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October 2024

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Looking Back, Moving Forward
A Message of Gratitude and Hope

Patrick J. Sweeney of *Sweeney & Sheehan* is the president of DRI.

Dear DRI members,

As my term as president of DRI soon comes to a close, I want to take a moment to express my deepest gratitude to each of you. Your dedication, your passion, and your unwavering commitment to this organization have made my tenure both meaningful and unforgettable. Serving as your president has been a true honor, and I am incredibly proud of all we have accomplished together as a ***DRI community***.

Our shared mission—to support civil defense attorneys in defending the interests of businesses and individuals—has never been more critical. DRI continues to be a beacon of knowledge, innovation, and collaboration in the legal space. The resources we provide, the conversations we initiate, and the relationships we foster are the foundation upon which our profession thrives.

I also want to extend my heartfelt thanks to the incredible staff, committees, and volunteers who have worked tirelessly alongside me. Your behind-the-scenes dedication ensures that DRI continues to lead the way, offering world-class seminars, webinars, publications, and so much more.

As I pass the torch to DRI President-Elect Anne Talcott later this month, I am filled with optimism for DRI's future. Anne's vision, leadership, and unwavering commitment to our organization assure me that DRI will continue to flourish. I know she will guide DRI with the same passion and purpose that have always defined us. Anne is a gifted leader and a trusted colleague, and I am excited to see the ways in which she will elevate our organization to new heights.

Before I sign off, I want to personally invite you to the ***DRI 2024 Annual Meeting*** in Seattle on October 16-18. This flagship event for civil defense practitioners is the perfect way to connect with your peers, grow your network, and engage with dynamic keynote speakers like two-time NBA champion and former US Senator Bill Bradley and travel expert and activist Rick Steves. Whether you are looking to earn valuable CLE credits, cultivate new business relationships, or simply enjoy the vibrant energy of Seattle, this meeting has something for everyone. Let's come together to celebrate our community, our profession, and the future of DRI.

I encourage you to save your spot and start planning your trip now. The relationships you build at this event can shape your career for years to come.

Thank you again for your trust, your support, and your belief in the power of this community. Serving as your president has been one of the greatest privileges of my career, and I look forward to continuing to support DRI in new ways as we step into the future.

With deep gratitude and best wishes,

Patrick J. Sweeney

ANNUAL MEETING

It's More Than a Meeting!

It's an experience that will shape your career. This year's Annual Meeting is where relationships build business, so join the most influential civil defense attorneys and in-house counsel from across the country to expand your knowledge, network, and professional profile this October 16-18 in Seattle.

You're Invited to

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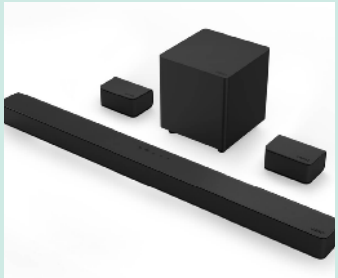

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ON THE RECORD

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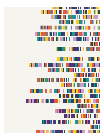

PROFESSIONAL LIABILITY

Federal Preemption as a Vehicle to Supreme Court Review of Climate Change Cases

By Steven M. Siros, Anand R. Viswanathan and Arie T. Feltman-Frank

...we predict that as the cases now move through the state courts, a patchwork of state court decisions on the federal preemption question will develop, depending on the state courts' characterization of the complaints at issue.

On February 20, 2024, the City of Chicago *sued* defendant fossil fuel companies in Illinois state court, asserting state law claims, including nuisance, violations of consumer protection laws, and product liability. Chicago has now joined multiple state and local entities that have filed similar lawsuits in state courts across the country against corporations involved in the production, marketing, and downstream distribution of oil- and gas-based products. In general, these climate change lawsuits are based on alleged injuries resulting from the defendants' production, marketing, and/or sale of fossil fuels.

In each of these cases, the defendants have argued or will likely argue that the state law claims should be dismissed because they are preempted by federal common law and/or the Clean Air Act. In this article, we first discuss the defendants' failed attempts to remove the cases to federal court on federal preemption grounds. Next, we predict that as the cases now move through the state courts, a patchwork of state court decisions on the federal preemption question will develop, depending on the state courts' characterization of the complaints at issue. Finally, we explore the possibility of federal preemption serving as a vehicle to Supreme Court review.

Failed Attempts to Remove Climate Change Cases to Federal Court

The defendants in these climate change cases originally attempted to remove the cases from state to federal district court (generally seen as a more neutral forum), arguing, among other things, that the state law claims are preempted by federal common law and/or the Clean Air Act. However, their attempts were unsuccessful. The US Courts of Appeals for the *First*, *Third*, *Fourth*, *Eighth*, *Ninth*, *Tenth*, and *District of Columbia*, citing the "well-pleaded complaint" rule (also known as the *Mottley* rule), remanded the cases back to state court. Under the "well-pleaded complaint" rule, federal question jurisdiction under 28 U.S.C. § 1331 must be based on the plaintiff's complaint, and affirmative defenses, like federal preemption, cannot serve as a basis for federal question jurisdiction. The Supreme Court has so far declined review of these cases (see *here*, *here*, and here).

Federal Preemption in State Courts

As these climate change lawsuits now move through state courts, those courts will be adjudicating federal preemption defenses. This is likely to lead to a patchwork of decisions on the federal preemption question, best exemplified by comparing two cases that have already considered this defense.

In *City of New York v. Chevron Corp.*, a case originally *filed* in federal

As these climate change lawsuits now move through state courts, those courts will be adjudicating federal preemption defenses.

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court, the City of New York asserted nuisance and trespass claims under New York law against domestic and foreign fossil fuel defendants. The claims were based on the defendants' production, marketing, and sale of fossil fuels and sought compensatory damages for the costs incurred and to be incurred by the City to protect its infrastructure, property, and residents from the impacts of climate change. The US Court of Appeals for the Second Circuit Court affirmed the district court's dismissal of the City's claims on federal preemption grounds.

First, the Second Circuit held that the City's claims were displaced by federal common law because they conflicted with federal interests in the uniformity of national energy and environmental policy and federalism. Although the City had not sought injunctive relief, the court still found significant conflict with federal interests because a substantial damages award would effectively regulate the defendants' behavior far beyond New York's borders by compelling them to develop new means of pollution control to avoid liability. *See also Kurns v. R.R. Friction Prods. Corp.*, 565 US 625, 637 (2012) ("[S]tate regulation can be... effectively exerted through an award of damages, and [t]he obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.") (cleaned up).

The Second Circuit continued that permitting the suit to proceed would risk upsetting "the careful balance that has been struck between the prevention of global warming, on one hand, and energy production, economic growth, foreign policy, and national security, on the other." *City of N.Y. v. Chevron Corp.*, 993 F.3d 81, 93 (2d Cir. 2021) (citations omitted). The court went on that, as states will invariably differ in their assessment of such proper balance, there is a real risk that subjecting the defendants' global operations to a "welter of different states' laws" could undermine important federal policy choices. Id.; *cf. Mayor & City Council of Balt. v. BP P.L.C.*, 31 F.4th 178, 203 (4th Cir. 2022) (explaining that the Second Circuit's analysis failed to mention any obligatory statutes or regulations explaining the specifics of energy production, economic growth, foreign policy, or national security and how New York law conflicts with them and therefore evaded the careful analysis that the Supreme Court requires for preemption based on a significant-conflict analysis).

The Second Circuit then held that the federal common law that displaced the City's claims with respect to domestic emissions was, in turn, displaced by the Clean Air Act. In so holding, the court relied on *Am. Elec. Power Co. v. Connecticut* and *Native Vill. of Kivalina v. ExxonMobil Corp.* In *Am. Elec. Power Co.*, the Supreme Court held that the Clean Air Act displaces federal common law public nuisance claims seeking injunctive relief in the form of abatement of carbon dioxide emissions. Then, in *Native Vill. of Kivalina*, the Ninth Circuit held that this includes the displacement of public nuisance claims seeking damages allegedly resulting from the climate change effects of such emissions (as

opposed to injunctive relief). Ultimately, the Second Circuit explained that, because the City's claims, if successful, would operate as a *de facto* regulation on greenhouse gas emissions, they were displaced by the Clean Air Act. The court rejected the City's argument that its claims focused on the production, promotion, and sale of fossil fuels, which the Clean Air Act does not regulate. The court explained that while these may have been the claims' focus, the claims ultimately depended on harms stemming from the emissions themselves.

The Second Circuit further held that the Clean Air Act does not authorize the City's claims. The court explained that, while the Clean Air Act's savings clause does permit state claims brought under the law of the source state, this was not the case. Rather, the court explained that the City was attempting to impose New York nuisance standards on emissions emanating "simultaneously from all 50 states and the nations of the world." *City of N.Y.*, 993 F.3d at 100.

The City's complaint was not limited to domestic emissions. As to foreign emissions, the court reasoned that the Clean Air Act has no extraterritorial reach and therefore does not displace the City's claims to the extent that they seek recovery from harms caused by foreign emissions. However, the court refused to recognize a federal common law cause of action targeting foreign emissions given "the need for judicial caution in the face of delicate foreign policy considerations." Id. at 103.

By comparison, in ***City & Cty. of Honolulu v. Sunoco LP***, the Supreme Court of Hawaii affirmed a ***circuit court's order*** denying fossil fuel defendants' motions to dismiss the case (amended complaint ***here***) on federal preemption grounds.

In this case, the City and County of Honolulu is asserting state law claims for nuisance and trespass (as was the case in *City of New York*) *but also* failure to warn. The claims are based on the defendants' promotion and sale of fossil fuel products and, in particular, their alleged concealment of the hazards that fossil fuel products pose, as well as the alleged misleading of customers, consumers, and regulators regarding the risk of climate change and its consequences. The City asserts that the alleged tortious behavior caused or will cause injuries to infrastructure, real property, and public resources in Hawaii and is seeking compensatory damages and equitable relief, including abatement of the nuisances.

In finding no federal preemption, the Hawaii Supreme Court reasoned that the federal common law that used to govern transboundary pollution abatement and damage suits no longer exists because it was displaced by the Clean Air Act and therefore no longer has a preemptory effect. The court then explained that, even if the federal common law has not been displaced, it does not preempt the City's claims, which are tortious marketing and failure to warn claims, not transboundary pollution abatement and damage claims (interestingly, as indicated above, the complaint also included nuisance and trespass claims).

Ultimately, the court characterized the defendants' alleged tortious marketing conduct as the source of the plaintiffs' alleged injury and the emissions themselves as being merely a "link in the causal chain." 153 Haw. 326, 360, 537 P.3d 1173 (2023). *Compare with City of New York*, supra (acknowledging this argument but reasoning that the claims ultimately depended on harms stemming from the emissions themselves). The court then held that the Clean Air Act does not preempt the City's claims because there is no potential conflict. The court explained that the City's claims potentially regulate marketing conduct while the Clean Air Act regulates pollution.

It is unclear exactly how other state courts will rule on this issue; indeed, we may begin to see a patchwork of state court decisions on federal preemption, depending on the courts' characterization of the complaints at issue. Some state courts may view the complaints before them, as the Second Circuit did, as disguised attempts to regulate emissions. This is more likely to be the case where the complaints are more easily read as seeking damages resulting from the emissions themselves. Other state courts may view the complaints before them, as the Supreme Court of Hawaii did, through a narrower lens as attempts to seek damages resulting from the alleged tortious conduct, the emissions themselves being merely a "link in the causal chain."

Federal Preemption as a Vehicle to Supreme Court Review

As these climate change cases move through the state courts, an important question will be whether the defendants will ultimately be able to appeal to the US Supreme Court. The "well-pleaded complaint" rule, the basis for the federal circuit courts' rejection of federal question jurisdiction, does not apply to the Supreme Court's appellate jurisdiction, which is broader. Two groups of defendants in *Sunoco* have already petitioned the Supreme Court for certiorari based on conflicts with the Second Circuit's decision in *City of New York*.

On February 28, 2024, ***petitioners*** sought certiorari from the Supreme Court, seeking to highlight the conflict between the Second Circuit's decision in *City of New York* with the Hawaii Supreme Court's decision in *Sunoco*. Petitioners claim that the Supreme Court needs to step in and address this issue now because of the enormous legal and practical implications of these lawsuits. Petitioners note that there are numerous climate change cases pending in various state courts that seek billions of dollars in damages for the alleged localized effects of global climate change. "If petitioners are correct that these "unprecedented" cases should fail at the outset, the "enormous" resources necessary to litigate and adjudicate them would be wasted."

Respondents claim, however, that certiorari is not warranted because there is no conflict with the Second Circuit's decision in *City of New York*. Respondents argue that petitioners' liability does not arise from lawful conduct in producing and selling fossil fuels but rather from "allegedly tortious conduct" and, more specifically, failing to disclose, failing to warn, and deceptive promotion in connection with petitioners' historic sales of fossil fuels.

Respondents also argue that due to the interlocutory nature of the Sunoco court's decision, this case would be a poor vehicle for considering petitioners' preemption defense. Rather, respondents argue that the Supreme Court should allow the issue to percolate, noting the Court will have other opportunities to take up petitioners' preemption defense and there is no need to short-circuit the state courts' analysis "which could yield insights (or reveal pit-

falls) that this Court 'cannot muster guided only by [its] own lights.'"

On June 10, 2024, the Supreme Court requested that the United States' Solicitor General file a brief expressing the views of the United States. This is not the first time that the United States has weighed in on the issue.

In March of 2019, the Solicitor General (Trump administration) submitted an ***amicus brief*** in *City of New York* in which the Solicitor General argued that the City's claims were preempted by the Clean Air Act. Further, in November of 2020, the Solicitor General took the position that claims involving cross-boundary pollution that seek to apply the law of an affected state to conduct in another state arise under federal law for jurisdictional purposes, even if such claims may be displaced by the Clean Air Act. *See* Amicus Brief of the United States in the matter of *BP P.L.C. v. Mayor and City Council of Baltimore* (filed Nov. 2020).

Most recently, the Solicitor General (Biden Administration) confirmed the United States' position that the Clean Air Act has displaced federal common law claims while at the same time backtracking on its position that claims involving cross-boundary pollution arise under federal law for jurisdictional purposes. *See* ***Amicus Brief*** of the United States in the matter of *Suncor Energy v. Board of Commissioners of Boulder County* (filed Mar. 2023). On the question of whether the Clean Air Act would preempt such claims, the United States simply stated that "even if the [Clean Air Act] preempts particular state-law causes of action in this sphere, such preemption would simply be a federal defense that provides no basis for removal."

While the United States' amicus brief will likely be filed later this month, we will have to wait until the Supreme Court starts its new term in October to see if it elects to grant certiorari in this case or whether the Court elects to allow the issue to percolate further.

Letter from the Chair

Collaboration and Advocacy in the Defense Bar

Erik Snapp is Associate Vice President, Assistant General Counsel at Eli Lilly and Company. He serves as the chair of the DRI Drug and Medical Device Committee. Any views, opinions or conclusions expressed in this column are those of the author, and do not necessarily reflect the views, opinions and/or conclusions of his employer.

Members of DRI's ***Drug and Medical Device Committee*** ("DMD") have packed this issue of *For The Defense* with articles on a wide array of topics: genomics, ethics, social media, Rule 702, Canadian litigation perspectives, pre-approval design claims, and medical device marketing. Regardless of your specialty, you will find something in these pages that will be interesting and relevant to your practice. Defense lawyers generally do a good job keeping each other up to date on issues worthy of publications or presentations. But is that enough? Can we do a better job of sharing our knowledge and experience? Can we use our DRI Committees to become better organized and unified on important legal and policy issues clients face day after day, year after year? I think we can.

The Plaintiffs' Bar Is (Apparently) Better Organized

I recently attended a conference where judges, lawyers from both sides of the "v." and academics engaged in robust discussions of topics important to clients (e.g., litigation funding, Rule 702 limits on junk science, early case vetting, and other notable issues). Maybe I'm giving our friends in the plaintiffs' bar too much credit, but they seemed to be miles ahead of the defense bar in presenting a coordinated, unified voice on these important issues. I've observed this phenomenon in other forums as well. Plaintiffs' counsel often sound like they are working off the same set of talking points. Their unified approach makes sense given that they typically have a shared objective when pursuing most types of litigation: to maximize recovery for their clients (and some might say for themselves). They also foster this collaborative advocacy through plaintiffs' counsel-only organizations and frequent litigation conferences.

Defense counsel, on the other hand, don't necessarily have the same shared purpose or the same incentives to collaborate and advocate with a coordinated voice for defense-friendly positions. Defense lawyers focus, as they must, on their client's legal and business objectives, which might or might not be aligned with those of their co-defendant(s) and others in the defense bar. They also must remain vigilant of privilege waiver issues and constant pressure from within their firms to build and grow exclusive client relationships. All of these factors inhibit, rather than encourage, collaboration and sharing of ideas and strategies among defense counsel.

DMD and DRI Facilitate Defense Bar Collaboration

As most of you know, DRI is the largest international membership organization of attorneys defending the interests of business and individuals in civil litigation. One of the ways DRI fulfills its mission of enhancing the skills, effectiveness, and professionalism of defense lawyers is by helping them collaborate and work together across practice areas, jurisdictions, and industries. DRI facilitates collaboration through many platforms and programs, including the upcoming ***2024 Annual Meeting***, ***committee seminars***, and ***publications like For the Defense and In-House Defense Quarterly***. Committees like the Drug and Medical Device Committee also develop their own industry or practice-specific ways to facilitate collaboration and advocacy.

Here are a few collaboration and advocacy initiatives we're working on within the DMD Committee:

- *"Walk-Ins" at DMD Committee Meetings:* Our committee holds (almost) monthly virtual meetings of our entire committee membership. These informal meetings give committee members an opportunity to share ideas and strategies and learn from each other. To facilitate the sharing of ideas, we schedule 10-15 minutes of each meeting for "walk-in" questions or issues that members are dealing with in their practices. Our idea is to provide a forum to bounce ideas and thoughts off fellow committee members and share views on issues others are facing. Who better to bounce ideas off than your DRI friends?
- ***DRI Communities:*** DRI Communities are online forums on dri.org where committee members can connect, share, and learn from each other on topics of common interest. Communities allow defense lawyers to post questions, share insights, access resources, and network with peers. DMD Committee members use the Communities page to share

information about experts and case law developments, but this resource is currently underutilized by our committee members. We're working to drive more collaboration and information sharing through the DMD Communities page.

- *Advocacy Outside the Courtroom:* Our DMD Committee members are undoubtedly skilled and accomplished advocates inside the courtroom for their clients' positions. They are also uniquely positioned to shape the legal, regulatory, and policy framework that governs the industry. Whether they are getting involved in DRI's amicus work though the ***Center for Law and Public Policy*** or submitting public comments on proposed changes to the federal rules, DMD Committee members can use their knowledge and expertise to bring about broader systemic change than they might by litigating a single case. As a committee, we are always looking for ways to help our members advocate for our clients' positions outside as well as inside the courtroom.

I look forward to seeing you at an upcoming virtual DMD Committee Meeting and to reading your comments and questions on the DMD Communities page. Collaboration works best when you develop relationships with your fellow defense counsel. A great way to do that is by taking advantage of the many ways DRI brings DMD lawyers together. To that end, mark your calendars now for our annual ***DRI Drug and Medical Device Seminar*** from May 7-9, 2025, in Nashville. See you there!

Amended Fed. R. Evid. 702 – Progress and Precedent

By James M. Beck

It is incumbent on defendants to use the 2023 amendments to Rule 702 to win real cases and to overturn prior, "incorrect" applications of the Rule...

In a major defense win, the amendments strengthening Fed. R. Evid. 702 took effect on December 1, 2023. The precise changes are reflected with new language in italics and deleted language struck out:

Rule 702: Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if *the proponent demonstrates to the court that it is more likely than not that*:

a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
b) the testimony is based on sufficient facts or data;
c) the testimony is the product of reliable principles and methods; and
d) ~~the expert has reliably applied~~ *the expert's opinion reflects a reliable application of* the principles and methods to the facts of the case.

These changes: (1) include the proponent's burden of proof (preponderance) in the language of the rule itself; (2) specify that "the court" – not a jury – must determine that all four of the substantive criteria for expert admissibility are satisfied; and (3) specify that the judicial gatekeeping function includes ensuring that expert testimony reliably applies the expert's "principles and methods" to the case-specific facts.

These 2023 amendments occurred because the federal judiciary's Civil Rules Committee, believed that many of their judicial colleagues were misapplying the prior (2000) version of Rule 702, and explicitly said so in the commentary to these amendments.

First, the Rules Committee saw fit to "emphasize" both the judicial gatekeeping function and the concomitant burden of proof on proponents of expert opinion. "[E]xpert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule." Committee Note to 2023 Amendments at (1).

