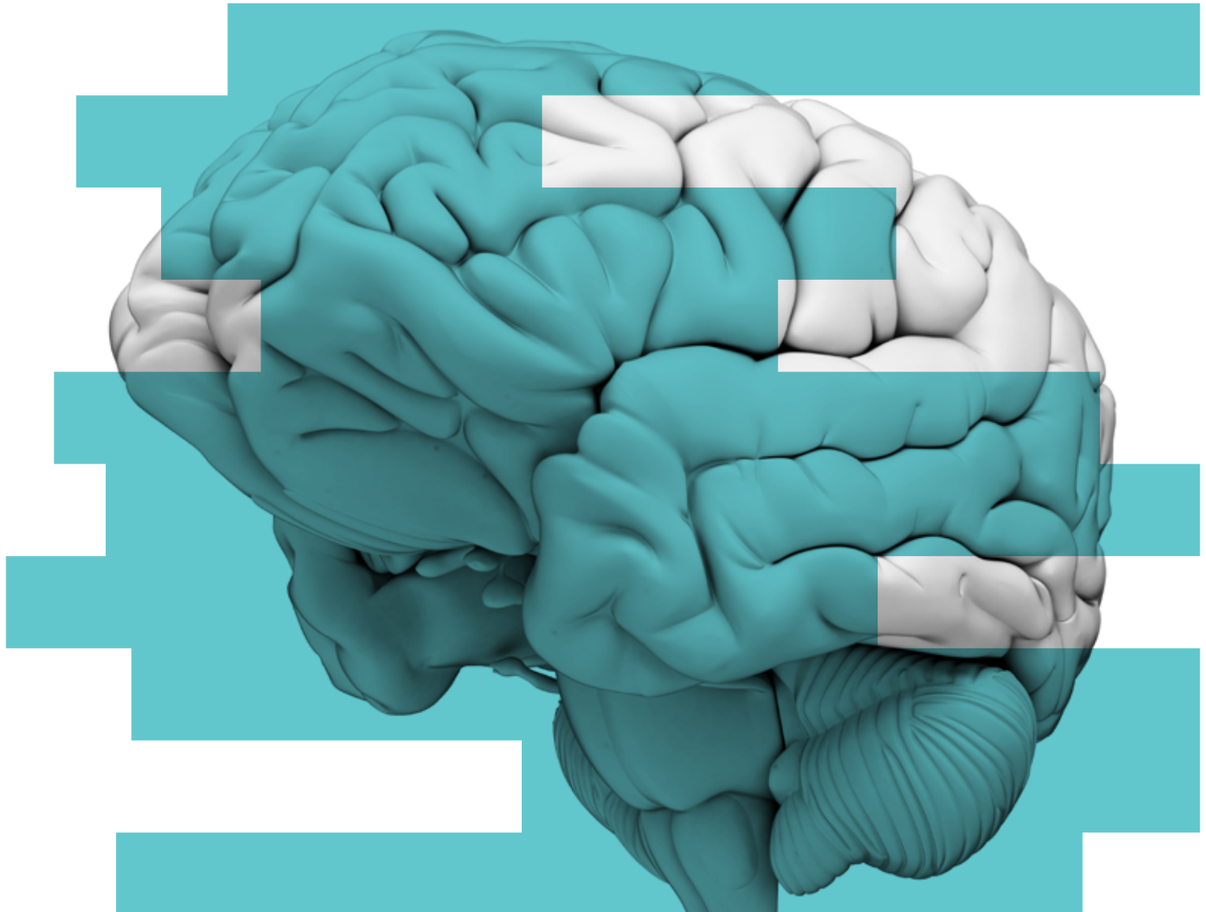
However, Dr. Omalu's diagnosis of CTE in Mike Webster was just the beginning. In November 2006, Omalu published a second case report[15] after finding CTE in the brain of former NFL player Terry Long, a 45-year-old former Pittsburg Steeler who committed suicide in 2005 by drinking antifreeze.[16] He later found evidence of CTE in the brains of retired NFL players Justin Strzelczyk (age 36) and Andre Waters (age 44).[17] Omalu's research appeared to show an association between playing professional football and CTE. But were these associations true, or merely the result of random error, bias, or confounding factors?

1. RANDOM ERROR

Epidemiologic studies are often based on relatively small sample groups. As a result, a study may erroneously find an association where one does not actually exist, or not find an association where one does exist, simply due to "chance" or "random error."[18]

One way to assess the potential for random error is by calculating a p-value. "A p-value represents the probability that an observed positive association could result from random error even if no association were in fact present."[19] For example, a p-value of 0.05—which is the most common significance level—means that there is a 5% chance that the study will erroneously find an association where no true association exists. Thus, the researcher can be 95% sure that the observed association is true. As long as the observed p-value for the study falls below the preselected significance level, then the relative risk or odds ratio can potentially be "statistically significant."

