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February 2025

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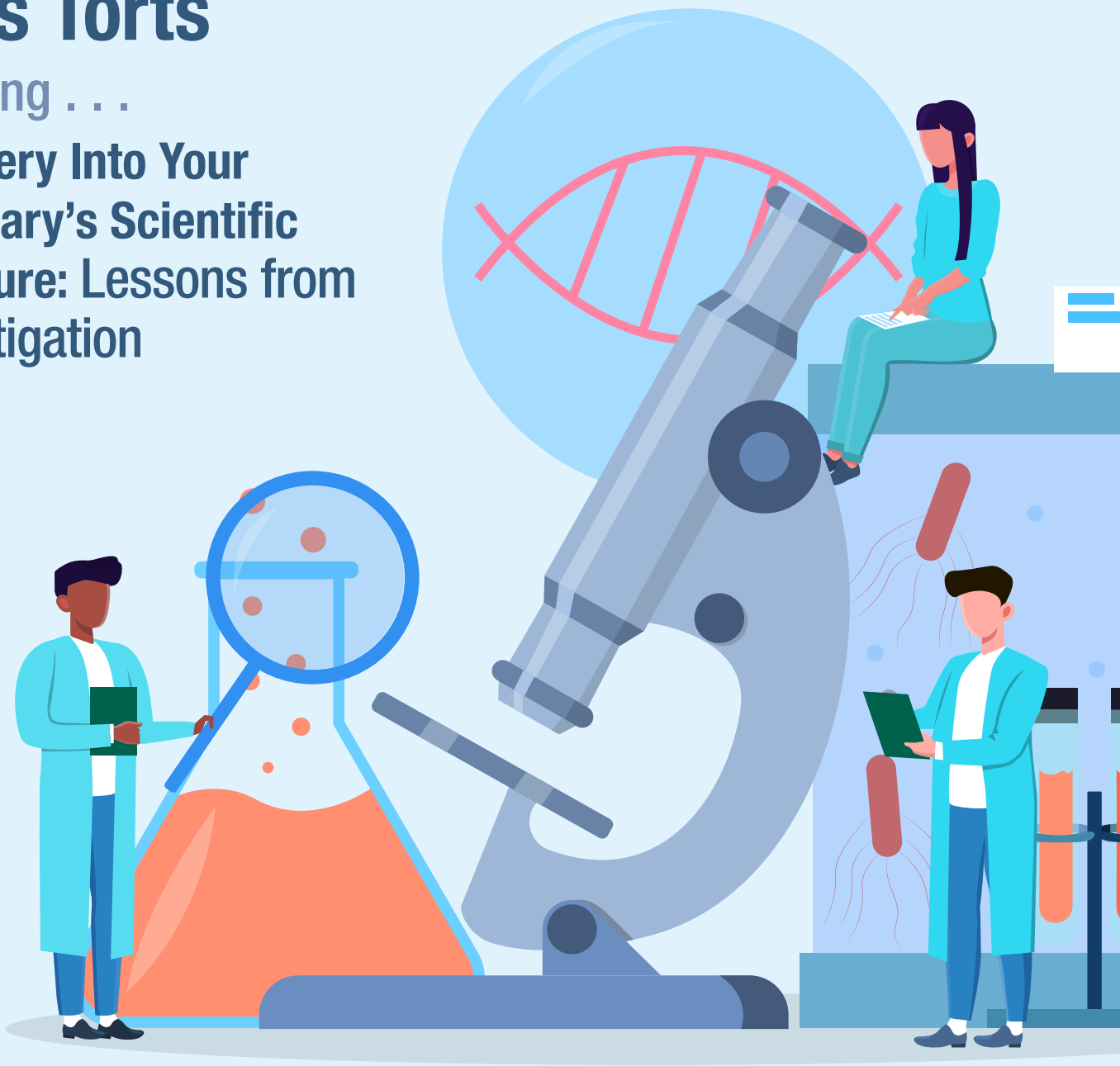

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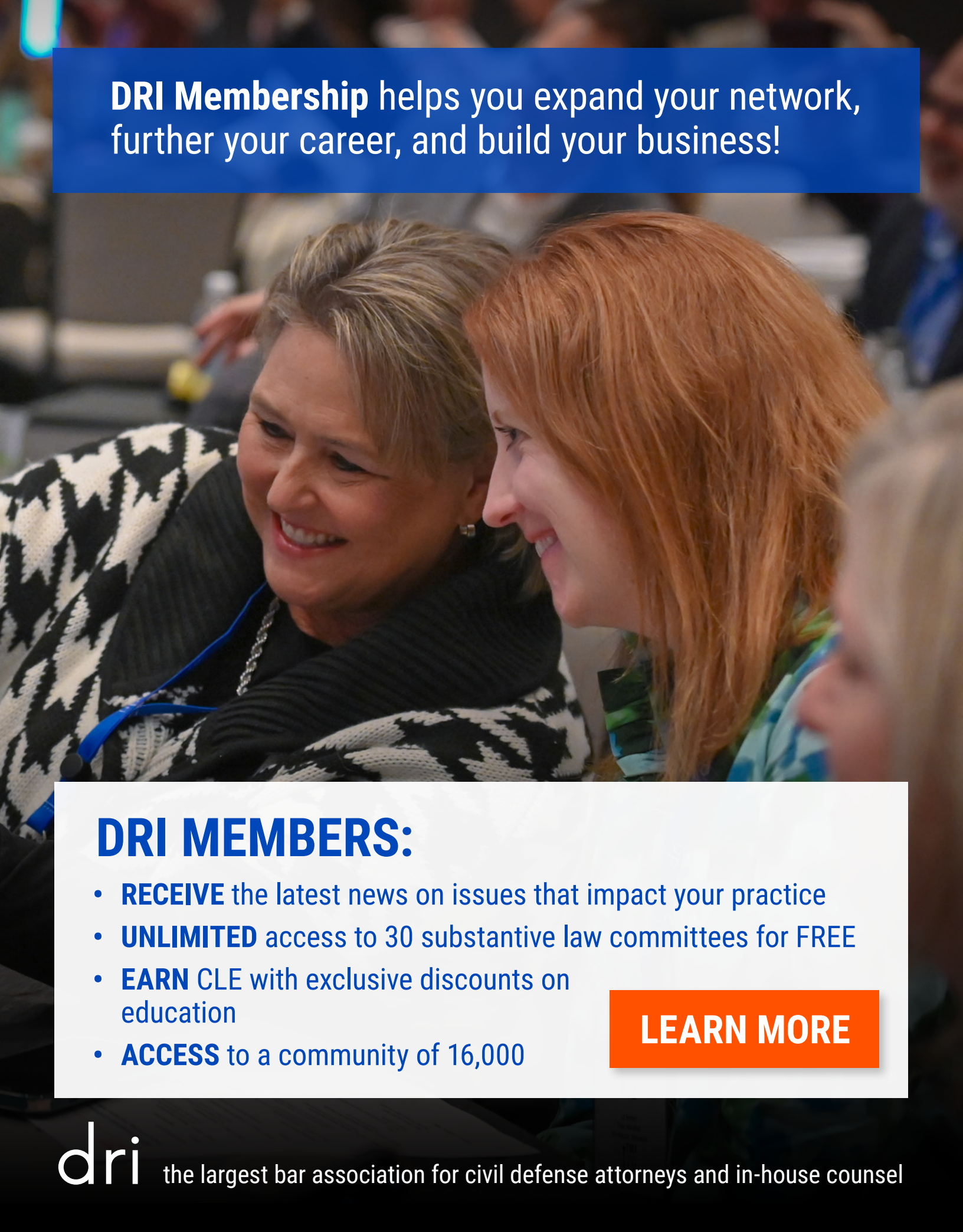
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Lessons from Talc Litigation

Discovery Into Your Adversary's Scientific Literature

By Abbie Eliasberg Fuchs, Dan Strecker, and Alex Anolik

The study or studies, their quality, and their applicability to the facts at hand become critical to the question of a party's liability or lack thereof.

In some litigation, the viability of an expert's opinion rests on the expert's asserted reliance on one or a handful of scientific studies. The study or studies, their quality, and their applicability to the facts at hand become critical to the question of a party's liability or lack thereof.

Despite how important scientific studies can be to a case, in many respects the studies are opaque. Generally, litigants have no access to the study authors, or the authors' data files, notes, and unvarnished opinions. The study authors choose what information to disclose and what to withhold, and the reader must rely on the authors' ethics and the peer-review process to ensure the data and methods are characterized accurately, fairly, and reliably.

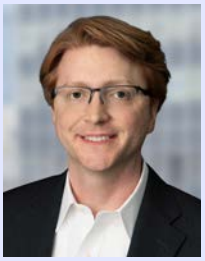
The material underlying and collateral to a scientific study could be used to differentiate the study data from the facts at hand, or otherwise discredit the study and thus the other party's position. If the material reveals gross deficiencies in a study, it could lead a court to exclude an expert's opinion and/or grant a dispositive motion. Recent decisions and developments in talc litigation provide a roadmap for how litigants can obtain this information and material in the right circumstance. They also demonstrate potential incidental benefits and downsides of seeking such discovery.