Second, too many courts were getting Rule 702 wrong, particularly as to its "reliability requirements":

> The Committee concluded that emphasizing the preponderance standard in Rule 702 specifically was made necessary by the courts that have ***failed to apply correctly*** the reliability requirements of that rule.

Id. (emphasis added).

Third, no "presumption" in favor of admissibility exists under Rule 702. Excusing the proponent from having to prove each of the Rule's four elements was "incorrect":

> The amendment clarifies that the preponderance standard applies to the three reliability-based requirements added in 2000 – requirements that ***many courts have incorrectly determined*** to be governed by the more permissive Rule 104(b) standard. But it remains the case that other admissibility requirements in the rule (such as that the expert must be qualified and the expert's testimony must help the trier of fact) are governed by the Rule 104(a) standard as well.
>
> Id. (emphasis added).

Specifically, courts applying the previous formulation of Rule 702 were "incorrectly" admitting experts under a "weight not admissibility" rationale far more frequently than the Rule's text allowed – particularly as to opinions lacking an adequate basis in fact to support experts' use of what are, in general, accepted methodologies:

> [M]any courts have held that the critical questions of the sufficiency of an expert's basis, and the application of

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> the expert's methodology, are questions of weight and not admissibility. ***These rulings are an incorrect application*** of Rules 702 and 104(a).

Id. (emphasis added). While the Rules Committee elected not to criticize particular decisions by name, the final "Memorandum" that the Committee's Reporter submitted prior to final adoption of the 2023 amendments listed the following "statements, made by some courts in the past" as "not supportable" and "certainly incorrect":

- "There is a presumption in favor of admitting expert testimony."
- "The sufficiency of facts or data supporting an expert opinion is a question for the jury, not the court."
- "Whether the expert has properly applied the methodology is a question for the jury, not the court."
- "The Federal Rules of Evidence establish a liberal thrust in favor of expert testimony."

"Under the amendment, it is quite clear that the statements above are wrong as a simple matter of textual analysis." Advisory Committee on Evidence Rules, May 6, 2022 Agenda Book, at pp. 148-49 (Tab 4A). This concern over judicial errors also led to the amendment to Rule 702(d) emphasizing judicial scrutiny of the "reliable application" of their methodology to the facts of particular cases.

The Committee Note confines "weight" to minor quibbles, such as "that the expert has not read every single study that exists." Id. Weight "does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis always go to weight and not admissibility." Id. Rather, "weight" is grounds for admissibility only "once the court has found it more likely than not that the admissibility requirement has been met." Id. "[I]t does not permit the expert to make claims that are unsupported by the expert's basis and methodology." Committee Note to 2023 Amendments at (2).

The full Committee "unanimously" adopted the 2023 Rule 702 amendments. Committee on Rules of Practice & Procedure, Agenda Book, Tab 7A, "Report to the Standing Committee," at 871 (June 7, 2022) (available at < https://www.uscourts.gov/sites/default/files/2022-06_standing_committee_agenda_book_final.pdf >). The amendments "emphasize that the court must focus on the expert's opinion and must find that the opinion actually proceeds from a reliable application of the methodology." Id. They "more clearly empower[] the court to pass judgment on the conclusion that the expert has drawn from the methodology." Id. Specifically as to weight versus admissibility, the Committee amended Rule 702 to change "misstatement[s]" in "contrary" decisions rendered by "many courts":

> [T]he Committee resolved to respond to the fact that many courts have declared that the reliability requirements set forth in Rule 702(b) and (d) – that the expert has relied on sufficient facts or data and has reliably applied a reliable methodology – are questions of weight and not admissibility, and more broadly that expert testimony is presumed to be admissible. ***These statements misstate Rule 702***, because its admissibility requirements must be established to a court by a preponderance of the evidence. The Committee concluded that in a fair number of cases, the courts have found expert testimony admissible even though the proponent has not satisfied the Rule 702(b) and (d) requirements by a preponderance of the evidence – essentially treating these questions as ones of weight rather than admissibility, which ***is contrary*** to the Supreme Court's holdings that under Rule 104(a), admissibility requirements are to be determined by the court under the preponderance standard.

Id. (emphasis added). The amendment also "clarif[ied] that it is the court and not the jury that must decide whether it is more likely than not that the reliability requirements of the rule have been met. Id. at 872. On this record, the Committee on Rules of

Practice and Procedure "unanimously gave final approval to the proposed amendment to Rule 702." Id.

It is incumbent on defendants to use the 2023 amendments to Rule 702 to win real cases and to overturn prior, "incorrect" applications of the Rule – especially in those circuits where such judicial errors appear in otherwise binding appellate precedent. Critically, the 2023 amendments are the binding law – not prior precedent. "All laws in conflict with such rules shall be of no further force or effect after such rules have taken effect." 28 U.S.C. §2072(b). The Supreme Court recognizes the federal rules to be "as binding as any statute duly enacted by Congress, and federal courts have no more discretion to disregard the Rule's mandate than they do to disregard constitutional or statutory provisions." *Bank of Nova Scotia v. United States*, 487 U.S. 250, 2550 (1988). Thus, federal rules "are binding upon court and parties alike, with fully the force of law." *In re Nat'l Prescription Opiate Litig.*, 956 F.3d 838, 844 (6th Cir. 2020) (citations omitted).

Obviously, this controlling effect extends to rules' amendments, just as it would with statutory changes, since Congress also must consent – and did consent in 2023 – to all such amendments. Indeed, in 2023 "Congress did not amend the Advisory Committee's draft in any way... [thus,] the Committee's commentary is particularly relevant in determining the meaning of the document Congress enacted." *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 165-66 n.9 (1988). The Supreme Court has explained that "Advisory Committee Notes are "a reliable source of insight into the meaning of a rule".... [W]hen the Committee intended a new rule to change existing federal practice, it typically explained the departure." *Hall v. Hall*, 138 S. Ct. 1118, 1130 (2018) (quoting *United States v. Vonn*, 535 U.S. 55, 64 n.6 (2002)). That is precisely what happened with Rule 702. In 2023, the Committee explicitly set out "to change existing federal practice."

Thus, neither the Supreme Court's landmark decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), nor (obviously) any of the prior judicial decisions that the Advisory Committee specifically stated (more than once) "incorrectly" applied the prior version of Rule 702, provide any basis for any further judicial disregard of the Rule's express terms. In particular, three relatively recent adverse appellate decisions are no longer valid.

- *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 9 F.4th 768, 788 (8th Cir. 2021), which assessed only whether the expert's opinions were "fundamentally unsupported," rather than applying Rule 702's criteria and burden of proof (relying on the pre-*Daubert* case *Loudermill v. Dow Chem. Co.*, 863 F.2d 566 (8th Cir. 1988)).
- *Puga v. RCX Sols., Inc.*, 922 F.3d 285, 294 (5th Cir. 2019), which followed a "general rule" that questions about the bases and sources of an expert's opinion go to weight, not admissibility (relying on the pre-*Daubert* case *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987)).
- *Mighty Enters., Inc. v. She Hong Indus. Co.*, 745 F. App'x 706, 709 (9th Cir. 2018), which considered the factual basis of an expert's opinion as a matter of weight, not admissibility (relying on *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998 (9th Cir. 2004), which in turn was based on language from other decisions following *Loudermill*).

To take full advantage of the 2023 amendments to Rule 702, defense counsel likewise need to amend – our own briefs. All pre-amendments briefing concerning expert admissibility under Rule 702 needs to be thoroughly revised to ensure that we are relying on the current, post 2023 amendments Rule 702 language. If we do not assert the updated language, plaintiffs certainly will not.

We also should stop calling Rule 702 motions "*Daubert* motions," both in briefs and in oral argument. Indeed, *Daubert* references should generally be minimized, since in 1996, the Supreme Court was interpreting a version of Rule 702 that has since been amended twice and which in no way resembled the current rule. Continued defense reliance on *Daubert* only gives weight to those aspects of *Daubert*, such as "liberal[ity]," that the 2023 amendments supersede and designate as "incorrect." Any reference defense briefs do make to *Daubert* should include, at minimum, a footnote pointing out that *Daubert*'s essentially common-law approach to expert admissibility has been superseded by amended Rule 702. While limited use of *Daubert*'s so-called "factors" is acceptable, those factors should be presented as considerations applicable to one of the four express elements of Rule 702 analysis.

To take full advantage of the 2023 amendments to Rule 702, defense counsel likewise need to amend – our own briefs

Defendants briefing Rule 702 motions should also cleanse their papers of any language that: (1) suggests a bias or presumption toward admissibility; (2) uses "weight" versus "admissibility" language; or (3) offers "cross-examination" as a solution to expert problems. Instead, we should rely on the favorable comments and history of the 2023 Rule 702 amendments as much as we can. As the Supreme Court has recognized, amendments to the language of the federal rules are to be treated in the same way as statutory amendments. Also, in order to fully implement the 2023 amendments, defendants should not be reluctant to take on bad decisions explicitly. Since they are undermined by formal rules amendments, they are no longer governed by stare decisis, since stare decisis, "in the area of statutory interpretation," is always subject to "Congress remain[ing] free to alter what we [courts] have done." *Patterson v. McLean Credit Union*, 491 U.S. 164, 173 (1989) (superseded by statute). That is precisely what happened to Rule 702 in 2023. Congress, in approving the Rule 702 amendments, did precisely that – "alter[ing] any reading [courts] adopt simply by amending the [rule]." *14 Penn Plaza LLC v. Pyett*, 556 U.S. 247, 280 (2009). Decisions based on "incorrect" interpretations of Rule 702 are ripe for overruling.

So far, in most courts, it seems that the 2023 Rule 702 amendments have had the

desired effect. Numerous decisions have explicitly referenced the amendments, and the relevant Rules Committee commentary in excluding expert testimony. Appellate authority is still relatively sparse. Most notably *Sardis v. Overhead Door Corp.*, 10 F.4th 268 (4th Cir. 2021), applied the amendments to reverse the admission of an expert even before they took effect. Id. at 283-84. *Sardis* "confirm[ed] once again the indispensable nature of district courts' Rule 702 gatekeeping function in all cases in which expert testimony is challenged on relevance and/or reliability grounds." Id. at 284. In *Doucette v. Jacobs*, 106 F.4th 156 (1st Cir. 2024), the court recognized that, "[i]n 2023, Rule 702 was amended to directly state that the proponent of the expert testimony must establish these reliability requirements by a preponderance of the evidence," id., at 169 n.17, while affirming a district court's *sua sponte* exclusion of an education-related causation expert. Id. at 169-70. The only other appellate decision to date is *In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Products Liability Litigation*, 93 F.4th 339 (6th Cir. 2024). But *Onglyza*, while noting the intervening amendment, id. at 345 n.4, did not apply it, since the "old rule... was still in force at the time of the district court's decision. Id.

In re Paraquat Products Liability Litigation, ___ F. Supp.3d ___, MDL No. 3004, 2024 WL 1659687 (S.D. Ill. April 17, 2024), excluded the MDL plaintiffs' general causation expert. *Paraquat* relied on the 2023 amendments, which became effective in the midst of the MDL's Rule 702 motion practice – after the motion had been briefed, but before it was decided. Id. at *4 n.8. Those amendments:

> emphasized that the proponent bears the burden of demonstrating compliance with Rule 702 by a preponderance of the evidence, and that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology.

Id. (citation and quotation marks omitted). *Paraquat* enforced the 2023 amendments by requiring "that expert testimony ***may not be admitted*** unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth." Id. at 4 n.9 (quoting Committee Note to 2023 amendments) (emphasis added by the court).

Paraquat found that the 2023 amendments were necessary because "courts had erroneously admitted unreliable expert testimony based on the assumption that the jury would properly judge reliability." Id. Specifically, "some courts had 'incorrect[ly]' held that an expert's basis of opinion and application of her methodology were questions of weight, not admissibility." Id. (again quoting Committee Note). Thus:

> Mindful of its role as the witness stand's "vigorous gatekeeper," the Court will closely scrutinize the reliability of proffered expert testimony before permitting an expert to share her opinion with the jury. Expert testimony that is not scientifically reliable should not be admitted. The gatekeeping function, after all, requires more than simply taking the expert's word for it.

Id. (citations and quotation marks omitted).

Paraquat's application of the 2023 Rule 702 was influenced by the MDL ruling in *In re Acetaminophen ASD-ADHD Products Liability Litigation*, 707 F. Supp. 3d 309, No. 22MD3043 (DLC), 2023 WL 8711617 (S.D.N.Y. Dec. 18, 2023). *Acetaminophen* had quite a bit to say about the 2023 amendments:

> Rule 702 was amended effective December 1, 2023. "Nothing in the amendment imposes any new, specific procedures." Fed. R. Evid. 702, Advisory Committee Notes, 2023 Amendments. Instead, one purpose of the amendment was to emphasize that
>
> > Judicial gatekeeping is essential because just as jurors may be unable, due to lack of specialized knowledge, to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors may also lack the specialized knowledge to determine whether the conclusions of an expert go beyond what the expert's basis and methodology may reliably support. Id.

Id. at 335 *16 n.27.

Similarly, in *Sprafka v. Medical Device Business Services, Inc.*, C.A. No. 22-331 (DWF/TNL), 2024 WL 1269226 (D. Minn. March 26, 2024), the court in non-MDL litigation excluded the plaintiff's causation expert. *Sprafka* found another part of the Committee Note important enough to quote – the part stating that prior Eighth Circuit precedent was wrongly decided:

> [M]any courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a).

Id. at *2 (quoting Advisory Committee Note to 2023 Amendment).

More recently, the court in *In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices & Products Liability Litigation*, C.A. No. 16-2738 (MAS) (RLS), 2024 WL 1914881 (D.N.J. April 30, 2024), agreed that earlier Rule 702 decisions should be reassessed in light of, inter alia, the "recent changes to Federal Rule of Evidence 702." Id. at *1. Plaintiffs' argument that the court should "ignore Rule 702's most recent clarifications" was soundly rejected. Id. at *2. The Rules Committee's "clarification is precisely why it would be inappropriate for this Court to preclude Defendants from challenging this Court's previous *Daubert* holdings." Id. at *3 (emphasis original).

> The 2023 amendments provide that Rule 702:
>
> 'clarif[ied] and emphasize[d] that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule.' The amendment was motivated by the Advisory Committee's 'observation that in "a number of federal cases... judges did not apply the preponderance standard of admissibility to Rule 702's requirements of sufficiency of basis and reliable application of principles and methods, instead holding that such issues were ones of weight for the jury."' The Committee emphasized that rulings which have held 'the critical questions of the sufficiency of an expert's basis for his testimony, and the application of the expert's methodology, are generally questions of weight and not admissibility' 'are an incorrect application of Rules 702 and 104(a).'

Id. (quoting *Allen v. Foxway Transp., Inc.*, No. 4:21-CV-00156, 2024 WL 388133, at *3 (M.D. Pa. Feb. 1, 2024) (footnotes omitted)) (which, in turn, quoted the Advisory Committee Note). The Advisory Committee Note "outline[d] a consistent and concerning misapplication of Rule 702 by federal courts in the ***past***." Id. (emphasis original). Thus, "it is self-evident that Defendants should be allowed to contest previous [Rule 702] holdings" in the MDL if they could "identify any incorrect application of Rule 702 in the [previous] 2020 Opinion." Id.

Among cases further removed from prescription medical product liability litigation, an extensive discussion of the 2023 Rule 702 amendment and the reasoning behind it took place in *State Automobile Mutual Insurance Co. v. Freehold Management, Inc.*, 3:16-CV-2255-L, 2023 WL 8606773 (N.D. Tex. Dec. 12, 2023). Like *Talcum*, *State Auto* involved a post-amendment reconsideration of an earlier Rule 702 decision, this time involving "forensic experts" on property damage. *State Auto* qualified the adverse pre-*Daubert* language from *Viterbo*, 826 F.2d at 422, that only "generally" could juries resolve "issues regarding the bases and sources of an expert's opinion that affect the weight of an opinion rather than [its] admissibility" because it recognized that *Viterbo* had been impaired by the 2023 amendments. *State Auto. Mut. Ins. Co.*, 2023 WL 8606773, at *10. The broad statement from *Viterbo* was "incorrect" under Rule 702:

> The court previously emphasized the word generally because the 2023 amendments to Rule 702 explain that issues pertaining to the sufficiency of facts or data relied upon by an expert and the sufficiency of an expert's bases do not always concern questions of weight that should be left to the jury.

Id. The 2023 amendments recognized that *Viterbo* was "an incorrect application of Rules 702 and 104(a)." Id. (quoting Committee Note to 2023 Amendment). *State Auto* also applied Rule 702(d)'s amended "reliable" application prong:

> Additionally, the 2023 amendments to Rule 702 "emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology"...:
>
> > Judicial gatekeeping is essential.... ***The [admissibility] standard does not require perfection. On the other hand, it does not permit the expert to make claims that are unsupported by the expert's basis and methodology.***

Id. at *11 (emphasis in original). *State Auto* demonstrates that the same Rule 702 principles apply across all types of cases involving expert testimony since December 2023. Indeed, a discussion verbatim to *State Auto* may be found in *Dewolff, Boberg & Associates, Inc. v. Pethick*, C.A. No. 3:20-CV-3649-L, 2024 WL 1396267, at *5-6 (N.D. Tex. March 31, 2024), which resulted in the exclusion of a totally different kind of damages expert (lost profits).

The most important aspect of the Rule 702 amendments, at least in the near term, is their recognition that a large number of previous expert admissibility decisions are "incorrect" or "incorrectly determined," as the Committee Note quoted in *State Auto* stated.

> The amendment was aimed at courts that had erroneously held that "the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility."

Johnson v. United States, No. 21-CV-2851 (MKB), 2024 WL 1246503, at *3 n.7 (E.D.N.Y. Jan. 16, 2024) (quoting Committee Note; excluding causation opinions). Other decisions that quote the Committee's determination that numerous prior decisions applying the previous version of Rule 702 were "incorrect" in the course of excluding purported experts from testifying are: *In re Deepwater Horizon Belo Cases*, Nos. 3:19cv963-MCR-HTC, et al., 2024 WL 3176927, at *17 (N.D. Fla. June 25, 2024) (magistrate recommending exclusion of causation experts in multiple cases); *Princeton Excess & Surplus Lines Ins. Co. v. Caraballo*, No. 1:21CV1981, 2024 WL 2294827, at *19 (N.D. Ohio May 21, 2024) (excluding insurance practices expert); *West v. Home Depot U.S.A., Inc.*, No. 21 CV 1145, 2024 WL 1834112, at *2, 4 (N.D. Ill. April 26, 2024) (excluding multiple medical causation opinions), *reaffirmed on reconsideration*, 2024 WL 2845988, at *2-3 (N.D. Ill. June 5, 2024); *Maney v. Oregon*, No. 6:20-cv-00570-SB, 2024 WL 1695083, at *2 (D. Or. April 19, 2024) (excluding prison procedures expert); *Davidson Surface/Air, Inc. v. Zurich Am. Ins. Co.*, No. 4:22 CV 547 CDP, 2024 WL 1674519, at *2 n.3 (E.D. Mo. April 18, 2024) (excluding weather opinion); *Coblin v. Depuy Orthopaedics, Inc.*, No. 3:22-cv-00075-GFVT-MAS, 2024 WL 1588752, at *2 (E.D. Ky. April 11, 2024) (plaintiff required to supplement cause-of-death report); *Lane v. Am. Airlines, Inc.*, No. 2024 WL 1200074, 2024 WL 1200074, at *4 n.3 (E.D.N.Y. March 20, 2024) (excluding causation experts on both sides); *Burdess v. Cottrell, Inc.*, No. 4:17-CV-01515-JAR, 2024 WL 864127, at *3 (E.D. Mo. Feb. 29, 2024) (excluding human factors expert "notwithstanding" the prior "liberal standard," given 2023 amendments); *Austin v. Brown*, C.A. No. 1:21-cv-02682-RMR-SBP, 2024 WL 1602968, at *10 (D. Colo. Feb. 22, 2024) (emphasizing the "incorrect" language; excluding police procedures expert); *Boyer v. City of Simi Valley*, No. 2:19-cv-00560-DSF-JPR, 2024 WL 993316, at *1 (C.D. Cal. Feb. 13, 2024) (excluding damages experts); *Allen*, 2024 WL 388133, at *3 (excluding industry standards expert); *Cleaver v. Transnation Title & Escrow, Inc.*, No. 1:21-cv-00031-AKB, 2024 WL 326848, at *2 (D. Idaho Jan. 29, 2024) ("The amendments are intended to correct some courts' prior, inaccurate application of Rule 702.") (excluding industry standards opinion); *Mann v. QuikTrip Corp.*, No. 4:22-cv-01060-JAR, 2023 WL 9023262, at *2 n.2 (E.D. Mo. Dec. 29, 2023) (excluding premises liability expert); *Greene v. Ledvance LLC*, No. 3:21-CV-256-TAV-JEM, 2023 WL 8636962, at *3 n.1 (E.D. Tenn. Dec. 13, 2023) (excluding causation expert).

