AMERICAN BAR ASSOCIATION
Tort Trial and Insurance Practice Section

Spring 2024

COMMITTEE NEWS

Toxic Torts and Environmental Law

When Faced with Emerging, Untested Science, Don't Forget Amended Federal Rule of Evidence 702

Carter F. Thurman
Hollingsworth LLP

***Carter Thurman** is a partner at Hollingsworth LLP in Washington, DC, where he focuses on product liability, toxic tort, environmental, and commercial litigation involving contract disputes.*

Toxic tort litigation involving emerging contaminants presents distinct challenges due to the complex interplay of law and science. Faced with an array of new and still-evolving scientific evidence, trial courts have a particularly important responsibility in serving as gatekeepers against expert testimony based on speculation or hypotheses rather than tested and reliable scientific evidence. Too often in the past, trial courts have abdicated their gatekeeping responsibility and passed these challenges off to juries that are even less equipped to distinguish between scientifically reliable and scientifically unreliable opinions.

On December 1, 2023, Federal Rule of Evidence 702, which governs the admissibility of expert testimony in federal courts, was amended for the express purpose of clarifying and confirming the trial court's gatekeeping responsibility in these situations. The aim of the recent amendments to Rule 702 is to provide clear guidance for federal judges, ensuring a more consistent and rigorous approach to the admission of expert testimony across federal courts. By doing so, the amendments

Read more on page 11

In This Issue

- Amended Federal Rule of Evidence 702 1
- Chair Message 2
- Editor Message 3
- Forever in Focus: Trends in PFAS Litigation and Regulations 4
- Ethylene Oxide: The interplay Between Exposure and Human Health Risk 5
- Understanding Jurors in a Post-Covid Landscape 6
- Using the Plaintiff Fact Sheet Process to Your Advantage – Lessons Learned from Decades of Experience... 7

Chair Message

Jennifer Seme
Rawle & Henderson, LLP

Jennifer Seme *is a partner in the Philadelphia office of Rawle & Henderson and her practice is focused on product liability, toxic torts, and environmental litigation.*

I want to start by taking a moment to thank Dan Strecker for his work pulling together the first TTEL Newsletter since Covid hit in 2020. We hope this will be the first of many to come. To that end, if you have an idea for an article, please contact Dan at dstrecker@HarrisBeach.com.

The TTEL Annual Conference kicks off with a reception on April 11th at the tranquil Omni Montelucia in Scottsdale, Arizona. The two-day program covers all things PFAS from regulatory action to environmental remediation to the status of multiple lines of PFAS related litigation. We also have panels discussing Nuclear Verdicts, Artificial Intelligence, and recent developments in litigation involving other toxic chemicals. The hotel block is nearly at capacity, so register soon through this link: https://web.cvent.com/event/C387D3FD-40A4-4073-BCDA-919C0240614D/summary

Thank you to our TTEL Conference Sponsors!

GOLD SPONSORS

ankura

RAMBOLL

EXPOSURE ASSESSMENT CONSULTING

SILVER SPONSOR

ENSAFE
creative thinking. custom solutions.

BRONZE SPONSORS

MRC

CMBG3 LAW

HARRIS BEACH PLLC
ATTORNEYS AT LAW
Discover True Engagement

RHP RISK MANAGEMENT

TTEL wants to hear from you, our members. Please contact the leadership team with ideas about articles, seminars, webinars, or other content regarding toxic torts and environmental litigation. Please sign up for TTEL emails and for updates through ABA Connect so you can stay up to date on Committee activities.

Editor Message

We are pleased to present this issue of the TIPS TTEL Spring Newsletter. It features five articles from prominent attorneys, scientists, and other legal professionals addressing diverse issues currently impacting toxic tort and environmental litigation: how to understand and apply the recent amendments to Federal Rule of Civil Procedure 702; a review of the history and current trends in the ever-burgeoning PFAS litigation; understanding ethylene oxide exposure and risk assessment; strategies for selecting, and presenting evidence to, post-COVID jurors; and leveraging the plaintiff fact sheet process in federal multi-district litigation.

We hope you enjoy it. We thank the authors for their generous contribution of time and energy to supply these articles, and section members for their support of this publication. Special thanks to Committee Chair, Jennifer Seme, for her help with this Newsletter, and for her leadership.

Committee members and nonmembers are encouraged to submit article proposals for upcoming Newsletters, the next of which will be published this coming summer. Articles should be between 1,000 and 3,000 words and must be relevant to legal, medical, scientific, or technological topics that impact environmental and toxic tort litigation today, or that would otherwise be of interest to those currently practicing toxic tort and environmental law. Please submit proposed articles via email, in Word format, to: dstrecker@harrisbeach.com.

Dan Strecker
Harris Beach

***Dan Strecker** is a member of Harris Beach's Mass Torts and Industry-Wide Litigation practice group. He leads national coordinating counsel teams defending manufacturers against complicated toxic tort and product liability claims across the country. Dan additionally concentrates in the areas of complex commercial litigation, government compliance, and white-collar defense/internal investigations.*

Connect with Toxic Torts and Environmental Law *website*

Stay Connected with TIPS

We encourage you to stay up-to-date on important Section news, TIPS meetings and events and important topics in your area of practice by following TIPS on **Twitter** @ABATIPS, joining our groups on **LinkedIn**, following us on **Instagram**, and visiting our **YouTube** page! In addition, you can easily connect with TIPS substantive committees on these various social media outlets by clicking on any of the links.

Forever in Focus: Trends in PFAS Litigation and Regulations



Paul LaFata, Marina Schwarz, Nathan Williams

Paul LaFata *represents and advises clients in complex product liability and mass tort litigation, including as national counsel in multidistrict and class-action proceedings. Mr. LaFata develops national defense strategies and has litigated cases from inception through trial and appeals in state and federal courts nationwide, including on winning trial teams in bellwether trials.*

Ms. Schwarz *takes on high stakes matters in the pharmaceutical, chemical, and environmental sectors. She is a recognized thought leader on perfluoroalkyl substances (PFAS), developed a dedicated PFAS website showcasing Dechert's expertise in this area, and regularly advises clients on PFAS-related litigation and transactional matters, including complex mass torts and class actions, legislative and regulatory compliance, public and government relations, pre-investment risk assessments, and business transactions.*

Nathan Williams *is a member of Dechert LLP's product liability and mass torts practice and focuses on complex product liability, mass torts and environmental exposure liability. He has experience defending clients against tort claims involving pharmaceutical product use and environmental exposure, navigating complex fact and expert discovery, and advising clients on litigation risk and settlement.*

Per- and polyfluoroalkyl substances (PFAS) have historically been used by a wide range of industries for many applications across the aerospace, biotechnology, construction, electronics, personal care, pharmaceutics, and textile industries, among others.[1] For the past two decades, and increasingly, PFAS have been the subject of litigation and regulatory scrutiny due to the ubiquity and persistence of certain PFAS compounds and allegations about exposure-based health risks. Spurred by news reports, political advocacy, documentaries, and popular media, PFAS impacts are widespread with industrial and commercial consequences. In response, many companies are actively working to assess and reduce or eliminate PFAS use in their business process.

Background

PFAS comprise thousands of chemical compounds known for their water-resistant and stain-resistant properties, as well as their stability.[2] Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) are among the more well-known PFAS compounds, sometimes referred to as "legacy" materials. For decades, PFAS have been used in the production of a wide range of products, such as apparel, paper goods, upholstery, floor coverings, wire insulation, surface coatings, cleaning products, personal care products (like cosmetics, shampoos, and dental floss), and firefighting foam.[3] Given the long and widespread use of these chemicals, the vast majority of Americans have had measurable exposure to PFAS, as demonstrated by data showing detectable levels of certain PFAS in the blood of most Americans.[4] And, though there have been efforts to phase out reliance on PFAS and to identify replacements, regulators continue to investigate and evaluate historical use of and continued exposure to many of these legacy chemicals. There is simultaneously growing regulatory and public scrutiny of materials that replaced these legacy PFAS, some of which are themselves PFAS.

The Present and Future of PFAS Litigation

Litigation related to PFAS began in earnest in the early 2000s and has since grown. Certain PFAS – so far primarily PFOA and PFOS—have been alleged to be capable of causing a variety of health outcomes and to persist in the environment. In regions of the country where PFAS have been found in drinking water, groundwater, and soil, actions have been brought by exposed individuals, state attorneys general, and water

Read more on page 15

Ethylene Oxide: The interplay Between Exposure and Human Health Risk

Alex LeBeau, PhD, MPH, CIH
Exposure Assessment Consulting, LLC

***Alex LeBeau**, PhD, MPH, CIH, is the owner of Exposure Assessment Consulting, LLC, in Orlando, Florida. As a toxicologist and certified industrial hygienist with more than sixteen years of experience, he has evaluated environmental and occupational exposure health claims in addition to performing chemical and biological agent exposure and risk assessments.*

In recent years, acute awareness has been focused on individual ethylene oxide health impacts by community stakeholders, regulators, and attorneys across the United States. Following several investigations in the 2010's, ethylene oxide received compounding scrutiny from a number of regulatory agencies and non-governmental organizations (NGOs) on the potential health hazards the compound presents, from both occupational and environmental exposures. This newfound exposure recognition – driven mainly by fugitive community exposures – has led to evolving assessments and methods to quantify community human health risk. Subsequent to these investigations have been the claims that ambient ethylene oxide exposures have caused cancer. The impacts that these exposures have on human health are heightened by many in the press, numerous communities, and at the federal level. An understanding of where, how, and why ethylene oxide exposures are occurring is necessary to contextualize current human health exposure and risk assessment efforts.