Non-party Discovery Into Studies Underlying Talc Litigation

During the past 20 years, tens of thousands of plaintiffs have filed suit alleging they developed cancer from asbestos allegedly contained in talc products like cosmetics or baby powder.[1] Many have relied on the 2020 report *Mesothelioma Associated With the Use of Cosmetic Talc*, by Dr. Jacqueline Moline and collaborators ("Moline 2020"). Moline 2020 claims to be "the first large case series to identify cosmetic talcum powder contaminated with asbestos as the cause of malignant mesothelioma in cosmetic talc users."[2] The authors assert they reviewed cases of anonymous individuals exposed to talc, but not asbestos, as part of a "medico-legal evaluation as part of tort litigation." The authors conclude exposure to asbestos-contami-

[1] Casey Cep, "Johnson & Johnson and a New War on Consumer Protection," The New Yorker (July 4, 2024, 1:33PM), ***https://www.newyorker.com/magazine/2022/09/19/johnson-johnson-and-a-new-war-on-consumer-protection***.

[2] Jacqueline Moline, MD, et al., Mesothelioma Associated With the Use of Cosmetic Talc, 62 J. Occup. Environ. Med. 11, 14 (2020).



Abbie Eliasberg Fuchs leads the Harris Beach Murtha Best Lawyers® (formerly U.S. News & World Report – Best Lawyers®) nationally ranked Tier 1 Mass Torts and Industry-Wide Litigation Practice Group and the Products Liability and Comprehensive General Liability Practice Group. She is national coordinating counsel to several Fortune 100 companies and concentrates in the areas of toxic and mass tort litigation, chemical exposure cases and complex products liability litigation. Abbie also defends international clients in litigation arising from their social media platforms, litigates commercial disputes, including breach of contract actions, as well as high-profile and high-exposure personal injury and property damage construction site cases. She also represents manufacturers, distributors and health care providers in litigation involving pharmaceuticals. **Dan Strecker** is a member of Harris Beach Murtha's Mass Torts and Industry-Wide Litigation Practice Group and the Products Liability and Comprehensive General Liability Practice Group. He leads national coordinating counsel teams defending manufacturers against complicated toxic tort and product liability claims. Dan also concentrates in the areas of complex commercial litigation, government compliance and white-collar defense/internal investigations. **Alex Anolik** is a member of Harris Beach Murtha's Mass Torts and Industry-Wide Litigation Practice Group and the Products Liability and Comprehensive General Liability Practice Group. He has extensive experience representing clients in high-exposure litigation involving mass torts, products liability, premises liability, construction accidents and toxic exposures. Alex has substantial courtroom experience from oral arguments, conferences and trials.

nated talc caused mesothelioma in these cases.[3] Dr. Moline and others, including Dr. Theresa Emory and Dr. John Maddox, subsequently authored additional articles building on the study (the "*Mesothelioma-Talc* articles").

At least one court has referred to the conclusions in Moline 2020 as "influential" and "groundbreaking."[4] On the other hand, information has emerged that undermines the integrity of its data. This information has led to the study's being described in court filings as "false"[5] and "fraudulent,"[6] and forms the basis for lawsuits brought by talc defendants against the study authors.[7]

The information emerged in the course of the lawsuit *Bell v. Am. Int'l Indus.* ("*Bell*"), a mesothelioma/wrongful death-talc case in North Carolina federal district court. The plaintiff disclosed Dr. Moline as an expert witness. One defendant learned the decedent may have been one of the anonymous individuals studied in Moline 2020.[8] Importantly, while Moline 2020 claimed none of its subjects had asbestos exposure (i.e., removing a potential alternative cause of their mesothelioma), this decedent had previously filed workers' compensation claims alleging asbestos exposure.[9] To confirm, defendant subpoenaed Dr. Moline's employer seeking the identities of the anonymous study participants. The employer's responsive production confirmed decedent was indeed one of them, undermining the reliability of all of the *Mesothelioma-Talc* articles.[10]

The Bell court initially granted plaintiff's motion for a protective order and limited the use of the information to the

[3] Id. at 1.
[4] Bell v. Am. Int'l Indus., 627 F.Supp.3d 520, 525, 530 (M.D.N.C. 2022).
[5] Complaint at 1, 64, LTL Mgmt. LLC v. Dr. Jacqueline Miriam Moline (D.N.J. May 31, 2023), ECF No. 1.
[6] Defendant Johnson & Johnson's Opposition to Plaintiffs' Steering Committee's Motion for Protective Order Regarding Subpoena Directed at Northwell Health, Inc. at 6, In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices, and Products Liability Litig. (D.N.J. Jan. 22, 2024), ECF No. 28919.
[7] Complaint at 57, 63, LTL Mgmt. LLC v. Dr. Jacqueline Miriam Moline (D.N.J. May 31, 2023), ECF No. 1; Complaint at 42, 49, LTL Management LLC, v. Dr. Theresa Swain Emory, Dr. Richard Lawrence Kradin, and Dr. John Coulter Maddox (D.N.J. July 7, 2023), ECF No. 1; Complaint at 31, 36, LTL Management LLC v. Dr. Theresa Swain Emory, Dr. Richard Kradin, and Dr. John Coulter Maddox (E.D.Va. May 9, 2024), ECF No. 1.
[8] Bell, 627 F.Supp.3d at 525.
[9] Id. at 525-26.
[10] Id. at 532.

Bell case, but later vacated it. The court found that permitting defense challenges to the article's premise, that none of the studied individuals had any known alternative asbestos exposures, in other talc litigation constituted good cause.[11] The court held that the information was relevant to the article's credibility, cross-examination of Dr. Moline as a retained expert and author of the article, and potential expert exclusion.

Similarly, the court approved the subpoena served by talc defendants in *Clark and Clark v. Cyprus Amax Minerals Co.* that sought the identities of study participants in *Mesothelioma-Talc* articles, after the order quashing it was reversed on appeal.[12] The appellate court issued the decision in *Matter of Johnson & Johnson v. Northwell Health, Inc.*, consolidating a proceeding initiated by Dr. Moline to quash the subpoena with a proceeding by the *Clark and Clark* talc defendants to enforce it.[13] The court noted the information sought by the subpoena was relevant to the credibility of the *Mesothelioma-Talc* articles, which "speak to the central issues in dispute" and were relied on by experts, both current and withdrawn.[14]

The court in the ovarian cancer-talcum powder MDL, In *Re: Johnson & Johnson Talcum Powder Products Mktg., Sales Prac., and Products Liab. Litig.* ("Talcum Powder MDL"), reasoned similarly but quashed the defense's non-party subpoena to obtain records relating to the *Mesothelioma-Talc* articles.[15] The court quashed the discovery on relevance grounds, since plaintiffs' experts in the *Talcum Powder* MDL did not rely on the *Mesothelioma-Talc* articles, and plaintiffs went so far as to propose excluding reference to the articles at trial. But the court reasoned that if the plaintiffs' experts had relied on the *Mesothelioma-Talc* articles, investigating their bases would be "fair game."[16]

A court in the eastern District of Virginia ruled differently, holding that an opposing party's expert's reliance on a study is not in itself a sufficient basis to investigate it through non-party discovery. The court quashed the talc defendant's subpoena served in connection with *Gref v. Am. Int'l Indus.* on Dr. Emory and Dr. Maddox's employer for documents relating to a *Mesothelioma-Talc* article.[17] In *Peninsula Pathology Associates v. Am. Int'l Indus.,* a proceeding to quash the subpoena initiated by Dr. Emory and Dr. Maddox's employer, the court weighed the defendant's interest against the cost to the employer to comply and the burden of revealing anonymous study participants.[18] Plaintiffs' experts (which included Dr. Moline, but neither Dr. Emory nor Dr. Maddox) relied on the studies, but the court reasoned that the reliance was relatively minor, and pointed out the already extensive publicly available information that could be used to discredit the study.[19] Further, defendant offered no basis to conclude plaintiff might have been a study participant.[20] Related, the talc defendant in *Gref v. Am. Int'l Indus.* also served a subpoena on Dr. Moline's employer seeking the identities of participants in Moline 2020, the employer moved to block such disclosure, and plaintiff withdrew his experts' reliance on the article.[21]

Talc Litigation Takeaways

Though courts have quashed talc defendants' subpoenas, they did so because they determined, based on the specific facts of the case before them, that the information sought was irrelevant or minimally relevant to the plaintiffs' experts' opinions.[22] For example, unlike the plaintiffs' experts in *Bell and Clark and Clark*, plaintiffs' experts in the *Talcum Powder* MDL and *Gref* did not rely on the *Mesothelioma-Talc* articles or their reliance was very limited and/or withdrawn. Moreover, the MDL and *Gref* defendants did not articulate specific information they reasonably believed could be disclosed by the discovery, such as the plaintiffs' being among the *Mesothelioma-Talc* articles' subjects (whereas in Bell, the decedent was one of the Moline 2020 subjects).