A second important aspect of the 2023 Rule 702 amendments is the strengthening of Rule 702(d), now requiring that an expert "must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology." Committee Note to 2023 Amendment. The factual basis of an opinion is a predicate to admissibility:

> I cannot find that [plaintiff] met its burden of establishing by a preponderance of the evidence that [the expert's] opinions are reliable, that is, that they have a sufficient factual basis and that he reli-

A second important aspect of the 2023 Rule 702 amendments is the strengthening of Rule 702(d)...

> ably applied an accepted methodology in reaching his conclusions. ***Because those questions go to the admissibility and not the weight of [the] opinions, they are for me to resolve instead of a jury.***

Davidson Surface, 2024 WL 1674519, at *6 (emphasis added). "The recent amendment is... a refocusing of the Supreme Court's instruction for district court judges to act as a gatekeeper to ensure proposed expert testimony 'is not only relevant, but reliable when testimony is challenged.'" *West*, 2024 WL 1834112, at *2 (quoting Committee Note). Under amended Rule 702, "[p]unting the reliability requirements of Rule 702 to the jury is inconsistent with this Court's gatekeeping function." *Ozuna v. Pena*, C.A. No. 22-915-SDD-RLB, 2024 WL 2955609, at *2 (M.D. La. June 12, 2024) (excluding future medical and earnings opinions).

Thus, "the 2023 amendments to Rule 702 make clear that reliability, both in theory and application, is the hallmark of admissible expert testimony." *Post v. Hanchett*, No. 21-2587-(D.D.C., 2024 WL 474484, at *2 (D. Kan. Feb. 7, 2024) (excluding tire expert) (citation and quotation marks omitted). Under the amended rule, "[c]ourts must probe more deeply" and

> [o]nly after the proponent has proved it more likely than not that the opinion is based in the evidence on which it purports to rely and represents a reliable application of the expert's methodology do challenges to the bases of an expert's opinion go to weight alone.

Hellen v. Am. Family Ins. Co., C.A. No. 22-cv-02717-REB-SBP2024 WL 1832451, at *1 (D. Colo. March 19, 2024) (excluding opinions of insurance practices expert). "Such is the point which the recent amendments to Rule 702 emphasize – an expert's opinions must be shown by a preponderance of the evidence to be supported by the evidence on which they ostensibly are based." Id. at *3. An opinion that "is not clearly supported by the evidence on which it purports to rely... is inadmissible." Id. at *5. "[T]he language of the amendment more clearly empowers the court to pass judgment on the conclusion that the expert has drawn from the methodology." *United States v. Diaz*, No. 24-CR-0032 MV, 2024 WL 758395, at *4 (D.N.M. Feb. 23, 2024) (quoting Committee Note) (limiting police officer expert testimony).

Other decisions have explicitly relied on new Rule 702(d) while excluding expert witnesses. *Doucette*, 2024 WL 3271906, at *9 (opinion "fell short" of amended Rule 702(d)'s reliability requirements), *Plantan v. Smith*, C.A. No. 2024 WL 3048648, 2024 WL 3048648, at *4-5 n.55 (E.D. Va. June 18, 2024), expressly applied the 2023 amendments, to reject the proponent's suggestion "that the Court should admit [the expert's] opinions, notwithstanding these gaps, and allow cross examination to make up for what the opinion may lack in reliability." Id. at *12 (that approach "would directly contradict" the amended rule); *Coblin*, 2024 WL 1588752, at *4 (expert failed to "rule out" other causes in differential diagnosis); *Thomas v. State Farm Mut. Auto. Ins. Co.*, ____ F. Supp. 3d ____, No. 4:22-CV-724 RLW, 2024 WL 195752, at *2 n.1 (E.D. Mo. Jan. 18, 2024) (excluding insurance practices expert).

Another judicial error that the Rule 702 amendment corrected was the notion that expert testimony was presumed admissible. Courts that "[i]n the past" had "operated on the presumption is that expert testimony is admissible" misconstrued Rule 702. Diaz, 2024 WL 758395, at *4. The Civil Rules Committee's express addition of "more likely than not" to the proponent's burden of proof corrected this error.

> In support of this change, the Committee noted that the changes "respond to the fact that many courts have declared the requirements set forth in Rule 702(b) and (d)... are questions of weight and not admissibility, and more broadly that expert testimony is presumed to be admissible." The Committee found that "these statements misstate Rule 702, because its admissibility requirements must be established to a court by a preponderance of the evidence."

Id. (quoting Committee Note; other citations and quotation marks omitted).

All the above is not to say, however, that courts have uniformly mended their "incorrect" ways and are uniformly doing what amended Rule 702 requires. One notable failure to do so is *Blue Buffalo Co. v. Wilbur-Ellis Co. LLC*, No. 4:14 CV 859 RWS, 2024 WL 111712 (E.D. Mo. Jan. 10, 2024), which is particularly notable for its disguised quote from *Loudermill*, one of the decisions identified by the Rules Committee as being "incorrect." *Blue Buffalo* laundered *Loudermill* through an intervening Eighth Circuit decision. *See* 2024 WL 111712, at *4 ("exclusion of expert testimony is proper 'only if it is so fundamentally unsupported that it can offer no assistance to the jury'") (quoting *Wood v. Minn. Mining & Mfg. Co.*, 112 F.3d 306, 309 (8th Cir. 1997), but "cleaned up" to remove *Wood*'s quoting of *Loudermill*).

The 2023 amendments to Rule 702 have repeatedly proven to be a valuable recalibration of expert admissibility standards.

The 2023 amendments to Rule 702 have repeatedly proven to be a valuable recalibration of expert admissibility standards. Defendants, particularly those involved in prescription medical product liability litigation, should rely on them to the maximum extent possible to seek exclusion of junk science opinions, notwithstanding adverse, pre-2023 precedents, which are no longer good law.

Medical Device Marketing 101

The Dos and Don'ts of Marketing

By Jocelyn Wiesner and Jennifer Roma

...what rules govern medical device marketing, and what can companies do to ensure that their claims stay on label?

Medical device marketing can be fraught with peril if not done correctly. Off-label or unsubstantiated claims can lead to enforcement action by the United State Department of Justice ("DOJ"), Food and Drug Administration ("FDA"), or the Federal Trade Commission ("FTC"), or they can become the centerpiece of product liability litigation. So what rules govern medical device marketing, and what can companies do to ensure that their claims stay on label?

What Are Medical Devices?

First, some relevant background. The Federal Food, Drug, and Cosmetic Act ("FDCA") broadly defines what constitutes a medical device as any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article apparatus which is (A) recognized in the official National Formulary or United States Pharmacopoeia; (B) intended for use in the diagnosis, cure, mitigation, or prevention of disease; or (C) intended to affect the structure or function of the body and which does not achieve that purpose through a chemical action. 21 USC 321(h)(1). Practically speaking, medical devices run the gamut from simple tongue depressors and scalpels to implantable devices like breast implants and artificial knees, to complex imaging devices like ultrasound machines. In certain circumstances, software can also be considered a medical device. But while these examples may all be considered medical devices, they—and their advertising—are not all regulated in the same way.

The FDA classifies medical devices into one of three classes based on a spectrum of potential risk. Class I devices, which represent nearly half of all medical devices available in the United States, are considered to have a low potential risk of illness or injury and are not intended to support or sustain life. They include devices like electronic toothbrushes and bandages. On the other end of the spectrum, Class III devices are those that "sustain or support life, are implanted or present a potential unreasonable risk of illness or injury." Only 10 percent of devices – such as pacemakers and breast implants – are classified as Class III devices.

Depending on their classification, devices will undergo different regulatory pathways to come to market. The overwhelming majority of Class I devices are exempt from any regulatory approval pathway and are not required to obtain FDA's review before marketing. Class II devices—those with intermediate potential risk such as pregnancy test kits, contact lenses and absorbable sutures—are usually reviewed under section 510(k) of the FDCA, which requires proof that the device is "substantially equivalent" to a legally marketed device that is not subject to premarket approval ("PMA"). 21 U.S.C. 360(k)); 21 CFR 807.81 et seq. In other words, the device must have the same intended use and technical characteristics of a non-PMA device already on the market. FDA does not require clinical data that independently demonstrates the safety and effectiveness of a new 510(k) device. But FDA does evaluate the differences between the new device and the predicate to determine if they raise different or new questions of

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safety and efficacy. *See*, e.g., FDA Guidance, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (July 2014).

Finally, the majority of Class III devices undergo premarket approval under the Medical Device Act. Otherwise known as PMA approval, this is widely considered the most rigorous approval pathway, requiring scientific evidence that the possible benefits outweigh the possible risks, and that the device will significantly help a large portion of the target population. While subject to the most onerous approval pathway, PMA-approved devices also enjoy a broad preemption defense that 510(k) devices often do not. *See Riegel v. Medtronic, Inc.*, 552 US 312 (2008).

Who Regulates Device Marketing?

How a device comes to market dictates whether FDA, FTC, or both, regulate its advertising. While the FDA has broad authority to regulate medical device *labeling* regardless of device classification (see 21 U.S.C. § 352(a)), its authority to regulate medical device *advertising* is rather limited. Under the FDCA, the FDA only regulates advertising for "restricted" medical devices, which make up a tiny fraction of all medical devices on the market. Restricted devices are those designated by the Department of Health and Human Services, based on their potential for harm, that are restricted to sale, distribution, or use, only upon authorization of a healthcare provider or upon any other conditions imposed by FDA. 21 U.S.C. § 360j(e). FDA can designate a device as restricted either by regulation or as part of the PMA approval process. Practically speaking then, only Class III devices are designated as restricted devices, meaning that FDA does not technically have authority to regulate advertising of Class I or II devices. FTC, in contrast, has authority to regulate advertising for all medical devices (though it defers to FDA on restricted devices).

Regardless of which agency has jurisdiction, advertising must be truthful and not misleading. The FDCA, for example, provides that a restricted device is misbranded if its advertising is false and misleading in any particular, 21 U.S.C. § 352(q), or if its advertising does not contain a brief statement of the device's intended use and relevant warnings, precautions, side effects, and contraindications. 21 U.S.C. § 352(r). The Federal Trade Commission Act ("FTCA") similarly prohibits "unfair or deceptive acts" as well as the dissemination of false advertisements – i.e., advertisements that are misleading in any material respect.

Among other things, FDA will consider a claim to be false or misleading if it is not properly substantiated. Albeit in a different context, FDA has provided some guidance on various sources of data that can

be relied on to substantiate a claim, ranging from well-controlled clinical trials to real-word data. *See* Communications from Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products (Draft Guidance Oct. 2023). A device is also misbranded if its label or labeling contains a misstatement or omission of material facts, lacks fair balance or adequate directions for use, or makes a misleading representation with respect to another device. 21 U.S.C. § 352(a).

FDA Oversight of Medical Device Marketing

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First, FDA *does* have oversight over "labeling," which is any written, printed, or graphic matter "accompanying" the device. 21 U.S.C. § 321(m). FDA interprets "accompanying" liberally, and has stated that it includes not just materials that physically accompany the device, but also materials that are disseminated by the manufacturer that supplement or explain the product. FDA also recognizes "promotional labeling," an amorphous category FDA describes as "any labeling, other than FDA-required labeling, that is devised for promotion of the product." *See*, e.g., Guidance for Industry, Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Draft, June 2014). Advertising, in contrast, is not specifically defined. The line between labeling and advertising accordingly can often be blurry, and it would not be unreasonable to act with the expectation that all advertising—no matter the device classification—will be subject to FDA oversight. In fact, FDA says on its web page dedicated to medical device labeling that "[m]ost, if not all, advertising is labeling." *See Device Labeling*, ***https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling***.

Second, FDA has taken the position that—even if it cannot directly regulate advertising—it can consider advertising to determine if a device is adulterated or misbranded under the FDCA: i.e., a device is misbranded if its advertising or labeling promotes a "new intended use" that requires either a new PMA approval or a new 510k clearance. FDCA §§ 501(1); 502(o). Indeed, in a 2021 rule FDA expressly stated that it may consider "any relevant" evidence to determine a device's intended use—including written advertising and oral representations made by sales representatives—which in turn can be used as evidence that a device is adulterated or misbranded. 21 CFR 801.4, 201.128.

Practical Takeaways

While the "golden rule" of marketing may seem obvious (i.e., do not make false claims and stay on label), questions always arise around the edges. Relative to prescription drugs, FDA has issued far fewer regulations or guidance documents related to medical device advertising. But available guidance documents and prior enforcement actions nonetheless do provide some helpful benchmarks. Below are some practical takeaways distilled from past FDA action in this space.

1. Stay on label.

Perhaps the number one rule of advertising, promotional claims must adhere to the labeled indications for use. Off-label promotion comes in multiple forms. It can include marketing a device that requires clearance or approval that it does not have, as well as marketing it for claims that are beyond the scope of the labeled indications for use. There are, however, some avenues in which a manufacturer can discuss off-label uses of a device.

While a company cannot *promote* a device for an off-label use, physicians are free to use devices for off-label purposes. To that end, in 2023, FDA issued new draft guidance regarding communications with healthcare professionals regarding unapproved uses. *See Communications from Forms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products* (Draft Oct. 2023). Among other things, FDA says that such communications must be based on "scientifically sound" data and provide "clinically relevant information." Manufacturers should take care to review this new guidance, ensuring that any proactive communications with healthcare providers adhere to the rules, and do not cross the line into promotional content.

Strictly speaking, the FDCA does not prohibit off-label advertising. Nor—as the Second Circuit famously held in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012)—can a manufacturer be prosecuted, consistent with the First Amendment, for truthful and not-misleading promotion merely because it is off-label. But as discussed above, FDA can and will use off-label advertising as evidence that a device is misbranded, and at least some federal courts have entertained this approach. See *United States v. Facteau*, 89 F.4th 1, 24 (1st Cir. 2023) *petition docketed* at 89 F.4th 1 ("it is not the case, as it was in *Caronia*, that the government set out to punish appellants for what they said about the product; rather, what appellants said about Stratus simply shed light on how they intended it to be used").

2. Consider if the claim is expanding a general indication.

Another potential area for confusion is general versus specific use claims. Broadly speaking, and perhaps somewhat counterintuitively, FDA guidance states that a manufacturer cannot increase the level of specificity for a device's intended use by, for example, narrowing the function, target population, organ system, or disease.

FDA last issued guidance on this issue over 25 years ago in 1998. Guidance for Industry: General/Specific Intended Use (Nov. 1998). In that Guidance, FDA provided a list of criteria to consider in determining if a claim fits within the scope of

the indication, including whether (1) the specific use would introduce new risks not normally associated with the general use; (2) it would impact public health to a significantly greater degree, such as by changing the target population; and (3) it has different endpoints or would bring the device from a tool intended to perform a task to a treatment, such as a radiofrequency device used to ablate tissue to a treatment of prostate cancer.

Recent enforcement action demonstrates that this issue is still very much alive and well with FDA. In December 2022, for example, FDA sent a warning letter to RightEye, LLC, the manufacturer of the RightEye Vision System, a Class II device intended for "recording, viewing, and analyzing eye movements in support of diagnosing visual tracking impairment in human subjects." FDA took issue with marketing claims, including that the RightEye system is "designed to identify [] ocular tremors, which may not only support doctors in diagnosing of [Parkinson's] disease but may also help detect the disease at an earlier stage...." While the device's intended use includes "support of ***diagnosing*** visual tracking impairment," FDA stated that the system was not cleared for the diagnosis of ***specific conditions*** and thus these claims are off-label.

Similarly, the Strattice Reconstructive Tissue Matrix—surgical mesh—was cleared for use as a patch to reinforce soft tissue where weakness exists, for the surgical repair of damages or ruptured soft tissue membranes, and for reinforcement of soft issues in plastic and reconstructive surgery. LifeCell Corporation accordingly advertised the Strattice Tissue Matrix for use by surgeons for soft tissue repair "including breast reconstruction." Although the Strattice had been cleared for use in plastic and reconstructive surgery, FDA said that these advertising claims fell outside of the intended use because the device had not been cleared ***specifically*** for breast reconstruction.

3. Watch out for implied claims.

A device can also be misbranded through direct comparisons to other products that are false or misleading. 21 C.F.R. § 801.6. FDA has not limited enforcement, however, to direct head-to-head comparisons. Rather, it has taken the view that even implied claims that do not reference any specific competitor product can run afoul of this regulation.

For example, Curatronic LTD manufactures the BioMove 3000 and 5000, an at-home system used in stroke rehabilitation. Certain of the promotional pieces made claims that the device is the "best Stroke rehabilitation system in the world [and] also the easiest stroke therapy device for use by the stroke survivor." Despite the fact that the claims made no direct comparisons to any particular product—and used what most would consider simple puffery—FDA still said they constitute comparative claims that require clinical data and a new 510(k) submission.

4. Be precise with regulatory status.

While practitioners and patients likely will not appreciate any material difference, enterprising plaintiffs' counsel may seize on marketing claims that describe a 510(k)-device as "FDA-approved," arguing that it misrepresents its regulatory status, and by proxy its safety and efficacy. Accordingly, manufacturers should be careful, when dealing with 510(k)-cleared devices, to say that they have been cleared, not approved.

5. Patient testimonials, even when accurate, must be on label and substantiated.

We have all seen patient testimonials explaining an individual's unique experience with a product. While those testimonials may be a completely accurate recitation of that person's experience—and may well contain cautionary language that individual results may vary—they can still prove challenging.

For example, in 2012, the FDA sent a warning letter to Teva Pharmaceuticals USA regarding promotion of Copaxone, an injectable medication used in the treatment of multiple sclerosis. In that letter, the FDA highlighted two patient testimonials. Both sets of testimonials stated clearly that "individual results may vary." While FDA did not dispute that the statements accurately reflected those patients' experiences, it stated that personal patient experiences "do not constitute substantial evidence to support" the claims which, in FDA's view, impliedly broadened the indications for Copaxone and thus constituted evidence of misbranding.

In 2019, FDA sent an untitled letter to Kowa Pharmaceuticals America, Inc. regarding patient testimonials contained in a direct-to-consumer video montage. Those testimonials included individual patient experiences of side effects with Livalo—a cholesterol medication—compared to other statins. As with Copaxone, the video included a SUPER (superimposed text displayed during the commercial) stating, "Individual results may vary." Notwithstanding that disclaimer, FDA said the claims made misleading suggestions about Livalo's side effects and thus misbranded Livalo.

FTC, for its part, issued updated guidelines in 2023 to address the use of endorsements and testimonials. *Guides Concerning Use of Endorsements and Testimonials in Advertising* (July 2023). Similar to FDA's approach, these guidelines explain that testimonials and endorsements must reflect the honest opinion of the "endorser," but also cannot convey express or implied representations that would be deceptive if made directly by the manufacturer.

6. Social Media Pitfalls.

Even patient testimonials unprompted and uncompensated by the manufacturer may present a risk. In today's online age, users frequently post reviews and comments reflecting their own personal experience with a device online. Prior draft guidance from FDA made clear that—as a general matter—manufacturers cannot be held responsible for such user-generated comments. *See* Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014). However, FDA also said in that guidance that a manufacturer can ***become*** responsible for third-party comments depending on its "control over, involvement with, or influence" over a product-related communication. So while a company would not responsible for statements made by independent third parties on an open discussion board, it could become responsible, for example, if it monitors the content and removes or edits any statements that do not portray its product in a favorable light. Id. Notably, FDA issued revised guidance in 2024 on this topic which did not

address when or if a manufacturer could become responsible for independent third parties. *See* Addressing Misinformation About Medical Devices and Prescription Drugs (July 2024) (defining independent third parties as those who are "not acting on behalf of that firm").

Accordingly, even where the company is not sponsoring a patient testimonial, it may still run afoul of the FDA. For example, BergaMet North America LLC maintained a Facebook page on which consumers could post directly. Several patients posted about their experiences with Cholesterol Command, including off-label uses of the product. BergaMet commented in response stating "that is amazing" or "thank you for sharing and congrats." In other instances BergaMet simply "liked" the post. No matter that all of these were independent third-party testimonials, FDA stated that these actions constituted endorsement and thus evidence of promotion for an off-label use.

Why Following the Dos and Don'ts of Marketing Matters

Staying on-label is more than just semantics. Promotional claims that stray too far risk a wide range of enforcement actions by FDA, DOJ, or FTC that can result in warning letters, monetary penalties, injunctions, product removal, or even jail time. Off-label claims, especially those that garner attention from FDA, can also form the centerpiece of civil litigation. Plaintiffs' counsel may argue, for example, that physicians were improperly induced to use a medical device or were misled about the relative safety and efficacy of a device. And while we as defense practitioners regard this argument as meritless, plaintiffs' counsel could even argue that typical defenses in product liability claims—such as the learned intermediary doctrine—would not apply at all if the manufacturer was engaged in off-label marketing.