A second way to assess random error is by using a confidence interval. A confidence interval is a range of values within which the true value is likely to fall. Suppose a study finds a relative risk (discussed below) of 2.66 with a 95% confidence interval of 2.14 to 3.36. The confidence interval tells researchers that they can be 95% sure that the true relative risk is somewhere between 2.14 and 3.36. The more narrow the confidence interval, the more precise the result. However, if the confidence interval includes 1.0, the result cannot be "statistically significant."[20]



2. BIAS

The overarching objection to the existing body of CTE research is that it is based on inherently biased case reports. Bias refers to anything "that results in a systematic (nonrandom) error in a study result and thereby compromises its validity."[21] There are two primary types of bias in epidemiological studies: selection bias and information bias.[22]

Selection bias results from the method by which study participants are chosen. CTE research is not based on the random selection of patients. Rather, researchers gain access to brains through donations from families or by direction of the players themselves before their deaths. Because the families of players who exhibited CTE-like symptoms during their lives are more likely to donate a brain for research, the sample of brains received is not representative.

Even Dr. Ann McKee, director of Boston University's CTE center and now the leading neuropathologist in the study of the disease, admits that "an autopsy series is terribly biased" and by itself is unable to detect incidence and prevalence of the disease.[23] In other words, case reports cannot establish why or how frequently the disease occurs in a given population.

Information bias results from "inaccurate information about either the disease or the exposure status of the study participants or a result of confounding."[24] Because concussions in football are underreported and largely undocumented, it is difficult to reconstruct accurately a player's medical history. As a result, researchers must often rely on interviews with family members about the player's exposures which test memory and are speculative at best. These interviews can also encourage "recall bias," in which family members are more likely to report past exposures once the disease has been confirmed.

ALONE, CASE REPORTS CANNOT ESTABLISH A CAUSAL LINK BETWEEN AN AGENT AND A DISEASE PRIMARILY BECAUSE THERE IS NO COMPARISON GROUP, AND THEY ARE GENERALLY EXCLUDED AT TRIAL.

3. CONFOUNDING FACTORS

A "confounding factor" is an "extra" factor in a study group which independently increases both the risk of disease and exposure.[25] If not properly accounted for, confounding factors can skew the results of a study by producing an observed association when no true association exists.

Critics of Dr. Omalu's work initially questioned whether the use of anabolic steroids was a possible confounding factor because both Mike Webster and Terry Long had used steroids during their football careers. After all, the known side effects of steroids include high blood pressure, heart problems, aggression, psychiatric disorders, depression, and drug dependence—symptoms commonly displayed by NFL players later diagnosed with CTE.[26]

While this theory has since been discredited through experimental testing on rats,[27] and by the discovery of CTE in players whose careers predated the use of steroids in the NFL,[28] other potential confounding factors—like age, mental health, and substance abuse—have gone "largely unaccounted for in the published literature."[29] Without conducting experimental studies that properly control for these factors, the link between football and CTE remains suspect.

STRENGTH OF ASSOCIATION

Once a true association is determined (understanding that bias and chance can never be ruled out), a researcher can then evaluate the strength of that association. The strength of an association refers to the "degree to which the risk of disease increases when individuals are exposed to an agent."[30] Epidemiologists commonly measure the strength of an association in terms of relative risk or odds ratio numbers.

Relative risk, which is most commonly used in cohort studies, is calculated by dividing the incidence rate of disease in the exposed group by the incidence rate of disease in the unexposed group. A relative risk of 1.0 means that there is no association between an agent and a disease, and that the risk of contracting the disease is the same in both exposed and unexposed individuals. A relative risk less than 1.0 means there is a negative association between the exposure and disease. A relative risk greater than 1.0 means there is a positive association between an agent and disease, which could be causal. The higher the relative risk, the stronger the association.

A BASIC TENET OF EPIDEMIOLOGY IS THAT AN ASSOCIATION DOES NOT EQUAL CAUSATION.

For example, suppose as a hypothetical that a researcher wanted to test the safety of modern football helmets compared to the leather helmets worn by early players. After selecting two equally-sized, equally-matched groups, the researcher would give leather helmets to one group (exposed group) and modern helmets to the other (unexposed group). Further suppose that at the end of the season, 66 out of 100 players with leather helmets sustained concussions, compared to only 22 out of 100 players with modern helmets. To calculate the relative risk, the researcher would divide the incidence rate of concussion among players with leather helmets (66/100 = 0.66) by the incidence rate of concussion among players with modern helmets (22/100 = 0.22), equaling a relative risk 3.0 (0.66/0.22 = 3.0). This relative risk not only shows a positive association between leather helmets and concussions (because it is over 1.0), but also implies that players who wear leather helmets are three times more likely to sustain a concussion.[31]

Many jurisdictions will only admit epidemiologic evidence if the relative risk is greater than 2.0—a level that permits an inference that the disease was more likely than not caused by the agent in question. Others courts reject this reasoning and will admit epidemiologic studies with a relative of 2.0 or less as evidence of causation, thereby leaving the sufficiency of the evidence to the jury to decide.[32]

ASSOCIATION VS. CAUSATION

A basic tenet of epidemiology is that an association does not equal causation. Rather, causation may only be inferred after a researcher considers all known evidence in light of scientifically recognized guidelines.