In determining the evidence sought by the nonparty subpoena was not relevant, the *Talcum Powder* MDL and *Peninsula* courts did not appear to consider whether the investigation was relevant to the *defense experts' opinions*. Further, it should be noted that in Bell, where defendants met with greater success, the plaintiff moved for a protective order *after* Dr. Moline's employer had responded to the subpoena, whereas plaintiffs in the other cases interjected before the employer did so.

Taken together, the decisions signal that courts may approve reasonable nonparty discovery to investigate the bases of scientific studies and other literature that adversaries rely on. The *Peninsula* and *Talcum Powder* MDL decisions delineate the outer boundaries of what might be permitted. These decisions suggest that the studies under investigation must be relied on by the other party's experts and must be more than incidental to the experts' opinions. Further, if the sought after information is otherwise available, or the party seeking the study cannot substantiate the reason for the investigation, it could weigh against allowing the discovery. For example, if the study was authored by the party's expert, the expert relies on the study, and there is reason to believe that the discovery will reveal information the investigating party can use, the discovery is more likely to be allowed.

Even though the discovery was rejected in two cases, the parties challenging the *Mesothelioma-Talc* articles may have succeeded in other respects. The information

[11] Id.
[12] Matter of Johnson & Johnson v. Northwell Health Inc., Appeal No. 2739-2740, 2024 N.Y. App. Div. LEXIS 5187, *2 (1st Dep't Oct. 8, 2024).
[13] Id.
[14] Id.
[15] In Re: Johnson & Johnson Talcum Powder Products Mktg., Sales Prac., and Products Liab. Litig., MDL No. 2738, slip op. at 1 (D.N.J. Feb. 29, 2024).
[16] Id. at 6.
[17] Peninsula Pathology Associates v. Am. Int'l Indus., No. 4:22-mc-1, 2022 U.S. Dist. LEXIS 241734, *9-10 (E.D.Va. Dec. 23, 2022).
[18] Id. at *1, *7-8.
[19] Id.
[20] Id.
[21] Gref v. Am. Int'l Indus., 20-CV-5589 (GBD) (VF), 2024 U.S. Dist. LEXIS 10895, *8 (S.D.N.Y. Jan. 22, 2024).
[22] Id. at 10.

developed in *Bell* and the use of that information to seek non-party discovery in the cases that followed appears to have disincentivized plaintiff experts from relying on the *Mesothelioma-Talc* articles.

Methods for Investigation

Such discovery is more likely to be permitted if the party seeking it can show the investigation will reveal information bearing on the credibility or admissibility of their adversary's expert's opinion, or will otherwise directly or significantly undermine their opponent's claims. Therefore, parties in toxic tort cases wishing to investigate scientific studies should develop a record that supports the discovery's reasonableness and relevance. For example, depending on the jurisdiction, parties could demand their adversaries' experts' reliance material, or look to the opposing experts' testimony in other litigation, to identify the studies they heavily rely on. Even if the other party's expert does not rely on a study, or the reliance is allegedly minimal, a party may consider if discrediting the study will nevertheless support its own defenses or experts' opinions.

Of course, these investigations into scientific studies will be subject to the same restrictions that are imposed on all nonparty discovery, such as those found in Rule 45 of the Federal Rules of Civil Procedure preventing unduly burdensome requests.[23] Therefore, narrowly tailored subpoenas are more likely to survive judicial review.

Conclusion

Investigation into dubious scientific support for toxic tort litigants' claims and defenses can help develop the record for summary judgment, expert exclusion, or trial. Parties considering engaging in nonparty discovery to investigate, distinguish, and/or discredit their opponents' scientific support should heed the lessons learned from recent decisions in talc litigation.

To avoid nonparty discovery being quashed, parties should develop their arguments and lay an evidentiary groundwork for the requests being made, and be prepared to answer: what information is sought, what is the basis to believe the information will be found, and how will the information impact the case? Parties should also consider the potential ramifications of success. On the one hand, the efforts undertaken in Bell appear to have disincentivized multiple future talc plaintiffs from relying on the *Mesothelioma-Talc* articles or retaining Dr. Moline, and has led to withdrawal of reliance on the *Mesothelioma-Talc* articles and proposals to exclude reference to them.[24] But if the party's adversary withdraws its reliance on flawed experts and science, a party may be deprived of otherwise available lines of attack and inadvertently teach their adversary how to make its theories stronger and less easily challenged.

[23] Fed. R. Civ. P. Rule 45(d)(1); see also Genus Lifesciences Inc. v. Lannett Co., 18-cv-07603-WHO, 2019 U.S. Dist. LEXIS 22550, *13 (N.D. Cal. Dec. 30, 2019) (nonparty discovery must be limited "if there is more convenient, less burdensome, or less expensive means").
[24] See, e.g., Bell, 627 F.Supp.3d at 525 (noting plaintiff "effectively withdrew" Dr. Moline by not presenting her for deposition by the deadline); In Re: Johnson & Johnson Talcum Powder Products Mktg., Sales Prac., and Products Liab. Litig., MDL No. 2738, slip op. at 8-9 (D.N.J. Feb. 29, 2024).

Medical and Life Sciences

New York 2024 Year in Review

By Judi Abbott Curry

In this article, senior partner Judi Abbott Curry reviews, analyzes and shares potential implications for future life science cases based on several key judicial holdings in New York in 2024

To that end, in-house and outside counsel-From medical devices to OTC drugs, preemption to expert preclusion, New York state and federal courts issued decisions in 2024 which further shaped the landscape in the medical and life sciences legal world. To prepare the best product liability and class action defense strategies for pharmaceuticals, medical devices, dietary supplements, foods, cosmetics and other FDA regulated products, it is often helpful to step back and review holdings that have affected the industry and may shape the years ahead.

In this article, senior partner Judi Abbott Curry reviews, analyzes and shares potential implications for future life science cases based on several key judicial holdings in New York in 2024 pertaining to:

- Medical Devices – Daubert Challenge to Expert Opinions
- Biologics - Causation Under Frye and PREP Act Extension
- Food Class Actions – PFAS, Plausibility and Deference to Primary Jurisdiction of FDA
- Dietary Supplements- Express Preemption of Labeling Claims
- OTC Drugs - Preemption Via Monograph

Medical Device Fracture *Daubert* Challenge- *Krom v. Smith & Nephew, Inc.,* No. 1:21-cv-01050 (AMN/DJS), 2024 WL 3378031 (N.D.N.Y. July 11, 2024) (appeal dismissed)

Plaintiff, a hip implant patient, alleged four products liability claims under New York law sounding in negligence, strict products liability, breach of express warranty and breach of implied warranty. Each claim relied on the same basic allegations, that defendant manufacturer's allegedly defective femoral stem implant product fractured and caused plaintiff injury. Defendant moved for Federal Rules of Civil Procedure (FRCP) Rule 56 summary judgment, premised upon a *Daubert* challenge to the testimony of plaintiff's two disclosed experts. Plaintiff's expert engineer was not qualified by experience, knowledge, skill, training or education to offer any opinions regarding the medical device at issue, as the expert had not attended medical school, had no medical training or background, never designed or prepared warnings for a femoral stem component or any other medical device and never worked for a medical device company, for the FDA or for any other agency that regulates medical devices. Even if the expert could be qualified to offer opinions, the Court found the methods underlying her industry standards and warning defect opinions were unreliable. To the extent her methodology was even described, it consisted primarily of speculation based on her personal and non-medical device experience. Plaintiff's second expert did not provide a report and an attorney-drafted summary of what the expert would testify about was insufficient under FRCP Rule 26. Neither expert posited that there was either a design or manufacturing defect, which plaintiff conceded during the pendency of the summary judgment motion.

Since the cause of plaintiff's femoral stem fracture following revision surgery was beyond the knowledge of a layperson, expert testimony was required. Even assuming plaintiff could posit admissible expert witness opinion evidence, which she could not, summary judgment was warranted. Because defendant provided warnings describing that the femoral stem could fracture and because the implanting surgeon was aware that the femoral stem could fracture, plaintiff's warning-based strict liability and negligence claims failed due

Judi Abbott Curry is a member at Harris Beach Murtha and concentrates in areas of mass tort, class action and complex product liability litigation involving pharmaceuticals, medical devices, implants, infusion pumps, compounded medicines, biologics, over-the-counter drugs, solvents, acids, benzene, per- and polyfluoroalkyl (PFAS), mixed chemical exposures, mold, Legionella, pesticides, cosmetics, food, beverages, nutritional supplements, commercial and consumer household goods. She represents hospitals, physicians, medical practices, nurses, physical therapists, pharmacists and other health care providers in claims of negligence, medical malpractice, hospital-based toxic exposures and medical device malfunctions.

to lack of causation. (*citing Tomaselli v. New York & Presbyterian Hospital*, 728 F. App'x 41 (2d Cir. 2018) (summary order). Also, the implanting surgeon was an informed intermediary and was sufficiently warned of the risk of fracture. (*citing Fane v. Zimmer, Inc.*, 927 F.2d 124, 129 (2d Cir. 1991).