To that end, in-house and outside counsel should work closely together to ensure that the marketing and sales teams are aware of FDA enforcement trends and know the parameters of the device's cleared or approved indications for use.

Pre-approval Design Defect Claims Against Pharmaceutical Companies

By Christopher McKeon

This article delves into this emerging trend of pre-approval design defect claims in pharmaceutical litigation and examines their implications for defense counsel and their clients.

A Divided Legal Landscape

Litigants nationwide are increasingly filing lawsuits against pharmaceutical companies, focusing on—not the design of an FDA-approved drug but rather—the safe design of drugs prior to submission of new drug applications to the FDA. These claims have seen limited success.

This article delves into this emerging trend of pre-approval design defect claims in pharmaceutical litigation and examines their implications for defense counsel and their clients. By understanding the nuances of these claims and the judicial responses to them, defense attorneys can better strategize their defenses and anticipate potential legal hurdles. The discussion includes an analysis of key cases, such as *Yates v. Ortho-McNeil-Janssen Pharmaceuticals* and *Holley v. Gilead Sciences*, and offers insights into how courts are construing preemption arguments. This information is crucial for pharmaceutical companies and their legal teams to navigate the evolving landscape of product liability litigation effectively.

Typically, a design defect claim for an FDA-approved drug requires allegations that the drug's design was defective thereby posing an unacceptable risk of injury, that the plaintiff suffered that injury due to the drug's faulty design, and that the plaintiff would not have been injured if they had consumed a properly designed version of the same drug. These claims generally require a change in design—namely, a change to the chemical composition of the drug—that would require FDA approval prior to being brought to market. Some plaintiffs have split up their allegations into post-approval and pre-approval claims. A subset of courts has bought into this approach. The post-approval claims are routinely dismissed as preempted because they require a major change necessitating prior FDA approval. The so-called pre-approval claims have however, in some instances, been a successful side-step to preemption. *See, e.g., Holley v. Gilead Sciences*, 379 F. Supp. 3d 809 (N.D. Cal. 2019).

Cases Finding Pre-approval Claims Are Preempted

A majority of courts, including the only federal court of appeals to rule on the issue, have found pre-approval claims, like post-approval ones, are preempted. In *Yates v. Ortho-McNeil-Janssen Pharmaceuticals*, the Sixth Circuit Court of Appeals held that a pre-approval design defect claim was preempted. 808 F.3d 281, 299-300 (2015). Plaintiff Yates brought a product liability action after suffering a stroke while utilizing a birth-control patch designed by defendant Ortho. The plaintiff contended that the defendants had a duty under state law to design their product "safely in the first instance, before submitting its new drug application to the FDA." Id. at 293. This contention was squarely rejected by the court. Id.

A majority of courts, including the only federal court of appeals to rule on the issue, have found pre-approval claims, like post-approval ones, are preempted.

The court in *Yates* began by applying the federal impossibility preemption analysis set out in *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 480, (2013), the court first noted that the applicable state law followed a "risk-utility" approach, which imposed liability if "the risk of injury might have been reduced or avoided if the manufacturer had used a feasible alternative design." *Yates*, 808 F.3d at 297. This rendered compliance with federal law impossible because, under

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FDA regulations, once a drug is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product or in the specifications provided in the approved application." Id. at 298 (cleaned up). The plaintiff's claim that the defendants should have altered the formulation of their product *after* the FDA had approved it was thus "clearly preempted." Id.

The plaintiff, however, additionally argued that "no federal law prohibited defendants from adopting a safer design" when the defendants first devised their product. Id. at 299. The court found this claim also preempted because the plaintiff's pre-approval duty argument was "too attenuated." Id. The court would have had to speculate not only that the FDA would have approved the alternate design, but that plaintiff would have utilized this different product, and not been similarly harmed. Id. This was, according to the court "several steps too far," and impossibility preemption under *Mensing* persisted, because the "ultimate availability" of the product to plaintiff remained predicated on the FDA's approval. Id. at 299-300.

Furthermore, the court reasoned that if, as claimed, the pre-approval duty would have resulted in a different product, then the plaintiff was functionally alleging that the FDA-approved formulation should have never been sold. However, in *Bartlett*, the Supreme Court disavowed a "stop-selling" rationale as "incompatible with preemp-

tion jurisprudence," which "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." 1333 S.Ct at 2477. A "never-start-selling" rationale, the Sixth Circuit ruled, had to be rejected for the same reasons.

Utts v. Bristol-Myers Squibb Co., applying California law, deemed a negligent design defect claim based on a pre-approval duty preempted for the same reasons as in *Yates*. 226 F. Supp. 3d 166, 186 (S.D.N.Y. 2016). Plaintiff Utts alleged he suffered severe internal bleeding caused by taking Eliquis, a prescription drug manufactured, marketed, and distributed by the defendants. Also applying *Bartlett* and *Mensing*, the court reasoned that to find a pre-approval duty, it would have had to "speculate" that, had the defendants' product been designed differently: the FDA would have approved the alternate design, the plaintiff would have been prescribed the alternate Eliquis, and the alternate design would not have caused the plaintiff's injuries. Id. at 185-86. Therefore, to assert preemption, defendants would have had to "continually [] prove the counterfactual conduct of the FDA and brand-name manufacturer," as explicitly disavowed in *Mensing*. Id. The court also found that, insofar as the design defect claim suggested that the defendants should never have sold the FDA-approved formulation of Eliquis, this was incompatible with *Bartlett*.

In *Gustavsen v. Alcon Lab'ys, Inc.*, the District Court of Massachusetts followed *Yates* in barring the plaintiffs' claim that the defendant manufacturer should have initially submitted a differently designed product for FDA approval. 272 F.Supp.3d 241, 255 (D. Mass. 2017). The court emphasized that the principal question in impossibility preemption analysis is "whether the private party could independently do under federal law what state law requires of it." Id. (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011)). As in *Bartlett* "defendants here could not have marketed droppers that complied with state… laws in the manner plaintiffs advocate without the FDA's prior approval. It is irrelevant that the defendants could have designed an entirely different product before they sought approval, which may never have been granted." Id. (citing *Yates*, 808 F.3d at 299). In the court's view, this holding did not create a "safe-harbor" shielding FDA-approved drugs from state law liability (as many of the "no preemption" decisions state), because state claims are still available to challenge brand-name manufacturers' failures to warn adequately of a drug's risks, as well as to challenge failures to make "moderate" or "minor" changes to a product's design. Id. at 255.

In *Bossetti v. Allergan Sales LLC*, the plaintiffs brought a defective design claim against defendant Allergan alleging that using Lexapro while pregnant resulted in their children being born with autism spectrum disorder. 2023 WL 4030681 (S.D. Ohio June 15, 2023). Extensively citing *Yates*, the court ruled plaintiff's pre-approval design defect theories were preempted. Id. at *5. Plaintiffs sought to avoid the *Yates* outcome by distinguishing their procedural posture, claiming that discovery was necessary before the court could rule on the defendant's preemption defense. Id. They argued that, unlike the plaintiffs in *Yates*, they had "not fully benefited from discovery" nor had an opportunity to "precisely explain" the duty they alleged Allergan violated. Id. However, the court reasoned that any pre-approval duty conceived of by plaintiffs would have led to an equivalent of the "stop selling" rationale disavowed in *Yates* and *Bartlett*, and therefore had to be dismissed. Id.

In sum, the courts finding pre-approval claims preempted primarily focus on the claims' attenuated and speculative nature, which is problematic alone, but the pharmaceutical drug context compounds the issue. These courts are seemingly driven by a concern that such claims are an unlawful end-run around preemption. Additionally, the successful assertion of a pre-approval duty "functionally" requires that the FDA-approved formulation of the drug should have never been sold and the claims, therefore, run afoul of the "stop-selling" rational specifically prohibited in *Bartlett*. *See also, Fleming v. Janssen Pharms., Inc.*, 186 F.Supp.3d 826, 833 (W.D. Tenn. 2016) (following *Yates* to find pre-approval claim too attenuated, and rejecting the plaintiff's argument that that *Bartlett* applied only to generic, as opposed to branded drugs); *Fortner v. Bristol-Myers Squibb Co.*, 2017 WL 3193928, at *3 (S.D.N.Y. July 26, 2017) (pre-approval claim preempted, following *Utts* and *Yates*); *Evans v. Gilead Scis., Inc.*, 2020 WL 5189995, at *9 (D. Haw. Aug. 31, 2020) (impossible for defendant to independently (without FDA approval) comply with plaintiff's theory and it was therefore preempted); *Brashear v. Pacira Pharmaceuticals, Inc.*, 2023 WL 3075403 at *3 (S.D. Ohio 2023) (pre-approval claim preempted since the alternative drug would have required FDA approval and the plaintiff failed to "specifically alleged facts that support the hypothetical scenario in which the FDA would have approved a differently formulated [drug].").

Cases Finding Pre-approval Claims Are Not Preempted

In the other camp, there are decisions where courts did not find pre-approval claims preempted. *Guidry v. Janssen Pharmaceuticals, Inc.* featured a set of claims similar to those in *Fleming*, which found they were preempted. 206 F.Supp.3d 1187 (E.D. La 2016). After a brief discussion of *Levine* and the relevant Louisiana state law, the court agreed with the *Yates* court "that, to the extent the plaintiff contends that the defendants should have adopted a new design for Invokana after it was approved by the FDA, her defective design claim is preempted." Id. at 1206. However, the District Court of Louisiana found that plaintiff's pre-approval defective design claims under Louisiana law were not preempted by federal law. Id. at 1209. In addressing the pre-approval claim, the court prefaced its discussion by stating that if it were to find the claim preempted "the result is that a Louisiana plaintiff can never bring a defective design claim against a drug manufacturer." Id. It then cited the Supreme Court's *Levine* decision, finding that a drug label may be inadequate under state tort law, even if it has been approved by the FDA, as evidence that "the FDA is not the be-all-end-all in drug regulations." Id. at 1207.

The court noted the defendant's reference to the Supreme Court's statement in *Mensing* that "the question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it," and conceded that "the defendants cannot independently sell pharmaceutical drugs without FDA

approval." Id. at 1208; *Mensing*, 564 U.S. at 620, 131 S.Ct. 2567. Nevertheless, the court asserted that "the dispositive question presented" in this case was whether a drug manufacturer could independently design a safe drug in compliance with its state law duties before seeking FDA approval. *Guidry*, F.Supp.3d at 1208. The District Court was "unpersuaded" by the *Yates* reasoning. Id. First, regarding "attenuation" of the pre-approval duty, it reasoned that "*all* defective design claims" under the Louisiana Products Liability Act require assumptions, and the only *additional* assumption "is that the FDA would have approved the safer, hypothetical drug." Id. Second, it did not "share the Sixth Circuit's reservations" about the "never-start selling argument," because, in its view, the whole point of products liability litigation is to "penalize manufacturers who design unreasonably dangerous products *in hopes that they never start selling them*." Id.

In *Holley v. Gilead Sciences*, the District Court for the Northern District of California declined to follow Yates and found "persuasive the weight of authority against a finding of preemption" of pre-approval design defect claims. 379 F. Supp. 3d 809, 824 (N.D. Cal. 2019). In the underlying lawsuit, as in *Evans* (which found the pre-approval claims preempted), plaintiffs alleged that they suffered kidney and bone damage when taking Gilead's drugs containing TDF. The court's analysis followed *Guidry*, framing the question as "not whether a drug manufacturer can 'independently sell pharmaceutical drugs without FDA approval," but whether "a drug manufacturer [can] independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval." Id. (citing *Guidry*, 206 F.Supp.3d at 1208). It emphasized the absence of a federal law "that restricts a brand-name drug manufacturer from designing a reasonably safe product prior to FDA approval," as well as the lack of a federal law that would prevent Gilead from developing and submitting for approval drugs that contained TAF rather than TDF, or a lower dosage of TDF. *Holley*, 379 F. Supp. 3d at 824. Because the defendant had not presented "clear evidence that the FDA would not have approved" the alternative product, the court concluded plaintiff's claims were not preempted. Id.

In rejecting the *Yates* approach, the Court in *Holley* largely cited the reasoning in *Guidry*. First, *Holley* agreed that "it is not too attenuated to assume that the FDA would approve a safer, alternative design of a drug that it has already approved." Id. at 824. Without addressing the other steps in the chain of causality laid out by the Court in *Yates*, it found this inference "especially" credible because the three allegedly safer drugs at issue in the litigation were actually approved by the FDA years later. Id. at 825. Additionally, the court agreed with the holding in *Young*, another case finding no preemption, that "[t]he preapproval theory does not argue that a manufacturer should have stopped acting, just that it should have acted differently." *Young v. Bristol-Myers Squibb Co.*, 2017 WL 706320 (N.D. Miss. Feb. 22, 2017), at *8. Under this view, a pre-approval duty is compatible with *Barlett's* rejection of the "stop-selling" rationale because if Gilead had initially offered for FDA approval the alternative TAF-containing drug, it would have complied with both state and federal law. *Holley*, 379 F. Supp. 3d at 825.

In *In re Xarelto (Rivaroxaban) Products Liability Litigation*, the bellwether plaintiff alleged to have suffered severe bleeding and other injuries due to Xarelto's allegedly defective design. 2017 WL 3188456 (E.D. La 2017). The District Court for the Eastern District of Louisiana, finding *Guidry* "directly on point", deemed plaintiff's Mississippi state law claims for design defect pre-approval not barred. Id. at *6. The court refused to engage in, what in its view was, an expansion of the preemption doctrine because doing so, according to the court, "would free pharmaceutical companies from state common-law liability—and limit states' constitutional right to protect its residents' welfare," thereby jeopardizing the interests the Supreme Court sought to protect in *Levine*. Id. at 4, 6. The court sought to distinguish *Bartlett* and *Mensing* because they applied to generic drug manufacturers, and neither Congress nor the Supreme Court had, in the court's view, directly spoken on the issue of preemption of claims against brand-name drug manufacturers. Id. (citation omitted).

In *Gaetano v. Gilead Sciences, Inc.*, the plaintiff brought similar claims regarding the same drug as were at issue in *Holley*, alleging Gilead should have brought TAF to market instead of TDF. The District Court for the District of New Jersey held plaintiff's New Jersey design defect state law claims not preempted. 529 F.Supp.3d 333, 341 (D.N.J. 2021). The court agreed with *Holley* on the relevant question: "whether a drug manufacturer can independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval." Although it conceded that *Gilead* could not sell a drug without FDA approval, the court stated that this did not bring the case within the holding of *Mensing* because the mere "possibility of rejection" is not sufficient to require preemption. *Id.* at 342. Second, echoing *Guidry*, the court stated that "sheer scope of Gilead's argument imperils both preemption doctrine and state police powers" since it "carries the implication that a plaintiff could never bring a design defect claim involving any drug that required FDA approval." Id. The court found that the claim was not "too attenuated" because an alternative, TAF-based drug was later approved by the FDA. Id. at 343.

In short, these courts largely find pre-approval claims are not "too attenuated" and that it's not an unreasonable assumption that the FDA would have approved the alternatively formulated drug. The courts appear driven by a concern that preemption of these claims would strip litigants of a remedy and prop up an unwarranted shield around pharmaceutical makers. They also reject the *Yates* never-start selling analysis in favor of the conclusion that the claims only require defendants to act differently and not cease acting all together. *See also, Estate of Cassel v. Alza Corp.*, 2014 WL 856023 (W.D. Wis. 2014) (claims not preempted, citing concern that doing so would foreclose "all design-defect claims"); *Trahan v. Sandoz, Inc.*, 2015 WL 2365502 (M.D. Fla. 2015) (rejecting preemption assertion reasoning it would "shield" drugmakers who have obtained FDA approval "from any future liability"); and *Young*, 2017 WL 706320 at *8 (agreeing with *Guidry* and adding there can be no preemption issue if no state law duty conflicting with a federal duty is identified).

Which is Correct?

To begin, the analysis largely depends on the specific state law duty that's being imposed. Implied preemption occurs when "state and federal law conflict" such that it is "impossible for a private party to comply with both state and federal requirements." *Mensing*, 564 U.S. at 618 (quotations omitted). In the pharmaceutical context, implied "conflict" preemption bars state law claims "when a party cannot satisfy its state duties without the federal government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency." Id. at 623–24. The alleged duty likely shapes the court's approach in determining whether such claims are too attenuated. However, consistent across all claims, regardless of the alleged duty, is that they require the assumption the FDA would have approved the alternatively formulated drug.

Forcing defendants to continually prove the counterfactual conduct of the FDA "is precisely the type of 'Mouse Trap' game the Supreme Court has disavowed."

This assumption alone is one too far and an unreasonable one. If there is a design defect claim asserted in the case, then necessarily the plaintiff is alleging the drug's design is faulty in some way or to some degree. In turn, it cannot reasonably or safely be assumed that an alternative formulation of a *faulty* drug would receive FDA approval, that belies logic. This assumption contains or implicates several sub-assumptions as well: that the alternative design would remedy the alleged defect, that plaintiff would have purchased and consumed the alternative drug despite its difference in design, and the alternative design would not have some other undetected defect that could harm the plaintiff. Forcing defendants to continually prove the counterfactual conduct of the FDA "is precisely the type of 'Mouse Trap' game the Supreme Court has disavowed." *Utts* 226 F. Supp. 3d at 186 (citation omitted).

The assumption turned out to be a fact in *Holley*, where the alternatively designed drugs were actually later approved by the FDA. The exceptional facts of *Holley* cannot be understated though. And in most cases, FDA approval cannot be assumed and there is only a mere possibility that the defendant could have developed and submitted approval for an alternatively designed drug. "*Mensing*, however, rejected a similar rationale." *Evans*, 2020 WL 5189995, at *9 (another court construing TAF / TDF claims and rejecting a pre-approval theory). "Merely requesting FDA assistance or asking the FDA for help in complying with state law would have satisfied Gilead's federal duty, but it would not have satisfied Gilead's state tort-law duty to provide an allegedly safer drug composition." Id. (cleaned up) "The only action Gilead could independently take—asking for the FDA's help by submitting a TAF-containing drug application—is not a matter of state-law concern." Id. (cleaned up).

Additionally, the *Yates* framing on the "stop-selling" rationale is far more consistent with Bartlett than *Holley*'s. The pre-approval claim necessarily requires that the defendant manufacturer should have never sold the FDA-approved formulation of its drug in the first place. The precedent is clear that a defendant manufacturer cannot be required to pull its approved drug from the market in order to comply with both state and federal law, the contention by the court in *Holley* that said rationale does not apply to initially bringing the drug to market is a non sequitur. *Bartlett*, 570 U.S. at 475. *Holley* and similar decisions found that pre-approval claims merely require the defendant to have "acted differently" but the different course of action necessarily requires the defendant "never start selling … [which] collides with the FDCA as a matter of law." *Bossetti v. Allergan Sales, LLC*, 2023 WL 4030681, at *5 (S.D. Ohio June 15, 2023).

Last, preemption of pre-approval claims does not create a "safe-harbor" forever shielding FDA-approved drugs from state law scrutiny. For starters, other non-design defect claims remain viable. This includes general negligence, failure to warn, manufacturing defect claims, and a litany of consumer protection laws. It is also not the case that a litigant could never bring a defective design claim. Design defect claims alleging alternative designs that were already FDA-approved persist. Similarly, design defect claims grounded in allegations that the defendant should have made "moderate" or "minor" changes to a product's design, which don't require FDA prior approval, can also still go forward. States are not without remedies and may still protect their interests through other, non-preempted claims.

preemption of pre-approval claims does not create a "safe-harbor" forever shielding FDA-approved drugs from state law scrutiny.

Conclusion

A majority of courts, including the Sixth Circuit Court of Appeals, have found pre-approval claims preempted. The consensus among these courts is that such claims are too speculative and attenuated. These courts have also found that such claims effectively suggest the FDA-approved formulation should never have been sold, conflicting with the Supreme Court's rejection of the "stop-selling" rationale in *Bartlett*. A small number of courts have come out the other way, driven by extraordinary facts and a concern of unjustly protecting faulty drugs from state law liability.

Twenty Years of Genomic Science and Implications for Defense Counsel

By Paige Sensenbrenner

Just as all areas of science, commerce and industry are affected, the work of lawyers practicing in those areas will be equally affected.

In 2005, a month before he took his seat as the 17th Chief Justice of the United States, then Judge John Roberts stated in an interview, "politicians – and judges for that matter – should be wary of the assumption that the future will be little more than an extension of things as they are." Justice Roberts was prescient, and his advice was, and is, just as sound for lawyers as it was for politicians and judges. Technology is evolving more rapidly than ever before. New iterations and next-generation advancements in virtually every field are developed and released in less time than the preceding platforms. Just as all areas of science, commerce and industry are affected, the work of lawyers practicing in those areas will be equally affected. That holds true for attorneys advising and representing pharmaceutical companies.