Ethylene oxide is a colorless, sweet-smelling flammable gas at room temperature that has a variety of uses in everyday life. At some point you have used products made with ethylene oxide, whether you know it or not. In fact, more than 97% of ethylene oxide is used as a chemical intermediate in the production of other industrial products, including surfactants, adhesives, perfumes, textiles, personal care items, and even the antifreeze in your vehicle. In addition to serving as a manufacturing intermediate, ethylene oxide is a registered EPA active ingredient for use as a sterilizing agent in a number of different healthcare scenarios. Ethylene oxide is also available for spice and herb sterilization (e.g., licorice, sesame seeds, spearmint, etc.) with established residue thresholds. Ethylene oxide is also found in tobacco smoke and a byproduct of fuel combustion, both serving as additional environmental exposure sources.

Historically, ethylene oxide exposure concerns centered mainly around occupational exposure scenarios. Health-based occupational exposure thresholds are established to be protective of those that are using the material daily as part of the work process. Manufacturing systems utilizing ethylene oxide are typically closed systems (e.g., sealed) because of the chemical's physical characteristics during use. The use of ethylene oxide as a sterilant may create more unique exposure scenarios than manufacturing because the sterilization systems may have exposure points that cannot be easily engineered out of the process.

Read more on page 23

Understanding Jurors in a Post-Covid Landscape

Derek M. Stikeleather
Goodell, DeVries LLP

Derek Stikeleather *chairs the Appellate Practice Group at Goodell, DeVries in Baltimore. In 2021, he persuaded the Appellate Court of Maryland to reverse the largest birth-injury verdict in US history, a $229 million verdict that produced a $205 million judgment, and enter JNOV for the defendant Hospital.*

Carrie J. Williams
Goodell, DeVries LLP

Carrie Williams *is a partner at Goodell DeVries and a member of the firm's Appellate Practice Group. She represents clients across the firm's practice groups in pre-trial and appellate matters. Prior to joining Goodell, Carrie spent 16 years as an appellate attorney for the State of Maryland*

Introduction

The COVID-19 pandemic touched nearly every aspect of modern life. Our families, schools, workplaces, religious institutions, and healthcare providers were all affected by the worst global healthcare crisis in 100 years. Even though the worst of the pandemic is (hopefully) behind us, some of its effects are just now becoming clear. One example is jurors' altered attitudes towards scientific evidence, experts, and institutions. Jurors are more skeptical—and sometimes even hostile—to broadly accepted scientific principles and mainstream scientists. This article will examine why the pandemic has given rise to what we have called "QAnon Jurors," how to spot them, and how, if at all, to persuade them.

A. The COVID-19 Pandemic's Effect on our Decision-Making and Worldview: the Rise of "QAnon Jurors."

Research shows that when people are confronted with death and their own mortality, they often gravitate toward their pre-existing belief system and worldview as a way to manage anxiety.[1] Known as "Terror Management Theory," social scientists have found that, in times of prolonged turmoil and uncertainty, this desire to seek comfort in one's own worldview can promote ideological extremism in individuals and, on a societal level, increased polarization.[2] During the COVID-19 pandemic, this natural tendency to lean into extreme versions of one's pre-existing belief system led some people to minimize the threat of the virus and ignore the warnings of public health professionals.[3] These same people grew distrustful of scientists and other experts, eschewed expert opinions in favor of "doing their own research," and ultimately resorted to conspiracy theories when faced with evidence of sky-rocketing COVID infection rates and death.[4]

The pandemic's existential threat to global public health and the related economic and social upheaval pulled most people from their routine face-to-face interactions with community institutions and public events and drew many into online communities. While widely available digital communication allowed a remote-work revolution that saved the economy, it also allowed online fringe conspiracy groups to thrive.

One of the most highly publicized online fringe groups is QAnon, which emerged in 2017 among far-right Americans. QAnon revolves around a core belief that a cabal of Satanic and cannibalistic pedophiles operate a global child sex-trafficking ring that supports the Democratic Party and opposes Donald Trump. It is fed by anonymous

Read more on page 28

Using the Plaintiff Fact Sheet Process to Your Advantage – Lessons Learned from Decades of Experience with High-Volume MDLs

In today's legal landscape, the efficient handling of case-related information is more critical than ever, especially in the fast-growing arena of multidistrict litigation (MDL), which now makes up over 70% of the total US civil case docket.

The caseload has grown so much over the past decade, that the MDL subcommittee of the Advisory Committee on Civil Rules has been diligently working towards establishing a new Rule 16.1 in the Federal Rules of Civil Procedure. This new rule hopes to provide guidance on managing these large and complex matters.

While opinions on the breadth and efficacy of the new rule vary, Defense attorneys are hoping to establish a better system to prevent unvetted or frivolous claims from being brought into an MDL. A cornerstone of this system lies in the early vetting process facilitated by the Plaintiff Fact Sheet (PFS). PFSs serve as standardized forms deployed prior to extensive discovery and are meant to gather key details from plaintiffs in mass tort and MDL cases.

These standardized documents are essential tools in the preliminary discovery phase, designed to collate critical details from plaintiffs in mass tort and MDL scenarios. The strategic use of PFSs aids in the efficient organization, evaluation, and prioritization of claims, thereby equipping legal teams with the necessary insights to evaluate case merits, discern patterns, and formulate comprehensive strategies. As an organization who has spent the last four decades working alongside premier defense teams on the nation's most high-stakes, high-volume litigations, MRC has a comprehensive understanding of the intricacies involved in the PFS process and its downstream effects on case outcomes.

In this article, we want to share with you best-practice strategies that not only mitigate the inherent 'data problem' associated with high-volume cases but also pave the way for substantial cost savings for clients, more favorable case resolutions, and ultimately, a smoother litigation experience for defense teams. As we dive into the nuances of managing complex litigation data, it becomes evident that efficiently managing the preliminary stages of the PFS process can significantly influence the trajectory of high-volume matters, ensuring not just legal success but also peace of mind for the defense team involved.

Natalie Baker Reis
Medical Research Consultants

A graduate of The University of Texas School of Law and a former practicing attorney, Natalie Reis helps lead business development efforts for Medical Research Consultants (MRC), a litigation support and healthcare compliance provider that specializes in PFS Management, Record Retrieval, Nurse Review & Analysis, and MMSEA Reporting services. For more information on MRC, please visit www.mrchouston.com.

Brittnee Williams
Medical Research Consultants

A graduate of Cornell University's Brand Management Program, Brittnee Williams brings over a decade of expertise in marketing and branding within the healthcare and technology sectors. She now spearheads marketing initiatives as the Manager of Marketing at Medical Research Consultants (MRC), a leading provider of litigation support services, based in Houston, Texas.

Strategies

Begin with end in mind.

When developing a PFS, defense teams should have their ultimate objectives at the forefront. The principle of "beginning with the end in mind" entails foreseeing the crucial decisions that will emerge when later assessing the risk to the client. Often, PFS documents are filled with a vast array of questions that, on the surface, appear comprehensive. However, as legal teams delve deeper, they may discover that the questions critical for transitioning a plaintiff from a low- to high-risk category are not directly asked or answered in the PFS. This gap forces the legal team to engage in more extensive—and expensive—analysis of multiple questions to find the answers they need. To avoid these pitfalls, it is vital to establish the criteria for each priority group or subgroup during the PFS formation phase. This proactive approach allows for crafting questions that align directly with your evaluation criteria, streamlines the risk assessment process, and economizes time and resources while refining your legal strategy. This equips you to navigate the complexities of multidistrict litigation with enhanced precision and confidence.

What does an acceptable PFS response look like?

Navigating the complexities of PFSs demands a clear understanding of what qualifies as an acceptable response. This involves determining the sufficiency of answers for each PFS question, identifying the most beneficial data format, and deciding between structured or open-ended response options. For instance, when asking about exposure dates, would a specific date format be more useful than an open text field? Can certain questions be better addressed through a predefined list of options rather than allowing for any text input? It is also crucial to establish clear guidelines on what types of responses will be deemed unacceptable. By answering all of these questions, and using ePFS software, you can automate the flagging of deficiencies without needing to manually review each document.

Ask the important questions first.

After identifying the key data points necessary for your analysis and establishing criteria for acceptable responses, position these questions early in the document. In our experience responses tend to be most detailed and comprehensive at the start, where engagement is highest. As respondents progress through the form, fatigue can set in, leading to shorter, less informative answers, or even omitted responses. Ensuring that vital information is solicited first maximizes the likelihood of collecting complete and accurate data.

Use software to your advantage.

Harnessing the power of software is essential for efficient litigation support. It is crucial to ensure that every piece of data collected is accurately entered into a well-

The strategic use of PFSs aids in the efficient organization, evaluation, and prioritization of claims, thereby equipping legal teams with the necessary insights to evaluate case merits, discern patterns, and formulate comprehensive strategies.

structured database. Quick data capture and reporting capabilities will significantly accelerate your decision-making process for the case. Proper database configuration is key, ensuring that data is stored in its appropriate format—dates as dates, numerical values as such, and employing picklists whenever possible to standardize responses for streamlined reporting. An effective database system should enable automatic identification of missing information, computation of total claims, and sorting of plaintiffs into defined risk categories. Moreover, centralizing provider details in one database significantly expedites the process of record retrieval. We have found that a properly formed PFS paired with a database software solution can greatly narrow the focus to high-priority cases, particularly for bellwether selection, effectively reducing the need for extensive record retrieval and nurse review efforts.