Insofar as the warranty claims were concerned, the Court noted that prior to his surgery, plaintiff had no contact with defendant manufacturer, received no information from defendant, and was unaware of any warranty by defendant. Plaintiff did not address the continued viability of the breach of warranty claims given this factual record and the Court deemed the breach of warranty claims abandoned.

Medical Devices: Potential Implication for Future Cases

Causation is a matter within the unique purview of expert witness opinion evidence. Even a medical device fracture requires proof of defect in design, manufacture or warning through expert opinion. A known risk of fracture may trigger the learned intermediary defense.

Expert Opinion of Biologic Causation Under *Frye - Wholey v. Amgen Inc.*, 232 A.D.3d 565 (1st Dept. 2024)

Plaintiffs alleged that Wholey's use of Enbrel, an FDA-approved biologic product, to address rheumatoid arthritis, caused her to develop squamous cell carcinoma of the tongue (SCCT). Defendants moved to exclude the opinions by plaintiffs' general causation experts, and for summary judgment dismissing the complaint. The trial court excluded plaintiffs' causation experts from testifying, and found plaintiffs failed to sustain the burden of establishing that the experts' theory of causation was generally accepted in the relevant scientific community, under the *Frye* rule (*see Frye v United States*, 293 F. 1013 (D.C. Cir. 1923)).

Plaintiffs' experts acknowledged there were no clinical studies or medical literature to support their causation theory. Plaintiffs' experts also failed to establish that their reliance upon an individual case occurrence, as well as FDA warnings and adverse case reports related to the use of Enbrel, was an accepted methodology of determining a causal connection between plaintiff's SCCT and her use of Enbrel. The First Department has held that "observational studies or case reports are not generally accepted in the scientific community on questions of causation" (*citing Heckstall v Pinkus*, 19 A.D.3d 203, 205 (1st Dept 2005)).

Plaintiffs could cite no New York cases that support their "steppingstone methodology" argument, and to the extent they relied on a federal case to advance that

argument (*In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 612 F. Supp. 2d 116 (D. Mass 2009)), the Special Master persuasively distinguished the case, noting that the class of drugs analyzed there was understood to share the same mechanism of action. Here, by contrast, plaintiffs' experts did not rebut the statements of Defendants' experts that Enbrel had a unique mechanism of action compared with other similar drugs. In any event, the Appellate Division observed, federal expert admissibility standards under *Daubert v Merrill Dow Pharms., Inc.*, 509 U.S. 579 (1993) are less stringent than New York's *Frye* rule. As there was no other evidence in the record to create a factual issue as to whether Wholey's use of Enbrel caused her SCCT, dismissal of the complaint was affirmed.

Biologics: Potential Implication for Future Cases

New York state strictly applies the *Frye* "general acceptance" rule to medical product causation, which is considered a more stringent standard than *Daubert*, and requires that experts posit an accepted methodology of determining causal connection between use of the product and the disease alleged.

PFAS in Food Packaging Class Action- *Winans v. Ornua Foods North America Inc.*, 731 F. Supp. 3d 422 (E.D.N.Y. 2024)

In this putative class action relating to the alleged presence of per- and polyfluoralkyl substances ("PFAS") in Kerrygold Salted and Unsalted Butter Sticks labeled as "PURE IRISH BUTTER", defendant Ornua Foods North America Inc. moved to dismiss under FRCP Rules 12(b)(1) and 12(b)(6) the claims for deceptive business acts or practices in violation of New York General Business Law § 349; false advertising in violation of GBL § 350; selling of adulterated or misbranded food in violation of the New York State Agriculture & Markets Law § 199-a; negligence *per se*; and unjust enrichment. In response to a New York state law banning PFAS in food packaging, Ornua had issued a recall of its Kerrygold Butter products because the packaging contained PFAS.

The federal district court found plaintiff had Article III standing to bring her claims. Although some courts have required testing to prove that the PFAS allegations were plausible (actual presence of PFAS in product), here there was a recall, and thus no need to prove the presence of PFAS. It was also plausible to plead that the PFAS could migrate from the packaging to the butter itself. However, plaintiff lacked standing to seek injunctive relief individually and on behalf of a class. The public injunction claim was dismissed.

Ornua's motion to dismiss was denied in reference to the GBL §§ 349 and 350, AML § 199-a, unjust enrichment and negligence *per se* claims. These claims survived, as the misrepresentations were plausibly pled. Ornua urged the Court to read the phase "pure Irish butter" as meaning "butter purely from Ireland," rather than "pure butter from Ireland." Assuming the butter contained PFAS, the Court concluded that a reasonable consumer could be misled by the "pure Irish butter" label and it was plausible that a reasonable consumer reading the label would conclude that the adjective "pure" modifies the noun "butter." The word "pure" is a common product label, and other courts have concluded that a reasonable consumer viewing the product would interpret the terms to mean that the product is free of other substances.

"All Natural" Foods Multidistrict Litigation Claims - *Bustamante v. Kind, LLC*, 100 F.4th 419 (2d Cir. 2024)

In this multidistrict litigation, plaintiffs-appellants asserted that the phrase "All Natural" that appeared on the labels of KIND food products was deceptive and misleading. Plaintiffs sought damages on behalf of themselves and three classes, based on common law fraud, as well as consumer protection and false advertising laws in New York, California and Florida.

After the parties completed discovery, KIND moved for summary judgment, to preclude plaintiffs' experts from offering testimony in opposition to its motion for summary judgment, and to decertify the classes. The district court excluded the expert reports, finding that the consumer perceptions surveys upon which the expert theories were based were biased, leading, and methodologically flawed. These failures, and expert opinions which challenged ingredients as "typically" sourced or not "natural" provided no useful information about how a reasonable consumer understands "All Natural." Plaintiffs' purported evidence failed to present any cohesive definition of what a reasonable consumer would expect from products labeled "All Natural."

The Second Circuit affirmed the district court's grant of summary judgment and preclusion of the opinions of plaintiffs' experts. Notably, while the "evidence" to which plaintiffs pointed may have sufficed to overcome a motion to dismiss, or to support a motion for class certification, it failed to raise a triable issue of fact at summary judgment. Because plaintiffs failed to produce admissible evidence demonstrating what a reasonable consumer acting reasonably, would expect of KIND products bearing the "All Natural" label, summary judgment was proper.

Deference to Primary Jurisdiction of FDA - *White et al. v. Beech-Nut Nutrition Co.*, No. 23-220-cv, 2024 WL 194699 (2d Cir. January 18, 2024)

Plaintiffs, parents of babies allegedly exposed to dangerous levels of lead, arsenic, cadmium and mercury in baby food, appealed from the Northern District of New York's order dismissing their claims without prejudice in deference to FDA under the primary jurisdiction doctrine. Beech-Nut had filed a motion to dismiss, or alternatively sought to stay the 70 count putative class action, arguing that FDA had primary jurisdiction over plaintiffs' claims. In deferring under the primary jurisdiction doctrine, the district court reasoned that FDA was working on its initiative, "Closer to Zero: Action Plan for Baby Foods" where, by April 2024, FDA planned to finalize action levels for lead and propose action levels for arsenic, with cadmium and mercury consideration.

However, circumstances changed and FDA no longer expected to finalize lead action levels in April 2024, and it revised its expected timeline for issuing draft guidance on proposed action levels for arsenic and cadmium. [In fact, FDA did not issue its guidance for industry on the action levels for lead in processed food intended for babies and young children until January 6,

2025.] Thus, on balance, the Second Circuit concluded that the potential costs resulting from these indefinite delays outweighed any possible benefits that could be obtained from deferring to the agency. In doing so, the Court found it unnecessary to apply the so-called *Ellis* factors. *Ellis v. Trib. Television Co.,* 443 F.3d 71, 82-83 (2d Cir. 2006) ((1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made). For these reasons, the Court vacated the judgment of the district court and remanded the case for further proceedings.

Foods: Potential Implication for Future Cases

While New York federal courts continue to scrutinize purported class actions involving food products which might contain PFAS to ensure the claims are plausibly pled, and they often require testing to prove PFAS presence, the testing requirement may be unnecessary if the presence is not in dispute, such as evidenced by a recall. In other instances, FDA may have the initial right and burden to promulgate standards for foods, but where FDA fails to act as promised, deference will not be afforded.

Dietary Supplement Labeling Express Preemption- *Jackson-Mau v. Walgreen Co.*, 115 F.4th 121 (2d Cir. 2024)

In a putative class action against a glucosamine-based dietary supplement manufacturer and retailer, asserting three causes of action under New York law: deceptive business practices in violation of GBL § 349, breach of contract, and unjust enrichment, consumer alleged that the dietary supplement she purchased was mislabeled because it contained a different formulation of glucosamine than the one displayed on the front of the label and disclosed on the label's Supplement Facts panel. The complaint alleged the product's label, which displayed the name "Glucosamine Sulfate" and identified the dietary ingredient as "Glucosamine Sulfate Potassium Chloride," misled her into believing that the product contained single-crystal glucosamine when it in fact contained blended glucosamine.

