dri™ The Voice of the Defense Bar

Rx For The Defense

The newsletter of the
Drug and Medical Device Committee

7/9/2020 Volume 28 Issue 2

Committee Leadership

In This Issue

From the Leadership

Chair's Corner

By Gail Rodgers

Hello DMD Colleagues and Friends,

I write this from New York City on Day 101 of some iteration of lockdown. Sadly, virtually all of our lives have changed dramatically over the past few months. Some have lost loved ones, others have lost jobs, opportunities, or have had an innumerable list of events and opportunities canceled or adapted in ways we never imagined (zoom school!?). For the first year since 2004, I missed seeing so many of you at our Seminar in May.

In honor of our seminar, we did zoom calls in early May. Several groups gathered, including one for in-house counsel and one for young lawyers. It was so much fun! There were guest appearances by pets, spouses, children and a few beards-gone-wild. It was great to connect, even virtually, with the DMD community.

And then we saw the senseless murders of George Floyd and so many others. And the threat made by Amy Cooper at a Black man bird watching in the Ramble of Central Park. My back yard, where my husband and I walk our dogs.

So what did we do? We had a zoom dialogue on racism. Several members of our committee opened up about their experiences. Some were violent and hate filled. Others were systemic—such as assuming the only Black attorney in the courtroom could not possibly be an attorney. We listened to and learned from each other. Some members heard difficult stories that they had never imagined.

As much as I love the substantive and professional development that our Committee and Seminar provide, it truly is the community that matters. And our community gives me hope.

We saw people coming together, reconnecting, welcoming new members and sharing ideas. Our community is truly listening to each other, learning new techniques (virtual everything!), bridging new barriers and trying new ways of practicing law (remote depositions anyone?). Yet we continue to support each other and provide our companies and clients with excellent representation.

We will make a new normal. A better normal. And someday, someday, we will all be back together for a Seminar in real life.

Until then, we will zoom zoom zoom! I am excited to announce that we will hold a virtual seminar November 5–6! Get ready for the stellar presentations you experience every year, just done virtually. And we will have plenty of networking too!

Watch your email and DRI community page for upcoming invitations for remote substantive meetings, conversations of support and happy hours just for fun. For anyone interested in networking or getting more involved in the committee, reach out to me or any of the Committee leadership.

Stay well and sane,

Gail

Gail Rodgers is a partner in the New York City office of DLA Piper. She concentrates her practice in pharmaceutical and medical device litigation, mass torts and government and internal investigations. Gail represents clients on a wide variety of compliance matters, including the Foreign Corrupt Practices Act (FCPA) as well as advising and enhancing compliance programs in response to investigations. Gail has extensive experience in a wide variety of state and federal litigation, including providing strategic advice at each stage of litigation, managing national discovery teams, and implementation of national resolution programs. Gail serves as the chair of the DRI Drug and Medical Device Committee.

From the Editors

By Heather Howard and Jennifer Eppensteiner


Happy summer, or March 125th (we've lost count, but we also lost Apri, May, and June along the way!). As a publication that existed online pre-pandemic, access to *Rx for the Defense* has not changed, but our feature article reflects our changed environment. While we were disappointed not to see all of our DRI friends and colleagues in Boston in May, we look forward to seeing everyone again when we are no longer physically distanced.

Should you find yourself with extra time on your hands, or have an interesting topic idea for a future issue of *Rx for the Defense*, please contact Heather Howard at hhoward@kslaw.com or Jenn Eppensteiner at jeppensteiner@reedsmith.com to find out more information about the publication guidelines and the selection process.

Heather Howard is counsel in the Atlanta office of King & Spalding LLP, where she is a member of the firm's Trial & Global Disputes practice. She focuses her practice on the defense of pharmaceutical and medical device manufacturers in product liability suits at the trial level and on appeal. She serves as the newsletter editor for the DRI Drug and Medical Device Committee.

Jennifer Eppensteiner is a senior associate in Reed Smith LLP's Life Sciences Health Industry Group, resident in the Princeton, New Jersey office. Jennifer advises drug and medical device manufacturers on complex product liability litigation, including federal multidistrict litigation (MDL) and consolidated state court actions. Jennifer currently serves as the assistant newsletter editor for the DRI Drug and Medical Device Committee as well as Young Lawyer liaison to the Drug and Medical Device Steering Committee.

Feature Articles

PREP Act Update: Liability Immunity for "Covered Countermeasures" During the COVID-19 Pandemic

By Gerald P. Schneeweis and Anthony B. Portuese


Public health emergencies like the current worldwide COVID-19 pandemic require assessment and balancing of risks in a short amount of time. As we've seen during this emergency, one of those risks is the potential unavailability of an adequate supply of safe and effective drugs and medical devices to allow healthcare providers to treat seriously ill patients. Another risk is that the infection rate will spin even further out of control before one or more vaccines can be properly researched, designed, tested, analyzed, approved, manufactured, distributed and made available to a large percentage of the world's population.

