In-House

DEFENSE QUARTERLY

WINTER 2023

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By Michael K. Callahan

Are You Maximizing Your DRI Membership?

Michael K. Callahan is assistant general counsel-litigation at Eversource Energy in Boston, Massachusetts. He is the Second Vice Chair of the DRI Corporate Counsel Committee.

Whether you're the sole in-house counsel at an organization or part of a larger legal team, we are always looking for assistance when it comes to advising our clients. In-house counsel are in the unique position to develop strong relationships with senior executives, internal stakeholders, and decision makers, which is critical when you're advising them about matters. Being in-house allows you to learn and understand the business, its culture, and its approach to risk. As in-house counsel, you are in the best position to identify potential risk, provide risk mitigation, identify lessons learned, and proactively seek to reduce or eliminate those risks going forward.

The daily exposure to legal issues, questions, risks, and challenges provides in-house counsel with a unique lens into the company that few others have. Seeing the big picture from a broad perspective allows the in-house lawyer to address trending issues and, if necessary, bring them to the attention of the C-suite.

My six-year-old grandson frequently greets complete strangers with a loud "hello" when we walk around our town. I think it's awesome, and I like to see the reactions from the recipients of his enthusiast salutations. One day, I asked him why he does it, and his unassuming response was "everybody needs a hello."

In a similar vein, we all need a little help once in a while – whether it's as simple as an unsolicited "hello," navigating the complexities of a transaction, handling the strategic decisions of a litigation matter, or any one of the myriad legal challenges each of you face as in-house counsel.

In-house counsel membership in DRI provides that help and has been a great benefit to me and my practice. Not only does it provide an opportunity to connect with other in-house counsel and share information, but it is also a forum by which to learn how other in-house counsel are addressing the challenges we all face. There are a variety of resources to assist in-house counsel on substantive legal issues as well as legal department operation through online education, webinars, seminars and meetings. Moreover, the networking opportunities provide real-time ability to connect and exchange information in practice areas or legal department operations from other in-house counsel. Membership also allows you the opportunity to stay up to date with the latest technology and trends in your industry.

In-house counsel membership in DRI provides that help and has been a great benefit to me and my practice.

The benefits easily outweigh the cost of admission. Are you making the most of your membership? Check out these key benefits:

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Finally, DRI offers many opportunities for you to take a leadership role in a wide variety of areas while at the same time benefiting from the knowledge and experiences of other in-house attorneys. Maximize your DRI membership by taking advantage of all these opportunities in 2023.

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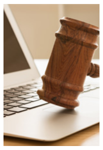


DRUG AND MEDICAL DEVICE

New Hire Wasteland:

By Julie Pugh, Esq., Jayne Pittman, Esq., and Rinaldo J. Cartaya, III, Esq.

Identifying and Fostering Talent in a Candidate Barren Environment

Today, all of us know about one or more companies affected by the lack of good employees due to the shutdown which occurred after the worldwide pandemic began in March of 2020. The workforce in all industries looks a lot different now than it did at the end of 2019. One significant challenge has been how employers address the labor shortage combined with the "Great Resignation." The construction industry has continued to suffer shortages both in workers, attorneys, and claim professionals to manage the large workload associated with construction litigation and pre-litigation matters.

Today, the hiring landscape has changed, and employers have had to adapt new practices to recruit, hire, and maintain a competent work force. This article will define the current state of the employment market, recruiting techniques, interviewing tips, retention methods, and offer best practices by both a lawyer and an adjuster involved in the hiring and retention of employees within their large organizations.

Candidate Barren - New Hire Wasteland

The current state of the unemployment market continues to limit job candidates. Even the most recent unemployment numbers reflect an incredibly low (3.7% October 2022) unemployment rate, which has led to an inflationary effect on the salaries commanded by those seeking employment.

Julie Pugh, Esq., currently serves as an Assistant General Counsel for Litigation and Employment at a large construction distribution company. Prior to her in-house experience, she was a partner at a large Cincinnati law firm. She has varied and unique experience in her talent acquisition and retention of staff in the current job market environment. **Jayne Pittman, Esq.**, is a Florida Board Certified Construction lawyer at the Florida law firm of Conroy Simberg, where she is Chair of the firm's Construction Practice Group as well as the Managing Partner in the Orlando office. Jayne specializes in the practice of construction law defending general contractors, subcontractors, manufacturers, suppliers and design professionals in complex construction defect litigation, and products liability cases in civil, federal and arbitration venues. **Rinaldo J. Cartaya, III, Esq.**, is a partner in the Orlando office of Quintairos, Prieto, Wood & Boyer, P.A., and chairs the firm's Construction Practice Group. He represents general contractors, subcontractors, distributors, manufacturers, and design professionals in all areas of construction litigation and transactional capacity in civil, federal, and alternative dispute resolution venues.

According to the *Bureau of Labor Statistics News Release October 2022 USDL-22-2097*, the National unemployment rate had rose by 306,000 to 6.1 million in October 2022. Among the major worker groups, the unemployment rates for adult women (3.4 percent) and Whites (3.2 percent) rose most in October 2022, while the jobless rates for adult men (3.3 percent), teenagers (11.0 percent), Blacks (5.9 percent), Asians (2.9 percent) and Hispanics (4.2 percent) showed little or no change over the month. Of interest was the "long-term unemployed," which was defined as those who had been jobless for 27 weeks or more, had little change at 1.2 million workers in October 2022 which accounted for 19.5 percent of all unemployed persons.

The same press release defined the labor force participation rate at 62.2 percent, which has shown little net change since 2022 began. Employment participation changed little over the last month in major industries like construction, retail trade, and government.

In addition to the above statistics, the pandemic changed workers' expectations which in turn means that employers need to adjust their obsolete recruiting practices. In the past, a fair wage combined with a generous benefit package (health insurance and retirement benefits) was sufficient to attract workers. Many employees have had time during the pandemic to reevaluate their priorities and desires when it comes to their individual careers. Some employees enjoyed the work from home situation which allowed them to have more time to care for an ailing parent or homeschool a young child. Recruiters now need to be inventive to attract new employees and to encourage others to return to the active workforce. Employers will need to ensure that they are showing their best to prospective employees and that the company understands the employees' desires. Employers will continue to be challenged to keep up with the current expectations of today's workforce and tomorrow's candidates.

Where Do Workers Look for Jobs?

How do today's workers look for jobs? Where should employers advertise their open positions? Companies should consider both the tech-savvy and non tech-savvy candidates.

Identifying "Passive Talent"

Although ZipRecruiter, Monster, and most recently LinkedIn, have dominated the online job seeking marketplace, word of mouth and familial connections continue to foster the most likely successful job candidates. In the litigation arena, "passive talent," meaning sourcing those who are not looking for a job, remains the method of choice for recruiting talent. A number of benefits to recruiting passive talent exist. The candidate typically knows the area of law for which one is recruiting. The candidate's work ethic is known to the legal community, and their reputation has preceded their recruitment. More importantly, the candidate knows what the job description will entail.

> The construction industry has continued to suffer shortages both in workers, attorneys, and claim professionals.

On the contrary, some negatives to the passive talent recruitment process also exist. Generally speaking, the candidate was content working with their current employer and an increased salary is usually necessary to lure them to a new role. Another common recruitment tool is a flexible work schedule or hybrid office environment, which may appeal to some who are at a company that requires working from the office. Both recruitment tools may place a strain on the core business, and it also may lead to other employees requesting similar benefits.

Reputation

A positive company reputation and being known as a great place to work is one of the strongest recruitment tools in a candidate barren environment. Many prospective employees seek historically favorable work environments and read the annual "Best Employer to Work For" lists released every year.

Online reviews are also an incredibly influential recruitment tool (or deterrent). Online forums such as Indeed or Glassdoor allow prospective employees to read current and former employee reviews of the workplace. Many of these online forums disclose salaries or pay ranges and often give personal insights into the work life balance. Online reviews are a double-edged sword, as many of the online reviews are often filed by disgruntled employees or former employees. Word of mouth can be the most successful recruitment tool. Industry reputation and peer opinions are simple ways for passive employment candidates to collect the requisite information they need to determine whether to risk meeting with a prospective employer company. Word of mouth is also the best way for employers to identify prospective employees, especially those that are not actively seeking new employment opportunities but would make an excellent new addition to a workplace team.

The Hiring Process - Posting the Right Job

Companies face an ever-increasing challenge trying to locate potential hires. The last thing a manager wants to do is recruit a potential candidate only to realize they misunderstood the job responsibilities.

Accurate and Thorough Job Descriptions Matter

There are myriad elements to listing the job description befitting the role you are seeking to fill. A thorough job description will include the following:

- Location of the job, including whether or not the work will be done remotely
- Salary band/range
- Mission / vision / values
- Brief description of each Essential Job Function
- Physical and mental requirements
- Soft skill and technological requirements
- ALWAYS include that other duties, tasks, and responsibilities may be assigned at any time

As the employer, a key tip is to vet the job description with the hiring manager and ask that person to put some thought into the ideal candidate. In a law firm, the managing partner usually conducts interviews of candidates, but the direct supervisor may also be included for input as to what the caseload requires, what the needs of the legal team are, and what they want in a new associate or team member.

Once the job description is complete, a simplified job posting can be created. It may also be beneficial to post the same job with various/alternate titles to reach the widest audience of candidates.

Interview Tips

When interviewing qualified candidates, begin with an introduction of the company, the interviewer, and the open position. Be prepared to sell the company. It is key to know the details, how many offices, type of work, how long in business, client's expectations and then define how the position fits into the organization. Tie the introduction into the first question asked of the candidate.

Once the landscape has been set, begin the interview to get to know who the applicant is and why they want this position. It is best to ask job related questions which are open ended and wait for the applicant to answer. Eliminate distractions during the interview. If it is held in person, pick a conference room or a quiet office away from the daily distractions. If it is on Zoom, make sure that you look into the camera and pay attention to the candidate. Eliminate any background noises like pets or other guests. Never look at your phone or computer during an interview, as that action can be distracting and shows a lack of interest in the candidate. In addition to speaking, good interviewers are also good listeners. End the interview by turning the table and letting the candidate formulate and ask questions. This is a great opportunity to hear what the candidate is looking for and get a good example of how they create questions.

Expect to be asked about a remote work option. As an employer, be clear as to what the working situation will be for the position. If hybrid, remote work, or flex time are options, include those details in the job description and when selling the company. This is also a way to expand the talent pool. An employer offering remote work may consider posting the position outside traditional geographic boundaries.

Diversity, Equity, Inclusion Considerations

A successful organization should have a well written and circulated Diversity, Equity, Inclusion (DEI) mission statement. The hiring team should also be advised to use the organization's strategic diversity plan when sourcing and hiring candidates.

It may also be beneficial to post the same job with various/alternate titles to reach the widest audience of candidates.

Extending the Offer

Hopefully, every interview results in an offer to the right candidate. Once the hiring decision has been made, be sure the person who extends the offer is positive and enthusiastic in the presentation of the offer. If possible, provide the offer in writing with a legally compliant offer letter, including a list of the contingencies (background check, and drug screen etc.). It is also a good practice to give a deadline to accept the job offer. Normally, 48 hours is sufficient time for a candidate to respond. Ensure that the offer letter is clear that a lack of response means that the job offer expires. Within the acceptance period, a candidate may engage in salary negotiations. A negotiation over the terms of the job is not a negative development, but be viewed as a positive step. The hiring manager should be prepared to immediately respond to such a request and engage in discussion the terms of the position in a welcoming way.