Benefits

Effective management of PFS data ensures vital data is securely stored and readily accessible, empowering legal teams with the insights needed to make informed decisions, construct stronger arguments, and streamline case preparation. By employing the strategies listed above during the PFS formation, capture, and review process, Defense teams see the following benefits:

- Automating portions of the deficiency review process that would otherwise be spent performing manual tasks.
- Developing a data-driven case strategy, enabling quick adjustments as the case evolves
- Strategically allocating budget in alignment with case risks to minimize discovery costs and scope.

Digital PFS Solutions

An additional benefit of utilizing a digital plaintiff fact sheet solution is its capability to refine the management of PFS data. This technology offers a seamless approach to organizing these crucial documents.

Legal experts gain access to a cohesive platform designed for efficient plaintiff data oversight, empowering them to:

- **Build Strategy Sooner:** Gain immediate insight into plaintiff data, facilitating improved classification, prioritization, and the formulation of discovery strategies based on the most relevant data available.
- **Control Project Costs:** Through early case assessment, align record retrieval and medical review services with case risk and priority, optimizing resources and minimizing unnecessary expenditures.
- **Ensure Security and Compliance:** Choose a solution dedicated to protecting client data that's built on a foundation of HIPAA compliance, with

When developing a PFS, defense teams should have their ultimate objectives at the forefront. The principle of "beginning with the end in mind" entails foreseeing the crucial decisions that will emerge when later assessing the risk to the client.

a robust security infrastructure and data backup measures to safeguard client information.

This digital approach not only makes PFS data management more efficient but also serves as a strategic asset, allowing legal experts to concentrate on their core strengths—developing compelling case strategies and advocating for their clients.

Conclusion

In the complex world of litigation, effectively managing plaintiff fact sheets stands as a critical component of successful case outcomes. As we anticipate the outcome of Rule 16.1 and its potential to reshape MDL procedures, the critical role of cutting-edge technology and sophisticated data management strategies becomes unmistakably apparent.

Navigating plaintiff fact sheet management requires a balanced approach that combines technological innovation with strategic oversight. Implementing strategies such as key question prioritization, establishing criteria for acceptable responses, and governing data formats are vital for enhancing data quality. This approach not only improves efficiency, but also enables the foundation of a better case strategy. As defense firms increasingly focus on utilizing the early vetting capabilities of the PFS to filter out unvetted or frivolous claims in MDLs, we will hopefully see the tide turn on the number of multidistrict litigation cases that make up the US civil case docket.

When Faced... continued from page 1

seek to ensure expert evidence presented in court is reliable, thereby improving the fairness and integrity of the judicial process. Practitioners challenging unreliable expert testimony should understand both the amendments, and the Committee Notes and deliberative papers, so they can help guide judges to understand the amended rule.

Rule 702 was modified in response to critiques highlighting the failure of many courts to properly hold proponents of expert testimony to their preponderance of the evidence standard to establish the reliability of an expert's factual bases, methodologies and—most importantly—application of those facts and methodologies in reaching their conclusions. Rule 702 was amended as follows (new language underscored; deleted language stricken):

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise **if the proponent demonstrates to the court that it is more likely than not that**:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the ~~expert has reliably applied~~ **expert's opinion reflects a reliable application of** the principles and methods to the facts of the case.

Fed. R. Evid. 702 (2023). The revised Rule explicitly demands that all four elements of admissibility be proven by a preponderance of the evidence and stresses that courts must evaluate whether the expert reliably applies their methodology to the facts of the case, not just the reliability of the underlying facts and methodologies used by the expert.

The drafters of the amended Rule provided important guidance as to the meaning of these changes in the Advisory Committee Note and other documents explaining their reasoning and rationales. These materials are generally given great weight in the interpretation of federal rules,[1] and they are particularly important in understanding the Rule 702 amendments given the Advisory Committee's repeated admonition that much of the case law previously applying Rule 702 was wrongly decided. The Advisory Committee Note offers a detailed blueprint for applying the new Rule correctly, spotlighting three pivotal updates. First, the amended Rule "clarify[ies] and emphasize[s]" that the proponent of the evidence must demonstrate by a

preponderance of the evidence that the "proffered testimony meets the admissibility requirements set forth in the rule."[2] No longer should trial courts ignore challenges to the sufficiency of an expert's basis, or to the application of the methodology, and simply let such issues go to the jury as such "rulings are an incorrect application of Rule 702 and 104(a)."[3] Second, the "preponderance [of the evidence] standard applies to the three reliability-based requirements added in 2000 – requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard."[4] Lastly, the amendment clarifies that the validity of facts and methodologies alone does not suffice if their application exceeds their logical extent, ensuring that each expert's conclusion must be directly derived from a sound application of their expertise and methodology—"each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology."[5]

Additionally, the working papers from the Advisory Committee delve deeply into the amended rule's intended meaning, critiquing the frequent permissive approach toward admitting expert testimony and providing specific instances from cases.[6] These cases often imply a default inclination towards allowing expert testimony or suggest that the adequacy of an expert's methodology is a matter for the jury to decide.[7] The Advisory Committee working papers provide extensive examples of courts not properly applying Rule 702.[8] Critics argue that the recent amendments address and rectify over two decades of Rule 702's misapplication, suggesting that case law established on these misinterpretations should now be disregarded.

Although the amendments have only been in effect for a short period, early court decisions indicate a shift towards stricter scrutiny of expert testimony.

Although the amendments have only been in effect for a short period, early court decisions indicate a shift towards stricter scrutiny of expert testimony. For instance, in *In Re Google Play Store Antitrust Litigation*, after unsuccessfully challenging an expert at the class certification stage, Google moved to exclude plaintiffs' same expert economist at the merits stage.[9] This time, Google was armed with the upcoming amendments to Rule 702. The Court, citing the upcoming amendments, noted the preponderance standard's application to each element of Rule 702 and the revision to subpart (d) that requires an expert's opinion to reflect a reliable application of the principles and methods to the facts of the case.[10] The Court referred to the amendments as "an amplification of the existing FRE 702 standards."[11] Ultimately, the Court determined that the expert's model is "not within accepted economic theory and literature" and was "based on assumptions . . . that are not supported by the evidence" and granted Google's motion to exclude the merits opinion.[12]

More recently, in *In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Products Liability Litigation*, the Sixth Circuit affirmed the district court's exclusion under Rule 702 of plaintiffs' sole expert based on a finding that the expert had not

"reliably applied" his methodology to the "facts of the case."[13] While the Sixth Circuit did not directly rely on the amendments to Rule 702, as the amendments went into effect after the district court's decision, the Sixth Circuit noted that "Rule 702's recent amendments . . . were drafted to correct some court decisions incorrectly holding 'that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility.'"[14]

The recent amendments to Rule 702 should have significant implications for upcoming litigations involving novel theories of causation that hinge on largely untested scientific and technical evidence. The amendment's emphasis on the rigorous evaluation of expert testimony's relevance and reliability could impact the admissibility of scientific evidence, especially related to various exposures and its alleged health effects. Practitioners need to understand how Rule 702 was amended and what those amendments are intended to achieve—the requirement of sound science in the courtroom.

Endnotes

1 *See, e.g.*, *Horenkamp v. Van Winkle & Co.*, 402 F.3d 1129, 1132 (11th Cir. 2005); *C.B. v. City of Sonora*, 769 F.3d 1005, 1018 (9th Cir. 2014) (ascribing weight to the advisory committee's note) (citing cases); *In re Cooper Tire & Rubber Co.*, 568 F.3d 1180, 1188 (10th Cir. 2009) (giving persuasive weight to advisory committee notes while interpreting the Federal Rules of Civil Procedure).

2 Appendix A: Rules for Final Approval, Proposed Amendment to the Federal Rules of Evidence, in Committee on Rules of Practice and Procedure January Agenda Book 879, 892 (June 7, 2022), available at https://www.uscourts.gov/sites/default/files/2022-06_standing_committee_agenda_book_final.pdf.

3 *Id.*

4 *Id.* at 893.

5 *Id.* at 894.

6 *See* Administrative Office of the U.S. Courts, *Records of the Rules Committees*, available at https://www.uscourts.gov/rules-policies/records-rules-committees (last visited Mar. 4, 2024).

7 Daniel J. Capra and Liesa L. Richter, Mem. To: Advisory Committee on Evidence Rules Re: Possible Amendment to Rule 702 (Apr. 1, 2022), in Advisory Committee on Evidence Rules May Agenda Book 125, 148 (May 6, 2022), available at https://www.uscourts.gov/sites/default/files/evidence_agenda_book_may_6_2022.pdf.

8 *See, e.g.*, Hon. Patrick J. Schiltz, Report of the Advisory Committee on Evidence Rules (Dec. 1, 2020), in Committee on Rules of Practice and Procedure January Agenda Book 441, 445 (Jan. 5, 2021), available at https://www.uscourts.gov/sites/default/files/2021-01_standing_agenda_book.pdf (explaining that "[t]he Committee has determined that in a fair number of cases, the courts have found expert testimony admissible even though the proponent has not satisfied the Rule 702(b) and (d) requirements by a preponderance of the evidence."); T.D. Schroeder, *Toward a More Apparent Approach to Considering the Admission of Expert Testimony*, 95 Notre Dame L. Rev. 2039 (2020) (analyzing flawed opinions); Capra and Richter, *supra* note 7, at 148 (discussing three pre-2000 cases relied on by plaintiffs to suggest there is a presumption in favor of admitting expert testimony or that whether an expert's methodology has a sufficient basis is a question for the jury).

9 Order re Merits Opinions of Dr. Hal J. Singer, *In re Google Play Store Antitrust Litig.*, No. 3:21-md-02981 (N.D. Cal. Aug. 28, 2023), ECF No. 588.