Defendants moved for summary judgment on the ground that the state law mislabeling claims were wholly preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., which establishes national standards for the labeling of dietary supplements. The district court granted summary judgment for defendants on federal preemption grounds. On appeal, the Second Circuit affirmed.

A dietary supplement manufacturer must declare the names of the dietary ingredients that are present in the supplement in the Supplement Facts panel, usually found on the side of a product's label. See 21 C.F.R. § 101.36(b), (e). Dietary ingredients for which FDA has not established a Reference Daily Intake or Daily Reference Value must be declared by their "common or usual name[s]," determined by testing the ingredient with a validated method of identification. Id. § 101.36(b)(3)(i). Thus, in the absence of an established Reference Daily Intake or Daily Reference Value, glucosamine must be declared by its common or usual name. Reliable and appropriate methods of identification may be found in compendia, such as the official United States Pharmacopoeia. The Second Circuit agreed that defendants had shown that the product's glucosamine-based dietary ingredient passed compendial identity tests.

Plaintiff's mislabeling theory as to the Supplement Facts panel was expressly foreclosed by 21 U.S.C. § 343-1(a) (4), which preempts "any [state] requirement for nutrition labeling of food that is not identical to the [common or usual name] requirement of section 343(q)." *Id.* Because FDA has not established Reference Daily Intakes or Daily Reference Values for glucosamine-based dietary ingredients, *see* 21 C.F.R. § 101.9(c), the product was properly branded under section 343(q) as determined by a reliable and appropriate method of identification. Plaintiff's state law claims as to the Supplement Facts panel would thus impose under state law a labeling requirement for blended and single-crystal glucosamine that is "not identical to" the "common or usual name" requirement imposed by 21 U.S.C. § 343(q) and implemented by 21 C.F.R. §§ 101.36(b) (3), 101.9(g)(2). This is exactly what the FDCA does not permit, affording express preemption under FDCA.

Medical products that generally do not require FDA's pre-approval, such as dietary supplements, are nonetheless subject to standards set out by the Food, Drug, and Cosmetic Act

OTC Drug Preemption of Ineffective Claims - *In re: Oral Phenylephrine Marketing and Sales Practices Litigation,* No. 23-md-3089-BMC, 2024 WL 4606818 (E.D.N.Y. October 29, 2024) (appeal filed 12/20/2024)

Plaintiffs brought nearly one hundred cases, consolidated in a multidistrict litigation, against defendant retailers and manufacturers of over-the-counter ("OTC") cough and cold medicines containing the drug phenylephrine ("PE"). Plaintiffs, purchasers of these medicines, alleged that defendants knew that PE was ineffective as a nasal and sinus decongestant but produced, marketed and sold products containing PE to consumers anyway. The parties agreed that plaintiffs would file a "streamlined" complaint, and defendants would move to dismiss it, to test claims and defenses common across the consolidated cases. The complaint asserted various claims under New York state law, as well as a civil Racketeer Influenced and Corrupt Organizations Act ("RICO") claim. Defendants contended that the state claims were preempted by the federal Food, Drug, and Cosmetic Act (the "FDCA"), that plaintiffs lacked standing to assert the RICO claim, and that the RICO claim was precluded by the FDCA.

FDA approved PE as a "safe and effective" nasal decongestant since 1985. In 2007, three individuals petitioned FDA to increase the allowed maximum dose of PE because a meta-analysis of existing studies indicated that, at the current dosage level, PE was likely no better than a placebo. FDA's Nonprescription Drug Advisory Committee ("NDAC") reviewed the petition but, finding further study was needed, did not recommend that the FDA declassify PE as "safe and effective" or change any regulations governing the labeling and dosage of PE products. A group of manufacturers associated with one another, including through the Phenylephrine Task Group of the Consumer Healthcare Products Association, banded together to defend the effectiveness of PE. Plaintiffs alleged that the task group provided deliberately misleading submissions to the NDAC on multiple occasions and disseminated similarly misleading information to the public in the form of press releases, studies and surveys, and that was a violation of RICO.

The district court dismissed plaintiffs' claims as preempted. The existing PE monograph and the general monograph did not suggest that manufacturers have a freestanding duty to update their indications in response to new scientific information. Indeed, the Court found it unclear if manufacturers could even do so without misbranding the product: if they updated the "Uses" section to indicate that PE is not an effective nasal decongestant, they would be using alternative language describing exactly the opposite of those indications for use established in the applicable OTC drug monograph. Here, the Court reasoned that by promulgating the monograph regulation as one means of OTC drug approval, FDA determined that it is neither false nor misleading to represent that PE is an effective decongestant. Manufacturers, of course, are obligated to respond to newly acquired scientific information if, for example, the drug is found to be dangerous to health. But manufacturers are not obligated to update their indications simply because the drug may be ineffective.

In addition to their state law claims, plaintiffs alleges that the RICO defendants violated RICO by engaging in numerous acts of mail and wire fraud in furtherance of a scheme to defraud the public and mislead FDA into believing that PE is an effective decongestant. Defendants moved to dismiss plaintiffs' civil RICO claim for lack of statutory standing and preclusion by the FDCA. Applying the "direct purchaser" rule, a standing doctrine that bars downstream indirect purchasers from bringing an antitrust claim to plaintiffs' civil RICO claim, the Court dismissed plaintiffs' claim for lack of standing.

By excepting state product liability law from express preemption in the FDCA's OTC drug provisions (21 U.S.C. § 379r), Congress allowed states to layer additional state protections atop federal ones, but only when those protections relate to safety; whether a drug is effective remains within the exclusive purview of FDA. This division reflects a balance between twin aims of the FDCA: safety and uniformity.

Preemption under OTC Monographs - *Collaza v. Johnson & Johnson Consumer, Inc.*, No. 23-cv-06030 (ALC), 2024 WL 3965933 (S.D.N.Y. August 27, 2024) (appeal filed on 9/27/2024)

Plaintiff brought a purported class action complaint alleging Tylenol Extra Strength Rapid Release Gelcaps purchased did not work faster than cheaper Tylenol alternatives. FDA published a tentative final monograph on acetaminophen in 1988 which set the "conditions under which a category of OTC drugs or specific OTC drugs [including acetaminophen] are generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(7)(i). FDA had also published two nonbinding guidance documents on acetaminophen dissolution rates. Defendant argued that the 1988 monograph's requirements for "immediate release" labeling on OTC drugs like acetaminophen preempted plaintiff's New York state common law claims of violation of New York General Business Law § 349 and § 350, unjust enrichment and declaratory relief. Other courts in New York, Massachusetts and California previously came to the same conclusion that similar allegations as to "rapid release" acetaminophen products were preempted by the FDCA's regulation of "immediate release" tablets. Plaintiff suggested that "immediate" and "rapid" are not synonymous. However, the "immediate release" and "rapid release" terms both referred to the products' dissolution rate and were sufficiently similar such that they were covered by the FDA regulations.

Even though FDA did not use the exact words "rapid release" in its regulations, this does not mean that FDA does not regulate the subject matter of OTC acetaminophen dissolution standards. FDA published regulations and guidance addressing when an OTC acetaminophen product can be considered "immediate release," "rapidly dissolving" and "very rapidly dissolving." Plaintiff's claims were thus preempted.

OTC Drugs and Dietary Supplements: Potential Implication for Future Cases

Medical products that generally do not require FDA's pre-approval, such as dietary supplements, are nonetheless subject to standards set out by the Food, Drug, and Cosmetic Act which can provide preemption of labeling claims. Monographs which describe the conditions under which OTC drugs are generally recognized as safe and effective can provide a preemption basis.

Vaccines- 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

Effective January 1, 2025, the Secretary of the Department of Health and Human Services has amended its Declaration under the PREP Act to provide liability immunity to certain individuals and entities against any claims arising out of the manufacture, distribution, administration or use of medical countermeasures, including COVID-19 vaccines, through December 31, 2029. The Secretary has determined there is a credible risk that COVID-19 may in the future constitute an emergency and has amended the Declaration to prepare for and mitigate that future risk, by extending the time period of federal liability immunity.

Five Myths About Appellate Lawyers

By Lawrence S. Ebner

This article identifies and attempts to debunk what I believe are several of the common myths about appellate lawyers and the services that we provide.

Appellate practice has become increasingly popular, especially among younger attorneys, and even law students, who relish the challenge of writing persuasive appellate briefs on complex legal issues and presenting oral arguments before federal and state appellate courts. But I continue to be surprised about some lingering misconceptions concerning what we appellate lawyers do, when, where, and how we interact with trial counsel, and the economics of engaging us.

This article identifies and attempts to debunk what I believe are several of the common myths about appellate lawyers and the services that we provide.