Retaining Talented Employees

The more connected current employees feel to the organization, the higher the likelihood that the employees will be loyal and willing to stay with their current employer. Managers need to ensure they are embracing and exemplifying the organizational culture. Newly hired employees begin to feel connected through a thoroughly planned onboarding training schedule. Keep the employees incentivized by sticking to a consistent review schedule during the first year of employment, such as having a formal review after 90 days, 6 months, and one year. These reviews should outline goals and recognize both failures and successes with proper recognition. Assign a mentor or a welcoming team member (who is not the employee's direct supervisor) to help the employee get acclimated. This mentor can also help the new employee identify a clear advancement process within the organization.

Other retention efforts may include in office raffle prizes, discount coupons for standing or walking desks, plants to refresh the workplace, development of in-office workout or relaxation spaces.

Further examples of benefits that can be developed would include counseling/mental health benefits, parental leave, childcare and or elder care time benefits.

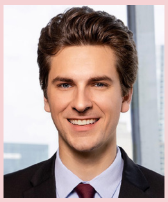
Can you Keep a Secret?

By Jessalyn H. Zeigler, Jeremy Gunn, Garrah Carter-Mason, and Johnny Cerisano

Current Trends in Privilege Law

As every first-year law student knows, attorney-client privilege is a common-law doctrine that protects from disclosure confidential communications between client and counsel. The privilege encourages "full and frank communication between attorneys and their clients" and promotes "broader public interests in the observance of law and administration of justice." *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981). Even so, this area of the law can, and does, change, and there are several areas attorneys must keep abreast of to preserve and protect privilege and avoid disclosure of privileged communications. Over the last decade, the Federal Rules of Civil Procedure and case law have continued developing the contours of the doctrine. This article explores three recent developments and trends on privilege law as it relates to (1) dual-purpose communications containing legal and non-legal advice, (2) communications with insurance brokers, and (3) testifying, but non-reporting experts.



Jessalyn H. Zeigler is a member at Bass, Berry & Sims PLC where she chairs the Product Liability and Torts practice group and works closely with clients facing claims related to product liability, crisis management, environmental, health & safety, healthcare liability, or general business litigation. Jessie advises on class action claims, multidistrict litigation, and single-action claims for various types of product and mass tort cases including automotive products, pharmaceuticals, medical devices, food, chemicals, and industrial/commercial/consumer goods manufacturers. She can be reached at jzeigler@bassberry.com. **Jeremy Gunn**, a senior associate in the Nashville office of Bass, Berry & Sims, represents clients in business and contract disputes, class actions, antitrust matters and product liability claims. Jeremy served as a law clerk to the Honorable John Preston Bailey of the U.S. District Court for the Northern District of West Virginia. **Garrah Carter-Mason**, an associate in the Nashville office of Bass, Berry & Sims, represents clients in complex business litigation, product liability claims and government investigations. She served as a law clerk the Honorable Judge Eli J. Richardson of the U.S. District Court for the Middle District of Tennessee. **Johnny Cerisano**, an associate in the Memphis office of Bass, Berry & Sims, represents clients in complex business litigation, product liability claims, and government investigations. Johnny served as a judicial clerk to the Honorable S. Thomas Anderson of the U.S. District Court for the Western District of Tennessee.

Dual-Purpose Communications

In an increasingly complex regulatory, compliance, and business environment, corporate counsel fulfill multiple roles by providing legal and business advice when communicating with corporate employees. This fact makes the privilege analysis more complex, considering attorney-client privilege "protects only those disclosures necessary to obtain informed legal advice." *Fisher v. United States*, 425 U.S. 391, 403 (1976). Though the scope of attorney-client privilege is defined by the purpose of the communication, *see Swidler & Berlin v. United States,* 524 U.S. 399, 410 (1998), federal courts have grappled with whether attorney-client privilege protects communications that have multiple purposes and provides a combination of legal and business advice. This section addresses when communications containing both legal and non-legal advice are protected by the attorney-client privilege.

In response to a three-way circuit split, the U.S. Supreme Court granted the petition in *In re Grand Jury* to address when a communication containing both legal and non-legal advice is protected by the attorney-client privilege. 23 F.4th 1088, 1091 (9th Cir. 2021), *cert. granted In re Grand Jury*, No. 21-1397, 2022 WL 4651237 (U.S. Oct. 3, 2022). However, only two weeks after hearing oral argument, the Supreme Court dismissed the writ of certiorari as "improvidently granted," meaning that the Court should not have accepted the case. *See In re Grand Jury,* No. 21-1397, 2023 WL 349990 (U.S. Jan. 23, 2023). Accordingly, the issue as to whether dual-purpose communications are protected by attorney-client privilege is still open. While it is unclear why the Supreme Court declined to hear this case, cases are usually dismissed as improvidently granted when the Supreme Court: (1) discovers after the cert grant that the case is a poor vehicle for resolving the issue before the Court; (2) perceives a "bait and switch," which happens when petitioners rely on a different argument in briefing than they did in their petition for cert; or (3) is unable to reach a consensus and apparently thinks that a dismissal as improvidently granted is preferable to fractured opinions with no controlling rationale.[1] Here, the third reason seems most likely, as the Court dismissed the case only two weeks after oral argument, hinting that there was likely disagreement on the best path forward.

Some courts generally use a "primary purpose test" to assess whether a dual-purpose communication's predominant purpose is to provide legal advice or non-legal advice. In *In re Grand Jury*, the Ninth Circuit adopted the "primary-purpose test" and found that "dual-purpose communications can only have a single 'primary' purpose." 23 F.4th at 1091–92. There, a company and law firm were served with grand jury subpoenas requesting communications relating to a criminal tax investigation. Both the company and the law firm produced documents in response to the subpoena but withheld others based on attorney-client privilege and work-product doctrine. *Id.* at 1090. After the government moved to compel the withheld documents, the district court granted the motion in part, finding that the documents were either not protected by any privilege or discoverable under the crime-fraud exception. *Id.* The company and the law firm rejected the district court's ruling and continued to withhold documents. *Id.* at 1090–91. The government later moved to hold the company and law firm in contempt, and the district court granted that motion. *Id.* at 1091.

> Some courts generally use a "primary purpose test" to assess whether a dual-purpose communication's predominant purpose is to provide legal advice or non-legal advice.

On appeal, the Ninth Circuit affirmed the district court's finding that the primary-purpose test applies to attorney-client privilege claims for dual-purpose communications. *Id.* at 1090. The appellate court determined when deciding whether attorney-client privilege should apply to dual-purpose communications, especially in the context of tax law where "attorney's advice may integrally involve both legal and non-legal analyses," courts must analyze whether the communication was made to obtain legal advice. *Id.* at 1091–93 (quoting *United States v. Sanmina Corp.*, 968 F.3d 1107, 1118 (9th Cir. 2020)). The Ninth Circuit concluded that the district court did not err in finding that "the predominate purpose of the disputed communications was not to obtain legal advice," and thus, affirmed to hold the company and law firm in contempt. *Id.* at 1095. Since the U.S. Supreme Court dismissed its prior grant of certiorari, this opinion stands as the current law in the Ninth Circuit.

By contrast, the D.C. Circuit has taken a broader view of privilege by holding that communications are privileged when "obtaining or providing legal advice was one of the significant purposes." *In re Kellogg Brown & Root, Inc.*, 756 F.3d 754, 758 (D.C. Cir. 2014). In *In re Kellogg*, a company appealed a district court's ruling that attorney-client privilege did not protect communications related to a prior internal investigation overseen by the company's legal department. In an opinion authored by Justice Kavanaugh, the *In re Kellogg* court ruled that the district court erred and rejected the idea that a court should "try to find the one primary purpose in cases where a given communication plainly has multiple purposes." *Id.* at 760. Instead, the D.C. Circuit explained that courts should determine whether "obtaining or providing legal advice was one of the significant purposes of the attorney-client communication." *Id.*

Finally, the Seventh Circuit has held that "a dual-purpose document—a document prepared for use in preparing tax returns and for use in litigation—is not privileged." *United States v. Frederick*, 182 F.3d 496, 501 (7th Cir. 1999). Judge Posner reasoned that "otherwise, people in or contemplating litigation would be able to invoke, in effect, an accountant's privilege, provided that

[1] See Debra Cassens Weiss, Attorney-Client Privilege Case Dismissed by Supreme Court, ABAJournal, (Jan. 23, 2023, 11:22 A.M.), https://www.abajournal.com/news/article/attorney-client-privilege-case-is-dismissed-by-supreme-court.

they used their lawyer to fill out their tax returns." *Id.* While the holding is confined to the tax law context, the reasoning conflicts with the tests adopted by the Ninth Circuit and D.C. Circuit.

The Supreme Court recognized over forty years ago that "the vast and complicated array of regulatory legislation confronting the modern corporation" necessitates that corporations "constantly go to lawyers to find out how to obey the law." *Upjohn Co. v. United States*, 449 U.S. 383, 392 (1981) (internal citations omitted). Consistent with this understanding, some court observers hoped the Supreme Court would adopt the reasoning in *Kellogg* and resolve the current circuit split through *In re Grand Jury*; particularly, because corporate counsel need the ability to openly communicate legal advice in business communications without fear that advice is going to later be divulged through litigation.[2] Until the Supreme Court decides to resolve this circuit split, advocates and corporate counsel should continue monitor evolving case law on dual-purpose communications in order to safeguard corporate communications and prevent protracted discovery disputes. For many companies who operate throughout the country, the practical effect is they should seek to keep other purposes out of their legal advice communications. Perhaps lawyers will consider marking communications with clients as "Confidential and Privileged Attorney-Client Communication: Primary Purpose Legal Advice" going forward.

Communications with Insurance Brokers

Attorneys and their clients often work with third parties to obtain legal advice and develop litigation strategy. However, such open communications may jeopardize the attorney-client privilege. In the world of insurance, this section addresses how to protect from disclosure communications between counsel and insurance brokers. If the purpose of the communications was to obtain legal advice, then communications between counsel and insurance brokers are generally protected.

While generally the attorney-client privilege is limited in that only "confidential" communications (*i.e.* communications made exclusively between an attorney and client) are protected and the presence of a third party on a communication generally loses the privilege, courts have recognized circumstances when a third-party disclosure does not vitiate the protections of the doctrine. *See, e.g., High Point SARL v. Sprint Nextel Corp.*, 2012 WL 234024, at*7 (D. Kan. Jan. 25, 2012) (subsequent history omitted) (discussing the "common interest" doctrine which protects disclosures to third parties when the third party has a close, common interest with the represented party). Counsel must remain abreast of developments in this changing area of the law as well.

open communications may jeopardize the attorney-client privilege.