Since the completion of the Human Genome Project, one field of science that is having – and will continue to have – game-changing effects on medicine and pharmacology is genomics. A genome is an organism's complete set of DNA, and genomics is the study of the structure and function of a genome. The goal of the Human Genome Project was to decode all the nucleotide base pairs that make up human DNA and map and sequence all the genes that constitute the human genome. The Project was completed in 2003 and reported that the human genome is composed of 3.1 billion base pairs, constituting 20-25 thousand coding genes. While this announcement marked one of the greatest scientific feats in history, it also set the stage for significant additional work and scientific discovery. Scientists are continually investigating the role and function of each gene and how this new knowledge can be used to treat disease and improve healthcare. One of the immediate benefits in that regard has been the expansion of personalized medicine and pharmacogenomics.

Pharmacogenomics and Personalized Medicine

Pharmacogenomics looks at how individuals' genetic makeups can affect their response to drugs. Genetic variations can alter drug absorption, distribution, metabolism and excretion (ADME) in each person. According to the Centers for Disease Control, "pharmacogenomics is an important example of the field of precision medicine which aims to tailor medical treatment to each person or to a group of people. Pharmacogenomics looks at how your DNA affects the way you respond to drugs. In some cases, your DNA can affect whether you have a bad reaction to a drug or whether a drug helps or has no effect."

Pharmacogenomics is changing and guiding drug therapy in the clinical area right now. Virtually all cancer patients undergoing treatment at any modern cancer center will experience some level of genomic sequencing. The results of those tests will inform the appropriate chemotherapy or immunotherapy for that particular patient. Notably, the genomic sequencing results also become part of that patient's healthcare record.

Additionally, some medical centers are using genomic testing to guide drug therapy for various segments of their patient population, not just cancer patients. For instance, The Mayo Clinic has established the Center for Individualized Medicine. The Center "is transforming patient care through advanced genetic tests and indi-

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Virtually all cancer patients undergoing treatment at any modern cancer center will experience some level of genomic sequencing.

vidualized treatments … by finding accurate diagnoses earlier, providing safer drug therapies and customizing treatment plans based on each patient's unique genetic makeup." Mayo plans, in the near future to employ an "individualized medicine" approach for all of its patients. *See About the Center*, Mayo Clinic Center for Individualized Medicine, ***https://www.mayo.edu/research/centers-programs/center-individualized-medicine/about/about-the-center*** (last visited Apr. 18, 2024).

While some healthcare providers and institutions have embraced and enthusiastically utilized personalized or precision medicine, that does not hold true for all. Some commentators and authors have noted "the clinical implementation of precision medicine generally, and pharmacogenetics specifically, has been much slower than many experts originally anticipated." (Gary Marchant, Kathryn Scheckel and Doug Campos, Outcall, Contrasting Medical and Legal Standards of Evidence: A Precision Medicine Case Study, J. Law Med Ethics 2016 Mar: 44 (1); 194-204). This slower-than-expected implementation is thought to be due, in part, to lack of reimbursement, outdated business models, and regulatory uncertainty. But "another important impediment has been unfamiliarity and reluctance of healthcare providers to integrating genetic tests into clinical decision-making." *Id.*

PharmGKB is a National Institutes of Health (NIH) funded website that provides information about how genetic variations affect response to medications. It is a database that collects and maintains information on clinically actionable gene-drug associations. Pharm GKB lists approximately five hundred medications with genetic or genomic information contained in the drug label. Yet, many prescribers still fail to heed genomic-based warnings or instructions provided in drug labels.

To facilitate the use of pharmacogenomics in clinical care, Representatives Eric Swalwell (D-CA) and Dan Crenshaw (R-TX), introduced H.R. 7848 on March 29, 2024, known as the "Right Drug Dose Now Act." The Act requires the Secretary of Health and Human Services (HHS) to review and refresh the National Action Plan for Adverse Drug Event Prevention by including current scientific and technological developments in drug-gene interactions, the impact of pharmacogenomic testing, and the means to identify genetic associations in adverse drug events. The Act also includes an educational component focused on health care providers. It instructs the Department of HHS to provide educational materials on reducing adverse drug reactions by pharmacogenomic testing, the role of genetics and genomics, use of specialists, and the integration of pharmacogenomics into comprehensive medication management. Lastly, the Act seeks to improve Electronic Health Records (EHR) to allow EHR systems to automatically alert healthcare providers about the appropriateness of pharmacogenomic testing and drug-gene associations.

The ultimate goal, as reflected by the Act, and promoted by various medical associations and writers, is the establishment of an integrated EHR system that would include pharmacogenomic information regarding various drugs. When available, a patient's EHR would include genomic or genetic test results for that particular patient. Thereafter, when a health care provider orders a drug for the patient, the EHR system will automatically query that patient's EHR and inform the prescriber of any contraindications, potential adverse drug events, or the need for pharmacogenomic testing. Such developments will revolutionize the practice of medicine as well as open the door to more defenses for pharmaceutical companies in personal injury cases.

Genetic or Genomic Evidence and Genetic-Based Claims

The use of genetic evidence is fairly common in response to claims filed under the National Childhood Vaccine Act. In those suits, claimants typically allege that developmental disorders are the result of vaccine administration. And in a number of those cases, the Secretary of HHS has been able to demonstrate that the claimed damages were due to genetic variants—not vaccine administration.

Two examples are *Snyder v. Secretary of Health and Human Services*, 553 F. App'x 994 (2014) and *Faoro v. Secretary of Health and Human Services*, 128 Fed. Cl. 61 (2016). In each case, the claimant experienced a normal birth and infancy. Following vaccinations, however, each claimant developed a seizure disorder and mental deficiencies. Genetic testing revealed that each child carried a mutation of the SCNIA gene, which supported a diagnosis of Dravet's syndrome—a genetic condition, not a vaccine-related injury.

In other cases, claimants have sued pharmaceutical companies for manufacturing drugs posing risks to claimants with a certain genetic makeup. One of the first reported cases of a plaintiff claiming injury resulting from a genetic characteristic was *Mills v. Bristol-Myers-Squibb*, No. CV 11-00968-PHX-FJM, 2011 WL 4708850, (D. Ariz. Oct. 7, 2011). There, the plaintiff alleged, in part, that BMS's anticoagulant drug, Plavix, was defective because it posed "a higher risk of adverse events for patients who carry the genetic variant CYP, who are poor metabolizers of the drug." *Id.* at *2. The plaintiff, however, failed to establish that she carried the CYP variant, only claiming "upon information and belief" that she was a CYP carrier. *Id.* The court ruled that "plaintiff's genetic makeup is a fact solely within her control" as tests were available to determine if she possessed the CYP variant. *Id.* For that reason, and others, the case was dismissed.

But a more recent case, alleging violation of Hawaii's consumer protection law, appears to be the first reported appellate opinion addressing a tort premised on pharmacogenomics. In *EX REL Holly T. Shikada v. Bristol-Myers Squibb*, 526 P. 3d 395 (Haw. 2023), the State of Hawaii alleged that Plavix (clopidogrel) was less effica-

But a more recent case, alleging violation of Hawaii's consumer protection law, appears to be the first reported appellate opinion addressing a tort premised on pharmacogenomics.

cious in Asian populations due to a specific genetic variant in the CYP2C19 gene. The State did not claim that clopidogrel caused a physical injury. Instead, the State claimed that those individuals with the CYP2C19 variant were poor metabolizers of the drug, making it less effective.

In 2010, the FDA had required BMS to add a black box warning for Plavix, addressing the efficacy issue in patients with the CYP2C19 variant. But the State claimed that BMS and Sanofi were aware of the problem before issuance of the black box warning and failed to disclose this efficacy issue in the interest of raising profits. As a result, the State argued that BMS and Sanofi's behavior constituted a violation of Hawaii's Unfair or Deceptive Acts or Practices (UDAP) law. The State moved for summary judgment on the issue of materiality – a necessary element of the claim – arguing that it would "eliminate any unnecessary time at trial." *Shikada*, 526 P. 3d at 402. The State took the position that there was "no doubt that the information contained in Plavix's federally mandated black box warning is material as a matter of law." Id. at 402. The trial court granted summary judgment on this issue.

The case proceeded as a bench trial on all remaining issues. Evidence was presented at trial that the black box warning had not altered doctors' prescribing habits with regards to clopidogrel and that routine genetic testing was not performed beforehand. In fact, the State's own public health journal recommended that "doctors not change their prescribing practice based on the boxed warning and that genetic testing not be done." *Shikada*, 526 P. 3d at 417.

At the conclusion of trial, the court imposed a per-prescription based penalty of $834 million. The court reasoned that patients were "injured … by denying them the drug's full promised [benefit], hindering their ability to give informed consent and preventing them from taking an alternative drug or undergoing genetic testing to determine whether they were poor responders." *Shikada*, 526 P. 3d at 423.

On appeal, the Hawaii Supreme Court reversed the granting of summary judgment on materiality and vacated the $834 million award. But the court did not vacate the trial court's ruling in its entirety. The court rejected the defendants' preemption arguments, finding that the case was not about labeling, but rather about conduct. The court further held that Hawaii's UDAP statute was to be applied "in a way that maximizes consumer protection," and that consumer injury was not an essential element of the claim for "unfair acts." *Shikada*, 526 P. 3d at 446. The court did not disturb the trial judge's finding that the case had "nothing to do with the black box warning" or "with doctors' prescribing habits" and that defendants "suppressed research for financial reasons." *Id.* at 447. Upholding the trial judge's finding, in part, the court held that "the Court's ruling

that Defendants committed unfair acts or practices under UDAP stands." *Id.* at 448. The court remanded the case back to the trial court for trial to determine whether the "omitted information was material to consumers making it an injury each time they received the prescription without that information." *Id.* at 425, 426. And if there was a finding of materiality, the court was instructed to award damages.

Following remand, the Circuit Court of the First Circuit held bench trial in the fall of 2023 and the trial court issued its opinion on May 21, 2024. *State of Hawaii, Ex Rel. Anne E. Lopez, Attorney General vs. Bristol-Myers Squibb Company, Sanofi-Aventis U.S., LLC*, et al.; No. 1CC141000708 (JHA). The court held that defendants' non-disclosure of "clopidogrel resistance" in the drug label prior to the addition of the black box warning in 2010 constituted a material omission under the State's UDAP law. And while the state submitted no evidence of physical injury to any particular person, the court found that the evidence submitted satisfied the "injury to the public" element for the imposition of penalties under UDAP. Specifically, the court held:

> As found above, injury to the public has occurred given the evidence in this trial. Hawaii consumers and their prescribing physicians were denied material information by the drug manufacturer regarding the safety and efficacy of Plavix that was necessary in order for Plavix patients to make informed choices among their treatment options. The fact that the injury is neither calculated nor quantified does not mean there is no injury.

*Slip. op.*at 56-57.

Based on those findings and following its analysis of the UDAP penalty factors, the court assessed $458,006,000 in penalties against each defendant, Bristol-Myers Squibb and Sanofi-Aventis.

The *Shikada* case is worrisome if other states decide to follow Hawaii's lead. Unlike product liability claims usually filed against medical device and drug companies, the "consumer protection statute" as applied in *Shikada* required no finding of an actual injury. Instead, it was inferred. As Bexis points out in his Drug & Medical Device Law blog dated April 4, 2023, under *Shikada's* rationale, "defendants could be liable … for what amounts to negligence in the air-disfavored conduct that never actually hurt anybody." Bexis, *Trouble in Paradise*, Apr. 4, 2023, ***https://www.druganddevicelawblog.com/2023/04/trouble-in-paradise.html***. Thus, pharmaceutical manufacturers should be aware of not only personal injury claims, but pharmacogenomically-based false advertising or efficacy claims as well.

Discovery of Genomic Evidence

In most instances, genetic or genomic discovery by defendants will be focused on establishing alternative causation. Rule 35 of the Federal Rules of Civil Procedure provides:

> The Court where the action is pending may order a party whose mental or physical condition including blood group is in controversy to submit to a physical or mental examination by a suitably licensed or certified examiner. The Court has the same authority to order a party to produce for examination a person who is in the custody or under its legal control.

But Rule 35 only allows a court to order a party to undergo physical or mental examination. Courts have reached conflicting results when it comes to ordering genetic testing of the plaintiff. For example, in *Young v. United States*, 311 F.R.D. 117 (D.N.J. 2015), a case brought on behalf of a minor alleging medical malpractice, the defendant sought an order under Rule 35 compelling the minor's parents to submit to genetic testing. The parents responded with a motion for protective order. In granting the parents' motion, the court declined to expand the scope of Rule 35. The court does not possess the inherent authority "to order a non-party to submit to a physical or psychological examination." *Young*, 311 F.R.D. at 123. Thus, a Rule 35 examination is often limited to the named plaintiff.

Similarly, another court denied a request for expansive genetic testing, citing privacy concerns. In *Fisher ex rel. X.S.F. v. Winding Waters Clinic, PC*, No. 2:15–cv–01957–SU, 2017 WL 574383 (D. Or. Feb. 13, 2017), XSF, a minor, was born with brain damage, developmental delay, cognitive delay and physical disabilities. During infancy, XSF underwent chromosomal microarray genetic testing, which produced normal results. The defendants moved for an order under Rule 35, compelling XSF to submit to whole exome sequencing (WES), a substantially more expansive test. The defendants, however, could not identify the specific genetic variant or the condition they were seeking to uncover with WES. In fact, the defendants' expert opined that there were "1,300 diseases associated" with XSF's symptoms. Fisher, 2017 WL 574383 at *8. On the other hand, the plaintiff's expert opined that WES would uncover "vast amounts of genetic information that has nothing to do with the potential genetic syndrome." *Id.* at *3.

In light of the defendants' inability to designate a specific genetic variant targeted by WES, the court determined that defendants had failed to satisfy the "good cause" requirement under Rule 35 to allow the testing. The court also expressed concern that WES may produce genetic information that could well be disclosed against the family's wishes "in the future … in conjunction with an insurance application … or from a computer hack of electronic medical records." Fisher, 2017 WL 574383 at *8. The motion for genetic testing was denied.

However, other courts have allowed genetic testing. For example, in *Burr v. Winona Health*, No. 16-1085, 2018 WL 3647230 (D. Minn. Aug. 1, 2018), the court disagreed with *Fisher*. There, the defendants sought WES testing under Rule 35 to discover the cause of minor RB's injuries. The defendants' experts had identified genetic disorders and "specific conditions that could be likely culprits" of RB's disability. *Id.* at *2. The plaintiff opposed the defendants' requests.

Relying on *Fisher*, the federal magistrate denied the request for WES, and the defendants appealed to the district judge. The district court acknowledged the rationale in supporting the *Fisher* ruling and even noted that the defendants' request presented "an extremely close call." *Burr*, 2018 WL 3647230 at *2. The court stated that "plaintiffs' privacy and personal, physical integrity concerns are valid." *Id.* at *3. The court also stated, however, that a protective order is "adequate to protect Plaintiffs' private genetic information from disclosure to third parties." *Id.* The court also found that "genetic testing, including WES is …

within the array of examination that Rule 35 envisions." *Id.* at *3. The defendants' request for the plaintiff to submit to WES was granted.

Likewise, *In RE: Zostavax (Zoster Vaccine Live) Products Liability Litigation*, MDL No. 2848, 2022 WL 952179 (E.D. Pa. Mar. 30, 2022) demonstrates how genetic testing can establish alternative causation. Zostavax is a vaccine designed to be administered to adults fifty years or older to prevent shingles. In *Zostavax*, the plaintiffs alleged that Zostavax actually caused shingles in some patients.

The varicella zoster virus (VZV) causes both chicken pox and shingles. In people who have had chicken pox, VZV remains in their body for life. Following a bout with chicken pox, the VZV will follow nerve fibers and recede to ganglia adjacent to the spine. Once reactivated, possibly in response to some stressor, the virus will travel back up the course of nerve fibers to the surface of the skin causing painful eruptions – a rash. That form of the virus is known as the wild-type virus.

Zostavax, on the other hand, includes the "Oka strain of the VZV, a live – attenuated virus that is a weakened form of the natural or wild-type virus found in the body of someone who has had chickenpox." *Zostavax*, 2022 WL 952179 at *2.

This case presented the plaintiffs with a challenge: how to prove that a plaintiff's bout of shingles was caused by Zostavax as opposed to a naturally occurring episode of shingles resulting from reactivation of VZV. The defendant proposed that the plaintiffs submit to PCR testing, which analyzes the genetic makeup of the wild-type virus versus the attenuated Oka strain with its different genetics. The bellwether plaintiffs declined to submit to testing. Unable to prove their shingles were related to Zostavax, their cases were dismissed. Additionally, the remaining 1700 plaintiffs were ordered to undergo testing to prove that their shingles resulted from Zostavax administration.

We can expect that the increasing use of genomic evidence in other areas of litigation will most likely expand the number of discovery rulings. Asbestos litigation is a good example. For decades personal injury claims for malignant mesothelioma resulting from asbestos exposure have accounted for a substantial portion of lawsuits filed against asbestos suppliers, installers and premises owners. And asbestos exposure was widely regarded as the singular cause of malignant mesothelioma. Recent developments, however, have led scientists to estimate that 10-30 percent of malignant mesotheliomas result solely from germline genetic variants. *See*, e.g., S. Moolgavkar et al., *Pleural and Peritoneal Mesotheliomas in SEER: Age Effects and Temporal Trends, 1973-2005*, Cancer Causes & Control (2009) 20.6:935-944; V. Panou et al., *Frequency of Germline Mutation in Cancer Susceptibility Genes in Malignant Mesothelioma*, J. Clin. Oncol. (2018) 36(28):2863-2871 ("These data suggest that … those who develop malignant mesothelioma with minimal or no asbestos exposure may have an underlying inherited susceptibility."). As a result of these developments, asbestos defendants are now requesting blood or saliva samples from plaintiffs to test for germline variants in order to establish an alternative causation defense.

In *Thrash v. Boeing Co.*, No. 17-cv-01501-JST, 2018 WL 2573097 (N.D. Cal. Mar. 2, 2018), a federal district court considered a defense motion under Rule 35, which sought to compel the provision of a blood sample for genetic testing in a malignant mesothelioma case. Recognizing the claimant's physical condition was "in controversy" as contemplated by Rule 35, the district court found good cause, framing its analysis as follows:

> Defendants seek a sample of Thrash's blood in order to determine whether Thrash has a germline BAP1 mutation. [Claimants] argue that testing Thrash's blood and analyzing his DNA would be an undue invasion of his privacy and that, even if Thrash has that genetic mutation, it would be irrelevant because[, according to Claimants,] the mutation means only that a person is more susceptible to carcinogens, so Defendants would still be liable.

Id. at *2. The district court then addressed the claimants' *privacy* argument. The district court noted that California and federal law recognize an individual's right of privacy over genetic information, explaining that Rule 35 requires a balancing of "the need for the information sought against the privacy right asserted." Id. at *3 (internal citation omitted). Balancing the competing interests, the district court concluded:

> Thrash's expectation of privacy in his DNA is reasonable. There is no suggestion that Thrash is participating in any activities other than this lawsuit that would show he consented to the analysis of his DNA. While the act of drawing Thrash's blood itself is a relatively minor procedure, the test at issue here would reveal information about his long-term health and[,] possibly, the health of Thrash's family members. The requested intrusion is therefore not trivial.
>
> However, Defendants' interest in obtaining this discovery outweighs Thrash's privacy interests. [Claimants] allege that Defendants' acts caused Thrash to develop cancer. [Claimants] cannot be allowed to make these "very serious allegations without affording [Defendants] an opportunity to put their truth to the test." Testing a sample of Thrash's blood would allow Defendants to dispute the cause of [Thrash's] cancer.

Id. The district court rejected the claimants' relevancy argument, recognizing "[t]he standard for discovery is whether the information [sought] is relevant to a claim or defense, not whether it is ultimately persuasive. Those decisions are inappropriate at this stage." Id. "Given the potential significance of this test result," the district court held, "Defendants have shown a compelling need to test Thrash's blood for this

We can expect that the increasing use of genomic evidence in other areas of litigation will most likely expand the number of discovery rulings.

specific purpose that outweighs Thrash's privacy interests [and] Defendants' compelling need also constitutes good cause under Federal Rule 35." Id.

Notably, another potential source of genetic or genomic discovery beyond Rule 35 examinations has yet to be addressed by the courts: Are "at home" genetic test results discoverable? What are their limits? Are there any limits? At home genetic tests, such as CRI Genetics, AncestryDNA and 23andMe may be sources of relevant and probative evidence. But these tests likely fall outside the scope of Rule 35, as the test has already been conducted prior to litigation. And these companies are not health care providers, so the tests do not involve the health care provider--patient privilege for confidentiality. These advancements in genomic and genetic technology will present interesting questions for our courts and lawyers, and open the door for additional defenses to pharmaceutical manufacturers.