Myth # 1: Appellate lawyers are not really litigators.

Yes we are.

Many corporate clients, as well as an increasing number of state bar associations, recognize that appellate practice is a distinct litigation specialty. Like trial work, successfully handling an appeal requires its own unique set of litigation knowledge, skills, and experience. Presenting a closing argument to a jury, for example, is quite different in substance and tone than conversing with an appellate panel about a complex legal issue. And the process of drafting a comprehensive set of interrogatories bears little resemblance to authoring an appellate brief that complies with the applicable rules and is written in the elevated style that appellate judges expect.

"Appellate specialists typically exhibit increased competence, interest, and experience in legal research, knowledge of substantive law, in-depth analysis, and legal writing. They are useful in setting long-range strategy early in litigation. They are an important resource on legal issues at trial. And they are essential in the appellate courts where the culture is quite different from trial courts." American Academy of Appellate Lawyers, Appellate Lawyers Make A Difference, https://www.appellateacademy.org/find-an-appellate-lawyer.

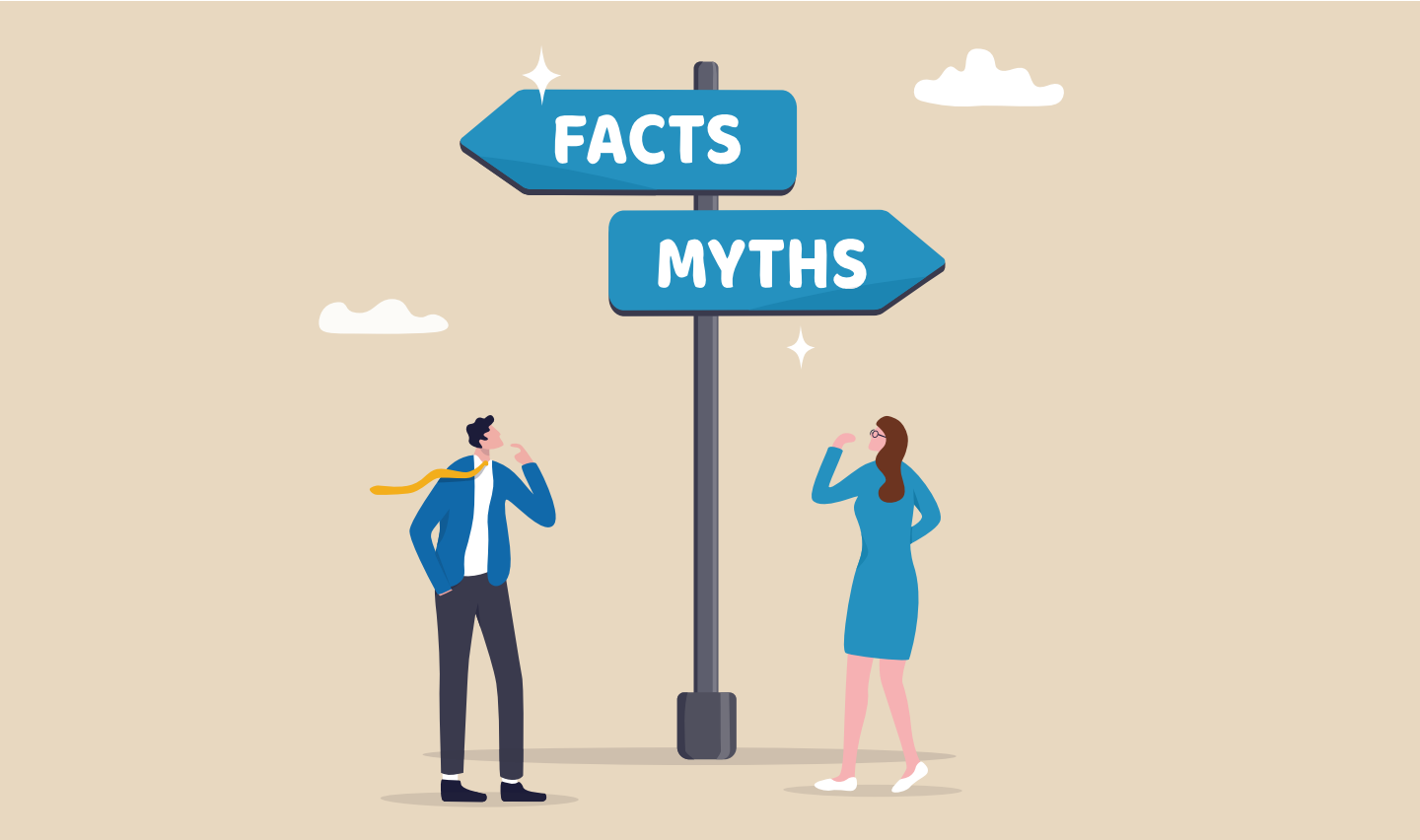
There unquestionably is a difference regarding what an appellate specialist can bring to a case for the benefit of the litigation team and its clients. Unlike decades ago, appellate and trial lawyers no longer function in separate worlds. Indeed, appellate and trial attorneys' differing legal skills complement each other at both the trial court and appellate court levels.

Myth # 2: Trial lawyers should handle their own appeals because they know the record better than anyone.

Few truly outstanding trial lawyers are equally talented appellate advocates. This is why appellate specialists increasingly are being added to trial teams, often from the outset of a case. "Experienced trial counsel understand that adding an outstanding appellate advocate to the trial team can reap benefits before, during, and after trial." American Academy of Appellate Lawyers, *supra*.

Appellate specialists add value at the trial-court level by working with the trial team in many ways, such as planning overall litigation strategy; framing and preserving legal issues; researching, briefing, and arguing threshold and dispositive motions; identifying discovery, trial testimony, and exhibits needed to be admitted into evidence for possible appellate purposes; preparing jury instructions and objections; and assessing the chances for success in the event of an appeal.

Lawrence S. Ebner, a Fellow of the American Academy of Appellate Lawyers, is Founding Member of ***Capital Appellate Advocacy PLLC*** in Washington, D.C., and Executive Vice President & General Counsel of the ***Atlantic Legal Foundation***. He is immediate past chair of the ***DRI Center for Law and Public Policy*** and a member and past chair of the DRI Amicus Committee.



Embedded appellate counsel, therefore, have detailed, first-hand knowledge of the procedural and evidentiary record and are well positioned to take the lead if a case goes on appeal. Even if not involved at trial, appellate litigators routinely review and work with the record on appeal. One of their key functions is to help decide which issues (among many potential issues) should be pursued on appeal, how to frame those issues, and the best way to support them with evidence from the record, including by preparing the required Statement of the Case. *See, e.g.*, Fed. R. App. P. 28(a)(6) (requiring an appellant's brief to provide "a concise statement of the case setting out the facts relevant to the issues submitted for review... with appropriate references to the record").

Along the same lines, unless a client otherwise directs, trial lawyers continue to fulfill an important role when their case goes on appeal. They are an essential resource to appellate counsel during every phase of an appeal. Ideally, trial and appellate lawyers should be an integral part of a litigation team throughout the life of a case.

Myth # 3: The Supreme Court Bar is composed of a small number of appellate superstars.

When legal media publish articles about "the Supreme Court Bar," they usually are referring to less than 50 repeat or up-and-coming players—highly skilled attorneys (including from the Office of the Solicitor General), many of them former Supreme Court law clerks—who every term collectively handle a significant percentage of oral arguments held by the Court.

But there is a lot more to Supreme Court practice than oral arguments, especially since the Court in recent years has held hearings in only about 50 to 70 cases per term. In reality, the vast majority of Supreme Court practice is in written form, primarily certiorari petitions and responses, merits briefs in certiorari-granted cases, and amicus briefs. Several hundred appellate attorneys around the United States, virtually all of whom have been admitted to the Supreme Court Bar, devote a substantial part of their practices to researching and drafting these very important Supreme Court petitions and briefs.

In other words, the real Supreme Court Bar not only consists of the small, elite, very talented group of attorneys who repeatedly appear before the Court to orally argue cases, but also hundreds of other attorneys who frequently write and file Supreme Court petitions and briefs.

On the other hand, tens of thousands of lawyers (some with only the minimum required 3 years of law practice) have submitted an application for membership in the Bar of the Supreme Court and received an impressive certificate to hang on their walls. The vast majority never have filed a petition or brief in the Supreme Court.

Myth # 4: Amicus briefs don't really matter.

Submission of amicus briefs has become a well-accepted part of practicing before the Supreme Court, federal courts of appeals, and many state appellate courts. Professional groups (such as DRI and its Center for Law and Public Policy), industry trade associations, nonprofit public interest law firms (such as the Atlantic Legal Foundation, where I conduct the amicus program),

and experts such as law professors, are frequent filers of private-party amicus briefs.