In recognition of the need to mitigate the effects of future pandemics, in December of 2005, Congress passed the "Public Readiness And Emergency Preparedness Act," 42 U.S.C. sections 247d-6d; 247d-6e (referred to herein as the "PREP Act" or "The Act").

The PREP Act incentivizes drug and device manufacturers to design, manufacture, test and supply (and healthcare providers to administer) critical medical products without the fear of incurring liability for actions that do not rise to the level of "willful misconduct." It is not automatically triggered by the declaration of a public health emergency; rather, it requires a formal, separate Declaration by the Secretary of the Department of Health and Human Services of enumerated "Covered Countermeasures" that would be subject to the Act's liability immunity.

Before the current public health emergency caused by the spread of COVID-19, there had been nine such "Covered Countermeasures" Declarations under the Act.

March 10, 2020 Declaration Regarding the SARS-2-CoV-2 Virus and COVID-19 Pandemic

On March 10, 2020, following his earlier declaration of a national public health emergency posed by COVID-19, an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus, or a virus mutating therefrom, Alex Azar, the Secretary of the Department of Health and Human Services, issued a PREP Act Declaration. It has an effective date of February 4, 2020, and a general expiration date of October 1, 2024. Secretary Azar's Declaration listed various medical products and activities as "Covered Countermeasures" that would qualify for the liability immunity when used against COVID-19 during this time frame including future vaccines, and existing drugs and devices that receive an Emergency Use Authorization from FDA. (85 Fed. Reg. 15,198,15,202 (March 17, 2020). The Declaration has been amended to list additional countermeasures, including those qualifying for a new FDA Emergency Use Authorization.

On April 14, 2020, HHS' Office of General Counsel issued an Advisory Opinion to provide further guidance about the "scope of the PREP Act immunity during the COVID-19 pandemic." Among other things, the Advisory Opinion emphasizes the broad nature of the immunity and reflects the view that a "good faith," but mistaken, belief that a product is a "Covered Countermeasure" should render the immunity applicable.

Features of the PREP Act Liability Immunity

The scope of the immunity conferred for "covered countermeasures" is quite broad:

> (a) Liability protections
>
> (1) In general
>
> Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) of this section has been issued with respect to such countermeasure.
>
> (2) Scope of claims for loss
>
> (A) Loss
>
> For purposes of this section, the term "loss" means any type of loss, including—
>
> (i) death;
>
> (ii) physical, mental, or emotional injury, illness, disability, or condition;
>
> (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and
>
> (iv) loss of or damage to property, including business interruption loss.
>
> Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

PREP Act, 42 U.S.C, 247d-6d (a)(1)(2).

A "Covered Countermeasure" must be a "qualified pandemic or epidemic product," or a "security countermeasure"; or a drug, biological product or device authorized for emergency use in accordance with Sections 564, 564A, or 564B of the FDCA, including products that have received Emergency Use Authorization (EUA) from FDA, which is issued where a drug or device has not yet been approved for specific use and FDA determines that there is no current FDA-approved or cleared product available. Section 247d-6d(i)(1)(A).

Once the formal Declaration by the HHS Secretary is issued, the PREP Act confers immunity to any "covered person" against:

> *... claims for loss sounding in tort or contract, as well as claims for loss relating to compliance with local, state, or federal laws, regulations, or other legal requirements.* Immunity applies when a covered person engages in activities related to an agreement or arrangement with the federal government, or when a covered person acts according to an Authority Having Jurisdiction to respond to a declared emergency.

These acts include any arrangement with the federal government, or any activity that is part of an authorized emergency response at the federal, regional, state, or local level. April 14, 2020 HHS Advisory Opinion, p. 2 (emphasis added).

This is a strong, if not "absolute," immunity and reflects the public policy behind it: to ensure the availability of resources to combat a national public health emergency.

The Secretary's Declaration is not subject to review by any court. The Act contains an express federal preemption provision. It immunizes against any claims for personal injury brought under either U.S. federal or state law as a result of a "covered countermeasure." It provides a sole

exception for "willful misconduct," which must be established under a "clear and convincing" evidentiary standard, and cannot be based on a manufacturer's acts to comply with an FDA or other governmental directive or guidance. While a claim can be brought to allege "willful misconduct," it can only be brought in the U.S. District Court for the District of Columbia, before a 3-judge panel, and a claimant needs to first exhaust the administrative claim remedy under the "Countermeasure Injury Compensation Act."

As to vaccines, The Act supplants the otherwise applicable "National Vaccine Injury Compensation Act" which provides for a different administrative compensation system in the Federal Court of Claims for injuries or death caused by enumerated vaccines administered during "normal" circumstances.