10 *Id.* at 8-9.

11 *Id.* at 9.

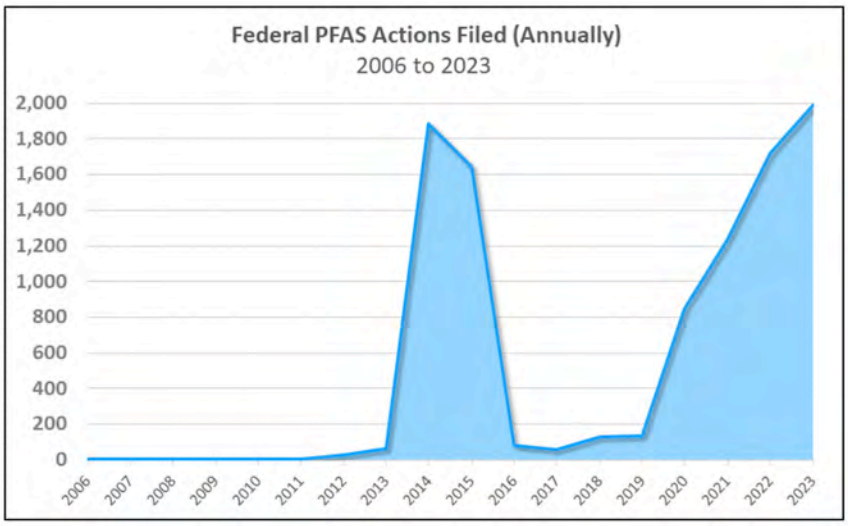
12 *Id.* at 16.

13 No. 22-6078, MDL 2809, 2024 WL 577372, at *5-6 (6th Cir. Feb. 13, 2024).

14 *Id.* at *6 n.7 (citing Fed. R. Evid. 702 advisory committee's note to 2023 amendments). Ultimately, the Sixth Circuit noted that the district court's reasoning was consistent with the updated rule, as the district court placed the burden on the plaintiffs to show that expert testimony was admissible. *Id.* at *3 n.4 (adding that "702(d) was rephrased to emphasize that an expert opinion must 'reflect[ ] a reliable application' of the expert's methodology") (alteration in original).

Forever... continued from page 4

authorities, asserting claims primarily against manufacturers of PFAS-containing materials, such as fluoropolymers (like Teflon™) and firefighting foam, as well as in some instances local processors and waste management companies. Common legal claims include medical monitoring and personal injury based on exposure to PFAS in drinking water, diminished property values due to the presence of PFAS in soil and water wells, and the costs of remediation. Indeed, more than 6,000 cases involving claims primarily arising from the alleged use of PFAS-containing firefighting foam have been consolidated for pretrial proceedings in a multi-district litigation.[5] And multiple eight- and nine-figure verdicts[6] and several high-value settlements (ranging from $17.5 million to over $10.5 billion)[7] have garnered considerable attention, some receiving national media coverage.



Given the perceived litigation successes and continued public scrutiny, PFAS litigation has expanded to additional industries, further along the supply chain, and across the product lifecycle. For example, in 2019, a putative class action was filed against two dozen carpet producers that allegedly used PFAS in their manufacturing processes.[8] In 2020, a roofing materials manufacturer was sued for the alleged release of PFAS into groundwater from the company's facility, as well as from the properties where its products had been installed.[9] The plaintiffs alleged that the manufacturer, which used PFAS-containing roofing granules purchased from a supplier, "participates in the chain of distribution and stream of commerce of roofing materials containing PFAS." In 2023, a class action complaint was filed against a Wisconsin paper mill that allegedly used PFAS in its milling processes and disposed of PFAS-containing waste on nearby properties.[10]

Given the perceived litigation successes and continued public scrutiny, PFAS litigation has expanded to additional industries, further along the supply chain, and across the product lifecycle.

One burgeoning area of litigation has emerged under fraud and consumer protection laws. Allegations typically include false or misleading advertising about a product being safe, natural, or environmentally friendly – claiming that a buyer would not have purchased or would have paid less for the products at issue and sometimes pairing those arguments with requests for medical monitoring. Defendants have included:

- Retailers for marketing allegedly PFAS-containing, disposable plates and bowls as "compostable";[11]

- A feminine hygiene products company, whose menstrual underwear allegedly contained PFAS and were marketed as "organic," "sustainable," and safe;[12]
- Fast food restaurants alleged to use PFAS-containing food wrappers and advertise food as safe;[13]
- Food company that used allegedly PFAS-containing packaging for its popcorn, which was advertised as having only "real," "natural" ingredients;[14]
- Beverage companies whose juice drinks allegedly contained detectable PFAS but were marketed as "all natural";[15]
- Personal care products companies that marketed their oral care products as "naturally sourced and naturally derived ingredients" or "pro-health" but allegedly contained PFAS;[16] and
- Cosmetics companies that represented their mascara products to be "safe," "appropriate for use," or contain "ingredients from nature," though PFAS was an alleged ingredient.[17]

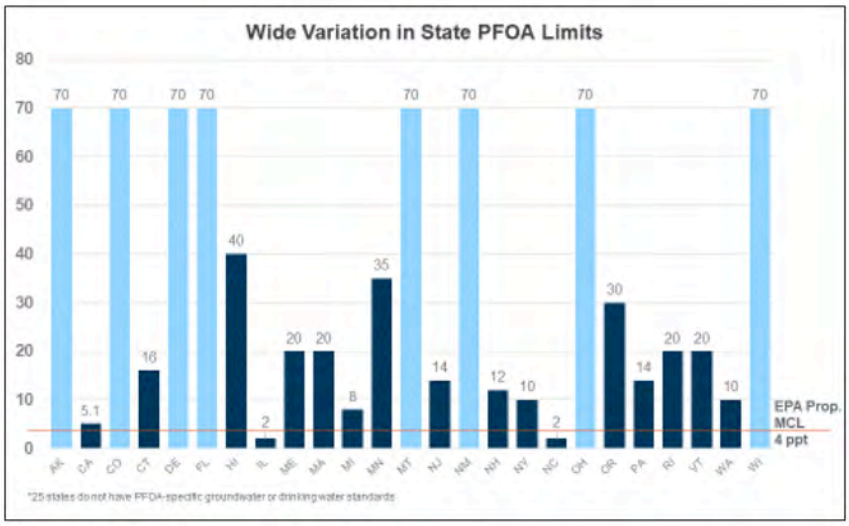
These lawsuits are often triggered by product testing reports. Product testing has already been published on fertilizers,[18] contact lenses,[19] cosmetics,[20] artificial lawn turf,[21] and others. As experience and recent examples show, litigation (or regulation) often follows these disclosures.

PFAS litigation has also taken the form of shareholder actions, alleging failure to disclose material information about potential PFAS liability;[22] actions related to insurance coverage for PFAS-related losses or liabilities;[23] actions against water authorities that distributed PFAS-containing water to consumers,[24] as well as actions by water authorities seeking damages and injunctive relief for water testing and data collection;[25] a class action seeking the establishment of a science panel to study PFAS;[26] citizen suits seeking to abate and enjoin disposal of PFAS-containing wastes;[27] and an action alleging RICO violations by companies involved in the disposal of paper mill waste and compost treatment.[28]

Intensifying Regulatory Activity

On the regulatory front, PFAS use and exposure are governed by an array of varying – and often conflicting - rules, guidelines, and advisories, as the federal government and many state governments have acted independently to regulate PFAS. A number of states have adopted drinking water guidelines or limits for one or more PFAS,[29]

whereas other states are also considering or have proposed standards. While federal agencies, such as the Environmental Protection Agency (EPA), have increasingly sought to coordinate efforts and promulgate standards that may promote uniformity in some areas, navigating the increasingly complex and ever changing PFAS regulatory space is growing more challenging and costly.



Federal agencies have been investigating PFAS for more than a decade. The CDC and ATSDR have been investigating potential associations between PFAS and health outcomes, and that work is expected to continue.[30] Yet, in recent years, under mounting public and political pressure, federal regulatory initiatives have accelerated in the areas of exposure limits, remediation, and reporting, as reflected by the following recent examples:

- **Drinking Water.** In March 2023, EPA announced a proposed National Primary Drinking Water Regulation for six PFAS (including PFOA and PFOS), which would set enforceable maximum contaminant levels (MCLs) in drinking water.[31] For PFOA and PFOS, EPA selected "the lowest concentration that PFOA and PFOS can be reliably quantified" with current EPA-approved methods.[32] Once finalized, states will be required to have a standard for public water systems that is no less strict than the MCLs.[33] EPA is expected to finalize the MCLs by early 2024.

- **Federal Superfund.** In early 2024, EPA is expected to finalize its designation of PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), or the federal Superfund law.[34] That designation would significantly broaden federal authority, including to ensure that releases are investigated and abated, that affected sites are remediated, and that response costs are reimbursed by potentially responsible parties (PRPs).[35] Once finalized, it would grant EPA broad authority to direct a host of PRPs to investigate and remediate sites where PFAS have been found.[36] Airports, hospitals, farms, performance clothing manufacturers – that is, owners and operators of sites where PFAS-containing materials were used, discharged, or disposed at any point – could fall within CERCLA's reach and, with it, face an increased risk of private litigation.