There is an art to drafting effective amicus briefs, which are quite different than party briefs. If an amicus brief follows the rules as to format and content—and offers something different than repetition of the supported party's or other amici curiae's legal arguments—they can be of considerable value to an appellate court. See Sup. Ct. R. 37.1 ("An *amicus curiae* brief that brings to the attention of the Court relevant matter not already brought to its attention by the parties may be of considerable help to the Court. An *amicus curiae* brief that does not serve this purpose burdens the Court, and its filing is not favored.").

In the Supreme Court amicus briefs filed in support of a pending certiorari petition can be particularly helpful, not only in terms of the number filed, but also if they add perspective on the importance of the question presented, such as the impact of the issue on an entire industry.

Merits-stage amicus briefs are similarly important. They not only can provide supplemental argument or other information that can influence, and sometimes is cited in, the Court's opinions, but also afford amici curiae a direct voice on issues that are important to their members and supporters.

The same is true in lower appellate courts. In fact, because fewer amicus briefs are filed in federal courts of appeals and state appellate courts, their influence on a decision can be even greater than in the Supreme Court.

Myth # 5: Appellate work is not profitable.

Some law firms still erroneously view handling appeals or writing amicus briefs as "loss leaders" for business development purposes. And in some firms egos get in the way of recruiting highly skilled and experienced appellate specialists.

Although appellate litigation activities usually involve fewer attorneys than trial work, they still can be profitable.

Like other practice areas, the key is efficient management of legal resources. Because the course of an appeal usually is well defined and involves a limited number of steps, and the record on appeal already exists, fee estimates for each phase of an appeal—for example, case evaluation and strategy, research and drafting of petitions and/or briefs, solicitation of amicus support, and preparation for and presentation of oral argument—can be more predictable than trial-court work.

For the same reason, flat-fee billing and appellate practice are especially compatible. An increasing number of clients and appellate lawyers find that phase-by-phase flat-fee billing (i.e., charging a predetermined flat fee for each successive phase of an appeal) is beneficial. Clients are better able to budget litigation expenses than when being billed by the hour. Along the same lines, as computerized legal research, coupled with prudent use of artificial intelligence, continues to improve efficiency, charging a flat fee for preparation of a brief may be more profitable than billing by the hour.

Equally important, many appellate brief writers find that they can do their best, most productive work when relieved of the pressure of billing by the hour while watching the clock tick.

Equally important, many appellate brief writers find that they can do their best, most productive work when relieved of the pressure of billing by the hour while watching the clock tick.

Conclusion

There are many reasons to involve one or more appellate specialists from the outset of a case in trial court through its conclusion in the appellate courts. DRI is fortunate to have many appellate litigators among its members, some of whom actively participate in DRI's Appellate Advocacy Committee and Amicus Committee.

Litigation Funding

Tipping the Scales from Justice for Litigants to Profits for Investors

By Maryan Alexander

Jury awards continue to trend toward higher verdicts, a phenomenon that is attributed in part to litigation funding.

Litigation funding is a burgeoning multi-billion-dollar industry that has disrupted the insurance and legal industries. Third-party litigation funding (TPLF) is a practice in which independent parties, typically hedge funds or investment firms, provide non-recourse financial support to assist plaintiffs pursuing litigation in exchange for a sizable portion of any settlement or verdict.

This arrangement allows litigation funders to collaborate with plaintiffs' lawyers as to litigation strategy. The entire practice operates largely in secret, and there is little transparency. The use of TPLF arrangements in several high-profile litigation matters such as Hulk Hogan's lawsuit against Gawker, the NFL concussion cases, and the #MeToo claims has gained a great deal of media attention, thereby exposing many aspects of these furtive TPLF practices. With that, numerous concerns regarding the practice have emerged.

How It Works

Litigation funders research and identify cases that are likely to yield large awards and work with law firms or plaintiffs' lawyers to pay the litigation costs in exchange for a share of the outcome. Like traditional investment practices, TPLFs invest capital in litigation as a mechanism to diversify investment portfolios to reduce risk and stabilize returns by expanding investment opportunities into the legal sector, which has traditionally been an untapped market. The returns on those TPLF investments can pay handsome rewards, especially in high-stakes cases.

There are two types of litigation funding:

- In the individual plaintiff model, the funder advances money to a plaintiff and then charges interest that can exceed the initial loan value.
- In the second model, the funder advances money to a plaintiff or a law firm for either a particular case or a portfolio of cases in exchange for a portion of the settlement or verdict. These payments are made on a non-recourse basis, meaning that if the plaintiff does not recover in the litigation, then the funder will not get paid. In effect, the non-recourse nature of funding agreements resembles contingency fee arrangements.

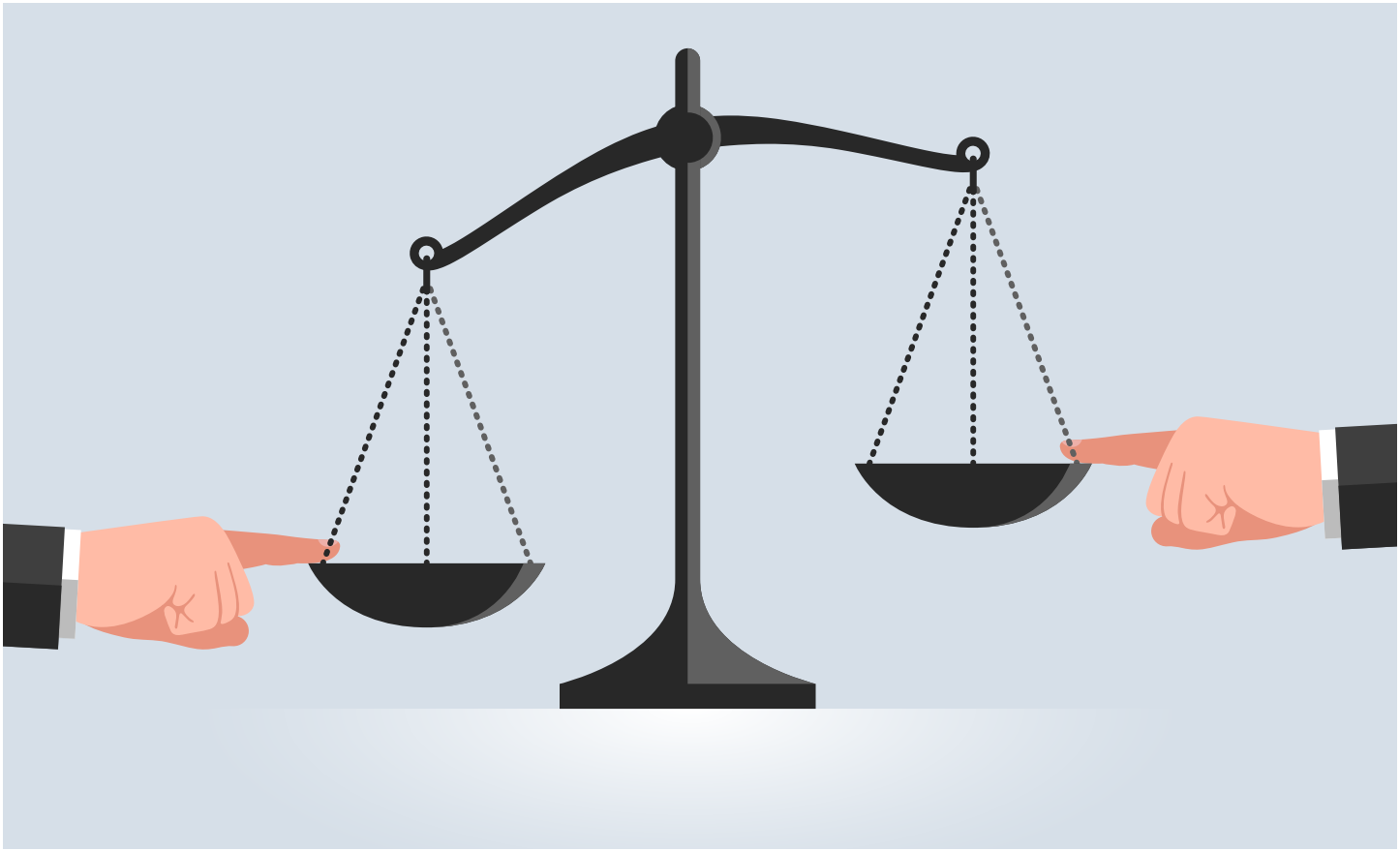
In addition to funding individual actions, TPLFs engage in "portfolio funding," a practice in which funders invest in multiple cases in different practice areas at a single law firm, which gives them an interest in the outcome of an entire portfolio of lawsuits. Portfolio funding only amplifies concerns. Essentially, it is analogous to buying ownership over a law firm, presenting conflicts of interest issues, and prioritizing profit maximization. It can jeopardize a law firm's duties to individual clients in favor of meeting the objectives of the firm's financier.

TPLFs have been touted as a mechanism to increase access to justice for plaintiffs who otherwise would be unable to pursue legal action against wealthy or powerful adversaries. Despite this perceived benefit, numerous concerns have emerged regarding TPLF practices as a few of the funding arrangements have become public.