One who complies with all other requirements of the PREP Act and the conditions of the Secretary's Declaration will not lose PREP Act immunity—even if the medical product at issue is not in fact a covered countermeasure—if that entity or individual "reasonably could have believed" that the product was a "covered countermeasure." (HHS General Counsel's Advisory Opinion, p. 2)

And as the HHS Advisory Opinion points out, not all operations are immunized just because the entity manufactures or distributes a product that has been declared a covered countermeasure.

> [A] liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use.
>
> In each case, whether immunity is applicable will depend on the particular facts and circumstances.

April 14, 2020 HHS Office of General Counsel Advisory Opinion.

The only statutory exception to this immunity is for actions or failures to act that constitute "willful misconduct," defined as:

i. intentionally to achieve a wrongful purpose;

ii. knowingly without legal or factual justification; and

iii. in disregard of a known or obvious risk that is so great as to make it highly likely that the harm will outweigh the benefit.

PREP Act, section 247d-6d (c)(1)(A).

Under the Act, "willful misconduct" cannot generally constitute an act by a covered entity to comply with an FDA regulation, unless a government enforcement action has been instituted. (42 U.S.C. 247d-6d(c)(4)).

As a corollary to the temporary liability immunity granted to "covered countermeasures," there is a "no-fault" system—the "Countermeasures Injury Compensation Program" (CICP), which is administered by an agency within the HHS. It is designed to compensate those who sustain "serious injury" (an injury that would usually require hospitalization, even if the patient was not actually hospitalized). It provides enumerated benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of a Covered Countermeasure. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. *See* Final Rule, published at 42 CFR Part 110 (October 7, 2011).

Limited Judicial Interpretation of the PREP Act

While consumer groups protested its enactment, the PREP Act appears to have generated virtually no case law in connection with other post-2005 pandemics. *Kehler v. Hood*, a decision from the United States District Court for the Eastern District of Missouri, did address some jurisdictional issues under the PREP Act. No. 4:11-CV-1416, 2012 WL 1945952 (E.D. Mo. May 30, 2012).

In June 2009, the HHS Secretary identified the H1N1 influenza virus as a public health emergency and designated the H1N1 vaccine a covered countermeasure under the PREP Act. The *Kehler* plaintiff received an H1N1 vaccine from his doctor in January of 2010 and later developed a severe case of transverse myelitis. He sued the doctor and her medical group in state court, alleging that before receiving the vaccine, he did not give informed consent, and that his physician was negligent in failing to consult with a specialist prior to administering the vaccine. Plaintiff did not sue the vaccine manufacturer, Novartis, but it was impleaded into the state court case by the medical provider defendants as a third-party defendant. It then removed the case to federal court on the basis of "federal officer" jurisdiction pursuant to 42 U.S.C. section 1442(a)(1).

The parties did not dispute that third-party defendant Novartis was protected by the PREP Act immunity and did not allege that Novartis had engaged in willful misconduct so

as to bring its claim within the statute's only recognized exception to the immunity. The district court found that since the PREP Act applied, as to Novartis, exclusive jurisdiction over the doctor's third-party complaint was in the District of Columbia, and thus granted Novartis' motion to dismiss it on the basis of lack of subject matter jurisdiction. The doctor and medical group (non-diverse, "local" defendants) argued that the PREP Act applied to them as well, and that the court should thus retain federal question jurisdiction as to the clams asserted in the Plaintiff's complaint. The court declined and issued an order of remand, noting that the complaint itself alleged medical negligence before the vaccine was administered. *Id.* at *4. The court reasoned that "the assertion of a federal defense, including the defense that claims are preempted by federal law, does not give rise to federal question jurisdiction." *Id.* at *3.

Parker v. St. Lawrence County Public Health Department, 102 A.D. 3d 140, 954 N.Y.S. 259 (2012) upheld PREP Act protections for a county that conducted a school-based vaccination clinic in response to the H1N1 outbreak. During the clinic, a nurse employed by St. Lawrence County inadvertently vaccinated a kindergartener in the absence of parental informed consent. The child's mother filed suit, arguing that the county had committed negligence and battery. The county moved to dismiss the complaint on the basis that the claim was preempted under the PREP Act. The lower court denied the defendant's motion to dismiss, asserting that the PREP Act was not intended by Congress to protect against claims arising from failure to obtain informed consent. The county appealed and both the United States and State of New York submitted amicus briefs supporting the county.

The appellate court dismissed the plaintiff's claims, finding that the federal PREP Act preempted the claims under state law and that the breadth of liability immunity provided under the PREP Act precluded the plaintiff's claims of negligence and battery. The court noted the alternative remedy provided by the countermeasure injury compensation program and the possibility of a federal cause of action for willful misconduct claims. *Id.* at 142–143.

Questions will no doubt arise regarding the existence and extent of PREP Act immunity as well as its intersection with other laws and regulations.

What Next?