The Bradford Hill criteria provides a number of factors for researchers to consider in assessing causation, including: (1) the existence of a temporal relationship; (2) strength of the association; (3) dose-response relationship; (4) replication of the findings; (5) biological plausibility (coherence with existing knowledge); (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge. While not all factors must be present for a causal relationship to exist, an assessment of causation requires this analysis.[33]

For years the NFL has maintained that there is no scientific evidence directly linking CTE to football-related participation. Nonetheless, since 2002, almost 100 former NFL players have tested positive for CTE, increasing health concerns among players and leading to some early retirements. As the number of players with CTE has continued to grow, so has the chorus of media outlets insisting that football causes CTE and denigrating NFL administrators for failing to acknowledge the same. In March 2016, an NFL executive publically acknowledged for the first time a link between football and CTE.[34]

Despite this acknowledgment, the science behind CTE is far from settled. After all, an association does

not equal causation. With only about 200 cases of confirmed CTE across a variety of disciplines, the study of the disease is still in its "infancy."[35] These limited results are further weakened by inherent selection bias in the CTE's brain bank, making it nearly impossible to extrapolate the results to the general population. As stated by the Third Circuit Court of Appeals, "[t]he NFL's recent acknowledgment may very well advance the public discussion of the risks of contact sports, but it did not advance the science."[36]

What's more, many of the leading CTE studies are based on incomplete or unreliable information. In two studies that collectively examined the brains of 93 former athletes, researchers were able to reconstruct the medical histories of only about half of the subjects, and those were taken second hand from family members. Moreover, virtually none of the published literature on CTE accounts for potential confounding factors.[37]

Some studies have even failed to confirm the presence of CTE under expected circumstances. In a 2013 study of six retired football players from the Canadian Football League, all six players had a history of repeated concussions and progressive neurocognitive decline prior to their deaths, but only three of the men had neuropathological findings consistent with CTE. The study concluded that "it is difficult to establish a definitive link between a history of multiple concussions and CTE" and that further research is required.[38]

CONCLUSION

Dr. Omalu's discovery of CTE has forever changed professional football. Since 2002, the NFL has revised return-to-play guidelines, altered kick-off rules in hopes of reducing collision speeds, instituted new concussion safety measures requiring that an independent neurologist be on the sidelines for every NFL game, banned "crown of the helmet" hits outside of the tackle box (the length of the offensive line), and donated over $100 million dollars to fund brain trauma research and concussion awareness initiatives. Dr. Omalu's research was also the impetus for the NFL's concussion injury litigation in which approximately 5,000 retired players sued the NFL for failing to warn them of the risks of concussions, resulting in an approved settlement of nearly $1 billion dollars.[39]

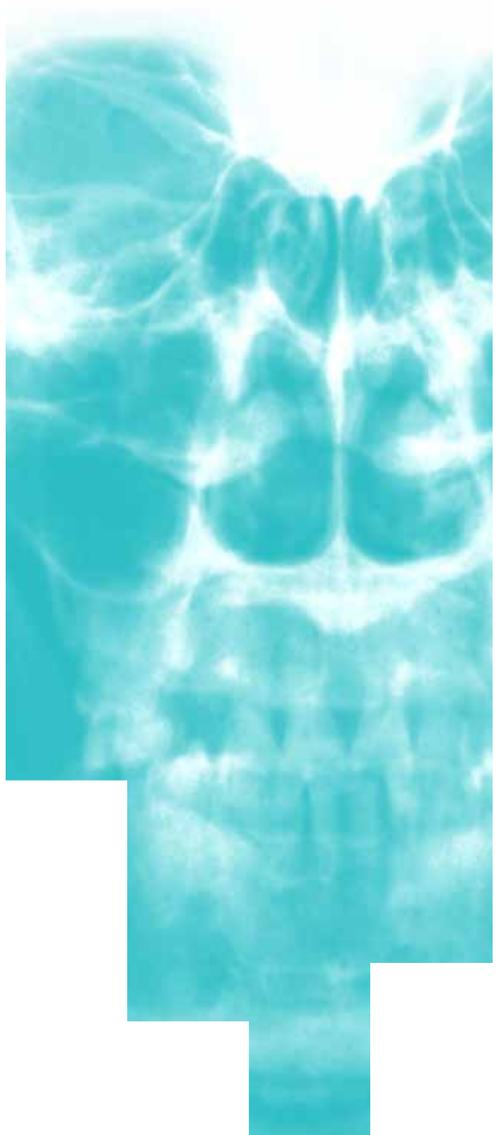
Important and unanswered questions remain about the relationship between football and CTE. Experimental studies of CTE in living subjects need to be conducted, brain banks expanded, and advancements in player safety incorporated at all levels of the game. And at each step along the way, with every study that is conducted, there to guide, interpret, and help researchers better understand America's favorite sport, will be epidemiology.