For example, in the insurance context, it may be necessary for an insured's or insurer's counsel to work with an insurance broker to gain information about a pending action or insurance claim. Counsel should know whether communicating otherwise confidential information with an insurance broker breaks the protection of client confidentiality. Generally, the answer is no, and courts find that the "necessary intermediary doctrine" applies. This exception dictates that the attorney-client privilege is not destroyed when a third party's participation is necessary to provide adequate legal representation. *M&C Holdings Delaware Partnership v. Great American Ins.*, 2021 WL 4453636, at *5–6 (S.D. Ohio Sept. 29, 2021). For the exception to apply, "[t]he purpose of the communication with the third-party broker or agent must be to assist the attorney in providing legal services to the client." *Id.* at *7 (citations omitted). To be clear, despite the name of the doctrine, *Great American Insurance* suggests that a third party's participation need not be necessary to the litigation. Instead, the disclosures to a third party are still protected if they are made simply *with the purpose* of obtaining legal advice or developing legal strategy. *See id.* at *7–8.

Discovery Land Co. LLC v. Berkley Insurance Co. illustrates this point. 2022 WL 194527 (D. Ariz., 2022). The dispute in *Discovery Land* arose when the plaintiff's initial funds for purchasing a Scottish castle were stolen—a royal conundrum. *Id.* at *2–3. Defendants argued that communications between plaintiff's counsel and insurance broker took place "in the ordinary course of business" and were not protected from discovery. *Id.* at *8. Ultimately, although the communications between Plaintiff's counsel and the insurance broker discussed the structure of the real estate deal, the court believed that the communications were also made "for the purpose of developing legal recommendations and strategies in connection with this anticipated litigation." *Id.* at *9. Thus, the communications were privileged. *Id.*

Conversely, in *Sony Computer Ent. America, Inc. v. Great American Insurance*, the defendant failed to establish that a meeting between the plaintiff, counsel of plaintiff, and plaintiff's insurance broker was held to obtain legal advice. 229 F.R.D. 632, 634 (N.D. Cal. 2005). There, "[the plaintiff] provided no evidentiary support for its claim that [the insurance broker] was present to further the interest of [the plaintiff] in the consultation or someone to whom disclosure was reasonably necessary to accomplish the purpose for which the lawyer was consulted" and, thus, "failed to carry its burden of proving the privilege." *Id.* The lesson is that, although

[2] See, e.g., Lucy Addleton, ACC Issues Statement Regarding US Supreme Court's Decision to Dismiss In re Grandy Jury case, (Jan. 24, 2023), https://www.thelawyermag.com/au/news/general/acc-issues-statement-regarding-us-supreme-courts-decision-to-dismiss-in-re-grand-jury-case/433821 (discussing the Association of Corporate Counsel's disappointment in the Supreme Court's decision not to decide the case, thereby leaving this area of law "amurky"); Association of Corporate Counsel, ACC Statement Regarding U.S. Supreme Court's Disappointing Decision to Dismiss In re Grand Jury Case (Jan. 23, 2023), https://www.acc.com/about/newsroom/news/acc-statement-regarding-us-supreme-courts-disappointing-decision-dismiss-re ("The dismissal of In re Grand Jury is a missed opportunity to provide [in-house counsel] to provide them needed clarity.").

communicating confidential information to an insurance broker does not ordinarily remove the attorney-client privilege, the party asserting the privilege must bear the burden of proof. Parties must adequately establish that the communications were made with the intent of receiving legal advice, and communications should be made with this standard in mind.

Ultimately, attorneys should still exercise caution when making confidential communications that include an insurance broker, ensuring that the communications address legal advice and strategy. *Sony* also warns attorneys that such discussions should be well-documented so that the communications may withstand motions to compel and preserve confidentiality.

Non-Reporting But Testifying Experts

Communications between counsel and expert witnesses are often protected by the attorney- client privilege, but not always. This section addresses attorney communications with experts who will testify at trial but are not required to file an expert report. Whether communications with such experts are protected is a complex determination that depends on the nature of the testimony and whether the expert will serve as a hybrid fact/expert witness.

Experts can make or break a case. And although expert reports are subject to disclosure to opposing parties, disclosure is not required for all expert communications, and advocates must understand what is protected from discovery prior to retaining their experts. Unfortunately, the expert disclosure requirements found in Rule 26 are not exhaustive, leaving attorneys with incomplete guidance. In response, however, courts have defined the bounds of the attorney-client privilege in the context of expert communications.

As the Eastern District Court of California has pointed out, the 2010 amended version of Federal Rule of Procedure 26 ("Rule 26") is "silent as to communications between a party's attorney and non-reporting experts." *United States v. Sierra Pac. Indus.*, 2011 WL 2119078, at *5 (E.D. Cal. May 26, 2011). The Court, however, provided the following language from the 2010 Advisory Committee Notes:

> The protection is limited to communications between an expert witness required to provide a report under Rule 26(a)(2)(B) and the attorney for the party on whose behalf the witness will be testifying, including any 'preliminary' expert opinions. . . . The rule does not itself protect communications between counsel and other expert witnesses, such as those for whom disclosure is required under Rule 26(a)(2)(C). The rule does not exclude protection under other doctrines, such as privilege or independent development of the work-product doctrine.[3] *Id.* (quoting 2010 Advisory Committee Note to Rule 26).

The issue thus arises as to whether a party has waived the attorney-client privilege when it discloses testifying, but non-reporting, expert witnesses. One area in which the distinction between reporting and non-reporting experts has been significant is testimony by employee opinion witnesses. Other potential examples include "former employees, in-house counsel, independent contractors, treating physicians, and accident investigators." *Id.* at 9.

In *Graco, Inc. v. PMC Global, Inc.*, the New Jersey District Court considered the issue when the plaintiff's employee opinion witnesses who had not yet been named as testifying witnesses and did not regularly give expert testimony, but had submitted affidavits containing expert opinions. 2011 WL 666056, at *4 (D.N.J. Feb. 14, 2011). The defendant had noticed the depositions of two of the plaintiff's employees and served requests for documents to be produced at the deposition, including all documents considered or relied on in drafting the affidavits, all drafts of the affidavits, and all communications with those individuals concerning their affidavits. *Id.* at *1. Objecting to the requests, the plaintiff asserted that the employee declarants "should be treated as non-experts and maintain[ed] that the material requested is protected by the attorney-client privilege or work-product privilege." *Id.* After acknowledging "a significant divergence between the 1993 version (and related case law) and the 2010 version of Rule 26," the Court found, based on the 2010 Advisory Committee Notes and on the plaintiff's "affirmative reliance on the facts and opinions set forth in [the witnesses'] respective affidavits," that the employee opinion witnesses "should be considered 'testifying witnesses.'" for Rule 26 analysis. *Id.* at *13. (citations omitted). Accordingly, the *Graco* Court decided the following about the employee opinion witnesses:

1) [Defendant] is not entitled to a written report . . . pursuant to current, and amended, Rule 26(a)(2) and the 2010 Advisory Committee Note;
2) [Defendant] is entitled to a disclosure stating the subject matter and a summary of the facts and opinions proffered . . . pursuant to amended Rule 26(a)(2)(C) and the 2010 Advisory Committee Note and supplements thereto pursuant to amended Rule 26(a)(2)(E);
3) [Defendant] is not entitled to any drafts, regardless of form, of expert reports, affidavits, or disclosures pursuant to amended Rule 26(b)(4)(B) and the 2010 Advisory Committee Note;
4) [Defendant] is entitled to all relevant discovery regarding the facts/data considered, reviewed or relied upon for the development, foundation, or basis of their affidavits/declarations . . . pursuant to amended Rules 26(b)(4)(B) and (C) and the 2010 Advisory Committee Note;
5) Communications between [the plaintiff's] counsel and the Employee Opinion Witnesses are protected by the attorney-client privilege [citation omitted];
6) [Defendant] is not entitled to documents and tangible things prepared in anticipation of litigation or for trial without showing it has a substantial need for the materials to prepare its case and, cannot, without undue hardship, obtain their substantial equivalent by other means pursuant to amended Rule 26(b)

[3] Rule 26 was again amended in 2015. However, the 2015 changes did not affect any of the privilege provisions of Rule 26. See 2015 Advisory Committee Note to Fed. R. Civ. P. 26.

(3)(A) and the 2010 Advisory Committee Note[.]

Id. at *14–15. The findings of Graco have also been affirmed elsewhere. *Benson v. Rosenthal*, 2016 WL 11678622, at *2–3 (E.D. La. May 12, 2016); *Mitchell v. Mgmt. & Training Corp.*, 2018 WL 4957290, at *4 (N.D. Ohio Mar. 9, 2018).

Yet the California District Court in *Sierra Pacific* found that "*Graco* . . . provides little assistance to address the issue presented in this motion." *United States v. Sierra Pac. Indus.*, 2011 WL 2119078, at *5 (E.D. Cal. May 26, 2011). Similar to *Graco*, the defendants in *Sierra Pacific* moved to compel the United States to produce testimony and documents relating to communication between two of the United States' designated expert witnesses and attorneys for the United States and another plaintiff. *Id.* at *1. These witnesses were employees of the United States and the other plaintiff who had investigated a large fire at issue, for which they had prepared an Origin and Cause Report. *Id*. The United States cited Graco to argue that its attorney's communications with employee witnesses were protected. *Id.* at *9. The *Sierra Pacific* Court was not persuaded by the decision in *Graco* in part because "the analytical basis for that result is not explained. *Graco* discussed at length the text of the 2010 amended *Rule 26* and the advisory committee notes, but it engaged in little analysis in support of its conclusion." *Id.*

During its analysis, the *Sierra Pacific* Court provided general guidance on non-reporting expert witnesses: "[s]ome of these non-reporting witnesses should not be treated differently than reporting expert witnesses. For example, there is no immediately apparent policy reason to treat an employee expert whose duties regularly involve giving expert testimony any differently than an employee expert whose duties involve only intermittently giving expert testimony." *Id.* at *10. On the other hand, "some non-reporting witnesses, such as treating physicians and accident investigators, should be treated differently than reporting witnesses with respect to the discoverability of their communications with counsel." *Id.* (citing Minutes, Civil Rules Advisory Committee Meeting (April 20-21, 2009) p.14) ("The Committee did not want to protect communications by one party's lawyer with treating physicians, accident investigators, and the like. An employee expert, moreover, may be an important fact witness."). In conclusion, the Court stated, "at least in some cases, discovery should be permitted into such witnesses' communications with attorneys, in order to prevent, or at any rate expose, attorney-caused bias." *Id.*

The *Sierra Pacific* Court, however, decided that "counsel's communications with [its employee experts] should not be protected." *Id.* The Court reasoned that the experts were "hybrid fact and expert witnesses" and "have percipient knowledge of the facts at issue in this litigation. . . . If their communications with counsel were protected, any potential biases in their testimony regarding the causes of the fire would be shielded from the fact-finder." *Id.* While the Court "decline[d] to hold that designating an individual as a non-reporting witness waives otherwise applicable privileges in all cases, . . . in this particular factual scenario, the United States waived its privilege and work-product protection by disclosing [the employees] as expert witnesses." *Id.* Although no circuit courts have addressed the issue, many district courts have found the reasoning in Sierra Pacific persuasive. *See, e.g., Garcia v. Patton*, 2015 WL 13613521, *4 (D. Colo. July 9, 2015); *Trading Techs. Int'l, Inc. v. IBG*, 2020 WL 12309208, at *2 (N.D. Ill. Sept. 14, 2020); *City of Mankato, Minnesota v. Kimberly-Clark Corp.*, 2019 WL 4897191, at *11 (D. Minn. May 28, 2019); *see also* Peter M. Durney, Julianne C. Fitzpatrick, Retaining and Disclosing Expert Witnesses: A Global Perspective, 83 Def. Couns. J. 17 (2016) (discussing the difference between testifying and non-testifying experts). The United States also made an argument that the decision would force it to protect its communications by retaining the witnesses for a nominal fee, thus transforming them into reporting experts, but the Court refused to rule on the permissibility or effect of such an action "given the history of this discovery dispute." *Id.* at *11.