The landscape of the current public health emergency seems to change constantly, and there has already been litigation commenced outside of the PREP Act "covered countermeasures" context alleging that businesses negligently failed to protect an individual from the risk of contracting COVID-19 disease. It is the authors' view that if there are widespread serious adverse effects from the administration of eventual COVID-19 vaccines, Plaintiffs' counsel may try to test the boundaries of the immunity in court. If that occurs, the authors believe that some questions may need to be answered:

- What types of facts underlying actions by manufacturers during the immunity period would be considered "willful misconduct" as defined under the PREP Act, so that the immunity would not apply?
- Would some courts refuse to apply express federal preemptive effect to such a claim?
- Will Plaintiffs' counsel attempt to state a separate claim for violation of an individual's civil rights as a result of a covered countermeasure?
- In instances in which a defendant mistakenly believes that a product is a covered countermeasure, is there any basis on which to allow a jury to decide whether a "reasonable person could have believed" it to be covered?
- Would a state court lawsuit that names a "local" defendant-manufacturer be removable to federal court under federal question or federal officer subject matter jurisdiction?
- Will PREP Act immunity completely bar lawsuits in another country–under its laws–for injuries allegedly caused by a vaccine manufactured by a U.S. company?

If and when issues about the application of the PREP Act immunity are framed, the authors believe that most courts will resolve them by applying the underlying purpose of the immunity—to provide incentives to those who can act to mitigate and potentially end a public health crisis.

Gerald P. Schneeweis is a member of Clark Hill PLC, resident in the San Diego office. He has represented pharmaceutical and medical device manufacturers, research entities and individual officers, directors and employees in product liability litigation asserting claims of design and manufacturing defect, failure to warn and off-label promotion. Gerry is a member of the DRI Drug and Medical Device Committee, the San Diego chapter of the American Board of Trial Advocates and the American Bar Association.

Anthony "Tony" Portuese is an attorney with government service and private practice litigation and corporate law experience. He has panoramic pharmaceutical (domestic and international, litigation, compliance, general counsel and government relations) and insurance industry experi-

ence over a progressively responsible career. A graduate of Rutgers College and Seton Hall Law School, Tony is privileged to have presented for the American Conference Institute's Drug & Medical Device, IADC, Lexis/Nexus/Mealey's, the Association of Corporate Counsel - New Jersey, the Momentum Group, and the Network of Trial Law Firms. He presently lives in Australia.

Winning Arguments Remain: Express Preemption for PMA Medical Devices in the Eleventh Circuit After *Mink v. Smith & Nephew, Inc.*

By David J. Walz and Caycee D. Hampton


In 2011, when the Eleventh Circuit issued *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296 (11th Cir. 2011), it created one of the most demanding standards in the nation for a plaintiff to plead a claim that survives express preemption under *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2007). Although *Wolicki-Gables* affirmed a summary judgment, the key holding was the rigorous application of *Riegel* at the pleading stage to require alleged violations of specific PMA requirements or particular federal specifications.

Six years later, when the court returned to the issue of pleading claims involving PMA medical devices in *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017), it allowed for the commonly cited "narrow gap" between express and implied preemption through which a plaintiff's claims might fit. The court allowed the manufacturing-defect claim to proceed beyond dismissal because the plaintiff "carefully . . . pointed to device-specific federal requirements" that the manufacturer allegedly violated. *Id.* at 1331. The plaintiff also alleged that defects in "hardness, durability, composition, and finish" that deviated from the device's "FDA[] requirements . . . were the proximate cause of his injuries." *Id.*

Based on *Mink*, plaintiffs often argue that they sufficiently alleged a parallel claim by citing any number of federal or FDA regulations coupled with blanket causation allegations. As plaintiffs argue it, that reading of *Mink* essentially allows any plaintiff savvy enough to plead "violation" and "causation" to survive express preemption at the pleadings stage. Fortunately, courts within the Eleventh Circuit are starting to see through, and reject, that tactic.

Manufacturers are succeeding in defeating post-*Mink* claims by employing several useful arguments. One fundamental point is that manufacturing defect was the only pure "defect" theory alleged in *Mink*. Thus, design and warnings claims are preempted like they were under *Wolicki-Gables*. For example, absent an "allegation that [the manufacturer] somehow altered the design of the device from the design approved by the FDA during the rigorous PMA process . . ., [a] design defect claim is expressly preempted." *Romer v. Corin Grp., PLC*, No. 2:18-CV-19-FTM-99MRM, 2018 WL 4281470, at *5 (M.D. Fla. Sept. 7, 2018).