DRUG & DEVICE APPLICATION

A discussion of CTE and professional football may seem a world apart from pharmaceutical and medical device litigation. However, the underlying scientific principles and methods to support or attack epidemiologic evidence are the same in both contexts. So the next time you are presented with epidemiological evidence, remember this discussion on CTE and ask:

1. *Was the type of study appropriate to the research question?*
2. *Was an appropriate sample size used?*
3. *How were the participants/controls recruited?*
4. *Were confounding factors considered and appropriately accounted for?*
5. *How strong is the association between exposure and disease?*
6. *How wide is the confidence interval?*
7. *Does the relative risk meet the jurisdictional requirement for admissibility?*
8. *Is the association consistent with other research or scientific literature?*
9. *How many Bradford Hill criteria are satisfied?*
10. *Do the numbers suggest causation?*

Practitioners should also consider holding a "Science Day" to educate the judge on epidemiology in cases where such evidence plays a crucial role. "Science Days" have been used in New Jersey and Illinois courts to allow parties to explain the history and background of products and to present relevant medical and scientific literature.[40] Among other things, a well-executed "Science Day" lays the groundwork for later motions to bar expert testimony based on unreliable epidemiologic studies.



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7. *Reference Guide on Epidemiology* at 608-09.
8. *Id.* at 555-57.
9. Hassan Murad et al., *New evidence pyramid,* 0 Evidence Based Medicine 2 (2016), http://ebm.bmj.com/content/early/2016/06/23/ebmed-2016-110401.full
10. *Reference Guide on Epidemiology* at 559.
11. Murad, *supra* note 9, at 2.
12. Id.
13. *See, e.g., DeGidio v. Centocor Ortho Biotech, Inc.,* 3 F. Supp. 3d 674, 684 (N.D. Ohio 2014) (noting the "widespread recognition among the federal courts that case reports alone cannot prove causation.") (internal quotations omitted).
14. Omalu, *supra* note 3, at 132.
15. Bennet I. Omalu et al., *Chronic Traumatic Encephalopathy in a National Football League Player: Part II,* 59 Neurosurgery 1086 (2006).
16. Lauren Ezell, *Timeline: The NFL's Concussion Crisis,* PBS (Oct. 8, 2013), http://www.pbs.org/wgbh/pages/frontline/sports/league-of-denial/timeline-the-nfls-concussion-crisis/
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18. *Reference Guide on Epidemiology* at 572-73.
19. *Id.* at 576.
20. *Id.* at 576-581.
21. *Id.* at 583.
22. *Id.*
23. Interview by Michael Kirk with Ann McKee, Director of Neuropathology, Dep't of Veterans Affairs, Bedford, Mass. (May 20, 2013) http://www.pbs.org/wgbh/pages/frontline/sports/league-of-denial/the-frontline-interview-ann-mckee/
24. *Reference Guide on Epidemiology* at 585.
25. *Id.* at 591.
26. Mayo Clinic Staff, *Performance-enhancing drugs: Know the risks*, Mayo Clinic (Oct. 15, 2015), http://www.mayoclinic.org/healthy-lifestyle/fitness/in-depth/performance-enhancing-drugs/art-20046134
27. James D. Mills et al., *Anabolic Steroids and Head Injury,* 70 Neurosurgery 205, 209 (2012).
28. Boston University CTE Center, *Member of NFL Hall of Fame Diagnosed with Degenerative Brain Disease* (Oct. 29, 2009), http://www.bu.edu/cte/news/press-releases/october-28-2009/
29. *In re Nat. Football League Players' Concussion Injury Litig.*, 307 F.R.D. 351, 399 (E.D. Pa. 2015), aff'd sub nom. In re Nat'l Football League Players Concussion Injury Litig., 821 F.3d 410 (3d Cir. 2016), as amended (May 2, 2016) (internal citation omitted).
30. *Reference Guide on Epidemiology* at 566.
31. Interestingly, some researchers believe that wearing leather helmets—or wearing no helmets at all—might actually decrease the number of head injuries among football players. They theorize that the increased safety of modern helmets emboldens players to hit with greater speed and violence and causes them to use the helmet itself as a weapon. If the hard plastic helmets were removed, the players would alter their tackling habits, thereby reducing head injuries.
32. *Id.* at 566-67, 612, 616.
33. *Id.* at 552, 598-600.
34. Bill Chappell, *In a First, NFL Executive Admits Football is Linked to Brain Damage,* NPR (Mar. 15, 2016), http://www.npr.org/sections/thetwo-way/2016/03/15/470513922/in-a-first-nfl-executive-admits-football-is-linked-to-brain-damage
35. *In re Nat. Football League Players' Concussion Injury Litig.*, 307 F.R.D. at 398.
36. *See In re Nat'l Football League Players Concussion Injury Litig.*, 821 F.3d 410, 443 (3d Cir. 2016), as amended (May 2, 2016).
37. *In re Nat. Football League Players' Concussion Injury Litig.*, 307 F.R.D. at 398-99.
38. Lili-Naz Hazrati et al., *Absence of chronic traumatic encephalopathy in retired football players with multiple concussions and neurological symptomatology,* 7 Frontiers in Human Neuroscience 1 (2013).
39. *See In re Nat'l Football League Players Concussion Injury Litig.*, 821 F.3d at 447.
40. *See, e.g., In re Depakote,* No. 14-CV-847-NJR-SCW, 2015 WL 4775868, at *3 n.2 (S.D. Ill. Feb. 13, 2015).