Graco and *United States v. Sierra Pacific Indus.* were decided shortly after the Rule change, but federal courts are still struggling to define the outlines of Rule 26. In 2016, a federal Minnesota case, *Luminara Worldwide, LLC v. RAZ Imports, Inc.*, 2016 WL 6774231 (D. Minn. Nov. 15, 2016), held that a non-reporting expert had no protection under the attorney-client privilege. In *Luminara*, the inventor of certain patents who had founded the plaintiff's predecessor corporation and acted as a paid consultant to the plaintiff on related technical issues was disclosed as a non-reporting testifying expert. *Id.* Defendants directed document subpoenas at the expert and deposed him, over the plaintiff's repeated objections. *Id.* at *2. The magistrate judge in the case agreed with the defendants that plaintiff had waived the attorney-client privilege about information provided to Patton for purposes of the case. *Id.* The magistrate reasoned that, because non-reporting experts were not mentioned in Rule 26(b)(4)(C), the protections of that Rule did not apply to a non-reporting expert, and he had to produce all information he "considered," which he ultimately held to be all materials the expert "generated, saw, read, reviewed, and/or reflected upon," including communications with counsel. *Id.* at *3. The district court upheld the magistrate's finding, and the plaintiff eventually withdrew the expert. This case is an outlier, as most courts have found otherwise, but it got the attention of defense counsel across the nation, and it has not been overturned.

Conclusion

The attorney-client privilege is multifaceted in its applications and exceptions. As the case law evolves, attorneys are expected to track new developments. Although such a task is challenging, it is important to remember that the privilege is ultimately about serving and protecting the client's interests. Therefore, along with maintaining current knowledge, attorneys should update clients on the changing landscape of the attorney-client privilege. In providing current information, attorneys and clients can better shield critical communications, leading to greater success in and outside the courtroom.

Launching Your Own Law Practice? These Marketing Tips Can Guide You

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Marketing a law firm can be a unique challenge – different practice groups may have different needs and you may be trying to market across many consumer bases, from corporations to local businesses or individuals. Individualized strategies are important, but your law firm's website may be a tool that you can use to form a solid foundation to work from – it is, after all, where many of your potential clients are going to make their first contact with your firm.

Here are a few ways to make the most of your online presence:

Create original content

There are a number of reasons creating original content can greatly help boost your firm's online marketing. Writing about emerging legal issues, common legal questions or specialty insights not only helps establish your attorneys as experts in the eyes of the public, it casts a wide net of opportunities for clients to make contact with your firm. Consider this example: If a new tax law or business ordinance passes, it's likely that many of those who'll be impacted by it will turn to an online search as their first step in understanding and implementing it. If they find your firm's post and it gives them helpful insight and information, then your firm gains credibility and maybe even a request for consultation.

Within these original posts, your website is laying out keywords and content that search engines like Google can pick up on and promote in search results, improving your site's search engine optimization (SEO).

Embrace SEO – and keep it up

Speaking of SEO, do your best to invest time, energy and money into regularly developing and maintaining SEO for your website. SEO can bring new prospective clients to your site, as well as raise your general community profile. *Here's a quick SEO guide* to help you boost your website rankings.

Good SEO relies on an organized website that runs well and is easy to navigate, including being accessible on mobile devices. While boosting your online success, investing in your online space also makes it more usable and convenient for users. And with all content, but especially legal topics, clarity is vital – the ease of accessing and understanding information forms the impression users have, and ultimately the trust you're building with prospective clients.

Create a social media strategy

Social media has always fallen in the "risk" category for businesses – especially those in the business of consulting about risk. But social media with a solid strategy is something to embrace and leverage, rather than fear.

Algorithms and subject censorship have complicated the use of social media in many ways, so it's not as simple as posting something to your profiles. Thoughtful scheduling and content planning can draw in valuable user engagement. This creates a great opportunity to showcase your firm's subject matter expertise, legal approach or philosophy, and what you value in the relationships you build with clients and the community. Through social media, you can showcase what's effectively a customer service experience that most would never see unless they stepped foot into your office.

Consider a multimedia approach

Social media sites like TikTok and Instagram, as well as podcasts, have become spaces for people to find valuable information from attorneys who are not offering legal advice, but are offering easy-to-understand explainers on timely legal topics, frank insights into everything from divorce, to the legal aspects of setting up a new business, to insights on diversity and inclusion in the legal field.

It's another place to showcase subject matter expertise – but it offers an opportunity to capture the audience where they are, instead of waiting for them to come to you. It also offers a space to add human faces and voices to conversations and information that can be difficult to understand through written mediums.

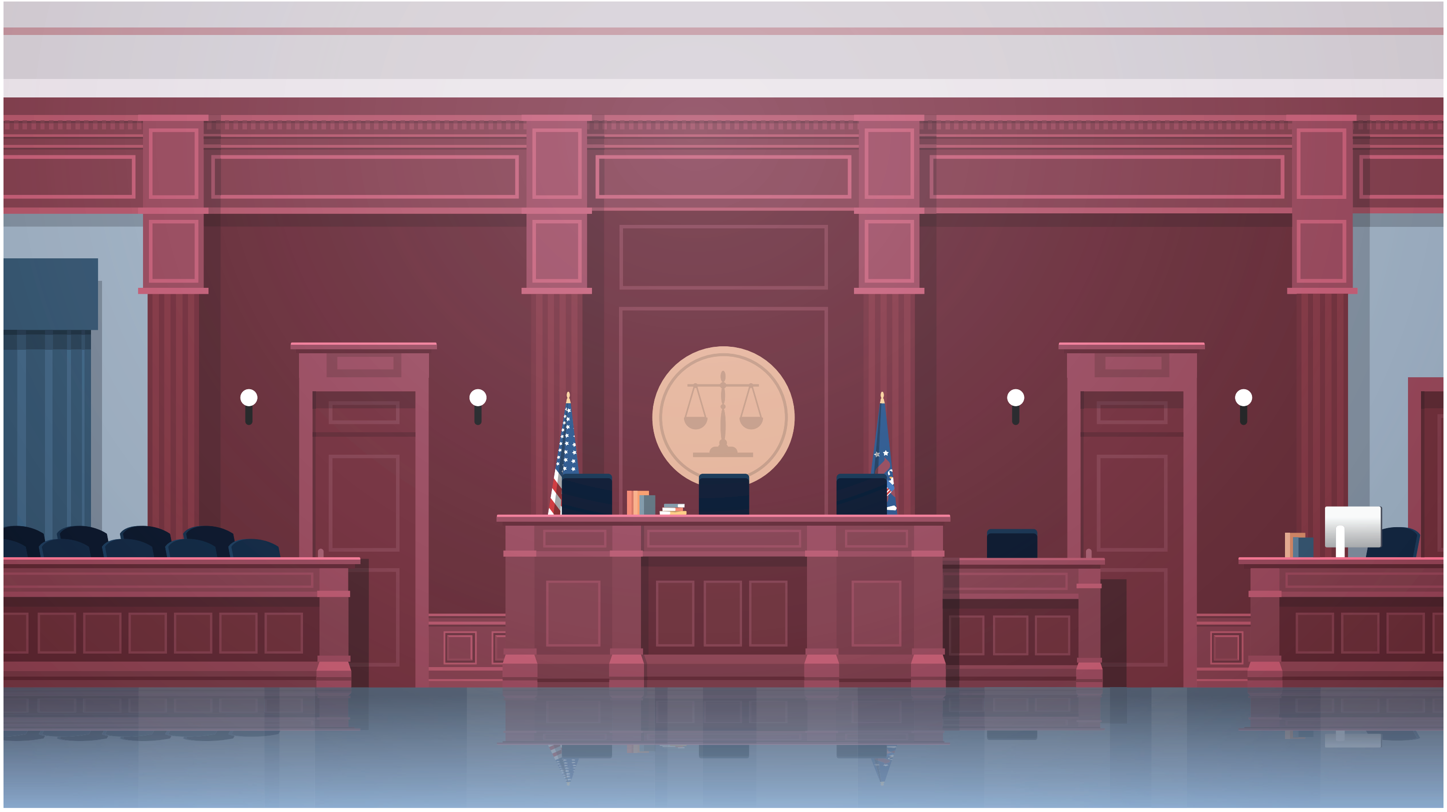
Closing Remarks:

Everyone needs an attorney at some point – and like with most things, they're often going to turn to the Internet to find one. A solid digital marketing strategy will put you at the top of their search results – and the top of their list for who to call.

While the tips we've given you will help you make a great start towards marketing your firm, remember that having a solid website URL is what brings everything together. A .Law domain is the premiere domain for lawyers, and is exclusive – meaning only those who are Bar-certified or are an accredited legal organization can have one. You can get more information – and your .Law domain – *here.*

By Abbie Eliasberg Fuchs, Bradley M. Wanner, and Daniel R. Strecker

2022 Year in Review



Harris Beach attorneys Abbie Eliasberg Fuchs, Bradley M. Wanner, and Daniel R. Strecker review and analyze key judicial holdings and legal developments in New York, the federal arena and across the country that have affected the industry and may shape the years ahead. To assist clients and lawyers to prepare the best defense strategies in these suits, they share potential implications for future cases pertaining to:

- Personal jurisdiction – limitation on scope of general personal jurisdiction in tort hotspot Pennsylvania and pending appeal to SCOTUS
- Discovery – new scheme for disclosure of insurance coverage in New York
- Evidence – limitation on use of prior deposition testimony in tort hotspot California
- Causation and expert evidence – causation standard in New York and Federal Rule 702 amendments
- COVID-19 – "take-home" liability
- COVID-19 – nursing homes

Personal Jurisdiction

Mallory v. Norfolk Southern Ry., 266 A.3d 542 (Pa. 2021), *cert. granted* 142 S. Ct. 2646 (2022)

In December 2021, the Supreme Court of Pennsylvania issued its decision in *Mallory v. Norfolk Southern Railway Co.*, declaring that Pennsylvania courts do not have general personal jurisdiction over foreign

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corporations based exclusively upon the corporation's registration to do business in Pennsylvania. In *Mallory*, a resident of Virginia filed an action against a Virginia corporation, with a principal place of business in Virginia, alleging workplace exposure to carcinogens in Ohio and Virginia. The plaintiff argued the defendant consented to general personal jurisdiction by registering to do business in Pennsylvania under the state's mandatory registration statute.