- **Waste Management.** EPA is expected to propose a rule designating PFOA, PFOS, the GenX compound HFPO Dimer Acid (HFPO-DA), and perfluorobutane sulfonic acid (PFBS) as "hazardous constituents" under the Resource Conservation and Recovery Act (RCRA). If that rule is promulgated, EPA could deem solid waste containing a "hazardous ***constituent***" to be "hazardous ***waste***" after accounting for factors such as the constituent's toxicity, concentration, environmental persistence, and bioaccumulation.[37] RCRA empowers EPA with "cradle to grave" control over hazardous waste, including enforcement powers such as inspections, testing, compliance orders, and penalties.[38] As with a CERCLA designation, a RCRA designation could also generate citizen suits to obtain injunctive relief, civil penalties, and litigation costs from companies. EPA has not disclosed a timeline for the proposed RCRA rulemaking.

- **Restrictions on New PFAS Use.** In June 2023, EPA issued a framework for reviewing new PFAS and significant new uses of existing PFAS before they enter commerce, under the Toxic Substances Control Act (TSCA) New Chemicals Program.[39] Companies are required to notify EPA before manufacturing (or importing) a new substance or using an existing substance in a new manner. Under the framework, EPA "qualitatively" assesses whether the PFAS is a persistent, bioaccumulative, and toxic chemical and evaluates the potential extent of exposures to the general population, consumers, and the environment.[40] Based on its determination, EPA could require further testing and assessment before the PFAS can be introduced into commerce.

- **Reporting.** Owners and operators of facilities that manufacture, process, or use certain chemicals are required to track and report data on environmental releases, except for de minimis amounts. In a rule finalized in October 2023, EPA eliminated this de minimis exception for over 180 PFAS.[41] Under the rule, suppliers may also be required to notify customers of the concentration of PFAS in their products. Also in October 2023, EPA finalized a rule – colloquially, called the "Billion Dollar PFAS Reporting Rule" – that requires current and historical manufacturers and importers of PFAS and PFAS-containing materials to report on uses, production volumes, disposal, exposures, and potential hazards.[42] Industry-wide compliance is estimated to cost approximately $850 million.[43]

In 2021, EPA established the EPA Council on PFAS to create and coordinate the agency's strategy for addressing PFAS issues.[44] Just as the federal government has made PFAS regulation a key commitment, the same goes for enforcement actions.

In 2023, EPA—enhancing its enforcement efforts—executed the "first-ever federal Clean Water Act enforcement action" to address PFAS discharges and EPA's Office of Enforcement and Compliance Assurance announced plans to focus enforcement efforts on PFAS manufacturers and commercial users.[45]

Even while state governments follow the federal government's lead in certain respects, states have taken independent action and assumed aggressive postures toward the chemicals. In California, PFOA, PFOS, and perfluorononanoic Acid (PFNA) have been listed as Proposition 65 chemicals—with three other PFAS under consideration for listing.[46] Under that law, businesses— including manufacturers, producers, suppliers, and distributors of anything from food to building materials sold or used in that state—are required to give notice where these chemicals are contained in consumer products or their components, present in workplaces, or released into the environment, or face penalties of $2,500 per violation per day.[47] Other states are regulating PFAS beyond PFOA and PFOS. In New York, the Department of Health proposed maximum containment levels for PFNA, perfluorodecanoic acid (PFDA), perfluoroheptanoic acid (PFHpA), and perfluorohexane sulfonic acid (PFHxS).[48] The proposal would also mandate giving notice to property owners where water contamination levels exceed statutory limits for nineteen other PFAS.

In 2023 alone, states introduced around 200 new bills attempting to regulate or restrict PFAS use. For example, Connecticut's environmental protection agency now requires entities to disclose historical industrial activities that could have resulted in the presence of PFAS in the soil or groundwater.[49] The governor of Minnesota recently signed into law a comprehensive bill that not only calls for new water quality standards, but among other provisions, would require companies to report any products that contain "intentionally added" PFAS and phase out certain products containing PFAS from the market by 2025.[50] With that legislation, Minnesota joins nearly a dozen states that have passed laws to limit or ban the sale and distribution of PFAS-containing products ranging from food packaging to apparel and textiles, cosmetics to children's products. Indeed, Maine has undertaken to phase out PFAS in consumer products altogether by 2030, except where the use is "unavoidable."[51]

Using new and existing laws, state agencies have been active in investigating historic use and possible releases of PFAS, negotiating consent agreements, or commencing legal actions to cover (or recover) alleged damages, such as investigation and remediation costs. Roughly half of state attorneys general have filed lawsuits to recover damages related to historical PFAS releases, some claims resulting in nine-figure settlements or financial commitments.[52] These complaints typically allege that PFAS manufacturing or use resulted in the release of PFAS into the local or wider environment, thereby harming public property and natural

resources. These actions, along with the passage of state laws to restrict the sale of PFAS-containing products, reflect state officials' growing interest in sources of alleged PFAS contamination. This expanded focus raises the possibility that additional industries will be targeted, particularly those involved in more widely used products that allegedly contain PFAS.

Internationally, there have also been efforts to regulate PFAS. For example, in February 2023, European Union's European Chemical Agency (ECHA) proposed to severely restrict the use of PFAS.[53] ECHA's proposal would prohibit, subject to limited exemptions, the manufacture, use, or marketing of any substance, mixture, or article containing the sum of all PFAS exceeding 250 parts per billion, or of any single PFAS exceeding 25 parts per billion, based on a targeted analysis of PFAS.

There is no sign that the pace of regulatory action will abate. As federal, state, and local governments and plaintiffs remain focused on PFAS, businesses and other stakeholders that manufactured or used PFAS should expect to face increasing risk of costs and potential litigation from private and public actors. In addition to the direct litigation and business risks, regulatory initiatives are likely to have implications for private litigation. For example, the designation of certain PFAS as "hazardous" substances could be used to attempt to bolster allegations that injuries were caused by PFAS exposure and that certain remedies are therefore appropriate and necessary, despite the fact that regulatory designations are not based on scientific findings of causation and, instead, subject to a lower, precautionary standard. Further, guidelines for water treatment techniques promulgated by federal agencies may be seen as an industry standard. Moreover, as federal action spurs public awareness and pressure, states and local governments may seek to restrict or prohibit those operations that involve the use or potential emission of any PFAS compound.

Companies – particularly manufacturers – should plan for greater scrutiny of their current and historical business processes by regulators, customers, and the general public.

Growing Public and Commercial Attention

Individual companies and industries are taking action to mitigate litigation risk and implement diligence processes to comply with new regulations. Internal audits of historical and current usage of PFAS have become a more common practice among companies. Additionally, customers are requesting certifications regarding PFAS content. These requests are driven in equal parts by regulatory diligence and commercial positioning, as companies seek to ensure they are compliant with state and federal laws and to align their processes with business objectives. For example, with the public attuned to PFAS issues, "PFAS-free" labels have become a key marketing theme for some companies that strive to position their products as safe and environmentally friendly. For some companies, though, confidentiality

and trade secret considerations cannot be divorced from, and may complicate, commercial diligence.

Conclusions

These trends in the litigation, regulatory, and commercial spheres all signal a sustained and heightening interest in PFAS. Companies – particularly manufacturers – should plan for greater scrutiny of their current and historical business processes by regulators, customers, and the general public.

Endnotes

1 Gluge et al., *An Overview of the uses of per- and polyfluoroalkyl substances (PFAS)* (2020). Environ. Sci.: Processes, 22:2345, 2349.

2 *Id.* at 2346.

3 *Id.* at 2349.

4 https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html.

5 *In re: Aqueous Film-Forming Foams Prods. Liab. Litig.*, No. 2:18-mn-2873-RMG (D.S.C.).

6 *In re: E.I. du Pont de Nemours & Co. C-8 Personal Injury Litig.*, No. 2:13-md-2433 (S.D. Ohio).

7 *E.g.*, *In re: Aqueous Film-Forming Foams Prods. Liab. Litig.*, No. 2:18-mn-2873-RMG (D.S.C.).

8 *Johnson v. 3M Co.*, No. 4:20-cv-8 (N.D. Ga.).

9 *Orange Cnty. Water Dist. v. 3M Co.*, No. 2:22-cv-01798 (D.S.C.).

10 *Rougeau v. 3M Co.*, No. 3:23-cv-546 (W.D. Wis.).

11 *Ambrose v. The Kroger Co.*, No. 3:20-cv-04009 (N.D. Cal.).

12 *Kanan v. Thinx Inc.*, No. 2:20-cv-10341 (C.D. Cal.).

13 *E.g.*, *Hussain v. Burger King Corp.*, No. 4:22-cv-02258 (N.D. Cal.); *Clark v. McDonald's Corp.*, No. 3:22-cv-628 (S.D. Ill.).

14 *Richburg v. Conagra Brands, LLC*, No. 1:22-cv-2420 (N.D. Ill.); *Ruiz v. Conagra Brands, LLC*, No. 1:22-cv-2421 (N.D. Ill.).

15 *Hernandez v. Wonderful Co. LLC*, No. 1:23-cv-1242 (S.D.N.Y.); *Lurenz v. Coca-Cola Co.*, No. 7:22-cv-10941 (S.D.N.Y.).

16 *Esquibel v. Colgate-Palmolive Co.*, No. 1:23-cv-742 (S.D.N.Y.); *Dalewitz v. Procter & Gamble Co.*, No. 7:22-cv-7323 (S.D.N.Y.).

17 *Hicks v. L'Oreal U.S.A., Inc.*, No. 1:22-cv-1989 (S.D.N.Y.); *Gruen v. Clorox Co.*, No. 3:22-cv-00935 (N.D. Cal.).

18 https://www.sierraclub.org/sludge-garden-toxic-pfas-home-fertilizers-made-sewage-sludge.

19 https://www.theguardian.com/environment/2023/may/09/contact-lenses-pfas-forever-chemicals.

20 https://news.nd.edu/news/use-of-pfas-in-cosmetics-widespread-new-study-finds/.