In turn, any theory that a manufacturer possessed a duty to provide warnings different from the FDA-approved warnings is expressly preempted because it necessarily would impose a requirement that is different from, or in addition to, the FDA-imposed requirement. *See Rowe v. Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1295 (M.D. Fla. 2018) (warnings claims expressly preempted where the plaintiff "[did] not allege that [the manufacturer] failed to give the warning required by the FDA and federal requirements" and therefore "attempt[ed] to hold [the manufacturer] to a state-law requirement that is different or in addition to what federal law requires"); *see also Tinkler v. Mentor Worldwide, LLC*, No. 1:19-CV-23373-UU, 2019 WL 7291239, at *5 (S.D. Fla. Dec. 30, 2019) (holding that a parallel claim might exist if, "for example, [] the FDA granted premarket approval based on specific warning language in proposed labeling, but then the manufacturer omitted such language from the labels that went to market, if such omission caused the plaintiff's injuries").

The battle after *Mink* focuses typically on manufacturing defect. Even here, though, multiple successful arguments exist. First, a plaintiff still must "identify the specific federal regulations or statutes that the [manufacturer] purportedly violated." *Green v. Medtronic, Inc.*, No. 1:19-CV-3242-TWT, 2019 WL 7631397, at *4 (N.D. Ga. Dec. 31, 2019). Allegations about "unspecified CGMP regulations" are insufficient because "CGMP regulations are 'general by design' and

manufacturers must tailor them to their specific safety and efficacy needs." *Id.*

Even if "violations of CGMP regulations could conceivably serve as the basis for [a] parallel products liability claim" under *Mink*, the plaintiff is not excused from the *Wolicki-Gables* standard of "identifying the specific CGMP regulations at issue and providing 'sufficient factual detail' to substantiate [the] allegations." *Id.* at *5 (citing *Cline v. Advanced Neuromodulation Sys., Inc.*, 921 F. Supp. 2d 1374, 1379 (N.D. Ga. 2012) (citing *Wolicki–Gables*, 634 F.3d at 1301)). "Gesturing to the entire federal regulatory scheme as if it were a monolith does not suffice." *Id.*; *see Sharp v. St. Jude Med., S.C., Inc.*, 396 F. Supp. 3d 1250, 1259 (N.D. Ga. 2019) (agreeing with the argument "that it is conclusory" to allege that a defect "was 'in violation of the PMA,' without specifically stating the PMA requirements violated").

This reasoning is consistent with the holding in *Wolicki-Gables* that, for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under 21 U.S.C. 360k(a), the plaintiff must show that the requirements are "genuinely equivalent." *Wolicki-Gables*, 634 F.3d at 1300 (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)). State and federal requirements are not generally equivalent if a manufacturer could be held liable under state law without having violated federal law. *See, e.g.*, *McMullen*, 421 F.3d at 489. Thus, to state a claim for a manufacturing defect, a plaintiff must identify a specific regulatory violation and allege "specific PMA requirements that have been violated." *Wolicki-Gables*, 634 F.3d at 1301-02.

Second, a plaintiff also must sufficiently allege a claim under state law to survive *Twiqbal*. Blanket allegations of a "nonconformity" that "caused" the plaintiff's injury are insufficient. *Sharp*, 396 F. Supp. 3d at 1256 (rejecting the argument "that 'it is enough to allege that the device did not conform to PMA requirements, and that this nonconformity was the cause of the plaintiff's injury'"). Likewise, allegations of a "malfunction" or that lack "facts that point to specific PMA requirement[s] that have been violated" fail on the pleadings. *Id.* at 1256–57.

Notably, courts should treat this point as a fundamental requirement to state a claim "and not wait for discovery on such matters." *Id.* at 1257 (rejecting the plaintiff's argument about "a need for discovery" to plead a claim). In short, conclusory allegations without "facts" supporting a claim based on a PMA requirement fall short of the *Twiqbal* standard. *See Wolicki-Gables*, 634 F.3d at 1302 (explaining that the complaint must "allege facts . . . demonstrating the presence of the elements of a parallel claim"); *Kaiser v. DePuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1191 (M.D. Fla. 2013) ("the complaint must set forth facts pointing to specific PMA requirements that have been violated").

Third, even presuming allegations sufficient to pass the tests above, a nexus is required and the alleged violations of specific federal requirements "must . . . relate to the plaintiff's medical device and alleged injury." *Lederman v. Howmedica Osteonics Corp.*, 950 F. Supp. 2d 1246, 1250 (M.D. Fla. 2013) (granting motion to dismiss and holding that "[p]laintiff fail[ed] to plead the necessary nexus between the [violations], his device, and his injuries"); *see Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1283 (N.D. Ga. 2014) (finding that "[p]laintiff lists a number of critical observations, but fails to allege how they are linked to her claims"). For example, if a plaintiff bases claims on FDA warning letters, the claims still require not only "alleg[ations] [of] the specific federal requirements applicable to his medical device" that were allegedly violated, as well as the violations themselves, but also "how those violations caused his claimed defect and injury." *Lederman*, 950 F. Supp. 2d at 1250.