However, the Court found Pennsylvania's statutory scheme affording Pennsylvania courts general personal jurisdiction based on registration, regardless of the corporation's contacts with the state, violates the Constitution's Due Process Clause as interpreted by recent United States Supreme Court precedent. That interpretation held a corporation is only subject to general personal jurisdiction where it is "at home" (i.e., the state of incorporation and the state of the principal place of business), or where there are "exceptional" facts to render the corporation "at home" in some other forum. With respect to specific jurisdiction, the Court noted there must be some connection between the forum and the underlying case for the exercise of such jurisdiction to comport with Due Process. In reaching this conclusion, the Court adopted reasoning from the United States Supreme Court that the "stream of commerce" theory may be relevant to the specific jurisdiction inquiry, but that it is not relevant to the general jurisdiction analysis. Further, the Court acknowledged that a corporation's consent to jurisdiction through registration was not actually voluntary, as it was imposed as a consequence of registration.

In April 2022, the United States Supreme Court granted *certiorari* on the question of whether Pennsylvania's statute (and potentially similar statutes) comport with the Fourteenth Amendment's Due Process Clause. A flurry of filings on behalf of *amici* followed the Court granting the petition for *certiorari* on behalf of both petitioner and respondent, as well as *amici*, who appeared but not in support of either petitioner or respondent.

Petitioner and the supporting *amici* generally argue that respondent made a voluntary and knowing choice to register as a foreign corporation and conduct business in Pennsylvania. Avoiding the argument that it is not feasible for an interstate railway to entirely avoid operating in Pennsylvania, they argue respondent has extensive operations in Pennsylvania and has benefitted from its registration as a foreign corporation, in particular having the right to use Pennsylvania courts to bring lawsuits. They also argue the Supreme Court's rationale for finding a corporation consents to general personal jurisdiction in its state of incorporation and principal place of business should also be applied to a corporation where it registers to conduct business and conducts substantial business, consistent with pre-*Daimler* decisions such as *International Shoe*. In support, they argue there is no valid rationale to distinguish the place of incorporation/principal place of business with the foreign corporation's registrations, in particular where many corporations have little actual connection with their state of incorporation but substantial connections and operations in the jurisdictions in which they register as foreign corporations. Further, petitioner and the supporting *amici* note there is an "anomaly" in the Supreme Court's current jurisprudence that affords greater general personal jurisdiction over individuals than corporations, since individuals may be subject to general personal jurisdiction wherever they are found, but this is not true for corporations. Finally, they contend a corporation has an alternate means to address issues where a case is brought in an improper jurisdiction by seeking dismissal and transfer under the doctrine of *forum non conveniens*.

Respondent and the supporting *amici* argued registration under Pennsylvania's statute did not involve consent, either express or implied. In particular, with respect to the notion of implied consent, respondent argued that accepting petitioner's interpretation of implied consent would cause the exception to swallow the rule. Further, respondent argued petitioner's construction of Pennsylvania's statute would negate the Supreme Court's recent articulation of general personal jurisdiction in Goodyear and Daimler, which restricts general jurisdiction to a corporation's state of incorporation and the location of its principal place of business. Respondent and its supporting *amici* also argue Pennsylvania's statute imposes an unconstitutional condition on foreign corporations.

Various amici contend the Pennsylvania Supreme Court's decision, to the extent it suggests registration is never a constitutional basis for jurisdiction, is incorrect; rather, they maintain that registration, combined with a "substantial connection" to the forum, is a traditional and constitutional basis for the exercise of general personal jurisdiction. Certain amici also argue the Dormant Commerce Clause is the more appropriate legal framework to analyze the exercise of jurisdiction over respondent. Of note, the Dormant Commerce Clause was not addressed before the Pennsylvania Supreme Court, suggesting the United States Supreme Court may remand the issue for the lower courts to consider this analysis.

The Supreme Court heard oral argument on November 8, 2022. Its decision is pending.

Personal Jurisdiction I Potential Implications for Future Cases

Where the Supreme Court is likely to come down on this issue is unclear, as its most recent decisions suggest support for the expansion of general personal jurisdiction over corporations beyond their place of incorporation and principal place of business. It does seem likely the Supreme Court will not adopt the extreme positions of petitioner (that registration as a foreign corporation always equals consent to general personal jurisdiction) or respondent (that registration as a foreign corporation can never amount to consent to general personal jurisdiction). The most likely outcome – at least the outcome that will garner the necessary five votes for a majority – seems to be the middle ground analysis proposed by neutral *amici*, which is somewhat of a combination of general and specific jurisdiction and a recognition the interests of individual states are limited when there is no nexus to the state, a hallmark of the Supreme Court's jurisprudence on jurisdiction dating back to I*nternational Shoe*.

Discovery

Comprehensive Insurance Disclosure Act, CPLR 3101(f)

The start of 2022 saw New York enacting the Comprehensive Insurance Disclosure Act ("CIDA"). Months later, New York amended the rule, scaling back some of the rule's burdens, but leaving several new obligations in place that defendants, carriers and defense practitioners must navigate.

CIDA amended CPLR 3101(f), governing disclosure of insurance policy information by defendants in civil litigation and applied it retroactively. Originally, CIDA made disclosure of insurance policies automatic, imposed a client certification requirement, and included "applications for insurance," which may detail a defendant's litigation history, in the definition of insurance policies. CIDA also would have opened the door for plaintiffs to obtain: copies of potentially unrelated excess and umbrella policies; the contact information for all associated insurance and third-party administrator representatives; any lawsuits that have reduced/eroded, or that may reduce/erode the limits, including the caption, date of filing and identity/contact information of the parties; and the amount of attorney fees that have reduced/eroded the limits, and the identity/address of any attorney receiving such fees.

CIDA imposed an ongoing obligation to disclose updated information that continued for 60 days after settlement or entry of final judgment; updated disclosure had to occur within 30 days of receipt of new information. CIDA added new CPLR section 3122-b, which requires the defendant (i.e., the party) and counsel to certify the information provided pursuant to 3101(f) is accurate and complete.

Amended CIDA scales back these requirements. Under amended CIDA, within 90 days of answering, a defendant must disclose copies of all policies, including primary, excess and umbrella policies, that relate to the claims being litigated; contact information for one claims representative; and the current limits, accounting for erosion. Defendants need not disclose unrelated policies, insurance applications, the identity of prior and pending litigation that has eroded or could erode limits, or information about the amount of attorney fees paid, and to whom. Updated disclosure, if applicable, must occur at predetermined intervals: upon filing of the note of issue, when entering court-supervised settlement negotiations, when entering voluntary mediation and when the case is called for trial. Amended CIDA leaves intact the CPLR section 3122-b certification requirement and obligation to provide updated disclosure for 60 days after settlement or final judgment.

Various *amici* contend the Pennsylvania Supreme Court's decision, to the extent it suggests registration is never a constitutional basis for jurisdiction, is incorrect;

Discovery | Potential Implications for Future Cases

Amended CIDA retains obligations new to defendants in civil litigation in New York: they must automatically disclose copies of related policies (although the law permits plaintiff to consent to receive only declaration pages, plaintiff may revoke that consent at any time) and residual limits within 90 days of answering. Additionally, disclosure must be certified by the client and the obligation to update disclosure continues for 60 days after settlement/judgment. However, amended CIDA dispenses with other burdens that were ripe for abuse and harassing litigation tactics, including an obligation to identify multiple claims personnel and detailed information about other prior and pending litigation, including itemizing the amount and recipient of associated attorney fees.

Evidence

Berroteran v. Superior Court, 12 Cal. 5th 867 (2022)

When defending litigation in one state, mass tort defendants must consider other jurisdictions' rules. For example, while some states generally prohibit a plaintiff from using a defendant's discovery deposition as part of the plaintiff's case in chief, others do not; a discovery deposition may resurface on a plaintiff's case in chief in another jurisdiction, sometimes years or decades later. California is among the states whose rules loom large when litigating elsewhere, and a 2019 appellate ruling made it much easier for California plaintiffs to use a defendant's previous discovery deposition at trial. The recent California Supreme Court decision in *Berroteran v. Superior Court*, 12 Cal. 5th 867 (2022), overturns that ruling, makes it more difficult for California plaintiffs to use a defendant's prior depositions for their case in chief, and clarifies the showing that a plaintiff must make in order to do so.

California Evidence Code section 1291(a)(2) provides an exception to the hearsay rule for prior testimony if, among other things (e.g., witness unavailability), the objecting party had "the right and opportunity to cross-examine the declarant with an interest and motive similar to that which the same party will have "at the [present] hearing." In *Wahlgren v. Coleco Industries, Inc.*, 151 Cal. App. 3d 543 (1984), the Fourth Appellate District, interpreting this provision and associated legislative commentary, excluded prior deposition testimony because a party at a deposition does not have the same interest and motive to cross-examine as at trial. In its 2019 decision in *Berroteran*, the Second Appellate District, encompassing Los Angeles, disagreed with *Wahlgren* to the extent *Wahlgren* espoused a blanket rule. *See Berroteran v. Superior Court*, 41 Cal. App. 5th 518, 534 (2019).

However, the California Supreme Court, in *Berroteran* (2022), overturned the Second Appellate District. The Court noted that, for strategic reasons, counsel are discouraged against, and generally do not, cross-examine their own witness at a discovery deposition. For this and other reasons, a party at a deposition generally does not have the same interest and motive to cross-examine. The Court held it is the proponent's burden to show that this prohibition does not apply. The Court outlined circumstances that, if shown, would warrant an exception. If the parties manifested an intent the deposition would serve as trial testimony, it creates a rebuttable presumption the interest/motive was similar; likewise, if the parties subsequently agreed the testimony could be used at other trials, the interest/motive was similar (but the Court noted that agreeing to use deposition testimony at trial in another case did not necessarily constitute agreeing to use it at trial in the case at hand).

In less clear-cut circumstances, the Court listed six "practical considerations" for determining if the opposing party's interest/motive to cross-examine at the deposition was similar:

(1) Timing - such as a deposition after the parties have been educated by earlier, similar lawsuits, or a deposition in anticipation of a mediation or settlement conference
(2) Relationship to the deponent - the interest in cross-examining increases as the relationship diminishes (the Court hypothesized that if a party is unlikely to cross-examine a witness at trial, lack of cross-examination at the deposition might still constitute "similar" circumstances)
(3) Availability of the deponent - when the deposition was taken, was the deponent in poor health or not amenable to subpoena?
(4) Conduct at the deposition - references to "testimony for the jury" (especially by opposing counsel) and the degree of cross-examination engaged in
(5) The specific testimony - especially testimony that is confusing or adverse (this should not be considered in isolation, since there may still be reasons not to cross-examine); and
(6) Similarity of the party's substantive positions - while relevant, the Court emphasized that this cannot establish similarity of interest/motive in isolation

The Court stated this analysis should be applied to each deposition from which the plaintiff seeks to introduce testimony.