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DAUBERT AND FRYE AND ANYTHING GOES, OH MY!

You have just bought your dream house in your dream neighborhood. You have paid your dues to the HOA; you have officially "arrived." One of the touted HOA rules is that homeowners with outside pets must have a fence. It makes sense. The HOA wants people to be able to walk through the neighborhood without fear of an uncontrolled dog. You have a dog and understand the rule to mean that you need a solid fence with a working gate. Consequently, you spend a significant amount of money building one.

After moving in, you quickly realize (after getting chased by a bold terrier) that your neighbor has a different interpretation of the rule. "I have a fence," he says. "But it clearly does not work; there is a gap large enough for your terrier to escape. It defeats the purpose of the rule," you proclaim. "The rules do not say it has to be a certain kind of fence or a certain size, just a fence. And I have a fence." What your neighbor has said is true; the rule simply says "fence." He has complied with the letter of the rule, even though his fence clearly is not achieving the purpose of that rule.

This same "open for interpretation" approach to evaluating expert testimony has led to significant disparities among the "fences" erected to protect litigants from the uncontrolled expert witness. While the articulated rules for admitting expert testimony are not that dissimilar across the courts, the judges' varying interpretations of the role of "gatekeeper" results in drastically different decisions depending on jurisdiction, or even within the same jurisdiction. How can litigants best defend themselves against dubious experts in those jurisdictions that provide more leniency in the "gate" standard than we would like? That is the 50 million dollar question…literally. Just this year, differences in control of the "gate" resulted in a trio of verdicts totaling 200 million dollars in one jurisdiction, while the same arguments and theories were excluded as being "litigation driven rather than objectively and scientifically grounded" in another.[1]

THE IMPACT OF THE GATEKEEPER

Merriam-Webster's dictionary defines a gatekeeper as "a person who controls access." Anyone familiar with the law understands the judge is the gatekeeper when it comes to expert evidence. But what does that really mean? Both the federal and varying state rules allow room for judges to interpret their "gatekeeping" role in different ways – which leads to dissimilar results even while following the letter of the rule.

By way of example, the trio of cases totaling 200 million dollars noted above was awarded in the 22nd Judicial District of Missouri. In one of those cases, the court

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opined that "it [was] clear that Plaintiff ha[d] established a factual basis, in terms of qualified and reliable expert testimony, to make a submissible case as to both general and specific causation."[2] No further detail or analysis regarding the expert testimony is provided in that Order. In contrast, the judge in the Superior Court of New Jersey (which granted Defendants' motions to exclude expert testimony) issued a 33-page opinion with five appendices pertaining to the experts' opinions.[3]

In fact, in the second case of the Missouri trio, the judge denied Defendants' Motion to Exclude the Testimony of several of plaintiff's expert witnesses, including two whose methodologies were specifically analyzed, questioned, and ultimately rejected by a similarly situated New Jersey gatekeeper.[4] And while the New Jersey court credited each expert's intelligence, qualifications, reputation, and general effectiveness as a witness, it ultimately determined that the gate was locked as to their expert conclusions.[5] The "dazzling" presentation was not enough to yield that gatekeeper's interpretation of how the fence must be guarded.[6]