Changes Coming

In 2020, Jennifer Doudna and Emmanuelle Charpentier won the Nobel Prize in Chemistry for their work in CRISPR gene editing. Working together, they developed a method to edit the human genome. Since then, scientists across the globe have been conducting research on the use of CRISPR gene editing to treat genetically induced disease. The results point to an era of change in clinical medicine and drug development.

In December 2023, the FDA approved the world's first medicine using CRISPR technology. The medicine, called Casgevy, will be used to treat patients with sickle cell disease by activating a dormant gene to produce normal hemoglobin. So far, the medicine has shown to be 94 percent effective one year following administration to treat patients with this painful and life=shortening disease.

ATTR amyloidosis causes people with a genetic variant to produce misfolded proteins that can accumulate in the heart, leading to congestive failure and, quite possibly, death. But doctors in London have developed treatment that remains in experimental stages. The treatment consists of an infusion that delivers lipid nanoparticles carrying CRISPR gene editing material to the liver where the mutant protein is produced. The infused medicine turns off the gene making the defective protein. The treatment has shown itself to be curative in some, eliminating the need for future hospitalizations and treatment.

These examples only scratch the surface of research currently underway to produce new medicines that will revolutionize treatment of debilitating disease. And there is much more to come. As that famous philosopher Bob Dylan once wrote, "The Times They Are A – Changin'".

Turning the Tables

By Chris Campbell, Sarah Carrier and Stephanie Peatman

...this guide explores the expanding landscape of personal tracking technology...

Strategies for Discovering and Using Plaintiffs' Digital Information in Mass Torts

Plaintiffs (and their physicians) have historically been the only ones able to testify as to what plaintiffs were experiencing as a result of their alleged injuries. Wearable fitness trackers quickly changed this, as real-time health monitoring provided an easy way for defendants to contradict injury allegations using objective and reliable data. (For more on the first iterations of wearable technology data in civil litigation, *see* "The Wearable Witness: Utilizing Apple Watch Data in Civil Litigation," 64 NO. 9 DRI For Def. 54, October 2022.)

Now, smartphones are rapidly rising as the most ubiquitous health monitoring technology, with apps tracking everything from physical movements to cough and snore frequency. In other words, an estimated 4.8 billion worldwide smartphone users are continuously compiling personal health data, often without even realizing it. *See*, e.g., World Economic Forum's "Charted: There are more mobile phones than people," available at ***https://www.weforum.org/agenda/2023/04/charted-there-are-more-phones-than-people-in-the-world/***. These capabilities are only growing. With this growth come new questions as to the discoverability and admissibility of digital health data in civil litigation. Accordingly, this guide explores the expanding landscape of personal tracking technology through (1) summarizing new devices and their features; (2) analyzing discovery trends relating to obtaining digital health data; and (3) providing practical tips for effectively using plaintiffs' own digital health information to rebut or weaken their claims.

New Devices and Capabilities

Digital health tracking has come a long way since counting steps. Some new wearable device and smartphone metrics include:

- Numerous physical activities including swimming, rowing, and horseback riding;
- Skin exposures such as UV, pollen, humidity and pollution;
- Heartrate and pattern variability;
- Skin temperature;
- Sweat tracking;
- Cough frequency;
- Blood pressure;
- Respiratory rate;
- Total, REM, and deep sleep;
- Brainwaves for focus, stress, and cognitive performance; and
- Perfusion (or circulatory/lymphatic fluid passage) for fertility tracking.

Other patient-specific metrics offer precise patient-specific monitoring such as fall detection for seniors, snore patterns for sleep apnea sufferers, glucose monitoring for those with diabetes, and tremor tracking for patients with Parkinson's disease. While chronic diseases such as these may not be at issue in many injury cases, they

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are vitally important to assessment of pre-existing comorbidities, for which defendants often are unable to obtain real-time, objective assessments.

According to the data published by The Centers for Disease Control and Prevention (CDC) in 2023, 6 in 10 adults in the US have a chronic disease, and 4 in 10 adults have two or more chronic diseases. *See* "Fitness Tracker Market Size, Share & Industry Analysis," available at ***https://www.fortunebusinessinsights.com/fitness-tracker-market-103358***. The insights user-enabled tracking devices can provide on these conditions is invaluable to litigants – but only if obtained and used effectively.

Despite the increasing availability of wearable and health application devices, there are very few court decisions offering guidance on use of digital health data.

Despite the increasing availability of wearable and health application devices, there are very few court decisions offering guidance on use of digital health data.

This scarcity of precedent, however, offers immense opportunities for tort defendants seeking to establish pre-injury baselines relating to health and activity levels, refute claims that plaintiff's injury has severely limited their ability to perform daily activities, monitor recovery progress (or lack thereof) with concrete evidence, and more.

Discovery of Digital Activity Data in Civil Litigation

It has been approximately ten years since the first known personal injury case utilizing personal tracker activity data as evidence. At that time, lawyers speculated that this data would revolutionize injury claims and become "commonplace" in litigation. Nonetheless, the landscape remains largely unchanged over the past decade. *See, e.g., Bartis v. Biomet, Inc.*, 2021 WL 2092785, at *2 (E.D. Mo. May 24, 2021); *Spoljaric v. Savarese*, 121 N.Y.S.3d 531 (N.Y. Sup. Ct. 2020), *Cory v. George Carden Int'l Circus, Inc.*, 2016 WL 3460781, at *2 (E.D. Tex. Feb. 5, 2016). This is largely in part because data compiled by wearables, smartphones, or other digital monitoring devices is simply that – just data. As with any discovery, the factors the court considers in allowing discovery are "the importance of the issues at stake, the amount in controversy, the parties" relative access to relevant information, the parties' resources, the importance of discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1).

Whether coming from your wrist or finger or biosensor-equipped headphones, the value of activity data lies in the ability to connect its use to plaintiffs' claims. *See* Fed. R. Civ. P. 26(b)(1) (permitting discovery as to "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case.").

Until courts offer further guidance on the discoverability and admissibility of this data, defendants can aim to obtain this data the same way they seek other electronically stored information ("ESI") such as social media, text messages, and online communications. *See* Fed. R. Civ. P. 34 (discussing production of ESI); *see also* Fed. R. Civ. P. 37(a)(3)(B)(iv) (A party may move to compel production when another party fails to produce requested ESI).

Accordingly, litigants are best served by considering the following when seeking to discover wearable and digital activity data:

1. Adequate Preservation: If there is a strong chance digital health data is available and will matter to your litigation, make sure to implement proper litigation holds at the outset. This includes sending a litigation hold/preservation letter to opposing parties to inform them of their obligation to preserve and/or not modify health tracking device or app data. *See, e.g., Small v. Univ. Med. Ctr. of So. Nev.*, 2014 WL 4079507, *29 (D. Nev. Aug. 18, 2014) ("[I]gnorance of technology… does not excuse counsel or clients from carrying out their duties to preserve and produce ESI.")
2. Definitions and Instructions: In light of the ever-changing nature of wearable and health device tracking devices, litigants should specifically define the information sought to target the exact types of data being sought. *See* Fed. R. Civ. P. 34(b) ("If a request does not specify a form for producing ESI, a party must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms"). This can be done, for example, through explicitly including terms such as "fitness monitoring accessories" but also "applications that exist on Plaintiff's mobile phone whose primary purposes is the monitoring of Plaintiff's exercise activities" in your ESI definitions. *See Cory v. George Carden International Circus, Inc.*, 2016 WL 3460781, *2 (E.D. Tex. 2016) (compelling production of both wearable device and smartphone activity data in personal injury suit).
3. Tailoring for Scope: It is imperative that discovery requests communicate the precise reason the digital health data is necessary to the litigation. For example, in *Spoljaric*, defendant sought activity data to demonstrate that plaintiff's injuries could not have been as severe as alleged because she lost fifty pounds during the litigation. Defendant contended such data was necessary to countering plaintiff's alleged mobility issues. The court denied the request, holding there were many factors that could contribute to weight loss.
4. Privacy Compliance: The primary way to overcome objections relating to plaintiffs' privacy here are that the plaintiffs, themselves, put their physical condition at issue by filing the personal injury suit. Further, defendants seeking device data are somewhat insulated in that wearable technology and smartphone companies are not considered "covered entities" under HIPAA – which would ordinarily apply for health information. *See* "The Health Insurance Portability and Accountability Act of 1996" ("HIPAA"). Pub. L. 104-191. Stat. 1936. Web. 11 Aug. 2014.Nevertheless, personal ESI data will often require authorizations and consent, so it is best to ensure pri-

vacy issues are agreed upon and properly complied with before accessing and using plaintiffs' data. *See Whitmire v. Perdue Foods LLC*, 2022 WL 59720 (W.D. Wash. Jan. 6, 2022) (denying motion to compel responses and production of health tracking data because parties failed to meet and confer in good faith); *see also Melendez v. Gulf Vessel Mgmt., Inc.*, 2010 WL 2650572, at *1 (W.D. Wash. July 1, 2010) ("There is no federal physician-patient privilege that bars a defendant from obtaining medical records.").

5. Accessibility: Keep in mind that plaintiffs will only have to produce what is "reasonably accessible." Fed. R. Civ. P. 26(b)(2)(B). Accordingly, it may often be preferrable to obtain through alternative means, where requiring production by plaintiff could be considered too costly or burdensome to the individual. *See id.* (providing that with respect to electronic discovery in particular, "[a] party need not provide discovery of ESI from sources that the party identifies as not reasonably accessible because of undue burden or cost"). To the extent that the plaintiff does not possess the relevant

data, consider subpoenaing it from the device or application developers.

6. Relevance: As the most recent activity tracking case has acknowledged: "Rule 26(b)... is widely recognized as a discovery rule which is liberal in scope and interpretation, extending to those matters which are relevant and reasonably calculated to lead to the discovery of admissible evidence." *Bartis v. Biomet*, Inc., 2021 WL 2092785, at *2 (E.D. Mo. May 24, 2021). Although now three years old, this case continues to provide the most comprehensive assessment of "relevance" for purposes of digital health data discoverability. *Bartis* established that wearable device data could reveal post-event activity information, which would plainly bear on "claims of long-term physical injury." Further, the *Bartis* Court's exploration into why such discovery does not constitute a fishing expedition, particularly where plaintiff's own descriptions of pain were inconsistent. *See id*. ([Plaintiff's] objection speaks to the Fitbit data's weight, not its discoverability.").
7. Breadth: While properly tailoring requests for burden, it is important that litigants seek device tracking information for adequate time intervals. Just as with traditional medical record requests, longer temporal bounds may be warranted where seeking to establish a pattern of activity. *See, e.g., Davis v. Solaris Oilfield Site Servs. Pers., LLC*, 2020 WL 13016561, at *3 (W.D. Pa. Jan. 15, 2020) ("Based upon the specific claims, defenses and facts of this case, the temporal period encompassed by Plaintiff's discovery request, ten years of medical records, albeit lengthy, is reasonable/proportional/appropriate.").

Once discoverable, attorneys must be intentional about analyzing, presenting, and admitting the digital tracking data to their client's benefit.

Using the Data: Next Steps

Once discoverable, attorneys must be intentional about analyzing, presenting, and admitting the digital tracking data to their client's benefit. There are many obstacles to presenting digital tracking evidence at trial and, as discussed above, these evidentiary hurdles have not yet fully played out in many courts. More generalized ESI admissibility assessments therefore prevail. *See, e.g., Lorraine v. Markel Am. Ins.* Co., 241 F.R.D. 534, 538 (D. Md. 2007) (setting out factors for admissibility of ESI).

Further, the nature of these monitoring devices opens the door to considerable authenticity and reliability concerns. Watches and rings are designed to be removable, such that one could easily let another individual use them for a period of time. These concerns are only exacerbated once expanded to digital health data collected on individuals' phones. This is where witnesses become important.

First, plaintiffs themselves may be called to authenticate digital health data. Federal Rule of Evidence 901(b)(1) (allowing a witness with personal knowledge to authenticate evidence). This is similar to authentication of social media posts, which courts have held operates under the same standards of traditional evidence. *See, e.g., United States v. Browne*, 834 F.3d 403 (3d. Cir. 2016) (holding "that it is no less proper to consider a wide range of evidence for the authentication of social media records than it is for the more traditional documental evidence."). Expert witnesses may also be vital to authenticating data. *See* Federal Rule 901(b)(3) (allowing authentication through a computer forensics expert, who could confirm the data's origin); *see also* FRE 901(b)(9) (through providing evidence on a process or system and showing that it produces an accurate result).

Litigants can also utilize FRE 901(b)(4), which involves authenticating data through distinctive circumstances or characteristics. For instance, the data may be connected through distinguishing features such as application usernames, activity goals, and other individual references tying the data to the plaintiff. *See id*. (allowing authentication "through appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances").

Alternatively, if admitting tracking data proves difficult, an expert witness's reliance on these metrics is a safe way to assure the information will reach the jury, often in a more palatable way than raw data itself would provide. *See United States v. Locascio*, 6 F.3d 924, 938 (2d Cir. 1993) ("[T]he facts that form the basis for an expert's opinions or inferences need not be admissible in evidence '[i]f of a type reasonably relied upon by experts in the particular field.' …Thus, expert witnesses can testify to opinions based on hearsay or other inadmissible evidence if experts in the field reasonably rely on such evidence in forming their opinions." (quoting Fed. R. Evid. 703)).

Regardless of the endgame, tort defense counsel must stay apprised of digital health data collection, characteristics, and capabilities so that they can fully understand the accompanying risks and benefits. While uncertainties remain, defendants may – for the first time – be able to drive litigation strategy and reduce exposure like never before, through offering objective, quantifiable data, such that unfounded claims may resolve more quickly and favorably.

Canadian Insights on Drug & Device Litigation

Trends from Recent Life Sciences Jurisprudence

By Edona Vila, Glenn Zakaib and Robert Stefanelli

In this article, we identify key trends emerging from this recent life sciences jurisprudence covering both class proceedings and individual claims.

Recently, Canadian courts have released a series of decisions involving individual proceedings and class proceedings in respect of alleged defective drugs and medical devices. These decisions provide important insight as to the evolving litigation landscape respecting these products in Canada. In this article, we identify key trends emerging from this recent life sciences jurisprudence covering both class proceedings and individual claims.

Class Proceedings Trends: Actual and Demonstrable Harm is Required for Certification

Two recent decisions involving product liability claims for drug manufacturers have confirmed that plaintiffs must allege and demonstrate actual harm or loss to meet the test for certification of a class proceeding, and therefore cannot base their claims on potential future harms. By way of background, in Canada, to certify (or "authorize" in Quebec) a class proceeding, a proposed representative plaintiff must prove her proposed class action satisfies five statutory criteria set out in provincial legislation. Save for some differences in language across various provincial legislation, the crux of the certification test revolves around establishing five criteria: 1) a valid cause of action; 2) an identifiable class of two or more persons, with a cause of action against the defendant; 3) common issues raised in the class members' claims; 4) the class proceeding must be the preferable procedure for resolving the common issue(s); and 5) there must be a representative plaintiff who would fairly and adequately represent the class interests and does not have a conflict of interest with the other class members.

In both *Dussiaume v Sandoz Canada Inc.*, *2023 BCSC 795* and *Palmer v Teva*, *2024 ONCA 220*, the court found the representative plaintiffs had not demonstrated a realized injury (physical or psychological) that was compensable for the purposes of certification, and the court declined to certify the action as a class proceeding.

In *Dussiaume*, the court granted the defendants' motion and struck the plaintiff's putative class action, brought on behalf of a class of those who purchased one or more of the drugs distributed by the defendants containing ranitidine – a histamine H2-receptor antagonist known by its branded name, Zantac. The court found that the plaintiff did not plead a claim for any injury that manifested in adverse effects or health conditions. The plaintiff's allegations of resulting potential cellular carcinogenic changes were deemed to be a "potential future harm" or an "increased risk of harm" claim pleaded in a different way, and the court concluded that such a claim for potential future harm was bound to fail. The court also addressed the psychological injury claims and affirmed that "claims for worries about increased risk of physical harm are also not compensable." (para. 71) The court ultimately found the plaintiff did not prove any compensable harm, nor could the plaintiff prove any causal link between the drugs and the alleged harm. Therefore, this case also failed to establish reasonable foreseeability.

In *Palmer*, the Ontario Court of Appeal ("ONCA") upheld a dismissal decision from a motion to certify a class action regarding alleged carcinogens in Valsartan, a blood-pressure drug manufactured by the defendant pharmaceutical company. There, the court provided clarity on what constitutes a physical injury in drug cases. In this

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case, the plaintiffs asserted that, as a result of ingesting allegedly contaminated *Valsartan*, they suffered genotoxic injury. In respect of this allegation, the court noted that a "physical change with no perceptible effect upon one's health is not compensable in negligence." (para. 52) This suggests that a court is likely to require an actual and provable negative health impact to substantiate such a claim. The court also commented on the level of psychological injuries required to ground a claim in negligence. While the court noted that distress caused by a speculative concern of an increased risk of future physical harm (e.g., concerns of a cancer diagnosis) may constitute harm, plaintiffs must demonstrate that their alleged psychological injuries rose above the normal fears and anxieties that could be expected of a reasonable person receiving a negative health diagnosis.

Class Proceedings Trends: Common Issues Cannot Be Overbroad

A class action is a specialized procedure available to a class of plaintiffs where such a procedure is preferable to each potential plaintiff bringing an individual action against a common defendant. Recent product liability class proceeding decisions have affirmed that plaintiffs seeking to certify class actions must ensure that the issues they propose can be resolved in common among all putative class members are neither too generalized (such that their resolution does not move the litigation forward for all members), nor too narrow (such that they are, in essence, individual issues that would be more preferably addressed through singleton actions). If plaintiffs do not draft their common issues in such a way that they fall within this appropriate range – not too general, not too individual – then Canadian courts may deny certification of the proposed class action.

For example, in *Price v Lundbeck A/S*, ***2022 ONSC 7160*** (affirmed in *Price v Lundbeck A/S*, ***2024 ONSC 845***), the court dismissed a class action certification motion where the representative plaintiffs alleged that Celexa – an anti-depressant drug – is a teratogen and can cause congenital malformations. However, the plaintiffs' proposed common issues were found not to advance the litigation even if a court found the issues were common among class members. Here, the plaintiffs proposed a common issue that Celexa is a teratogen. The court found that, even if a judge agreed that Celexa was a teratogen, each individual class member would still need to prove that taking Celexa caused his or her specific congenital malformation. The plaintiffs further provided no evidence of a workable methodology to establish, on a class-wide basis, that *Celexa* can cause any particular congenital malformation despite suggesting that eleven different malformations were possible.

The court's decision reiterates that common issues cannot simply be a common label that conveys a false sense of commonality, and instead plaintiffs are obligated to prove through some basis in fact that a significant element of their claim is capable of proof in common with other class members.