Evidence | Potential Implications for Future Cases

Mass tort defendants in California, or whose testimony may later resurface in cases pending in California, may be able to capitalize on *Berroteran* and reduce the likelihood of a discovery deposition's being used on a plaintiff's case in chief. When agreeing that a deposition may be used at trial, the risk of opening this door should be considered and, where possible, expressly addressed. Avoiding phrasing like "please tell the jury …" will diminish the argument that the party knew testimony would be used at trial. It may be advisable to state on the record that the deposition is for discovery. Where possible, avoiding extensive cross-examination may reduce the likelihood of a determination there was similar interest/motive. In the case of pre-existing testimony, it may be advisable to move *in limine* to exclude any transcripts plaintiff intends to use on plaintiff's case in chief, and use the existing record to develop evidence that the deposition was conducted for discovery purposes. If other counsel defended the deposition and stakeholders are amenable, a declaration that the deposition was for discovery purposes and addressing the above "considerations" could influence a court.

The California Supreme Court's decision in *Berroteran* affirms the legislative intent behind California Evidence Code section 1291(a)(2). However, the ruling does not provide a categorical ban against the use of deposition testimony at trial, especially where the parties have agreed or seemed to agree to the contrary. Practitioners should be guided by the above considerations if seeking to prevent present and past deposition transcripts from being used on a California plaintiff's trial case in chief.

Causation and Expert Evidence

***Nemeth v. Brenntag N. Am.*, 38 N.Y.3d 336 (2022)**

The New York Court of Appeals, in a near unanimous decision, set aside a $16.5 million verdict following trial based on Plaintiff's failure to establish causation as a matter of law.

At trial in *Nemeth*, Plaintiff's experts Sean Fitzgerald (geologist/microscopist) and Dr. Jacqueline Moline (occupational/environmental medicine) testified. Fitzgerald conducted a "glove box" test of the product at issue and concluded the number of released asbestos fibers from the product were several orders of magnitude higher than that found in ambient air. Dr. Moline relied, in part, on Fitzgerald's testimony that the Decedent's mesothelioma was caused by her exposure to asbestos in the product. Dr. Moline referred to her expertise and knowledge of the literature in the field and conceded there were no specific epidemiological studies regarding asbestos-contaminated cosmetic talc and peritoneal mesothelioma or precise quantification of the amount of asbestos to which Decedent was exposed. At trial, the jury returned a verdict against the Defendant, who appealed. The Appellate Division upheld the jury's verdict, finding there was a sufficient basis for Dr. Moline's opinion as to both general and specific causation.

Overturning the lower courts, the Court of Appeals reaffirmed the requirements for causation, as laid out in the seminal case of *Parker v Mobil Oil Corp.*, 7 N.Y.3d 434 (2006), which held that any opinion on causation should set forth (1) a plaintiff's exposure to a toxin, (2) that the toxin is capable of causing a particular illness (general causation) and (3) that plaintiff was exposed to sufficient levels of the toxin to cause the illness (specific causation). The Court reiterated its holding from *Parker* that while precise quantification of exposure is not always required, that does not dispense with a plaintiff's burden to establish sufficient exposure to a substance to cause the claimed adverse health effect, using expert testimony based on "generally accepted methodologies" to establish sufficient exposure to the toxin and that expert testimony is to be excluded when "there is simply too great an analytical gap between the data and the opinion proffered." Referring to its decision in *Matter of N.Y.C. Asbestos Litig. (Juni)*, 32 N.Y.3d 1116 (2018), the Court stated the fact that asbestos has been linked to mesothelioma is not enough for a determination of liability against a particular defendant; a causation expert must still establish the plaintiff was exposed to sufficient levels of the toxin from the specific defendant's product to have caused the disease.

In *Nemeth*, the Court found the basis for Dr. Moline's opinion that Decedent's "exposure to the contaminated talcum powder was a substantial contributing factor" in causing Decedent's peritoneal mesothelioma, did not meet the Court's requirements for establishing exposure to a toxin in an amount sufficient to cause decedent's peritoneal mesothelioma. Dr. Moline testified that "brief or low-level exposures of asbestos" could cause the disease, but "there are some exposures to asbestos that are trivial and don't increase a person's risk of developing mesothelioma," the exposure to twice the amount of asbestos in ambient air would not cause mesothelioma, and that mesothelioma may develop idiopathically. The Court held this testimony was insufficient to establish causation. Further, the Court held that Dr. Moline's description of mesothelioma as a sentinel health event of asbestos exposure and that virtually all cases of mesothelioma are related to asbestos exposure are no different than conclusory assertions of causation that are insufficient to meet *Parker*.

The Court also held the studies and scientific literature cited/relied upon by Dr. Moline did not provide the necessary support for her conclusion as to proximate causation. Dr. Moline's causation testimony attempted to rely on a "comparison to the exposure levels of subjects of other studies" but failed to provide "a specific comparison sufficient to show how the plaintiff's exposure level related to those of the other subjects." The Court reiterated its statement from *Parker* that "standards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation" and, therefore, Dr. Moline's testimony regarding the "permissible exposure limit" to asbestos promulgated by OSHA could not be used to fill this gap in proof as to the level of exposure sufficient to cause peritoneal mesothelioma. The Court held that Dr. Moline failed to provide any foundational basis for her opinion that exposure to asbestos at a level analogous to Decedent's was shown to be a substantial factor in causing mesothelioma of any kind.

Further, the Court found the glove box test conducted by Fitzgerald did not provide an estimate of the amount of product that would be inhaled, an identification of the number of released fibers and description of those fibers as of "an inhalable size," or establish causation by demonstrating that Decedent's exposure was comparable to similar exposures proven to be causally related to the development of mesothelioma. While a precise numerical value is not required, the Court held Fitzgerald's test simply failed to provide any scientific expression linking Decedent's actual exposure to asbestos to a level known to cause mesothelioma. The Court noted Fitzgerald failed to conduct the testing in an environment and location similar to where Decedent allegedly used the product.

the Court stated the fact that asbestos has been linked to mesothelioma is not enough for a determination of liability against a particular defendant

The Court also noted that Dr. Moline testified industrial hygienists could have estimated Decedent's inhalation levels, and Plaintiff could have introduced evidence regarding the inhalation levels known to cause peritoneal mesothelioma, but failed to do so. Based on the flaws in Fitzgerald's test, and Dr. Moline's reliance on that test to provide her opinions as to causation, her opinion was deemed insufficient. The Court emphasized the need to strike a balance between excluding unreliable or speculative information as to causation and not setting an insurmountable standard, depriving plaintiffs of their day in court. The Court held the requirement that plaintiff establish sufficient exposure to a toxin to cause the claimed illness through expert testimony based on generally accepted methodologies strikes that appropriate balance.

Amendments to Federal Rule of Evidence 702: Testimony of Expert Witnesses

The Committee on Rules of Practice and Procedure unanimously approved several amendments on June 7, 2022, to clarify Federal Rule of Evidence 702 — the federal standard for admissibility of expert testimony. The amendments (1) clarify that the proponent's burden for admissibility is a preponderance of the evidence, and (2) emphasize the court's duty, through trial, to ensure the expert's opinions/conclusions, not just methods, are reliable. These changes are in response to findings that federal courts too often fail to apply the preponderance standard and prevent experts from overstating their conclusions. Pending approval by the Judicial Conference, the Supreme Court and Congress, the amendments will take effect on December 1, 2023.

If amended, the below underlined language will be added to Rule 702's opening statement:

> 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 <u>the proponent has demonstrated by a preponderance of the evidence that</u> . . .

In *Daubert*, the Court noted that questions of admissibility, including expert testimony, should be established by a preponderance of proof. *See Daubert*, 509 U.S. at 592 n.10 (citing Rule 104(a) and *Bourjaily v. United States,* 483 U.S. 171, 175-76 (1987)). But the Federal Advisory Committee on Evidence Rules found judges routinely fail to apply the preponderance standard to Rule 702's admissibility requirements of sufficiency of basis and reliable application of principles and methods. See Advisory Comm. on Evid. Rules, Agenda for Committee Meeting, 17 (Apr. 30, 2021). In fact, between 2015 and 2021, nearly 300 federal decisions claimed questions related to the sources and basis of an expert's testimony go to credibility/weight, not admissibility. See Lawyers for Civil Justice, Comment to the Advisory Committee on Evidence Rules, 2-3 (Sept. 1, 2021)

To prevent further error, this amendment clarifies the proponent must demonstrate by a preponderance of evidence that Rule 702's reliability requirements are met. Whether the expert relied on sufficient facts or data and reliably applied sound methods are questions of admissibility, not credibility/weight of the evidence. See Advisory Comm. on Evid. Rules, Report of the Advisory Committee on Evidence Rules, 6 (May 15, 2022). Also, by noting the proponent must prove reliability by a preponderance of the evidence, the amendment debunks the "presumption of admissibility" for expert testimony (see Report of the Advisory Committee on Evidence Rules, 6 (May 15, 2022)) that some courts erroneously assert. *See, e.g., Cates v. Trs. of Columbia Univ.*, 16 Civ. 6524, 2020 U.S. Dist. LEXIS 55409, at *18 (S.D.N.Y. Mar. 30, 2020) ("There is a presumption that expert testimony is admissible . . .")

The proposed amendment to Rule 702(d) will focus the court's attention on the expert's opinion, not just their application of principles and methods:

d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

This is also not new law. *See General Electric Co., v. Joiner*, 522 U.S. 136, 146 (1997) ("[C]onclusions and methodology are not entirely distinct from one another . . . nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert."). However, the change will help curtail experts from overstating their opinions. Additionally, the change from "has reliably applied" (past tense) to "opinion reflects a reliable application" (ongoing) emphasizes the gatekeeping function continues even after an initial finding of admissibility. *See* Comm. on Rules of Practice and Procedure, June 2022 Agenda Book at 1039.

Causation and Expert Evidence I Potential Implications for Future Cases

While *Nemeth* involved a cosmetic talcum powder product allegedly contaminated with asbestos, the Court of Appeals ruling on the requirements to establish causation are applicable to all toxic tort cases. The *Nemeth* decision provides support for defendants in toxic tort cases seeking to challenge Plaintiff's allegations based on failure to establish causation through testing methods employed or relied upon by Plaintiff's experts. However, the ruling also provides plaintiffs some express guidance on how to satisfy the *Parker* standards in future cases.

Although the Rule 702 amendments may not take effect until December 1, 2023, they have already been cited to correct misapplications of Rule 702. In *Sardis v. Overhead Door Corp.*, 10 F.4th 268 (4th Cir. 2021), the court cited the proposed amendments and quoted the Advisory Committee's findings before reversing an order that denied a defendant's motion to exclude expert testimony. *See id*. at 283-84, 296-300 (holding the trial court abused its discretion and committed reversible legal error by abdicating its gatekeeping function under Rule 702). The court agreed that lower courts' failure to apply the proponent's preponderance standard is a "pervasive problem," in contravention of Rule 702 and *Daubert*, which the amendments will address. *See id*. at 284.

To avoid the misapplications of Rule 702 that caused the instant amendments, parties planning expert challenges should emphasize the following in their arguments:

1. there is no presumption of admissibility for expert testimony;
2. the proponent must satisfy the reliability requirements by a preponderance of the evidence;
3. the sufficiency of an expert's factual basis and reliability of its methods are admissibility, not credibility, questions; and
4. the expert's opinions/conclusions must remain within the bounds of a reliable application of their methods.

By emphasizing these long-recognized aspects of Rule 702, parties will gain credibility, minimize incorrect rulings, and preserve good arguments for appeal.