21 https://theintercept.com/2019/10/08/pfas-chemicals-artificial-turf-soccer/.

22 *In re 3M Co. Sec. Litig.*, No. 2:19-cv-15982 (D.N.J.).

23 *E.g.*, *Admiral Insurance Co. v. Fire-Dex, LLC*, No. 1:22-CV-1087 (N.D. Ohio).

24 *E.g.*, *Vincent v. Aquarion Water Co.*, No. UWY-CV23-6073975-S (Conn. Super. Ct.).

25 *E.g.*, *City of Millington v. 3M Co.*, No. 2:20-cv-01034 (D.S.C.).

26 *Hardwick v. 3M Co.*, No. 2:18-cv-1185 (S.D. Ohio).

27 *Tenn. Riverkeeper, Inc. v. 3M Co.*, No. 5:16-cv-01029 (N.D. Ala.).

28 *Ryan v. Greif, Inc.*, No. 4:22-cv-40089 (D. Mass.).

29 https://pfas-1.itrcweb.org.

30 *See* ATSDR, "Toxicological Profile for Perfluoroalkyls, Draft for Public Comment (June 2018), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf; Press Release, "CDC and ATSDR Award $7 Million to Begin Multi-Site PFAS Study" (Sept. 23, 2019), https://www.cdc.gov/media/releases/2019/p0923-cdc-atsdr-award-pfas-study.html.

31 EPA, Preliminary Regulatory Determination and Proposed Rule, PFAS National Primary Drinking Water Regulation, https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027.

32 *Id.*

33 EPA, Proposed PFAS National Primary Drinking Water Regulation: Frequently Asked Questions and Answers (March 14, 2023), https://www.epa.gov/system/files/documents/2023-03/Public%20FAQs_PFAS_NPDWR_Final_3.14.23.pdf.

34 EPA, Proposed Rule, CERCLA Hazardous Substances: Designation of PFOA and PFOS (Sept. 2022), https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0001.

35 *See* 42 U.S.C. §§ 9604, 9606, 9607.

36 *See* 42 U.S.C. § 9607.

37 40 C.F.R. § 261.11.

38 EPA, Summary of the Resource Conservation and Recovery Act, https://www.epa.gov/laws-regulations/summary-resource-conservation-and-recovery-act (last updated Sept. 6, 2023); EPA, RCRA Corrective Action Enforcement Authorities, https://www.epa.gov/enforcement/rcra-corrective-action-enforcement-authorities (last updated Apr. 14, 2023).

39 https://www.epa.gov/system/files/documents/2023-06/PFAS%20Framework_Public%20Release_6-28-23_Final_508c.pdf

40 https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/framework-addressing-new-pfas-and

41 88 Fed. Reg. 74360 (Oct. 31, 2023).

42 88 Fed. Reg. 70516 (Oct. 11, 2023).

43 https://www.epa.gov/system/files/documents/2022-11/2070-AK67_TSCA%208a7%20IRFA_11-25-22%20clean.pdf

44 EPA, Memorandum Regarding Per- and Polyfluoroalkyl Substances (Apr. 21, 2021), *available at* https://www.epa.gov/sites/production/files/2021-04/documents/per-and_polyfluoroalkyl_substances.memo_.signed.pdf.

45 Aug. 17, 2023 Ltr. from David Uhlman to EPA Reg'l Administrators, https://www.epa.gov/system/files/documents/2023-08/fy2024-27necis.pdf.

46 OEHHA, *Chemicals Known to the State to Cause Cancer or Reproductive Toxicity* (Mar. 19, 2021), *available at* https://oehha.ca.gov/media/downloads/proposition-65//p65chemicalslistsinglelisttable2021p.pdf; https://oehha.ca.gov/proposition-65/crnr/chemicals-selected-consideration-listing-dartic-and-request-relevant-information.

47 https://oehha.ca.gov/proposition-65/general-info/proposition-65-plain-language; https://oehha.ca.gov/media/downloads/crnr/art6businessqa.pdf; Cal. Health & Safety Code § 2529.7.

48 44 New York Reg. 16 (Oct. 15, 2023).

49 https://portal.ct.gov/-/media/DEEP/site_clean_up/property_transfer_program/ECAF/ ecafappDOC.docx

50 https://www.revisor.mn.gov/bills/text.php?number=HF2310&type=ccr&session=ls93&version=0;%20 https://www.revisor.mn.gov/bills/bill.php?f=HF2310&y=2023&ssn=0&b=house

51 Maine DEP, PFAS in Products, https://www.maine.gov/dep/spills/topics/pfas/PFAS-products (last updated Sept. 12, 2023).

52 *See* Minnesota 3M PFC Settlement, *supra*; Press Release, *Wolverine Worldwide's Expanded Efforts to Address PFAS Approved by Judge* (Feb. 20, 2020), https://wolverineworldwide.gcs-web.com/news-releases/news-release-details/wolverine-worldwides-expanded-efforts-address-pfas-approved.

53 https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea.

Ethylene Oxide... continued from page 5

Ethylene oxide has established occupational exposure thresholds, both enforceable (i.e., Occupational Safety and Health Administration Permissible Exposure Limit; OSHA PEL) and recommended (i.e., National Institute for Occupational Safety and Health Recommended Exposure Limit, NIOSH REL; and the American Conference for Governmental Industrial Hygienists Threshold Limit Value, ACGIH TLV). Because ethylene oxide is used as a registered antimicrobial pesticide (i.e., sterilant), the EPA uses a safety paradigm to evaluate use and prescribe safe use conditions on the product label, including the PPE necessary in occupational settings to protect below the established safety thresholds.

In recent years, the release of ethylene oxide from sterilization operations into the ambient environment in various communities across the United States alerted regulators to the potential for community exposures from the sterilization processes. There are both commercial facilities and operational (e.g., hospital, dental clinic) facilities that routinely use ethylene oxide for the sterilization of heat-sensitive and other types of medical devices. Depending on the facility type, there may be separate chambers for fumigation (i.e., sterilization of the equipment) and aeration (i.e., desorption of ethylene oxide from the sterilized surface), whereas other facilities combine the process in one chamber. The recognition of fugitive emission exposures from this process caught the attention of regulators and NGOs to highlight any potential human health risks from these facilities.

An understanding of where, how, and why ethylene oxide exposures are occurring is necessary to contextualize current human health exposure and risk assessment efforts.

It is important to understand how environmental/community releases are occurring to gain a better picture of ambient ethylene oxide concentrations. The levels that are observed from ambient air monitoring by EPA and others are presumed to originate from medical device sterilization facilities. The putative ways that ethylene oxide releases occur include but are not limited to: ineffective industrial hygiene control mechanisms, incidental releases during sterilization, leakage of material due to deferred maintenance or other mechanical issues, or simply gross accidental releases. However, other known operations involving ethylene oxide should be investigated to determine how they contribute to ambient levels. Understanding the different ways ethylene oxide is released into the environment is crucial in addressing the issue. By identifying and investigating various operations that involve ethylene oxide generation, a comprehensive approach to determining its impact on ambient levels can be developed.

To dissect how ethylene oxide may increase someone's health risk, the hazard and risk must first be understood along with the potential health endpoints. Generally, a hazard is identified as a potential source of harm from a substance whereas risk is the probability of potential adverse health effects resulting from exposure to a hazard. The degree to which risk exists is the driving factor when evaluating a hazard,

including the contribution of exposure factors. For this reason, there have been a few attempts to assess ethylene oxide human health risk from ambient exposures.

The major focus on ambient environmental ethylene oxide exposure has been on chronic inhalation health outcomes. Inhalation is identified as the primary pathway that ethylene oxide can enter the body. While acute ethylene oxide exposure can cause health effects (i.e., neurotoxicity), those effects are thought to occur at higher levels than the cancer-causing effects. For this reason, regulators focus on the chronic exposure outcomes for many of the current ambient exposure situations.

In the mid 2010's the EPA (via the National Air Toxics Assessment) identified ethylene oxide monitoring data in communities surrounding sterilization facilities (singled out via census blocks) and ultimately determined there was elevated carcinogenic risk in those areas. Along with updated scientific evaluations, the EPA concluded that the risk assessments at certain facilities showed an unacceptable level of risk based on the model input variables. Since the initiation of the recent EPA risk assessments, there have been assessments performed by other regulatory agencies in an attempt to understand the carcinogenic risk presented by ethylene oxide from the ambient environment.

It is important to provide an overview of the organizations that have identified ethylene oxide as a carcinogen. In 2012, the International Agency for Research on Cancer (IARC) identified that ethylene oxide is a group one carcinogen (carcinogenic to humans) based on their hazard assessment (the first step in determining if a substance is a human health risk driver). Findings by organizations like IARC typically initiate reviews and/or re-reviews by other organizations to perform their own hazard and risk assessments. Based on additional assessment, a number of different domestic organizations (e.g., EPA, National Toxicology Program) has identified ethylene oxide as a human carcinogen based on regulatory review of the data and underlying studies (epidemiological, mechanistic data, and animal models). However, other organizations like the Texas Commission on Environmental Quality (TCEQ) have evaluated the data and determined that ethylene oxide is "likely to be carcinogenic to humans" (as opposed to "carcinogenic to humans" as EPA and NTP have determined). This nuanced distinction highlights the different assessment processes that have been performed when striving to understand the carcinogenic potential. There are currently disagreements on the weight of evidence as to which cancer outcome is associated with ethylene oxide overexposure (i.e., lymphohematopoietic cancers vs. breast cancer).