Fourth, a manufacturing-defect claim cannot pass muster as a disguised "design" claim. State tort law usually defines a manufacturing defect as a deviation from intended specifications that renders the device unreasonably dangerous. Allegations that some aspect of the product posed a risk of injury, or the manufacturer failed to inspect, test, or validate the product sufficiently, or that quality control was insufficient, or about the general manufacturing process, are design claims, not manufacturing claims. *See generally Hall v. Sunjoy Indus. Grp., Inc.*, 764 F. Supp. 2d 1297, 1302-03 (M.D. Fla. 2011) (holding that a "claim fails because [p]laintiffs present no evidence on causation regarding how any general failure to test or inspect could prove a manufacturing defect in the specific [product] used by [plaintiff]").

Accordingly, courts recognize that a plaintiff cannot argue supposed "problems" with the product that "indicate a 'design' defect, which is preempted, as opposed to a manufacturing defect." *Sharp*, 396 F. Supp. 2d at 1259-60. Allegations that are aimed, at heart, at a device's design do not survive simply because a plaintiff gratuitously tosses in catch-phrases like "as manufactured" or "negligently manufactured."

Cases that allow manufacturing-defect claims to survive based on threadbare allegations tend to linger and consume through discovery the parties' and the court's resources before failing at summary judgment. That outcome is at odds with the reasoning in *Riegel* that protects manufacturers of PMA medical devices because FDA rigorously scrutinizes such applications by "'weig[hing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. §360c(a)(2)(C)). As the Supreme Court explained in *Riegel*, lay juries (unlike the FDA) are ill-equipped to perform cost-benefit analyses because "[a] jury … sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Id.* at 325.

The winning arguments outlined above help set the stage for early victories on dispositive motions with little or no time spent on discovery, thereby returning to the protections from unnecessary litigation that *Riegel* and *Wolicki-Gables* provided. Employing these arguments on express preemption will rebut plaintiffs' go-to tactics, reduce litigation costs for medical-device manufacturers, and help adhere to the principles set forth in *Riegel* and its progeny.

David J. Walz is a shareholder in the Tampa office of Carlton Fields, P.A. Dave focuses on the defense of actions involving all types of prescription medicines, medical devices, and over-the-counter medical products. He is a member of the DRI Drug and Medical Device Steering Committee, Product Liability Committee, and Trial Tactics Committee, along with various other professional and defense organizations.

Caycee D. Hampton is a litigation associate in the Tampa office of Carlton Fields, P.A. Caycee concentrates on the national and local defense of complex litigation for pharmaceutical, medical device, and cosmetic manufacturers in federal and state courts. Her practice includes general products liability, mass tort, premises liability, and medical malpractice cases.

Lien In: How Third-Party Lien-Based Medical Funding May Impact Your Case

By Anne A. Gruner and Dana J. Ash


Third-party litigation funding of lawsuits has gained significant prominence in the last few years. Many litigants are familiar with the traditional model in which hedge funds and other financiers invest in lawsuits in exchange for a percentage of any settlement or judgment. However, a potentially lesser-known structure in the personal injury and products liability context is that of lien-based medical treatment, in which third parties or even doctors themselves arrange and finance medical care on a lien basis, and recover from the plaintiff after the case resolves. Due to the nature of these arrangements and the potential implications when a treating physician may have a financial interest in the case, such lien-based medical funding raises unique considerations as to bias, medical billing, and related discovery and admissibility issues that should be considered.

What Are "Lien Doctors" and Lien-Based Medical Treatment?

The basic arrangement for lien-based medical financing is one in which a doctor will perform services on a lien basis and will recover the lien amount at the conclusion of the action from a settlement or verdict. To facilitate this practice, companies and directories have formed for the purpose of connecting attorneys with doctors who will perform medical treatment for prospective plaintiffs on a lien basis. Sometimes the arrangements are also made through a litigation finance company that contracts with doctors to provide the medical care; the companies purchase the services from the doctors at a discounted rate and in turn contract with the plaintiffs to recover the full cost of medical care from any settlement or judgment. The contracts commonly prevent the plaintiffs from submitting claims to insurance and often require full repayment of the debt regardless of the outcome of the lawsuit. *See* Sara Randazzo, Who Wins in a Personal-Injury Lawsuit? It

Can Be the Doctor. In a little-known but growing practice, doctors are taking payment through liens tied to any wins in court, The Wall Street Journal Online (Jan. 8, 2020).

Advocates of lien-based medical treatment and the companies promoting the practice cite reasons centered on increasing patient access to treatment—such as medical emergencies requiring out-of-network care, provider preferences, and circumstances in which a patient does not have medical insurance or cannot otherwise afford medical treatment. While these types of arrangements can be attractive for patients lacking insurance or other options for treatment, they have been criticized for the potential to inflate medical bills and consequently drive up litigation costs and damages.