In the New Jersey opinion, the court cites regularly to its use of The Reference Manual on Scientific Evidence as guidance to sift through the information available at the expert hearings.[7] The court described its gatekeeping responsibility as one "to assess whether the experts in the field would reasonably rely on methods and data as Plaintiffs' experts have done in this case."[8] In interpreting the letter of the rule in this way, the judge pointed to specific deficiencies in the experts' methods, even noting one of the experts mentioned above "ignored the rudiments of the scientific method…"[9] With respect to the specific causation theory set forth by the other expert whose testimony was admitted in Missouri, the New Jersey court found his "methodology" (described as "re-analyzing old studies and subjectively mingling the various risk factors for each Plaintiff in order to prove ovarian cancer *by the numbers*") was not a methodology that would be reasonably relied upon by other experts in the field.[10]

Ultimately, the opinions of these two witnesses rose or fell according to the forums' view of its gatekeeping role – they were allowed to present their "methodology" to juries in Missouri, but were denied passage through the gate in New Jersey because "their areas of scientific inquiry, reasoning, and methodology [were] slanted away from objective science and towards advocacy."[11] This begs the question: is the stark difference in guarding the fence against the same experts a result of the varying expert standards in those two jurisdictions, or tied to the judges' views of their roles as gatekeepers?

SO, WHAT IS THE STANDARD?

For many years, the standard known as *Frye* governed expert opinion admissibility, essentially universally. The *Frye* standard asked whether the evidence was "sufficiently established to have gained general acceptance in the particular field to which it belongs."[12] After the Supreme Court's *Daubert* decision, the prevailing standard became a series of factors for judges to consider.[13] The *Daubert* factors were later codified in Federal Rule of Evidence 702:

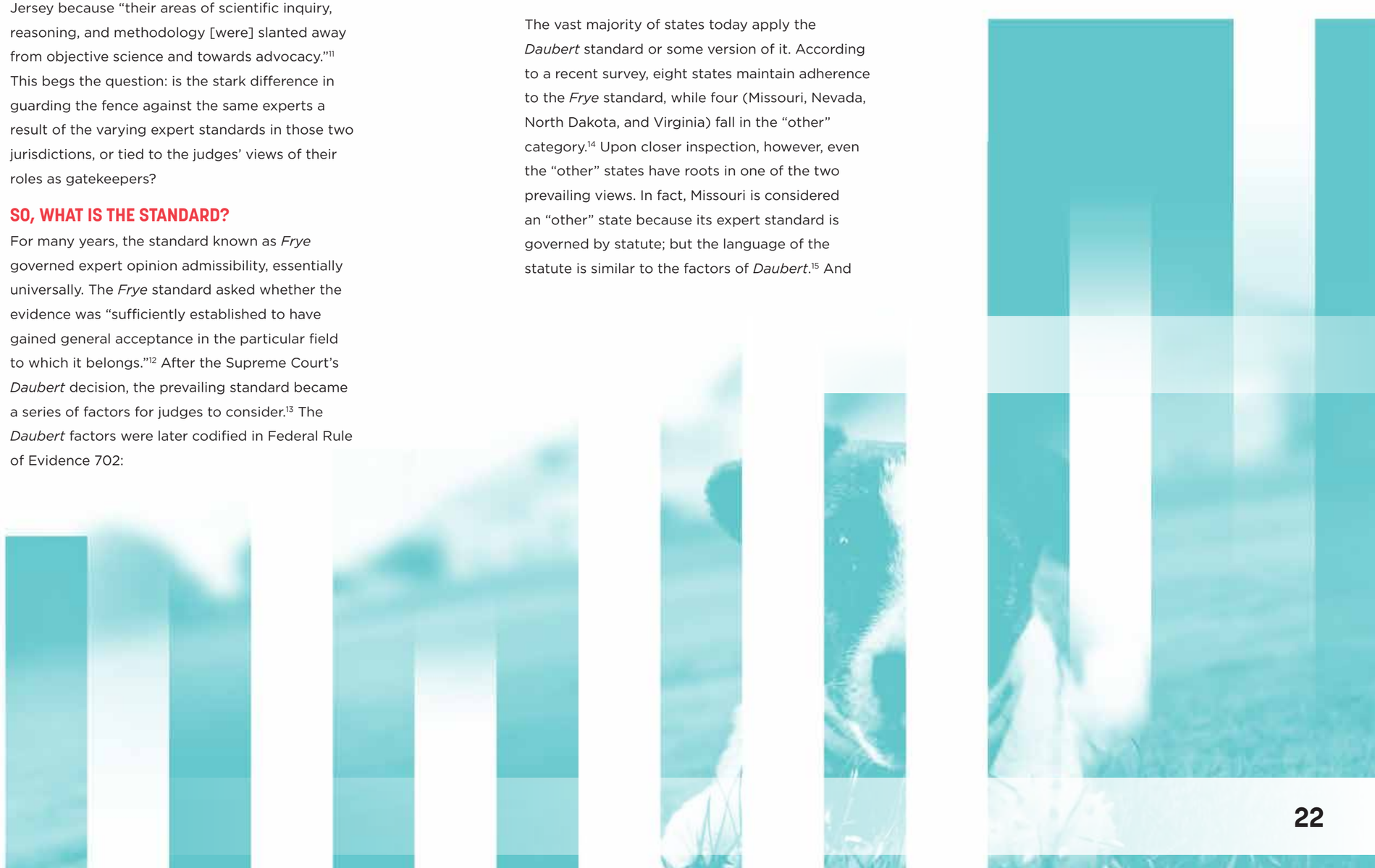
(a) the expert's scientific, technical, or other specialized knowledge that will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