An evaluation of how the regulatory information meshes with the exposure and risk assessment data is also a complicated process. There have been differing opinions on the most accurate risk level because of different methodologies used

when assessing risk by the various agencies. Many of the recent risk assessments have been focused on the non-occupational "bystander" exposure scenarios (i.e., ambient environmental exposures). Some of these recent risk assessments further divide this into residential and non-residential bystander site receptors (i.e., exposed population). Quantitative risk assessments typically employ exposure modeling to understand how the site receptors (e.g., bystanders) would be exposed and for identifying any elevated risk. Risk assessment models typically use the most sensitive endpoint for characterizing the cancer risk.

The ethylene oxide risk assessments have been evolving over the past decade. In a recent draft risk assessment, EPA selected a certain linear risk assessment model to quantify risk but, in a 2023 risk assessment addendum, EPA defaulted to their 2016 Integrated Risk Information System (IRIS) cancer characterization (TCEQ used a different model than EPA and, thus, identified different risk levels). The variations in the methodology make pinpointing the exact risk in the population more difficult when using these conservative assessment methods.

The exposure parameters used in the risk assessment models are also important to determine individual exposures. EPA based original modeling on census track information for locations surrounding sterilization facilities. When performing the assessment, the default for evaluating residential risk is to assume essentially continuous exposure (i.e., 24 hours a day for 365 days per year, which is then averaged over 70 years). These assessments are conservative to account for the upper bound of the possibility of cancer development. However, when needing a more realistic picture of exposure and risk for an individual, it is important to identify the exposure parameters of that person's exposure. For example, if the individual travels outside of their residential setting during work and/or weekends, is the model taking into consideration the reduced exposure duration? The standard risk assessment models also assume there is continuous exposure to ambient outdoor air, even when not outdoors. The exposure model should account for any attenuation offered by residential conditions (e.g., home fresh air intakes, natural versus mechanical ventilation, etc.) for a more realistic exposure picture.

Along with realistic exposure parameters, data quality from ambient air sampling should be well understood along with the laboratory analytical methodologies. If relying on ambient monitoring versus personal monitoring (the type typically performed in occupational settings), are the data comparable? Discrepancies in data may complicate the modeling process. If there are established ambient limits, you will need to ensure that the laboratory has a reliable method sensitive to detect down to that low level or the data may be uninterpretable.

In addition to exposure parameters, the dose is also important to consider when assessing a causal link between exposure and health outcome (think Hill's Criteria). Generally, exposure to a chemical is the opportunity to come into contact with a substance and the opportunity to internalize a dose. Dose is the amount that actually is absorbed into the body and has the potential for interaction with biological systems. Dose is important – not only because of the other various sources of ethylene oxide exposure in the environment – but because humans produce ethylene oxide within our body during certain metabolic processes. Are the exposure and any subsequent dose lower than what is naturally in our bodies? A comprehensive dose-assessment would provide clarity on the effects of exposure. To further understand body burden, there are established methods for identifying ethylene oxide in the body using biomonitoring. For example, ACGIH has an established biological exposure index (BEI) for ethylene oxide exposure from occupational use. Both exposure and dose assessment provide a well-rounded ethylene oxide risk perspective.

The future for health claims as they relate to ethylene oxide exposure remains uncertain. The risk assessment paradigm continues to evolve for overall risk as well as site-specific understandings of risk. Concurrent with the health risk assessment process, the federal process on reducing ambient emissions moves forward. On March 14, 2024, EPA adopted the ethylene oxide National Emission Standards for Hazardous Air Pollutants (NESHAP) final amendments for commercial sterilizers. The goal of this change is to reduce ethylene oxide emissions and lifetime cancer risk surrounding a number of commercial sterilization facilities. However, as with any change, there can always be downstream effects. Are any health claims made at the individual level supported by science? And how are changes in the sterilization processes affecting the medical equipment and devices that are implanted in humans? Are there risks for incomplete sterilization because of process restrictions/changes? It is important to continue to strive towards using the best scientific methods for evaluating exposure and risk to answer these causal questions.

The future for health claims as they relate to ethylene oxide exposure remains uncertain. The risk assessment paradigm continues to evolve for overall risk as well as site-specific understandings of risk.

References

ACGIH, American Conference of Governmental Industrial Hygienists, Threshold Limit Values (TLVs®) and Biological Exposure Indices (BEIs®), 2023.

ATSDR, Toxicological Profile for Ethylene Oxide, 2022 https://www.atsdr.cdc.gov/toxprofiles/tp137.pdf

CDC, Ethylene Oxide "Gas" Sterilization, 2008 https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/ethylene-oxide.html

CFR, 40 CFR 180.151: Ethylene oxide; tolerances for residues. https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.151

EPA, Hazardous Air Pollutants: Ethylene Oxide (EtO). https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide

EPA IRIS, Integrated Risk Information System, Ethylene Oxide. https://iris.epa.gov/ChemicalLanding/&substance_nmbr=1025

EPA, Final Amendments to Strengthen Air Toxics Standards for Ethylene Oxide Commercial Sterilizers. https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/final-amendments-strengthen-air-toxics-standards-ethylene

EPA, Ethylene Oxide (EtO). Draft Human Health and Ecological Risk Assessment in Support of Registration Review, 2020. https://www.epa.gov/sites/default/files/2020-11/documents/d458706-eto-final-dra-nov-3-2020.pdf

EPA, Ethylene Oxide (EtO). Addendum to "Draft Human Health and Ecological Risk Assessment in Support of Registration Review" - Inhalation Exposure Risk Assessment in Support of Registration Review. https://www.epa.gov/system/files/documents/2023-04/eto-draft-human-healh-ra-add.pdf

Kirman CR, Hays SM. Derivation of endogenous equivalent values to support risk assessment and risk management decisions for an endogenous carcinogen: Ethylene oxide. Regul Toxicol Pharmacol. 2017 Dec;91:165-172.

NIOSH, National Institute for Occupational Safety and Health, Pocket Guide, ethylene oxide. https://www.cdc.gov/niosh/npg/npgd0275.html

NTP, National Toxicology Program Report on Carcinogens, Ethylene Oxide, 2021. https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/ethyleneoxide.pdf

TCEQ, Ethylene Oxide Carcinogenic Dose-Response Assessment, 2020. https://www.tceq.texas.gov/downloads/toxicology/dsd/final/eto.pdf

Understanding... continued from page 6

postings of an individual (or individuals) called "Q," ostensibly a federal government insider willing to leak the deepest secrets about the United States government and the Democratic Party. Consumers of Q's posts then spread its salacious conspiracy theories among their social and political networks, a process that takes a life of its own and creates dozens of different versions of each post and can reach tens of millions of people.

Although QAnon preceded the pandemic and it is unlikely that, even today, a large percentage of any jury pool fully embraces all that QAnon promotes, the pandemic helped QAnon and other online extremist groups gain a previously unimaginable level of acceptance. Two in five Americans say that it is, at least, probably true that "regardless of who is officially in charge, there is a single group of people who secretly control events and rule the world together."[5] Many elected officials and even members of Congress trade in QAnon conspiracies and solicit the support of QAnon adherents. This is consistent with a more polarized social landscape that appears less like a bell curve and more like a barbell.

For purposes of this article, a "QAnon juror" is not someone who shows up to jury selection wearing a QAnon t-shirt and chanting "Hang Mike Pence!" More broadly, the shorthand label defines jurors who are not merely conservative or liberal but *extreme* and almost unreachable. They exist on *both* ends of the political spectrum, and their numbers are growing. But our focus tilts to those on the far right because they have traditionally been considered defense-friendly in civil trials, whereas the far-left juror has always been considered reliably plaintiff-friendly.

Post-COVID research shows that belief in conspiracy theories is the strongest predictor of a plaintiff-friendly juror.

B. The Importance of Identifying the "QAnon Juror."

Post-COVID research shows that belief in conspiracy theories is the *strongest predictor* of a plaintiff-friendly juror.[6] Other influential factors include a general distrust of institutions, anti-corporate sentiment, low levels of education, and a willingness to rely on one's intuition as opposed to facts.[7] Combined, this makes identifying potential "QAnon Jurors" critical to defense counsel's litigation success.

Further complicating matters, the "QAnon Juror" has upended the conventional wisdom about political affiliation and defense-friendly views. It is no longer the case that conservative or Republican jurisdictions are reliably defense-friendly. Jury consultant Nick Polavin's research shows that only when the conspiracy theory variable was controlled for were Republicans significantly more likely than Democrats to side with the defendant.[8] When belief in conspiracy theories was factored in, Republicans became more likely to side with the plaintiff than Democrats.[9]

In fact, far-right Republicans were found to be almost as plaintiff-friendly as far-left Democrats.[10] This makes sense given the importance of the above factors. Not only are far-right Republicans most likely to believe in conspiracy theories, but they are also most likely to have less formal education and, post-COVID, most likely to distrust medical science.[11] Lower-educated conservatives also harbor the strongest anti-corporate beliefs of *any* potential jurors.[12] All in all, learning how to recognize and avoid the "QAnon Juror" could fundamentally change a trial.

C. Using Voir Dire and Social Media to Identify "QAnon Jurors."

Social media and background research can be very helpful when evaluating potential jurors, but post-COVID the inquiry must be more nuanced than simple political orientation.[13] The good news is that conspiracy theorists typically disseminate their beliefs. If social-media research into potential jurors is feasible and permitted, look for posts supporting far-right political candidates, posts spreading COVID misinformation or expressing distrust for public health officials, or posts expressing support for other conspiracy theories.