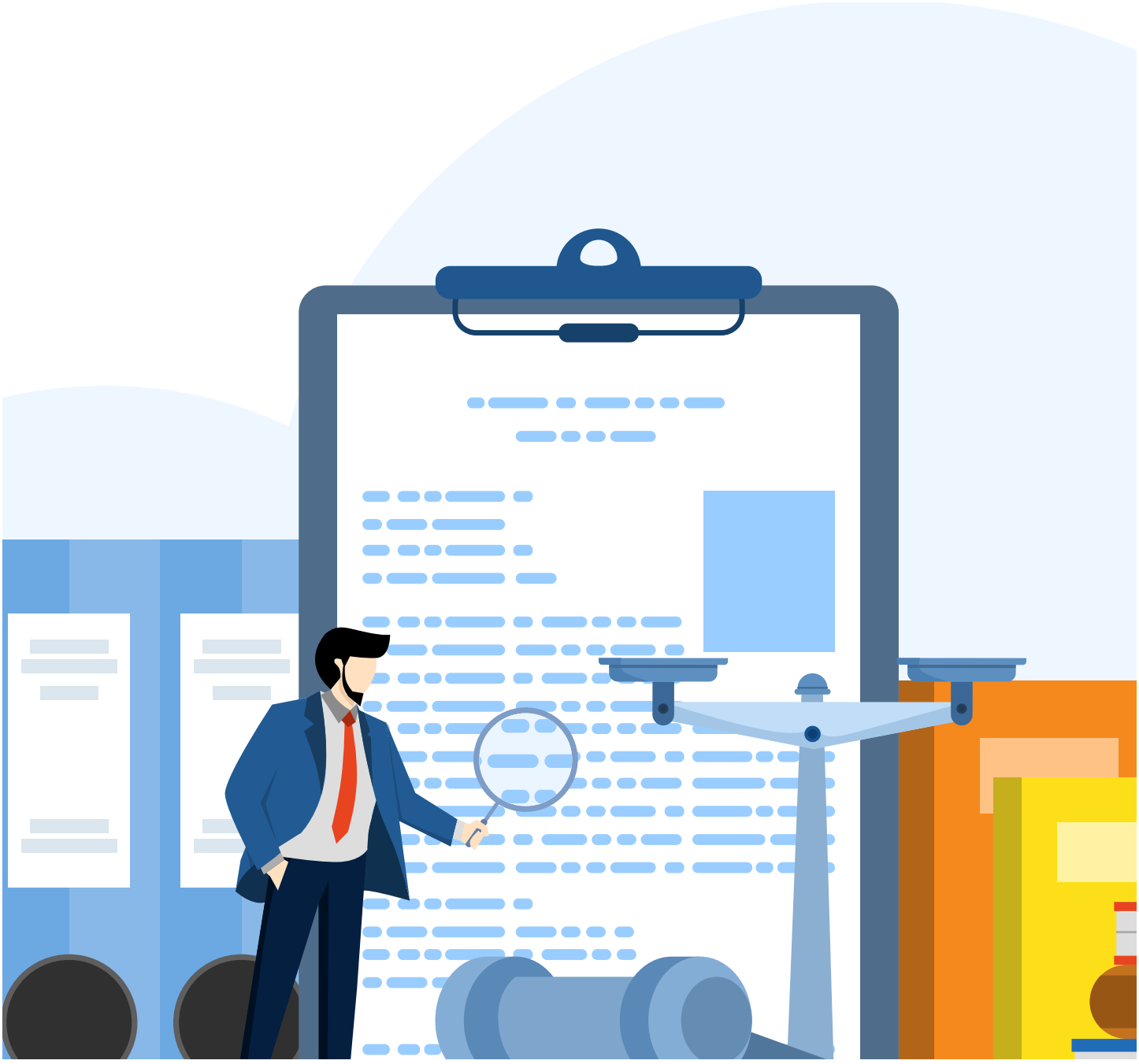
Class Proceedings Trends: Reliance on Mandatory Dismissal for Delay Provisions in Ontario

Several recent medical product liability decisions also addressed the mandatory dismissal for delay provisions brought in under amendments to Ontario's *Class Proceedings Act ("CPA")*. In Ontario, the legislation was amended in 2020 to include changes generally considered to make the test for certification stricter. In addition to the certification test changes, the amendments also included the introduction of dismissal for delay provisions under section 29.1 of the CPA and a transition provision under s. 39. Section 29.1 gives courts authority, on a motion, to dismiss a class proceeding for delay if certain steps outlined in the legislation have not been taken within one year from the date the action was commenced. Section 39 is a transitional provision that stipulates, among other things, that the pre-amendment *CPA* would apply to a plaintiff's class action commenced before the amendments came into force in October 2020 (the "Bright Line Rule"). However, with respect to dismissal for delay, any actions commenced before October 2020 were deemed to have been commenced on October 1, 2020, for the purposes of calculating the time for dismissal for delay under the provisions of s. 29.1. Since the introduction of these changes, Ontario courts have provided helpful guidance on how the amendments are interpreted and applied in the context of drug and medical device jurisprudence.

The court's decision reiterates that common issues cannot simply be a common label that conveys a false sense of commonality...

In *Adkin v Janssen-Ortho Inc.*, ***2022 ONSC 6670*** the court granted the defendants' motion under section 29.1 of the *CPA* to dismiss a proposed class action against three drug manufacturers. The plaintiffs commenced their action in October 2011 but had not taken any steps to progress the litigation since May 2012. In assessing the factors under section 29.1, the court noted that the plaintiffs never served or filed a complete motion record for certification, proposed a timetable for any next step, or asked the court to establish a timetable for completion of any other necessary steps to advance the proceeding. Therefore, the court determined that section 29.1 required it to dismiss the action for delay one year from the date the dismissal for delay provisions were enacted – namely, October 1, 2021.

In *Martin v Wright Medical Technology Canada Ltd.*, ***2024 ONCA 1***, the Ontario Court of Appeal addressed an interesting wrinkle in the application of these new provisions. The matter concerned two similar class actions brought around the same time against Wright Medical for allegations of a manufacturing defect in prosthetic hip implants. Both class actions – the *Martin* action and the *Rowland* action (***2015 ONSC 3280***) – were commenced before the October 2020 amendments and thus the older, more plaintiff-friendly legislation applied. However, by October 1, 2021, only the *Martin* plaintiffs had taken the required steps to move the action forward, therefore the



Rowland plaintiffs' action was subject to mandatory dismissal for delay. Both the *Martin* and *Rowland* plaintiffs wanted the *Rowland* cause of action against the defendants to be heard under the old *CPA*, and sought an order that the *Martin* action, operating under the old *CPA*, be amended to include the *Rowland* causes of action and continue under the old *CPA*. The Court of Appeal disagreed, stating that section 39 draws a "bright line" between actions commenced under the old *CPA* and those commenced under the amended *CPA*. The *Rowland* action was discontinued, but the plaintiffs' only right was to reconstitute their action and bring it again under the new *CPA*. The Court of Appeal found that the *Martin* and *Rowland* actions were substantially similar such that both actions should be heard at the same time, but that the *Martin* action would be governed by the old *CPA* test for certification, and the *Rowland* action would be governed by the new *CPA* test for certification. In this way, the Court of Appeal confirmed there is no legislative gap on this issue, and that joinder of new and old actions is not an avenue for plaintiffs to evade the new *CPA* provisions.

Class Proceedings Trends: Where Life Sciences and Privacy Laws Intersect

Interestingly, another recently certified class action provides a cautionary tale for life science companies collecting and storing data about their users, particularly through health-related applications (or

"apps"). In *Lam v Flo Health*, ***2024 BCSC 391***, the plaintiff brought an application to certify a class action on behalf of Canadian users (except those in Quebec) of the Flo Health & Period Tracker ("Flo") app. The plaintiff alleged that Flo intentionally violated user privacy by entering into contracts with third-party companies and granting them access to user information for purposes such as advertising and promotion.

The court approved the application for the action to be certified as a class proceeding for some of the common issues, including intrusion upon seclusion (in most jurisdictions), breach of confidence, and breach of relevant privacy legislation. The court found a basis for the claim that Flo inappropriately handled user information in the evidence tendered by the plaintiff. The matter was certified as a class action in March 2024, but the defendants have appealed the certification decision. Companies collecting and storing personal health information should monitor the outcome of this appeal and review their internal privacy policies accordingly.

Individual Claims: Pre-Trial Pleadings Motion Challenges

While many drug and medical device claims result in putative class proceedings given the collective nature of the alleged harms, in Canada, these proceedings are often advanced on an individual basis.

In the context of such individual claims, we highlight a 2024 decision that was before the Court of Appeal for Ontario where the court overturned the lower court's dismissal of the plaintiff's pleading. In *Fernandez Leon v Bayer Inc.*, ***2023 ONCA 629***, the plaintiff brought an action against the manufacturer of an implanted female contraceptive device, alleging that the device caused perforations of her internal organs. The manufacturer brought a motion to strike the claim on the basis that the plaintiff had failed to identify the specific defect in the product that caused the injury; therefore, no negligence in design or manufacture could be made out against the defendant device manufacturer. The defendant also relied on class action decisions that required the plaintiff to adduce some basis in fact of the defect in design or manufacture. The defendant, while successful with this argument at the first instance, was overturned by the Court of Appeal. The Court of Appeal held "the particulars of a specific defect are not in our view elements of the tort that are always required to be pleaded before the claim discloses a cause of action. To identify a specific manufacturing or design defect in every case would place too onerous a burden on a plaintiff at the stage of initiating a proceeding in a product liability action." (para. 12) The cause of action test at a motion to certify a class action is different than the test on a motion to strike an individual claim for no valid cause of action. In this regard, the Court of Appeal held that the manufacturer's reliance on class action certification decisions for determining the standard for whether there was a valid cause of action against the defendant was misplaced. Ultimately, the plaintiff was permitted to amend her claim with leave of the court.

Conclusion

The cases discussed above offer important insights into trends emerging out of recent Canadian drug and medical device product litigation. While the unique facts of each case will give rise to the need to deploy specific defense strategies, manufacturers of cross-border drugs and devices, and their counsel, should be aware of these trends in considering strategic handling of product liability class proceedings and singleton actions in Canada.

Ethical and Effective Joint Defense Groups

By Colin Murphy

This article will briefly chart the evolution of the joint defense privilege... and when it may apply today before discussing ethical considerations and practical tips for forming effective joint defense groups.

Coordinated mass tort actions in state and federal courts across the country have become a common and familiar procedural setting for defendants in product liability litigation. Intended to promote the just and efficient resolution of a large number of similar cases, these forums serve to facilitate coordinated discovery, mitigate the risk of competing rulings by different courts on the same issues, and encourage the broad resolution of similar claims. They also frequently involve a number of different co-defendants whose litigation interests may potentially align. In these situations, co-defendants' counsel may enter into a joint defense agreement in order to protect the confidentiality and privilege of their coordinated efforts. In doing so, it is important for counsel to build and maintain healthy relationships in order to advance litigation strategies that serve their respective client's shared interests. Counsel should also remain cognizant of their legal and ethical obligations to their clients, the court, and each other.

This article will briefly chart the evolution of the joint defense privilege—the legal foundation on which joint defense groups find footing—and when it may apply today before discussing ethical considerations and practical tips for forming effective joint defense groups.

The Joint Defense Privilege and its Evolution

The joint defense privilege is both an exception to—and an extension of—the attorney-client privilege. The joint defense privilege allows counsel for one defendant to communicate with counsel for a co-defendant while protecting such communications from disclosure to the plaintiff. Thus, the privilege allows attorneys representing different clients to share information and coordinate strategies without compromising the confidentiality protections provided by the attorney-client privilege and work product doctrine. The privilege is, therefore, an exception to the general rule that voluntary disclosure to a third party of purportedly privileged information waives the protections of the attorney-client privilege or work product doctrine.

The joint defense privilege finds its roots in criminal law's joint defense doctrine. The Virginia Supreme Court was the first to recognize the doctrine in an 1871 criminal case, *Chahoon v. Commonwealth*, 62 Va. 822 (1871). The Court explained that co-defendants had a right "to consult together about the case and the defense" and that a "necessary consequence" of such a right was "that all the information derived by any of the counsel from such consultation, is privileged, and the privilege belongs to each and all of the clients and cannot be released without the consent of all of them." Id. at 842.

Seventy-one years later, the Minnesota Supreme Court expanded the doctrine to civil cases in *Schmitt v. Emery*, 211 Minn. 547 (1942). In *Schmitt*, the plaintiff sought the production of a purportedly privileged document that the co-defendants shared with each other in preparing for trial. The Court denied plaintiff's request, holding that when "an attorney furnishes a copy of a document entrusted to him by his client to an attorney who is engaged in maintaining substantially the same cause on behalf of other parties in the same litigation," the communication is protected from disclosure by the attorney-client privilege. Id. at

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554. *Schmitt* marked the first steps toward widespread recognition of the joint defense privilege, and today, every US jurisdiction recognizes some form of the privilege.

When to Invoke and Protect the Joint Defense Privilege

As with any privilege, co-defendants seeking joint defense privilege protection bear the burden of establishing the doctrine's applicability. *Lugosch v. Congel*, 219 F.R.D. 220, 238 (N.D.N.Y. 2003). For the doctrine to apply, most courts require: (1) that the purportedly privileged communications were made in the course of a joint defense effort; (2) the statements were designed to further such effort; and (3) the privilege has not been waived. *See, e.g., Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp*, 805 F.2d 120, 126(3d Cir. 1986). At a minimum, defendants must make a showing of "actual cooperation toward a common legal goal." *In re Rivastigmine Patent Litigation*, No. 05 MD 1661, 2005 WL 2319005, at *4 (S.D.N.Y. Sep. 22, 2005). A written agreement, though not always necessary, provides strong proof of cooperation. *See, e.g., United States v. United Technologies*, 979 F. Supp. 108, 110 (D. Conn. 1997).

Generally, one party to a joint defense agreement cannot unilaterally waive the joint defense privilege for other members of the agreement. *United States v. Gonzalez*, 669 F.3d 974, 982 (9th Cir. 2012). The joint defense privilege only applies where each separate client or client group has its own attorneys. If a group of clients and their counsel communicate with an unrepresented party, there can be no joint defense privilege. In that scenario, the unrepresented party destroys the privilege and creates a waiver of the privilege as to the party who engaged in such communications with the third party. *Cavallaro v. United States*, 153 F. Supp. 2d 52, 61 (D. Mass. 2001), aff'd, 284 F.3d 236 (1st Cir. 2002) (rejecting joint defense privilege because one party was not represented by counsel).

Most courts will apply the joint defense privilege to client-to-client communications when a lawyer is either present or has directed the communication, which includes communications between a client and another client's lawyers, whether or not the client's own lawyer participates. *See United States v. Mikhel*, 199 F. App'x 627, 628 (9th Cir. 2006). Some courts permit the privilege when any member of a "client set" (i.e., the clients, clients' agents, clients' lawyers, and lawyers' agents) exchange communications, whether a lawyer is present or not. *See* Restatement (Third) of Law Governing Lawyers § 76 cmt. d (2000). Counsel should consult applicable law to understand the scope of protection provided by the joint defense privilege in different jurisdictions.

Ethical Considerations that Inform the Creation and Operation of Joint Defense Groups

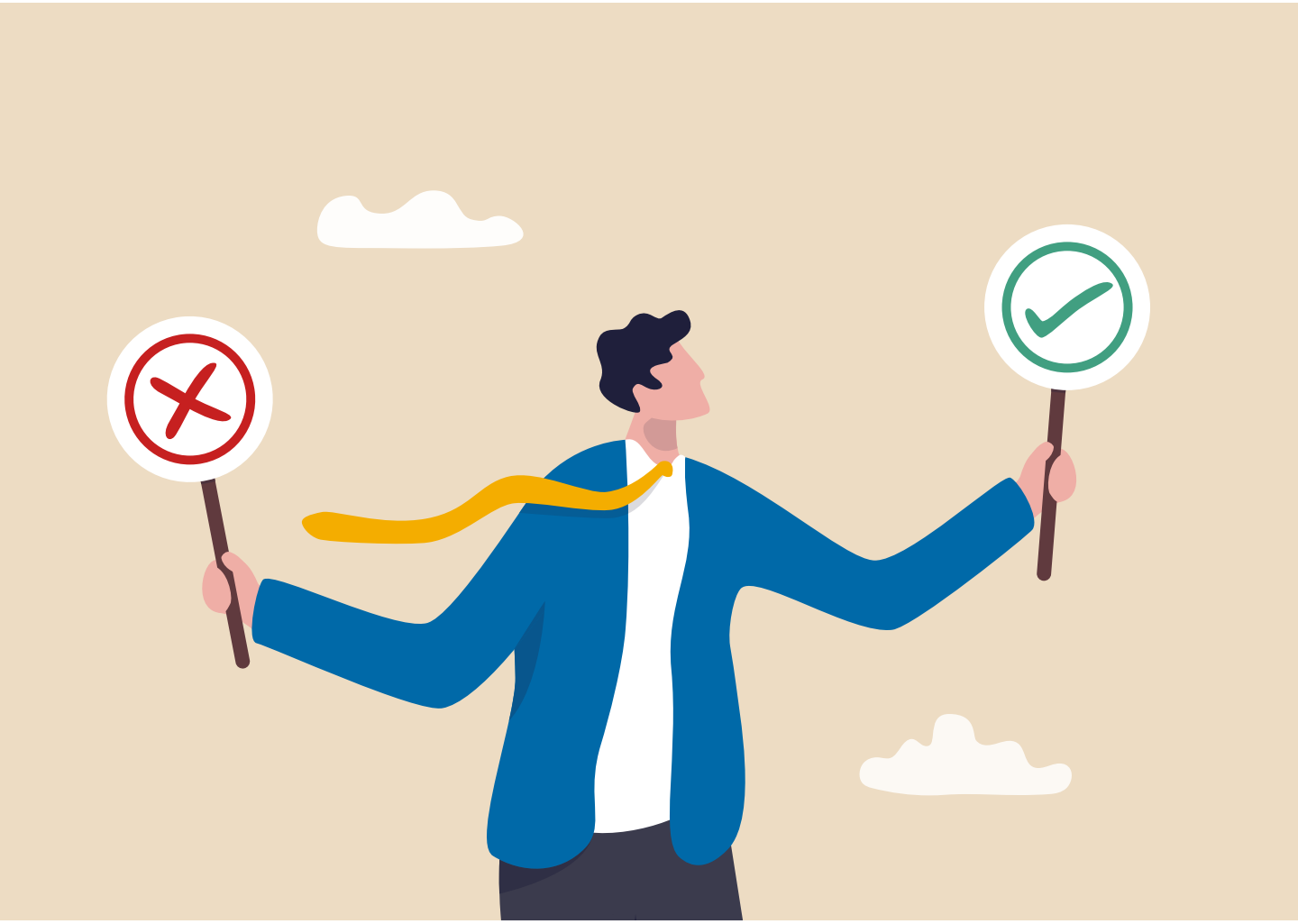
While it may be obvious that ethical rules apply with equal force inside or outside the confines of a joint defense group, what may not be obvious is that in certain scenarios, ethical obligations may require counsel to encourage their client to launch or enter into a joint defense group.

Because joint defense agreements can, in many situations, help clients advance their own interests by protecting strategy discussions and information sharing with co-defendants from disclosure, ethical obligations require counsel to diligently pursue joint defense agreements when such agreements benefit their clients. *See*, e.g., ABA Model Rule 1.3; comment [1] to ABA Model Rule 3.1 (explaining that attorneys have "a duty to use legal procedure for the fullest benefit of the client's cause."). Diligence also requires counsel to ensure that a joint defense agreement is in place before a client shares confidential information with a co-defendant or otherwise aligned party.

But counsel must be careful not to put the proverbial cart before the horse. Ethical obligations require counsel to "reasonably consult with the client the means by which the client's objectives are to be accomplished," ABA Model Rule 1.4(a)(2), and gain client consent before entering into a joint defense agreement with another party. During such a consult, counsel must provide the client with "sufficient information to participate intelligently" in deciding whether to enter into a joint defense agreement and "review all important provisions" of a potential agreement with the client. *See* Comment [5] to ABA Model Rule 1.4. This means counsel must inform the client of the benefits of such an agreement, as well as the potential risks. Importantly, counsel must make clear to their client that to gain the privilege protections provided in a joint defense group, the client generally must waive the attorney-client privilege as to the other members of the group. *See Haines v. Liggett Group Inc.*, 975 F.2d 81 (3d Cir. 1992).

Attorneys may wonder if their engagement in a joint defense group could create future conflicts of interest. Most courts recognize that a joint defense agreement does not create an attorney-client relationship between the attorneys of one defendant and a co-defendant within the group. *See, e.g., Diva Limousine Ltd. v. Uber Technologies Inc.*, No. 18-cv-05546-EMC, 2019 BL 8013 (N.D. Cal. Jan. 9, 2019). Joint defense agreements do, however, create duties of confidentiality owed by parties and their counsel who receive confidential information from other members of the group. *See, e.g., Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 2019 US Dist. LEXIS 119534, 2019 WL 3284673, at *4-5 (D.N.J. June 6, 2019) (finding joint defense agreement did not create an implied attorney-client relationship or impose a fiduciary duty—it "merely impose[d] a duty of confidentiality"). And because confidential information is often shared within a joint defense group, counsel may be "precluded from a later representation adverse to the

Most courts will apply the joint defense privilege to client-to-client communications when a lawyer is either present or has directed the communication... whether or not the client's own lawyer participates.



former sharing person when information actually shared by that person with the lawyer or the lawyer's client is material and relevant to the later matter." Restatement (Third) of the Law Governing Lawyers § 132 cmt. g(ii).

Ethical Practice can Lead to Effective Practice Within Joint Defense Groups

Ethical obligations not only can call for and inform the creation and operation of joint defense groups, but when taken seriously, ethical practice can produce effective practice—and effective practice can produce great results for our clients. But great results require that members of a joint defense group actively work toward ethical and effective practice. And in pursuing ethical and effective practice within a joint defense group, clarity and coordination are two of the most essential elements to implement in such a pursuit.

Sometimes, joint defense groups in mass tort litigation find themselves at a strategic disadvantage because plaintiffs' leadership groups seem to have greater clarity among themselves regarding items such as leadership structure and general coordination. A lack of clarity regarding leadership structure within a joint defense group can lead to frustration and infighting, which, at best, leads to wasted time and resources and, at worst, suboptimal results for clients. And wasting a client's time and resources because of such issues is arguably a violation of the ethical obligations we owe our clients. *See*, e.g., ABA Model Rule 3.2.