Impact on the Legal Industry – Rise in Frivolous Lawsuits, Conflicts of Interest

Among the slew of concerns is that TPLFs are fueling an increase in frivolous lawsuits and driving up jury verdicts. TPLFs face very little personal risk in their litigation investments, which is believed to incentivize funders to invest in voluminous lawsuits even when the claims are frivolous in the hope that businesses will opt for a quick settlement, rather than incur the high cost of defense.

Maryan Alexander is a partner at Wilson Elser. She can be reached at maryan.alexander@wilsonelser.com



Funding also can be used to shape case law. By investing heavily in litigation, funders can target certain areas of law and influence outcomes with the goal of changing precedent. Funders can do this by outspending their adversaries and hiring premiere litigation experts to testify at trial and present Hollywood-quality visual exhibits and high-tech computer animations for the jury.

Funders have the resources to fund mock trials to sharpen trial presentations. On the flip side, funders can invest in litigation with the objective of preventing the development of precedent adverse to their own interests. It is not difficult to imagine the number of ways TPLF can be used to manipulate the legal system.

Strategic Influence over Litigation

One of the most troubling aspects of these funding arrangements is the lack of transparency. Funding agreements with law firms and plaintiffs' lawyers are entered into without any disclosure to the judges, defendants, or sometimes the plaintiffs (particularly in class actions), who often are unaware of a third party with a stake in the outcome. Litigation funding agreements may have terms that give funders significant control over key elements of the litigation, including the right to provide input on settlement demands and overtures as well as the management of litigation expenses.

When TPLFs fund multiple related cases, they have an interest in gaining strategic influence over the litigation process and outcome in ways that align with their own financial interests rather than the interests of justice. TPLFs gain control by provisions in the funding agreements that give them the right to select the lawyer and the expert witnesses, and to direct any settlement discussions even if it is to the detriment of the plaintiff.

The result is plaintiffs are less likely to settle quickly or for lower amounts. They are positioned and incentivized to make egregious demands even if it takes longer to resolve the case. This is because an increased settlement means increased profits for the funder who will take a portion of the settlement proceeds.

Sysco v. Burford Capital

Sysco v. Burford Capital is a prime example of a TPLF interfering with and preventing a litigant from accepting a reasonable settlement at the expense of the litigants. The dispute illustrates the conflict of interest between funders and litigants and the significant control given to litigation funders through funding arrangements.

Sysco, a major food distributor, initiated antitrust lawsuits against several meat suppliers using $140 million in litigation funding from Burford Capital. When Sysco sought settlement of its antitrust claims, Burford objected. Sysco then filed a lawsuit against Burford for preventing it from accepting a settlement and prolonging the litigation for greater financial gains. Burford sought to substitute itself as the plaintiff in the Sysco antitrust lawsuits to assume control over Sysco's legal claims.

Litigation funding makes it possible for plaintiffs' firms to engage in expensive litigation tactics. For example, plaintiffs can engage consultants to orchestrate negative media campaigns surrounding the litigation. This may compel a corporate de-

fendant to salvage its reputation and opt for early resolution despite having meritorious defenses. If the corporate defendant opts to go to trial rather than settle, the negative media attention will potentially have tainted the jury. Either way, there is damage to the corporate defendant's reputation.

Bollea v. Gawker Media

In addition, the practice can conceal the true motivations behind a lawsuit as seen in Bollea v. Gawker Media. In 2012, Terry Gene Bollea, better known as Hulk Hogan, sued Gawker Media for invasion of privacy after Gawker published excerpts from a private video. In 2016, a Florida jury awarded Hogan $140 million in damages. The verdict eventually led to Gawker having to file bankruptcy.

After the trial, it was revealed that Peter Thiel, a Silicon Valley billionaire and cofounder of PayPal, secretly funded Hogan's legal battle against Gawker. Thiel had a personal vendetta against Gawker, stemming from its 2007 article that outed him as gay without his consent. Thiel's funding revealed how wealthy individuals can influence legal outcomes by bankrolling lawsuits and weaponizing the legal system against their adversaries.

Threat to National Security

The primary leaders in voicing concerns over TPLF practices have been insurers, legal professionals, and policymakers, but the impact of these practices reaches far beyond these entities. A growing area of concern is the threat that a foreign power could potentially use TPLFs to destabilize U.S. markets and key sectors of the economy, or to influence the outcome of litigation involving divisive or political issues to align with their own strategic interests.

The few TPLF agreements that have been disclosed show that funders have access to evidence and discovery used in the litigation. By taking control of high-stakes litigation, foreign adversaries may gain access to sensitive and confidential data such as proprietary information regarding technology or intellectual property and allowing it to come out in a lawsuit.

In another possible scenario, a foreign adversary could use TPLFs to hold U.S. corporations in costly litigation to gain a competitive advantage for foreign competitors. Every dollar that is put toward litigation is money that companies could be putting into hiring additional workforce, maintaining their current workers, innovating new products, investing in research and development, and expanding the business. Not to mention the opportunity cost that companies incur in man-hours lost to defending lawsuits or the reputational damage to their business.

Economic Cost to Consumer Households

Jury awards continue to trend toward higher verdicts, a phenomenon that is attributed in part to litigation funding. The U.S. Chamber of Commerce said in a recent report that the number of verdicts for more than $100 million reached a record in 2023, up nearly 400 percent from 2013. By driving larger verdicts, TLPF practices contribute to increased tort expenses initially borne by businesses, but then passed on to U.S. consumers in the form of higher prices for goods and services.

Higher tort costs also affect the availability and cost of insurance for businesses. As investor-funded litigation increases, so do the litigation defense costs incurred by corporate defendants and their insurers, resulting in increased premiums for insurance policies. Businesses eventually push these expenses on to their consumers.

In a study conducted by the U.S. Chamber of Commerce Institute for Legal Reform in 2020, using the estimated insurable cost paid in the U.S. tort system, found that tort costs in 2020 totaled $443 billion or 2.1 percent of U.S. gross domestic product broken down as follows: $229 billion in general and commercial liabilities, $196.5 billion in automobile accident claims, and $17.5 billion in medical liability claims. To give these figures perspective, the Institute for Legal Reform estimates these tort costs boil down to $3,621 on average per household, with these figures varying from state to state. The highest total tort costs per household in 2020 were New York ($5,408), Florida ($5,065), New Jersey ($5,059), California ($4,599), and Georgia ($4,157). .

Current Regulatory Landscape

Without transparency, it is unknown how much and to what extent litigation funding is being used to exploit the U.S. legal system. The calls for transparency are growing and several state legislatures have responded by enacting or considering legislation to regulate litigation funding.

The reoccurring theme in these calls for setting parameters for TPLF is the need for transparency.

These states have in recent years enacted laws to respond to the calls for regulating TPLFs:

- Montana signed into law Senate Bill 269 (May 2, 2023), which requires disclosure of TPLF agreements in civil cases, requires TPLFs to register with the Montana Secretary of State, makes litigation funders jointly liable for costs, and establishes a 25 percent cap on the amount a TPLF can recover from any lawsuit.
- Indiana passed House Bill 1160 (March 13, 2024), which mandates funding agreements are subject to discovery, restricts funder control of litigation, and prohibits funders from accessing proprietary data.
- West Virginia Senate Bill 850 (April 23, 2024) amends and expands existing laws initially enacted in 2019, requiring registration with the state's attorney general, and disclosure of the terms of the funding agreement regardless of whether it is requested in discovery.
- Louisiana Senate Bill 355 (August 1, 2024) limits foreign litigation funding, prohibits funders from controlling or manipulating litigation, ensures plaintiffs are aware of any outside influences on their cases, and makes litigation finance agreements subject to discovery in civil cases.

Several other states have proposed similar laws to require transparency. Florida House Bill 1179 (2024), if passed, would require disclosure of funding, restrict

funder control of litigation, and prohibit investors from recovering more than the litigant. Kansas House Bill 2510 (2024), if passed, would require disclosure of third-party litigation funding agreements.

Calls for regulation of TPLF practices also are happening at the federal level. In 2019, a proposed amendment to Federal Rule of Civil Procedure 26(a)(1)(A), seeking mandatory disclosures of any TPLFs, failed to pass. In 2024, Congressman Darrell Issa (R-CA) introduced the Litigation Transparency Act of 2024 to mandate litigants to disclose anyone who has the right to receive any contingency payment on the outcome of the litigation as well as to provide a copy of any litigation funding agreement.

The reoccurring theme in these calls for setting parameters for TPLF is the need for transparency. Proposed solutions almost uniformly call for mandatory disclosures of TPLF arrangements, including the identity of funders and the contractual terms of the funding arrangement. Some of the proposed regulations include amending the ABA Model Rules to explicitly address TPLF issues and regulating the TPLF industry by implementing licensing requirements, placing caps on funder returns, and prohibiting funder control over legal strategy. As more and more regulations are implemented, TPLF will become more transparent and the unsustainable negative impact it is having on the legal landscape should eventually wane.