COVID-19 "Take-home" Liability

Ek v. See's Candies, Inc., 73 Cal. App. 5th 66 (2021)

In *Ek v. See's Candies, Inc.*, plaintiffs allege that in March 2020, plaintiff, defendants' employee, contracted COVID-19 at work. While convalescing at home, plaintiff allegedly transmitted COVID-19 to her non-employee husband, resulting in his death. The family filed a complaint for negligence and premises liability against the employer. The family claims the employer failed to take adequate COVID-19 safety precautions by requiring employees, some of whom were allegedly symptomatic, to work closely together despite the risk of infection and transmission to non-employees.

Defendants moved to dismiss, asserting the suit was barred by the workers' compensation law because decedent's infection was derivative of the employee's. The trial and appellate court rejected defendants' position. The courts distinguished the claims from classic derivative causes of action barred by the workers' compensation law, such as loss of companionship or lost income due to caring for the injured worker. The courts analogized to cases holding that the workers' compensation law does not bar asbestos "take-home" liability, or other injury to third parties from toxic substances on or about the employee's person. The appellate court emphasized it expressed no opinion if the employer had a broader duty of care to decedent, and its ruling is limited to the narrower workers' compensation issue. It observed, however, that the duty "would appear worthy of exploration."

Kuciemba v. Victory Woodworks, Inc., 31 F.4th 1268 (9th Cir. 2022)

In *Kuciemba*, plaintiffs claim the non-employee plaintiff contracted COVID-19 from the employee plaintiff, her spouse. As a result, the non-employee plaintiff allegedly developed severe illness and was hospitalized for one month on a respirator. The employee plaintiff allegedly contracted the virus at work and brought it home. Plaintiffs blame defendant, the employer, for the non-employee plaintiff's resulting infection. Plaintiffs allege the employer violated government health orders and safety rules and was otherwise negligent in failing to protect against the spread of infection. For example, the employer allegedly forced the employee plaintiff to work in close contact with persons the employer allegedly knew were infected with COVID-19. Plaintiffs assert counts for negligence *per se* based on the statutory/rule violations, general negligence and premises liability.

Defendant employer moved to dismiss, arguing the claims are barred by the workers' compensation law because the non-employee plaintiff's infection was derivative of the employee plaintiff's. In a decision that diverges from the subsequent state court appellate ruling in *Ek* (discussed above), the U.S. District Court for the Northern District of California agreed but granted leave to amend. In their amended complaint, plaintiffs advanced the theory defendant is liable because it was foreseeable that an infected employee would bring the virus home, endangering members of the employee's household. The defendant employer moved to dismiss again, arguing it had no duty to protect against off-premises transmission of diseases like COVID-19. The District Court granted the motion and plaintiffs appealed to the Ninth Circuit.

Evaluating the facts and District Court decision, the Ninth Circuit recognized a possible analogy to the duty to protect employees' families from asbestos fibers brought home on clothing. The Ninth Circuit recognized that the "public policy" question, if such a duty should be extended to COVID-19, remains unanswered. The Ninth Circuit also questioned if the workers' compensation bar applies outside of classic derivative claims, such as loss of consortium. The Ninth Circuit acknowledged the interim California appellate decision in *Ek* (see discussion above) held that the workers' compensation bar did not apply in this context.

To resolve these questions, the Ninth Circuit issued an order certifying two questions to the Supreme Court of California:

(1) If an employee contracts COVID-19 at his workplace and brings the virus home to his spouse, does California's derivative injury doctrine bar the spouse's claim against the employer?
(2) Under California law, does an employer owe a duty to the households of its employees to exercise ordinary care to prevent the spread of COVID-19?

The California Supreme Court has discretion to review, or decline to review, these certified questions. If accepted, the court may answer the questions in a published opinion carrying the same precedential weight as its other decisions.

COVID-19 "Take-home" Liability | Potential Implications for Future CASES

Taken together, the decisions in *Ek* and *Kuciemba* indicate a theory analogous to asbestos "take-home" liability is a potential vehicle for cases for injury from COVID-19 in both state and federal courts. Even if the court rules unfavorably to the defendant employer's position, there remain other potential defenses to claims for alleged COVID-19 "take home" liability. Employers' adherence to safety protocols may disprove negligence allegations. A plaintiff's inability to prove notice of a specific COVID-19 risk at the worksite may allow defendant to prevail. Furthermore, plaintiff may be unable to prove the employee's infection occurred at the workplace, or that the non-employee contracted COVID-19 from the employee.

COVID-19 In Nursing Homes

***In Re COVID-19 Litigation Against Nursing Homes*, State of New York Litigation Coordinating Panel, Index No. LCP 0001/2022, October 19, 2022**

Upon the applications of firms representing plaintiffs suing New York nursing homes for their or their family's alleged injuries and/or death after contracting COVID-19 while residents of the homes, the New York Litigation Coordinating Panel (the "Panel") ruled that such cases will be coordinated pursuant to Uniform Rules for Trial Courts (NYCRR) § 202.69. The decision followed briefing dating back to February 2022, an August 2022 interim ruling finding coordination appropriate, and subsequent motions to renew/reargue the interim ruling. Ultimately, the Panel determined that despite the absence of mutuality of parties (i.e., plaintiffs and defendants are different from case to case), the similarity of the claims, common legal issues, such as the application of immunities (see discussion below), and common factual issues like the standard of care, warranted coordination. The Panel stated that discovery schedules can be established that accommodate the diversity between cases.

The holding applies to cases against nursing homes and residential health care facilities as defined in the Public Health Law (§§ 2801(2) and (3)) alleging failure to comply with government statutes, regulations and guidance for protecting and caring for patients, and/or failure to exercise reasonable care in protecting and caring for patients, "during the COVID-19 pandemic," resulting in injury or death. Arguably, therefore, coordination applies not just to claims overtly alleging injury/death from COVID-19, but also to non-COVID-19 claims arising in nursing homes contemporaneously with the pandemic.

The court reached a compromise decision regarding venue. One plaintiff firm sought coordination in Kings County, likely for its plaintiff-friendly reputation, but citing the proximity of Kings to many airports and the large number of cases venued in New York City and nearby Long Island. Another plaintiff firm sought to split the venue for coordination, requesting downstate cases be coordinated in Kings and upstate cases be coordinated in a more centrally located county. The defense sought coordination in a single centrally located county. The court declined to adopt any of the proposed solutions, instead holding cases will be coordinated in a location central to the appellate department in which they were filed: (1) cases filed in Fourth Department in Erie County, (2) cases filed in First Department in New York County, (3) cases filed in Second Department in Nassau County and (4) cases filed in Third Department in Albany County. In each county, the relevant administrative judges will appoint a coordinating judge.

Each venue's appointed judge will oversee pre-trial proceedings, including pre-answer motions, discovery, and post-discovery dispositive motions. The substantive impact of the Panel's decision will be mitigated by the fact that before trial, coordinated cases will be remanded to their county of origin (unless the parties agree to trial in the county of coordination).

***Ruth v. Elderwood at Amherst, et al.*, 209 A.D. 3d 1281 (4th Dept 2022)**

On April 3, 2020, New York enacted the Emergency or Disaster Treatment Protection Act ("EDTPA"). Retroactive to March 7, 2020, EDTPA granted healthcare providers immunity from civil liability, except in the instances of gross negligence or more culpable conduct, for injuries or death allegedly sustained directly as a result of providing medical services in response to COVID-19. Immunized services included those provided by nursing homes related to the diagnosis, prevention or treatment of COVID-19; the assessment or care of an individual with a confirmed or suspected case of COVID-19; and the care of any other individual who presented at a healthcare facility or to a healthcare professional during the period of the COVID-19 emergency declaration. On April 6, 2021, New York repealed EDTPA.

In *Ruth*, plaintiff sued defendant nursing home in Supreme Court, Erie County, one week after EDPTA's repeal, asserting negligence, medical malpractice, wrongful death, and other theories relating to the treatment of decedent, who in March/April 2020 contracted COVID-19 at the nursing home. The nursing home moved to dismiss, arguing immunity under EDTPA. Rejecting plaintiff's opposition that repeal was retroactive, the trial court granted dismissal.

On appeal, the Fourth Department upheld dismissal and held that EDTPA's repeal was not retroactive. The court conducted an in-depth retroactivity analysis. The court found a presumption against EDTPA repeal's retroactivity because repeal impacted/expanded defendant's substantive rights (e.g., at the time of the alleged treatment, EDTPA immunized defendant from civil liability). The court found a lack of the therefore-necessary "clear expression" of legislative intent to apply repeal retroactively. Doing so, the court noted a lack of express statement of retroactivity in the statutory language, ambiguity in the legislative sponsors' memoranda, and ambiguity and contradictions in statements during floor debate. The court rejected a post-enactment affidavit from the bill's sponsor stating that repeal was intended to be retroactive, since courts have deemed such statements generally irrelevant to statutory interpretation. Therefore, the court held repeal was not retroactive. Accordingly, the court did not reach the question whether retroactivity violated defendant's constitutional rights.

COVID-19 In Nursing Homes | Potential Implications for Future Cases

Claims by and on behalf of New York nursing home residents allegedly injured by deficiencies in care in relation to their contracting COVID-19, and arguably by/on behalf of nursing home residents whose claims arose during the pandemic, even if not directly involving COVID-19, are now subject to coordination in one of four venues based on appellate department of original filing. Such coordination will shape the substantive decision making and law arising from the cases, since it will encompass pre-answer and post-discovery dispositive motions. However, absent agreement of the parties, cases will be tried in their original venue.

Under *Ruth*, EDTPA immunity remains a viable defense to claims for deficient care in relation to COVID-19 in nursing homes wherever plaintiff cannot show culpability at a level of gross negligence or higher. It remains to be seen if *Ruth* will be appealed to the highest court in New York, the Court of Appeals.

By Judi Abbott Curry

2022 Year in Review

From pharmaceuticals to toothpaste, preemption to public health, New York state and federal courts issued decisions in 2022 that 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, personal care, and other FDA regulated products, it is often helpful to step back and review holdings that 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 2022 pertaining to class actions, pharmaceuticals, and medical devices.

Class Actions

Housey v. Procter & Gamble Company, No. 21cv2286, 2022 U.S. Dist. LEXIS 53603, 2022 WL

874731 (S.D.N.Y. Mar. 24, 2022) affirmed, No. 22cv888, 2002 U.S. App. LEXIS 35392, 2022 WL 17844403 (2d Cir. Dec. 22, 2022)

In a putative class action, plaintiff claimed Crest toothpaste with charcoal was deceptive in its packaging, promising safe whitening, gentle cleaning, and healthier gums. Plaintiff alleged violation of consumer protection statutes and state laws and that there is insufficient scientific evidence to substantiate charcoal toothpaste's safety, cosmetic and health benefits.

The Court found plaintiff's overbroad claims were not plausibly pled to demonstrate that charcoal in the product makes the toothpaste unable to provide the advertised benefits. In defendant's motion to dismiss under FRCP 12(b)(6), P&G correctly pointed out the three published articles principally relied upon by plaintiff did not support her claims. The federal district court found it was proper to consider the articles plaintiff cited in adjudicating a motion to dismiss. Plaintiff was preempted from claiming the toothpaste was ineffective, in light of FDA's monograph on fluoride toothpastes. Finally, in the absence of an alleged personal injury or a true price premium claim, plaintiff did not properly plead an injury. The Second Circuit upheld the New York federal court's decision dismissing the proposed class action, finding the customer failed to show the enamel-safe representations were deceptive and likely to mislead a reasonable consumer, and that she was injured from using the toothpaste.