The vast majority of states today apply the *Daubert* standard or some version of it. According to a recent survey, eight states maintain adherence to the *Frye* standard, while four (Missouri, Nevada, North Dakota, and Virginia) fall in the "other" category.[14] Upon closer inspection, however, even the "other" states have roots in one of the two prevailing views. In fact, Missouri is considered an "other" state because its expert standard is governed by statute; but the language of the statute is similar to the factors of *Daubert*.[15] And even the District of Columbia Court of Appeals – the original *Frye* jurisdiction – recently overturned its application of the *Frye* test in favor of *Daubert*.[16] In its opinion, the court noted: "General acceptance means just that; the answer cannot vary from case to case."[17] Only time will tell if *Daubert* will, in fact, lead to less variance from case to case in the D.C. Circuit, or whether variance will continue based on the gatekeepers themselves.



WILL CHANGING THE LAW "HELP" THE GATEKEEPERS?

We know that different jurisdictions apply different standards. We know that even similar standards can, and often are, interpreted in different ways by different judges. We know this leads to drastically different outcomes depending on the judge and venue. But unless and until the Supreme Court clarifies a more consistent *interpretation* of the standard, what can we do to change it or at the very least better prepare ourselves for the variances?

Some have advocated a stronger push for a universal standard, or to at least urge the adoption of *Daubert* by states that have not yet adopted some form of it. The Sunshine State had this same idea just a few years ago. In 2013, the Florida legislature passed House Bill 7015, a hotly contested piece of legislation to formally adopt *Daubert*.[18] Prior to the bill's passage, Florida followed the *Frye* test.[19] Surrounding the debate was the idea that *Daubert* was more stringent and would subject expert witnesses to greater scrutiny before presenting opinions to a jury.[20] The bill was championed "as a way to cut back on 'junk science' and civil-litigation costs."[21]

But the jury is still out on whether *Daubert* is the "better" standard. In fact, the Florida Bar Board of Governors voted in December of 2015 to maintain the *Frye* standard despite the legislation.[22] The Florida Supreme Court heard oral argument in September, 2016 to determine the prevailing standard.[23] Both practical and political questions abound, with strong proponents on both ends of the spectrum (and both sides of the "v") advocating for each position.

Meanwhile, Missouri is setting the stage for an expert standard battle of its own. Missouri case law acknowledges the statutory standard language is nearly identical to *Daubert*. In fact, *Daubert* is intended to provide guidance in interpreting the statute, with the caveat that the statute governs where the two diverge.[24] In response to a push for tort reform in the state, Missouri Senate Bill 59 to formally adopt *Daubert* was passed through both houses in 2016.[25] But Missouri Governor Nixon vetoed the bill, claiming it "does away with Missouri's well-established criteria on expert testimony and replaces it with a much more intricate, complicated and costly procedure."[26]

Politics aside, regardless of the standard you favor, there remains the question how much of a difference the specific standard actually makes. Though *Daubert* is often described as a more stringent standard, there are studies suggesting *Daubert* actually allows gatekeepers to substitute their own interpretation and methods of analyzing expert testimony and evidence.[27] A recent article exploring the impact of *Daubert* from a statistical standpoint even suggests little difference in judicial outcomes between *Daubert* and *Frye*.[28]

The Missouri versus New Jersey example described above is telling in this regard. The high dollar verdicts were from Missouri, a state close in form to *Daubert*, while summary judgment was granted in New Jersey, a state which follows a standard most people say is far less stringent than *Daubert*. Only time will tell if it is the standard, the judges, or the political environment that really makes the ultimate difference.

WHAT ELSE CAN WE DO?

BETTER EDUCATION?

Perhaps the solution is to better educate ourselves and our judges. Highly technical and specialized scientific concepts are finding greater importance in litigation, particularly as technology advances. In a system that can produce such drastically different results depending on a standard or a specific judicial interpretation, there is only so much we can control. But one thing we can control is the depth of knowledge we have on the technical and scientific concepts. This, in turn, can be better relayed to our judges to give them a deeper understanding of these complex issues. In a system full of gatekeeping

TODAY'S LITIGATION CLIMATE CALLS FOR THINKING OUTSIDE OF THE BOX FOR WAYS TO MAKE YOUR VOICE HEARD, REGARDLESS OF THE FENCE YOU FACE.

and fences we cannot always predict or trust, we should take better control of the things we can.