For example, some websites advertise that the lien doctors are vetted not only for their medical credentials, but for their willingness to testify in court. *See* Surgeons on a Lien (last visited Apr. 23, 2020). There are also arguments that so-called lien doctors are incentivized to testify favorably for a plaintiff; if the plaintiff does not recover, the doctor might not be able to recover on a direct lien, or may lose out on patient referrals from a third-party funding or referral company. Where the provider has a financial interest in the outcome of the litigation, serves as a witness in the case, and also has discretion over the rates charged and ultimately sought to be recovered, there should be obvious potential for bias. Concern should exist, and at least be explored, where financial arrangements might create incentives for physicians who treat litigants to provide unnecessary treatment or charge unreasonable rates for treatment. The potential impact can be multiplied, as jurors might base non-economic injury awards to some extent on amounts of economic damages awards. As a result, discovery into the existence and nature of lien and medical funding agreements, and attempts to introduce such evidence at trial, can be of critical importance.

The Significance of These Funding Arrangements and the Collateral Source Rule

Broadly speaking, courts have been reluctant to require disclosure of third-party litigation funding, determining that such funding agreements (a) are simply not relevant to the issues being tried and, to a lesser extent, (b) may warrant work-product protection. *See, e.g.*, *Kaplan v. S.A.C. Capital Advisors, L.P.*, No. 12-CV-9350, 2015 WL 5730101, at *3, 5 (S.D.N.Y. Sept. 10, 2015) (rejecting argument seeking third-party funding information to determine if such arrangements affected strategic decisions or affected the interests of the class, stating that the defendants had offered "no nonspeculative basis" for their concerns); *MLC Intellectual Prop., LLC v. Micron Tech., Inc.,* No. 14-cv-03657, 2019 WL 118595, at *2 (N.D. Cal. Jan. 7, 2019) (rejecting arguments for discovery of funding agreements to show bias or conflicts of interest); *Lambeth Magnetic Structures, LLC v. Seagate Tech. (US) Holdings, Inc.*, Nos. 16-538, 16-541, 2018 WL 466045, at *1, 5 (W.D. Pa. Jan. 18, 2018) (denying discovery into communications and agreements between plaintiff and litigation funding organizations and finding such materials were protected as work product). In addition to this general reluctance, within the medical financing context, collateral source rules have been relied upon to preclude introduction of information about funding for the plaintiff's medical treatment.

The collateral source rule, in general terms, is based on the principle that a plaintiff's recovery should not be reduced, and a tortfeasor may not benefit, due to compensation from a source other than the defendant. Typically, this rule is used to bar admission of evidence that a plaintiff's medical bills have already been paid by the plaintiff's insurer, so that the plaintiff may recover the full value of the medical bills from the defendant. This stems from a policy consideration that an at-fault defendant should not benefit from the plaintiff's decision to purchase insurance.

Because of the distinctions between pre-existing insurance coverage which may indemnify a plaintiff, versus third-party funding which is acquired post-incident and inherently seeks to maximize the recovery from a lawsuit, some courts have begun to recognize that funding arrangements for the provision of medical services and payment of medical bills should be treated differently, and may be discoverable and/or admissible for certain specific purposes. Other courts have determined that such arrangements do not constitute collateral source payments if the plaintiff retains full responsibility for the full medical costs. These cases are still emerging and, as illustrated by the examples below, are heavily dependent on the jurisdiction.

Discoverability and Admissibility of Medical Financing

Financing of medical expenses has been found to be discoverable in certain jurisdictions as an exception to the collateral source rule where the evidence is for some other evidentiary purpose, such as to show bias. In *ML Healthcare Serv., LLC v. Publix Super Markets, Inc.*, 881 F.3d 1293, 1303 (11th Cir. 2018), the Eleventh Circuit upheld the district court's decision to allow at trial evidence of a financial relationship between the plaintiff, her doctors, and the related third-party investment company ML Healthcare. In

this slip-and-fall case, the plaintiff sued defendant Publix supermarket alleging medical injuries. *Id.* at 1296–97.

At trial, the district court denied the plaintiff's motion in limine to exclude evidence related to the funding entity ML Healthcare, and also denied the plaintiff's motion to quash trial subpoenas for ML Healthcare witnesses to testify regarding the funding relationship. *Id.* at 1297. The Court reasoned that Georgia's collateral source rule was not an absolute bar to evidence of third-party indemnity and, while it precludes a tortfeasor from receiving a set-off on the damages due to payments from a third party, there are potential evidentiary circumstances in which collateral source payments may be admissible. *Id.* at 1301. Under the applicable contract, ML Healthcare contracted with the plaintiff's doctors to purchase the medical bills generated at a discounted rate, and in turn also contracted with the plaintiff to recover the full cost of the medical expenses from any settlement or judgment, capturing the delta between billed and actually paid medical expenses generated by the collateral source rule. *Id.* The contract also required the plaintiff to repay the medical bills in full in the event of no award or an insufficient award. *Id.* at 1301–02. Defendant Publix argued that since there was a risk that the plaintiff would not be able to pay the difference in the event of a lower award or no award, the relationship incentivizes ML Healthcare to work with doctors who will win their lawsuits through favorable causation opinions, creating an inherent risk of bias. *Id.* at 1302. The Eleventh Circuit agreed with the district court's decision to admit the evidence to show potential bias on the part of the plaintiff's testifying treating doctors, considering both relevance and prejudice considerations under Federal Rules 401 and 403. *Id.* at 1302–03. Since Publix ultimately did not use the ML Healthcare evidence at trial to challenge the reasonableness of the claimed medical expenses, the Eleventh Circuit did not rule on whether the district court's related decision to allow admission of such evidence for that purpose was proper. *Id.* at 1304.