Goe v. Zucker, 43 F.4th 19 (2d Cir. 2022)

Second Circuit affirmed dismissal of a proposed class action challenging the scope of medical exemptions to New York's mandatory immunization requirements for school-age children. Plaintiffs, parents of medically fragile or immune-compromised children, whose requests for medical exemptions were largely denied, claimed New York's recently revised immunization requirements and their enforcement violated their Due Process 14th Amendment rights. Plaintiffs claimed that when their physicians certify a need for a vaccine exemption, school officials cannot deny a request for an exemption and deprive the children of fundamental rights to life and liberty, and to an education.

The Second Circuit disagreed, holding the regulations in question do not force a child to be vaccinated, but permit a medical exemption where appropriate. Further, there is no *fundamental* right to a medical exemption simply on the say-so of a treating physician. While the right to an education is important, there is no fundamental right to an education. Inasmuch as the new regulations were reasonably related to a legitimate state objective– protecting communities from serious, vaccine- preventable diseases through immunization - the Court affirmed dismissal of the purported class action complaint.

Harris v. Pfizer Inc., 586 F. Supp. 3d 231 (S.D.NY. 2022)

In a proposed class action over a recall of Pfizer's stop-smoking drug Chantix due to contamination with excess levels of nitrosamine (a possible carcinogen), plaintiffs claimed they did not know Chantix contained the chemical and it was not listed as an ingredient. Nitrosamines are common in water and foods, including cured and grilled meats, dairy products, and vegetables, and so everyone is exposed to some level of nitrosamines. The U.S. Food and Drug Administration, in collaboration with regulatory counterparts around the world, has set internationally-recognized acceptable daily intake limits for nitrosamines. If drugs contain levels of nitrosamines above the acceptable daily intake limits, FDA recommends these drugs be recalled by the manufacturer as appropriate.

Pfizer moved to dismiss the case for lack of standing pursuant to FRCP 12(b)(1) and for failure to state a claim pursuant to FRCP 12(b)(6). Plaintiffs were required to plausibly allege Pfizer represented Chantix was free of nitrosamines contamination, which they could not do. Plaintiffs' complaint did not contain any fraudulent misrepresenta-

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tions or misleading statements of Pfizer. Plaintiffs' claim that they did not receive the drug "Chantix" because it was contaminated was insufficient to show fraud.

Because the plaintiffs claimed only economic harm, rather than personal injury, the economic loss doctrine barred their negligent misrepresentation claim. The Southern District of New York, Judge Denise Cote, dismissed the Amended Complaint and entered judgment for Pfizer.

Class Actions I Potential Implications for Future Cases

New York federal courts scrutinize purported class actions involving FDA-regulated products to ensure the claims are plausibly pled and do not hesitate to dismiss complaints at the outset where the complaint lacks plausibility on its face. Although courts typically adjudicate these motions on the four corners of the pleading, it is permissible for courts to go behind the complaint and review the documents they cite, such as publicly available scientific studies, in order to ascertain plausibility of the allegations. An FDA monograph can be a source of preemption where the product is not a drug or a device.

Pharmaceuticals

Vardouniotis v. Pfizer, 2022 N.Y. Misc. LEXIS 75*; 2022 N.Y. Slip Op. 30040(U) (N.Y. Cnty. Jan. 10, 2022)

Plaintiff alleged her use of Chantix to quit smoking caused various injuries, including chronic pain, muscle spasm, arthritic changes in the neck, cervical injuries, exhaustion, depression, and anxiety, among others. Plaintiff alleged Pfizer never attempted to include all her claimed side effects in the Chantix labeling. However, Pfizer did add a boxed warning to the Chantix label about the risk of changes in mood and behavior before plaintiff used the drug. After reviewing a large clinical trial, FDA determined the risks of serious neuropsychiatric events were lower than previously suspected and concluded the benefits of stopping smoking outweigh the risks.

Pfizer moved to dismiss the amended complaint based on failure to state a cause of action and based on documentary evidence to refute plaintiff's factual allegations. New York's Supreme Court, New York County found that Plaintiff sufficiently buttressed the failure to warn claim with articles and information pertaining to newly acquired information that could have permitted a change of the Chantix label under the CBE (changes being effected) regulation. Therefore, the failure to warn claims were not preempted.

Additionally, the informed intermediary doctrine was not sufficient to require the wholesale dismissal of the failure to warn claims, as the complaint alleged the physician did not receive adequate warnings. However, the failure to warn claim was dismissed to the extent it was premised on a failure to warn plaintiff and the public, as opposed to the prescribing physician. The Court declined to dismiss the warranty and unjust enrichment claims at this pleading stage but dismissed the plaintiff's request for punitive damages, as nothing in the complaint alleged that Pfizer engaged in any morally culpable conduct.

Reynolds-Sitzer v. Eisai, 586 F. Supp.3d 123 (N.D.N.Y. 2022)

Plaintiff alleged the first-in-class oral selective serotonin 5HT2c receptor agonist weight loss drug Belviq caused her to develop thyroid cancer. Upon a motion to dismiss pursuant to FRCP 12(b) (6), the Court evaluated plaintiff's claims under the products liability theories of negligence, strict liability, express warranty, and implied warranty. Plaintiff also asserted fraudulent misrepresentation and concealment. For the defective design claim, defendants' motion argued plaintiff's complaint did not identify a particular problem in the design of the drug or plead facts alleging the existence of a feasible alternative design. Plaintiff claimed that since Belviq was designed as a serotonin receptor agonist for weight loss, this posed a substantial likelihood of harm and a safer alternative was a drug that did not affect the serotonin pathway.

From pharmaceuticals to toothpaste, preemption to public health, New York state and federal courts issued decisions in 2022 that further shaped the landscape

Although plaintiff did not posit an alternate design, the Court ruled that requiring plaintiff to do so at the pleading stage would require technical or scientific knowledge that goes beyond Rule 8's notice pleading requirement. As such, the design defect claim was plausibly pled to withstand a motion to dismiss. As for the failure to warn claim, defendants sought dismissal only to the extent the allegations were premised upon on duty to warn plaintiff directly or, for that matter, anyone other than the prescribing physician. The Court found that defendants were getting ahead of themselves, and a motion premised upon the learned intermediary doctrine would be more appropriate after discovery. The breach of warranty claims was not time barred due to the New York Executive Order 202.8 "COVID-19 toll." Further, under New York law, where a product is for retail sale or intended for human consumption, there is no requirement for pre-suit notice under the New York Uniform Commercial Code. Lastly, the Court found the allegations of fraud did not meet the particularity requirements of Rule 9 and therefore were dismissed.

Pharmaceuticals I Potential Implications for Future Cases

The learned intermediary doctrine, known as the informed intermediary doctrine in New York, is an important tool to defend against warning claims for FDA regulated products. However, New York state and federal courts are unlikely to dismiss failure to warn claims at the pleading stage, where the extent of knowledge of the prescribing physician is not yet known. The better course is to take discovery, including testimony from the prescriber, to show the physician assessed the risks and benefits of the drug, advised the patient of its possible risks and side effects, and exercised appropriate independent medical judgment in prescribing the product.

Moreover, an early pre-answer dismissal motion of the design defect claims based upon the absence of a safer alternative feasible design may not result in outright dismissal, but rather provide plaintiff with the opportunity to replead; and in some cases, claim the technical or scientific knowledge to plead the precise type of alternative safer feasible design requires discovery from the manufacturer.

Medical Devices

Redd v. Medtronic Inc., 21-CV-06448, 2022 U.S. Dist. LEXIS 223697, 2022 WL 17584377 (S.D.N.Y Dec. 12, 2022)

Plaintiff alleged medical screws inserted into his back during spinal surgery broke one year after surgery, necessitating a second surgery. Defendant Medtronic moved to dismiss the complaint and plaintiff, proceeding *pro se*, did not submit an opposition. The Court, while finding *pro se* complaints are held to less stringent standards than those drafted by lawyers, dismissed the constitutionally-based claims against Medtronic.

Considering plaintiff's complaint with the liberality required of *pro se* pleadings, the Court construed the complaint as asserting a product liability claim under New York law. However other than alleging the screws were broken, the complaint failed to speak to their design, manufacture or warnings, and the products liability claim was therefore dismissed.

Poulin v. Boston Sci. Corp., 22-CV-553, 2022 U.S. Dist. LEXIS 222564 (W.D.N.Y. Dec. 9, 2022)

Plaintiff alleged decedent's death by cardiac arrest was due to a vena cava filter, a medical device implanted into a blood vessel to prevent blood clots from traveling into the lungs and maintain blood flow; this product liability action alleged failure to warn, design defect, breach of express and implied warranty, and consumer fraud.

Following removal to federal court based upon diversity jurisdiction, defendant moved to dismiss the amended complaint for failure to state a claim. Upon autopsy, the filter was found to be partially embedded into the vessel and focally perforating with a blood clot found to be near totally occluding the filter. To support the dismissal motion, defendant submitted the device's instructions for use (IFU) containing warnings of both perforation of the vena cava and migration of the filter.

Because the plaintiff disputed the authenticity of the IFU, particularly that the version supplied to the Court was not in effect at the time of the implant, the Court did not consider the IFU and its warnings on the motion. Because plaintiff alleged an absence of any warning, as opposed to an inadequacy of a specific warning, plaintiff was not required to identify how the missing warning was inadequate and the Court permitted the failure to warn claim. Plaintiff's design defect claim was dismissed, as the pleading did not adequately allege a safer alternative feasible design, or one that would have prevented the injuries. The breach of express warranty claim was dismissed because it was premised only upon marketing materials and the implied warranty claim was concededly time barred. Plaintiff's allegations of consumer fraud and deceptive trade practices premised upon New York General Business Law §349 were dismissed, as there were no allegations the alleged misrepresentations were directed to consumers, including physicians and their patients, and plaintiff did not allege reliance on the alleged materially misleading conduct. Finally, the motion seeking dismissal of the punitive damages allegations was denied as premature, pending discovery.

Medical Devices | Potential Implications for Future Cases

The Court may dismiss a design defect claim upon a pre-answer motion to dismiss if the pleading does not even allege a safer alternative feasible design would have prevented the injuries. Claims of consumer fraud and deceptive trade practices premised upon New York General Business Law are not typically claimed in personal injury product liability medical device cases and are subject to dismissal where there are no allegations, or reliance on, claims that the alleged misrepresentations were directed to consumers.

The developments of 2022 indicate that it is critical to remain informed about changes in the law in order to develop the strongest product liability defense of pharmaceuticals and medical devices. We know it takes an enormous investment to develop innovative pharmaceuticals and medical devices to improve life experiences. That's why our attorneys, with a national reputation for aggressively defending some of the largest entities in the regulated pharmaceutical, medical device, cosmetics, and nutritional supplement industries, leverage their combination of medical and legal credentials to protect your critical life sciences products.