CREATIVITY?

Acknowledging the variances between and within jurisdictions should equip us to confront these issues with more creative and effective solutions. Consider requesting a "science day" in court, which are becoming more popular for this very reason. A "science day" can be a good opportunity to present the technical and scientific issues in a clear and concise way prior to *Daubert* or other hearings on expert testimony. This is an important tool in any litigation that will present highly technical or complex scientific, epidemiological, or toxicological concepts. Today's litigation climate calls for thinking outside of the box for ways to make your voice heard, regardless of the fence you face.

KNOWING THE JUDGE?

Above all else, it is of critical importance to not only know the standard used in your jurisdiction, but the *way* that gate is controlled by your judge. This will not only impact your strategy in motion practice, but should impact which expert(s) you designate. One expert's methodology may play better under a *Daubert* approach than a *Frye* approach, or vice versa. It is important to consider these issues in light of who is controlling your gate. This makes critical thinking about the "big picture" of litigation more important than ever and can be a powerful tool if executed timely and effectively.

FACE THE FENCE TO UNLOCK THE GATE.

There is not, and may never be, consistency in how the fence is controlled or how the gate is opened. But being armed with the knowledge of these challenges will allow you to better craft your strategy to face the unknown fences you will encounter and the gates you will need to unlock.

1. Compare *Gloria Ristesund v. Johnson & Johnson et al.* (Mo. Cir. May 17, 2016), *Jacqueline Fox v. Johnson & Johnson et al.* (Mo. Cir. Feb. 26, 2016), and *Deborah Giannecchini v. Johnson & Johnson et al.* (Mo. Cir. Oct. 27, 2016), No. 1422-CC09012-01 with *Brandi Carl v. Johnson & Johnson et al.*, No. ATL-L-6546-14 (N.J. Super. Ct. Law Div. Sept. 2, 2016) and *Diana Balderrama v. Johnson & Johnson et al.*, No. ATL-L-6540-14 (N.J. Super. Ct. Law Div. Sept. 2, 2016).
2. *Hogans v. Johnson & Johnson*, 2015 WL 10353123, *2 (Mo. Cir. Jan. 26, 2015).
3. *Carl v. Johnson & Johnson*, 2016 WL 4580145 (N.J. Super. Ct. Law Div. Sept. 2, 2016).
4. Compare *Ristesund v. Johnson & Johnson*, 2016 WL 2770656 (Mo. Cir. May 17, 2016) with *Carl v. Johnson & Johnson*, 2016 WL 4580145 (N.J. Super. Ct. Law Div. Sept. 2, 2016).
5. *Carl*, 2016 WL 4580145 at *15, 18.
6. *Id.* at *15.
7. *Id.* at *2.
8. *Id.*
9. *Id.* at *16.
10. *Id.* at *19.
11. *Id.* at *21.
12. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).
13. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).
14. Michael Morgenstern, *Daubert v. Frye – A State-by-State Comparison, The Expert Institute* (Sept. 18, 2016), https://www.theexpertinstitute.com/*daubert*-v-frye-a-state-by-state-comparison/.
15. Mo. Ann. Stat. § 490.065 (2016).
16. *Motorola, Inc. v. Murray*, 2016 WL 6134870 (D.C. Oct. 20, 2016).
17. *Id.* at *3 (internal citation omitted).
18. 2013 FL H.B. 7015 (2013).
19. Eric Giunta, *Rick Scott Signs Expert Witness Standard Overhauls into Law*, Sunshine State News (June 4, 2013), http://www.sunshinestatenews.com/story/rick-scott-signs-expert-witness-standard-overhauls-law.
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21. *Id.*
22. Gary Blankenship, *Frye standard endorsed by Board of Governors*, The Florida Bar News (Jan. 1, 2016), https://www.floridabar.org/__85256AA9005B9F25.nsf/0/03A3F1132F4308A685257F1D00698136?OpenDocument.
23. W.J. Kennedy, *Daubert vs. Frye: Florida Supreme Court sets oral arguments over expert testimony standard*, Florida Record (Apr. 13, 2016, 11:43 am), http://flarecord.com/stories/510714673-florida-supreme-court-sets-oral-arguments-over-expert-testimony-standard.
24. *State Bd. of Registration for Healing Arts v. McDonagh*, 123 S.W.3d 146, 155 (Mo. 2003).
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26. Office of Missouri Governor Jay Nixon, *Gov. Nixon highlights reasons for vetoes in advance of veto session*, (Sept. 13, 2016), https://governor.mo.gov/news/archive/gov-nixon-highlights-reasons-vetoes-advance-veto-session.
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28. *Id.* at 21.

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