Through voir dire or a juror questionnaire, information about the following factors should be sought to the extent possible:

- Unvaccinated for COVID-19
- Lack of trust in government institutions such as the EPA or FDA
- Lack of trust in scientists or public health institutions
- Belief in an intuitive ability to tell if information is true or false
- Less formal education
- Low income
- High religiosity
- Ingroup loyalty (i.e., importance of loyalty to the groups with which one identifies)

These factors have been most closely identified with a belief in conspiracy theories.[14] By adjusting previously held beliefs about political affiliation and plaintiff-friendly jurors, and by looking for signs of conspiracy theorists, it is possible to spot and strike "QAnon Jurors."

D. What to do if a "QAnon Juror" Slips Through

Jury selection is not foolproof and is admittedly reliant on snap judgments that factor likely *associations* between limited pieces of a potential juror's biographical

data and the juror's likely views about the case. The key is realizing which data points are reliably helpful and which are unhelpful misconceptions; a conspiracy-minded juror can slip through the most careful selection process. Fortunately, once a "QAnon Juror" is seated, there are ways that defense counsel can tailor their trial strategy accordingly.

One tactic defense counsel may choose is an appeal to the processing style of the "QAnon Juror." Research has identified two general processing modes, logical and intuitive.[15] People in logical processing mode carefully analyze facts and evidence to arrive at a rational conclusion. Intuitive processing, on the other hand, relies on "gut feelings," emotional reactions, and heuristics. The "QAnon Juror" is more likely to engage in intuitive processing, relying on their instincts and weighing feelings over facts.[16]

Counsel must choose whether to appeal to the intuitive processing of the "QAnon Juror" or appeal to the remaining jurors' belief in evidence-based, scientific analysis.

Defense counsel can tailor their approach to appeal to intuitive information processors. Carefully constructed, fact-intensive refutations of the plaintiff's allegations will not be effective.[17] Rather, a simple, relatable narrative that focuses on the conduct of the key parties is essential.[18] So is timing. Defense counsel cannot wait until after the plaintiff's case to introduce their message. The narrative and should begin immediately, during voir dire and opening statements.[19]

Another tactic defense counsel might choose, particularly in liberal jurisdictions, is to lean into the remaining jurors' belief in scientific consensus and government institutions. Emphasizing the importance of embracing evidence-based scientific principles and resisting emotional decision-making can give liberal jurors a way to feel good about supporting the defense.[20] Themes leveraging this belief in science have proven particularly persuasive among liberal jurors since the pandemic.[21]

Conclusion

The pandemic changed everything, and litigation is no exception. Much of the conventional wisdom about defense-friendly jurors has expired. Now, identifying and striking "QAnon Jurors" is crucial to defense counsel's litigation success. If, despite social media research and careful voir dire questions, a "QAnon Juror" ends up on the jury, defense counsel must tailor their litigation strategies accordingly. Counsel must choose whether to appeal to the intuitive processing of the "QAnon Juror" or appeal to the remaining jurors' belief in evidence-based, scientific analysis.

Endnotes

1 Pyszczynski, Tom, et. al, *Terror Management Theory and the COVID-19 Pandemic*, J. Humanist Psychol., 2021 March; 61(2); 173-89.

2 Lorie Sicafuse, PhD., *Impact of the COVID-19 crisis on jurors' attitudes & decisions, Part I of IV*, available at https://www.courtroomsciences.com/blog/litigation-consulting-1/impact-of-the-covid-19-crisis-on-jurors-attitudes-decisions-133 (last visited Sept. 3, 2023).

3 Pyszczynski, *supra* note 1.

4 See Chris Barncard, During pandemic, proponents of 'doing your own research' believed more COVID misinformation, University of Wisconsin-Madison News (Aug. 15, 2023), available at https://news.wisc.edu/during-pandemic-proponents-of-doing-your-own-research-believed-more-covid-misinformation/ (last visited Sept. 3, 2023).

5 https://today.yougov.com/topics/politics/articles-reports/2022/03/30/which-groups-americans-believe-conspiracies

6 Nick Polavin, *Who Needs Evidence? The Rise of Conspiracy Minded Jurors, For The Defense,* May 2023, at 39, available at https://digitaleditions.walsworth.com/publication/?m=55594&i=791404&p=40&ver=html5 (last visited Sept. 4, 2023).

7 *Id.*

8 *Id.*

9 *Id.*

10 *Id.*

11 *Id.* According to a Pew study, Republicans' confidence in medical scientists fell from 83% in 2016 to 66% in 2021. The number is likely far lower among far-right Republicans.

12 Stratton Hores, et. al, *Jury Selection is Critical in Preventing Shock Verdicts*, Reuters, Aug. 3, 2022, available at https://www.reuters.com/legal/legalindustry/jury-selection-is-critical-preventing-shock-verdicts-2022-08-03/ (last visited Sept. 3, 2023).

13 Polavin, *supra* at n. 5.

14 *Id.*

15 CSI-Courtroom Sciences, Inc., *Impact of the COVID-19 crisis on jurors' attitudes & decisions, Part III of IV,* available at https://www.courtroomsciences.com/blog/litigation-consulting-1/impact-of-the-covid-19-crisis-on-jurors-attitudes-decisions-134 (last visited Sept. 3, 2023).

16 *Id.* Some research suggests that, in the wake of the pandemic, jurors are generally more likely to make decisions using intuitive processing. Defense counsel may want to consider adopting some strategies for persuading intuitive processors regardless of whether there is a "Q-Anon Juror" present.

17 *Id.*

18 *Id.*

19 *Id.*

20 *Id.*

21 *Id.*

Calendar

April 10-12, 2024	**Motor Vehicle Product Liability Conference** Contact: Janet Hummons – 312/988-5656 Yasmin Koen – 312/988 5653	**Omni Scottsdale Montelucia** Scottsdale, AZ
April 11-13, 2024	**Toxic Torts & Environmental Law Conference** Contact: Theresa Beckom – 312/988-5672 Sara Lossett – 312/988-6372	**Omni Scottsdale Montelucia** Scottsdale, AZ
May 1-4, 2024	**TIPS Section Conference** Contact: Janet Hummons – 312/988-5656 Theresa Beckom – 312/988-5672	**Loews Hollywood Hotel** Hollywood, CA
May 22-24, 2024	**Fidelity & Surety Law Spring Conference** Contact: Janet Hummons – 312/988-5656 Yasmin Koen – 312/988 5653	**Estancia La Jolla Hotel** La Jolla, CA
August 2-4, 2024	**ABA Annual Meeting** Contact: Janet Hummons – 312/988-5656	Chicago, IL
September 19-20, 2024	**Aviation Litigation Conference** Contact: Theresa Beckom – 312/988-5672 Sara Lossett – 312/988-6372	**Ritz Carlton Pentagon City** Arlington, VA
September 25-27, 2024	**FSLC Fidelity Fall Conference** Contact: Janet Hummons – 312/988-5656 Yasmin Koen – 312/988 5653	**Philadelphia Marriott** Philadelphia, PA
October 16-19, 2024	**TIPS Fall Meeting** Contact: Janet Hummons – 312/988-5656 Theresa Beckom – 312/988-5672	**Royal Sonesta Kauai** Kauai, HI

Member Roster

Chair
Jennifer Seme
Rawle & Henderson LLP
1339 Chestnut St, #17
Philadelphia, PA 19107-3519
(267) 838-6786
jseme@rawle.com

Chair-Elect
Poorad Razavi
Cohen Milstein Sellers & Toll PLLC
11780 US Hwy 1 N, Ste N500
Palm Beach Gardens, FL 33408
(561) 515-1400
prazavi@cohenmilstein.com

Council Representative
John McMeekin
Rawle & Henderson LLP
1500 Market St, Fl 19w
Philadelphia, PA 19102-2126
(215) 370-9626
Fax: (215) 563-2583
jmcmeekin@rawle.com

Diversity Vice-Chair
Sonny Haynes
Womble Bond Dickinson (US) LLP
1 W 4th St
Winston Salem, NC 27101-3972
(336) 7213632
sonny.haynes@wbd-us.com

Immediate Past Chair
Scott Pfeiffer
Cray Huber
303 West Madison, Ste 2200
Chicago, IL 60606-3315
(312) 332-8498
sdp@crayhuber.com

Law Student Vice-Chair
Elizabeth Nisbet
540 Telford Pl
Atlanta, GA 30342-2160
enisbet1@student.gsu.edu

Membership Vice-Chair
Steven Corhern
Balch & Bingham LLP
1901 Sixth Ave N, Ste 1500
Birmingham, AL 35203
(205) 226-8765
scorhern@balch.com

Scope Liaison
Kathleen Strickland
Ropers Majeski PC
535 Middlefield Rd, Ste 245
Menlo Park, CA 94025-3468
(415) 972-6328
kathleen.strickland@ropers.com

Social Media Vice-Chair
Steven Schulwolf
Schulwolf Mediation
6102 Mountain Villa Cv
Austin, TX 78731-3518
(312) 428-4728
steve@schulwolfmediation.com

Vice-Chairs
Mason Dressler
5025 Lindenwood Ave
Saint Louis, MO 63109-1728
mason.dressler@gmail.com

Abbe Fletman
First Judicial District
City Hall 540
Philadelphia, PA 19107
(215) 686-2636
Fax: (215) 683-7028
abbe.fletman@courts.phila.gov

Jonathan Huber
Nelson Mullins
101 Const Ave NW, Ste 176
Washington, DC 20001-2187
(202) 689-2966
jonathan.huber@nelsonmullins.com

Daniel R. Strecker
Harris Beach PLLC
333 Earle Ovington Blvd, The Omni
Uniondale, NY 11553-3610
(212) 912-3513
dstrecker@harrisbeach.com