Members of a joint defense group can avoid the pitfalls unclear leadership structures create by applying a few best practices. Often, at the outset of mass tort litigation, it is clear who the lead defendant is in such litigation. For example, in the prescription drug context, mass tort litigation may involve the original manufacturer of the prescription drug—who is typically the lead defendant—as well as the other manufacturers who have since manufactured generic versions of the prescription drug (i.e., 505(b)(2)'s). In such cases, the lead defendant should generally lead early discussions regarding the leadership structure of the joint defense group. Ideally, these early discussions should lead to defined roles and responsibilities for the members of the group. Counsel within the newly formed group should inform their clients of the benefits of such structure, such as cost savings and coordinated strategy, and work to gain client consent regarding the group's leadership structure. While an equal division of roles and responsibilities among the members of a joint defense group is unlikely, an equitable division is possible—with the lead defendant generally holding greater decision-making power, but also carrying a greater burden. Once the leadership structure is agreed

upon, co-defendants must diligently play their part to ensure that the group—and their own client—reap the potential benefits the joint defense group can provide.

A clear leadership structure can help a joint defense group avoid the pitfalls that a lack of coordination among the group can create. Mass tort litigation can require an immense amount of coordination between co-defendants. Without coordination, co-defendants can be left wondering about matters such as who is handling what hearing, and how many members of the group should attend court hearings? In mass tort litigation, optics matter and perception matters, and joint defense groups should coordinate the attendees of such hearings in light of such considerations. Likewise, mass tort litigation typically requires much motion practice, so members should discuss and nail down details on who is taking on the first draft of the motion and who all must review and comment before filing. A lack of clarity on the coordination of such items can lead to frustration, wasted resources, suboptimal results, or missed deadlines. The devil is in the details, and clear leadership and coordination is not only an ethical obligation of attorneys practicing in the context of a joint defense group, but a best practice that can encourage effectiveness.

Most courts recognize that a joint defense agreement does not create an attorney-client relationship between the attorneys of one defendant and a co-defendant within the group.

Perhaps more concerning than a lack of clear leadership and coordination is a lack of mutual care that, unfortunately, is sometimes present in a joint defense group. Joint defense groups in mass tort litigation will find themselves at a strategic disadvantage as compared to their counterparts on the other side if members of the group do not show the requisite care to not only the objectives of the group but also the other members of the group. The requisite care required to create an ethical and effective joint defense group is multi-faceted, including components such as civility, candor, and, as mentioned above, clear lines of communication, and the carrying of equitable burdens.

Unsurprisingly, most rules governing attorney conduct call for attorneys to conduct themselves with civility and in a spirit of cooperation. *See*, e.g., ABA Model Rules of Professional Conduct, Preamble and Scope. Failure to abide by these standards of professionalism within a joint defense group can strain relationships, close lines of communication, and result in lost trust and credibility. And such relational losses within a joint defense group can lead to inconsistent approaches, higher costs, extended litigation, and potentially unfavorable results.

Civility among members of the group should be a given, but if members can move beyond mere civility to mutual care and respect, joint defense groups can reach new heights in the services they provide to the respective clients within the group. True, an attorney's loyalties reside with their client, but attorneys within a joint defense group must realize that showing care and respect to other members of the group can produce greater outcomes for their client that may not be possible apart from a harmonious joint defense group.

Closely related to the practices of civility and care is the practice of candor. While most rules governing attorney conduct prohibit attorneys from knowingly making false statements of material fact or law, *see*, e.g., ABA Model Rule 4.1, members of a joint defense group should aspire to create a culture where members are comfortable moving beyond the bare minimum candor requirements. Candor is more than an ethical obligation in such groups; it is usually an excellent strategic move that is in the client's best interests. As discussed, other members of the group will have a duty of confidentiality regarding information shared within the group to advance the group's interests. Moreover, members of a joint defense group likely expect robust candor from their colleagues within the group, and thus should deliver the same for the benefit of the group.

How can joint defense groups move toward cultures of civility, care, and candor? Communication and conscientiousness are key. Joint defense groups should set up regular lines of communication to keep members up to speed and allow members to contribute to the group's objectives. While it may seem obvious, regular meetings where members can see and hear from one another can go a long way in building a harmonious joint defense group. At a minimum, the leadership of the group must ensure that all members get the information they need in a timely manner.

Conscientiousness of the other members and their particular roles and responsibilities within the group also helps move the group toward ethical and effective practice. Teams in the business world, sports world, and legal world seem to enjoy the best results when they approach the team's objectives with a mindset of "How can I help?" Can I submit my brief a day or two early to ease the reviewer's burden? In what other ways can I ease the group's burdens and move the litigation along in a mutually beneficial manner in addition to my regular responsibilities?

Conclusion

If you practice mass tort civil defense, at some point in your practice you may find yourself considering whether a joint defense agreement may be helpful to a client's case. As discussed, ethical obligations may even require the exploration of such a joint defense agreement. When operating within a joint defense group, remember that ethical practice marked with clarity of vision and direction, civility, care, candor, and conscientiousness will almost assuredly produce an effective practice and, hopefully, a better defense of your client's interests.

Client Ownership of Work Product

By Douglas R. Richmond

Lawyers' and clients' interests in maintaining work product protection are normally aligned, but...that is not always the case.

When lawyers consider protecting information related to clients' representations from discovery by adversaries and others, they typically focus on the attorney-client privilege and work product immunity. In analyzing these doctrines, lawyers generally understand that the attorney-client privilege belongs to the client or, stated another way, that the client "owns" the privilege. Although lawyers may assert or waive the attorney-client privilege, they do so as the client's agent. A lawyer has no independent right to either claim or waive the privilege. For instance, a lawyer cannot unilaterally waive the privilege because the lawyer believes the client will somehow benefit from the disclosure of an otherwise confidential communication. Nor can a lawyer waive the attorney-client privilege over the client's objection. *Ctr. Partners, Ltd. v. Growth Head GP, LLC*, 981 N.E.2d 345, 356 (Ill. 2012). On the other side of the coin, if a client has knowingly waived the privilege regarding a communication, a lawyer cannot later claim that the privilege applies to the disclosed information and attempt to withhold it on that basis. *S.F. Residence Club, Ltd. v. Baswell-Guthrie*, 897 F. Supp. 2d 1122, 1216 (N.D. Ala. 2012); *Sorenson v. Riffo*, 2008 WL 2465454, at *3 (D. Utah June 16, 2008).

In contrast to the attorney-client privilege, which is exclusively the client's right to assert or waive, courts frequently state that the lawyer holds work product immunity. *See, e.g., Curtis v. Super. Ct.*, 276 Cal. Rptr. 3d 676, 688 (Ct. App. 2021) ("The work product privilege is held by the attorney, not the client."); *Carlino E. Brandywine, L.P., v. Brandywine Vill. Assocs.*, 301 A.3d 470, 482–83 (Pa. Super. Ct. 2023) ("Unlike the attorney-client privilege, the right to assert attorney work product protection belongs to the attorney, not the client."). This view is understandable. In formulating the work product doctrine, courts recognized that lawyers who are representing clients in connection with anticipated or pending litigation must enjoy a reasonable degree of privacy, free from intrusion by adversaries or opposing lawyers. Moreover, lawyers' creation of tangible work product and their formulation of opinion work product reflect their efforts and exercise of their professional skills, and the application of their experience, expertise, and specialized knowledge. Lawyers clearly are interested in controlling access to their work product and in preventing its use by others. But in fact, both the lawyer and the client hold work product immunity. *Malik v. United States Dep't of Homeland Sec.*, 78 F.4th 191, 199 (5th Cir. 2023) (quoting *In re Grand Jury Proc.*, 43 F.3d 966, 972 (5th Cir. 1994)). And because both the lawyer and the client hold work product immunity, either one may assert it to avoid the discovery of information or materials covered by the doctrine. Similarly, under the majority rule, either the client or the lawyer may waive work product immunity, but only with respect to themselves. *In re Grand Jury Proc.*, 43 F.3d at 972; *In re Doe*, 662 F.2d 1073, 1079 (4th Cir. 1981).

Given the widespread belief among lawyers that work product immunity is solely theirs to assert or to waive—a belief fueled by courts' cursory framing of the work product doctrine—it may surprise some lawyers that clients also own work product immunity and may waive the doctrine's protections. It should not. After all, a lawyer creates work product as part of the client's representation and for the client's benefit. The client presumably paid the lawyer to gather the information, cre-

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ate the materials, or formulate the strategy constituting work product. Work product protection enhances the client's representation by ensuring that the client receives frank and thorough legal advice from the lawyer, undiluted by the lawyer's wariness of discovery. At bottom, the client "is the ultimate and primary beneficiary" of work product immunity. *Brown v. Carolina Ins. Co.*, 634 So. 2d 1163, 1167 (La. 1994). Clients' joint ownership of work product and the rights that come along is therefore logical.

Recognizing clients' ownership of work product is also consistent with professional responsibility law, which generally holds that the client is presumptively entitled to full access to the lawyer's file in any matter in which the lawyer represented the client. As a rule, lawyers cannot withhold work product from their clients. *Clark v. Milam*, 847 F. Supp. 424, 427 (S.D. W. Va. 1994); *Gottlieb v. Wiles*, 143 F.R.D. 241, 247 (D. Colo. 1992). Certainly, lawyers cannot invoke work product immunity to deny clients access to their files in situations where the lawyer and client are not adverse to one another. *In re Fundamental Long Term Care, Inc.*, 489 B.R. 451, 475–76 (Bankr. M.D. Fla. 2013). Finally, a lawyer must defer to the client with respect to the objectives of the representation. With those principles in mind, enabling the client to waive work product immunity reasonably follows.

Recognizing clients' ownership of work product is also consistent with professional responsibility law...

The client's ownership of work product in addition to the lawyer's ownership of such information or materials is seldom an issue. The work product doctrine safeguards the client's interests in litigation by preventing an adversary from exploiting the lawyer's efforts on the client's behalf. More broadly, the work product doctrine protects the integrity of the adversary process and, in so doing, advances both the lawyer's and the client's interests. Where the lawyer and the client are aligned in interest, requiring the lawyer to surrender work product to the client does not penalize the lawyer's diligence and preparation and therefore poses little threat to the adversarial system. *In re Black Diamond Mining Co., LLC*, 507 B.R. 209, 216 (Bankr. E.D. Ky. 2014). The client and the lawyer normally are of like mind where work product immunity is concerned.

Work Product Protection Where the Client's and Lawyer's Interests Diverge

Occasionally, however, lawyers' and clients' interests diverge, and the client may want to waive work product immunity over the lawyer's objection or at least without the lawyer's consent. In that situation, the lawyer may not refuse to honor the client's waiver or otherwise prohibit the client from sharing work product with a third party. Where the client's interests and the lawyer's interests conflict, the client's interests must prevail. *See S.E.C. v. McNaul*, 271 F.R.D. 661, 666–67 (D. Kan. 2010). To hold otherwise would contravene the established principle that a lawyer is a fiduciary to a client and must therefore serve the client's interests. *Martin v. Valley Nat'l Bank of Ariz.*, 140 F.R.D. 291, 320 (S.D.N.Y. 1991). The lawyer "cannot fairly be authorized to subvert the client's interests" by preventing the client from using the work product as it deems necessary. Id.

Courts enforce the majority rule even when the third party is an adversary, or the disclosure increases the likelihood that the work product will fall into an adversary's hands. *M and C Corp. v. Erwin Behr GmbH & Co.*, 2008 WL 3066143 (E.D. Mich. Aug. 4, 2008), is illustrative.

In *M and C*, the law firm of Kemp Klein represented Behr Industries Corp. (BIC) in lengthy litigation with M and C Corp. (M & C). Howard & Howard represented M & C in that litigation. BIC and M & C finally settled their dispute. As part of the settlement, BIC "waived any 'attorney-client or other legal privileges held by Behr Industries Corporation'" with respect to documents and file materials held by Kemp Klein. Id. at *2. After settling, BIC terminated Kemp Klein's representation and hired Howard & Howard to represent it. Meanwhile, M & C was litigating against BIC's former corporate parent, Erwin Behr GmbH & Co. (Erwin). Howard & Howard represented M & C in its lawsuit against Erwin.

Courts enforce the majority rule even when the third party is an adversary, or the disclosure increases the likelihood that the work product will fall into an adversary's hands.

In M & C's case against Erwin, Howard & Howard demanded that Kemp Klein turn over all files from Kemp Klein's representation of BIC. Kemp Klein provided reams of material but refused to produce its lawyers' research, notes, working papers, and internal communications on the basis that such materials belonged to the law firm, not BIC, and that BIC was not entitled to receive them. When Howard & Howard subpoenaed the disputed records, Kemp Klein moved to quash the subpoena, and the battle was joined.

In resisting the subpoena, Kemp Klein relied on cases involving typical work product discovery disputes in which a party tries to obtain opposing counsel's work product. The *M and C* court, however, thought that Kemp Klein's reliance on such cases was misplaced. The question presented by Kemp Klein's motion to quash was whether it could "invoke the work product doctrine against [M & C] even though Kemp Klein's former client ha[d] clearly indicated its preference (through the request of current counsel of BIC for the documents and the written waiver by BIC) that the material be produced to [M & C]." Id. Kemp Klein argued in part that it was "withholding the material out of con-

cern 'for the integrity of its work product.'" Id. M & C countered that the material was relevant to the role Kemp Klein played in Erwin's allegedly improper sale of BIC and a sister subsidiary, which was an issue in M & C's current case against Erwin.

In ruling on Kemp Klein's motion, the court embraced the majority rule, which rests on the premise that that the work product doctrine is intended to safeguard lawyers' efforts on behalf of their clients by preventing opposing counsel from obtaining a free ride on their work. Id. (quoting *Martin*, 140 F.R.D. at 320). In this way, work product immunity protects the integrity of the adversary process. Accordingly, the work product doctrine does not permit lawyers to withhold the fruits of their professional labors from their clients. Id. (quoting *Martin*, 140 F.R.D. at 320).

The *M and C* court considered application of the majority rule to be particularly appropriate here because neither BIC nor Kemp Klein were parties to the pending action and BIC had specifically waived work product immunity regarding the disputed documents. Consequently, the court denied Kemp Klein's motion to quash.

Broidy Capital Management, LLC v. Muzin, 2023 WL 7552702 (D.D.C. Nov.

14, 2023), is a more recent case in point. In *Broidy*, lawyers at ArentFox Schiff LLP (ArentFox) defended Joseph Allaham in a lawsuit brought by Broidy Capital Management, LLC and Elliott Broidy (collectively, Broidy) against Allaham and others. Allaham settled with Broidy in August 2023. As part of the settlement, and without ArentFox's consent, Allaham gave much of his correspondence with ArentFox to Broidy. While Allaham and Broidy settled their dispute, Broidy continued to pursue its case against the remaining defendants. ArentFox, moving on its own behalf, asserted that Allaham had divulged materials protected by the work product doctrine. The firm sought an order from the court directing Broidy to either promptly return or destroy all of the firm's work product in Broidy's possession as well as any material that either referred to or was derived from the firm's work product. ArentFox also sought sanctions against Broidy for improperly reviewing and using the firm's work product. The court denied ArentFox's motion. Describing work product immunity as a privilege (as courts often do), the court found that Allaham had validly waived work product protection. Id. at *1.

The court acknowledged that a lawyer generally may invoke work product immunity based on the lawyer's independent privacy interest. But when a lawyer's and client's wishes or interests with respect to disclosure of work product conflict, the lawyer must follow the client's lead and may not independently assert the doctrine. As indicated earlier, "an attorney cannot 'withhold the fruits of his professional labors from the client, who presumably paid for and was the intended beneficiary of those labors.'" Id. (quoting *Martin*, 140 F.R.D. at 320). Those principles doomed ArentFox's attempted invocation of work product immunity and consequently its motion for a protective order and sanctions.

ArentFox argued that it had an independent right to protect the confidentiality of its lawyers' work product. The general rule, however, did not help ArentFox because lawyers cannot protect their work product at their clients' expense. Nor could ArentFox object to Allaham's disclosure of the firm's work product to Broidy on the basis that he was no longer a party to the litigation. First, work product immunity survives the termination of litigation. Id. (citing *FTC v. Grollier*, 462 U.S. 19, 25 (1983)). Second, Allaham acquired the subject documents while still a defendant in the case. For that matter, his agreement to turn over the documents to Broidy likely enabled him to settle out of the litigation. Against that backdrop, it was clear that Allaham had a legitimate interest in sharing the documents with Broidy—an interest that ArentFox, as his fiduciary, had to respect.

It is not clear from the opinion in *Broidy* why ArentFox fought to keep its work product out of Broidy's hands. It is easy to imagine a situation, however, in which a client wants to waive work product immunity to settle a lawsuit, avoid criminal charges, or minimize the consequences of its criminal conduct through a plea agreement. But extending the analysis, it is also easy to conceive of the lawyer for a disclosing client being concerned that the client's abandonment of work product protection will expose the lawyer to liability to a third party or to criminal liability. *See, e.g., In re Doe*, 662 F.2d at 1079 (involving a lawyer's potential criminal liability for allegedly suborning perjury and otherwise procuring false testimony in a former client's criminal trials). In such circumstances, the lawyer will surely want to claim work product immunity and, in doing so, attempt to prevent a third party or the government from using her work product against her in subsequent litigation or a later criminal prosecution. Indeed, in *M and C*, Kemp Klein's fear of potential tort liability to M & C stemming from the firm's representation of BIC may well have been the driving force behind the firm's objection to releasing its work product.

The Lawyer's Options When the Client Waives Work Product Immunity

A client's waiver of work product immunity is not the end of the story insofar as the lawyer is concerned. Under the majority rule, the client's waiver of work product immunity applies only to the client; the client cannot waive the lawyer's work product immunity. *In re Grand Jury Proc.*, 43 F.3d at 972 ("[T]he work product privilege belongs to both the client and the attorney.... Thus, a waiver by the client of the work product privilege will not deprive the attorney of his own work product privilege, and vice versa."); *In re Doe*, 662 F.2d at 1079 (stating that either the lawyer or the client may waive or forfeit work product immunity, but only as to themselves). Accordingly, a lawyer may move in limine to prevent the use of her work product at the trial of any case against her. The lawyer should also be able to preclude an adversary's use of her work product in discovery or as evidence in support of motions. Moreover, some courts modify the majority rule and hold that while the client may waive work product protection for the lawyer's ordinary or tangible work product, the client may not waive immunity for the lawyer's opinion work product. *See, e.g., In re Asia Glob. Crossing, Ltd.*, 322 B.R. 247, 262 (Bankr. S.D.N.Y. 2005) ("Although the client can also waive the privilege as to non-opinion work product, the attorney may still contest the waiver as to opinion work product."). Finally, some courts do not permit the client to waive work product immunity without the lawyer's consent. *See, e.g., QBE Ins. Corp. v. Griffin*, 2009 WL 2913478, at *3 (M.D. Ala. Sept. 4, 2009) ("Nor can the client unilaterally waive the [work product] privilege; the attorney may contest disclosure even in the face of a client's waiver.").

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On the other hand, the client's waiver of work product immunity can spell trouble for a lawyer. First, if the work product disclosed by the client establishes a prima facie case of fraud or criminal activity by the lawyer, the crime-fraud exception to work product immunity will likely eviscerate the lawyer's protection. Relatedly, if the work product disclosed by the client provides prima facie evidence of illegal activities by the lawyer, there then exists the extraordinary circumstances required

to discover even the lawyer's opinion work product, which otherwise receives almost absolute protection from discovery. *In re: Grand Jury 2021 Subpoenas*, 87 F.4th 229, 255 (4th Cir. 2023) (quoting *In re Grand Jury Proc. #5*, 401 F.3d 247, 252 n.3 (4th Cir. 2005)). Second, assuming application of the majority rule, prohibiting the use of the lawyer's work product in discovery or at trial is an incomplete remedy because the court cannot cleanse the opposing lawyers' minds of knowledge of the lawyer's work product gained through review of materials or information provided by the client. Opposing counsel will be playing on a field slanted in their favor. As a practical matter, there is nothing the lawyer or court can do to relevel the field. Third, in a subsequent criminal case, the government may be able to overcome the lawyer's objections to the use of her work product by arguing inevitable discovery.

Conclusion

Lawyers' and clients' interests in maintaining work product protection are normally aligned, but as *M and C* and *Broidy* illustrate, that is not always the case. The bottom line is that clients, like lawyers, generally may waive work product immunity at least with respect to themselves. Any waiver of work product immunity by a client potentially has profound implications for the lawyer. Lawyers' best hope when a client's disclosure of work product jeopardizes their interests is that the jurisdiction does not follow the majority rule or has no case law on point, such that they can effectively argue that their opinion work product should not be disclosed or, better yet, foreclose the client's planned disclosure of all work product. Furthermore, many of the cases recognizing the majority rule are federal district court decisions. These decisions are neither authoritative nor precedential; they are simply persuasive authority. Assuming they can craft thoughtful contrary arguments, lawyers should be prepared to challenge the majority rule in appropriate circumstances. The obvious problem for lawyers litigating the ownership of work product is that the majority rule is the majority rule for a reason—it is legally sound. The rule's practical effects will depend on the case.