However, another Georgia federal court has held that the existence of third-party funding relationships may be admissible (with a limiting instruction regarding collateral source payments) for the purpose of challenging the reasonableness of claimed medical expenses, since there is a motivation to increase the plaintiff's medical bills to enhance the funder's recovery. *See Rangel v. Anderson,* 202 F. Supp. 3d 1361, 1374 (S.D. Ga. 2016).

Beyond Georgia, the rationale that third-party medical funding arrangements may be relevant and discoverable as evidence of potential bias has been applied in other jurisdictions. For example, in Utah, the district court granted the defendants' discovery motion regarding objections by the third-party funder to a deposition subpoena, and determined that the information sought from the third-party medical financing company was permissible because it was "relevant as to bias, prejudice, credibility, and/or the financial interest of" the company and the plaintiff's treating physician. *Estrada v. Kaczinski*, No. 2:17-cv-952, 2018 WL 6313390, at *2 (D. Utah Dec. 3, 2018). The court specifically based its ruling on the fact that the case was in the discovery phase and did not address whether such evidence would be admissible at trial under Utah's collateral source rule. *Id.*

In Nevada, the Supreme Court of Nevada went a bit further and stated that evidence of medical bill liens held by a third-party financer could be admissible to show bias on behalf of the plaintiff's treating physicians who testified at trial. *See Khoury v. Seastrand*, 377 P.3d 81, 93–94 (Nev. 2016). However, the Court ultimately ruled that the trial court's exclusion of such evidence was not prejudicial, since the witnesses were paid to prepare for and testify at trial and were cross-examined on bias in that context, and because the plaintiff's experts also provided causation opinions beyond those of the treating physicians. *Id.* at 94.

Third-party financing of medical treatment may also be discoverable where the plaintiff does not actually obtain a benefit from the financing arrangement and retains liability for the full amount of medical expenses, on the theory that such an arrangement does not compensate or indemnify the plaintiff so as to constitute a collateral source. In *Ortiviz v. Follin*, No. 16-cv-02559, 2017 WL 3085515 (D. Colo. July 20, 2017), the District of Colorado denied the third-party funder's motion to quash a subpoena for third-party funding discovery because there was "at least a fair basis" for concluding that the third-party funding arrangement "is not a collateral source." *Id.* at *3. There, the plaintiff contracted with a third party that paid the plaintiff's medical bills at a discounted rate, and in turn, the plaintiff granted the third party a lien against any future recovery in the full amount of the medical bills. *Id.* at *1. The discovery was sought to show the reasonable value of the plaintiff's medical expenses. *Id.* The court reasoned that the collateral source rule only applies "when the third party compensates or indemnifies the plaintiff," and in this case, the funding agreement required the plaintiff to pay the funder the full amount of his billed expenses regardless of his recovery." *Id.* at *3. In circumstances such as these, where the plaintiff does not receive at least partial indemnification or payment for his injuries, there is not concern for the jury reducing the verdict by an amount the plaintiff has already

recovered. *Id.* However, while allowing the discovery, the court left open whether such information would later be admissible evidence at trial. *Id.* at *4.

While these cases show some potential for discovery and even admissibility of medical financing arrangements, there are still of course cases precluding it and the viability of subpoenas, motions to compel, motions in limine, and the like on these issues will depend on a case-by-case analysis dependent on the jurisdiction. As litigation funding continues to thrive, case law may continue to emerge and develop in this area.

Takeaways

Due to the emergence of third party litigation funding in recent years, most defendants have revised their standard discovery requests to include written discovery targeting the existence and nature of third-party litigation funding arrangements. Since many jurisdictions have been reluctant to order the discovery of such materials where the argument for disclosure is to reveal a potential risk of bias that is only general or speculative, defendants in the products liability and personal injury context may consider refining requests to specifically target arrangements with doctors or other companies that may have financed the plaintiff's medical treatment—as some courts may offer more leeway in permitting discovery of such arrangements due to the more targeted concern of bias on behalf of a medical provider-witness arguably with a financial interest in the case.

In addition to written discovery, counsel should be mindful to question treating physicians during deposition on their relationship with the plaintiff-patient, how they were referred, and whether they have any contingent right to benefits or compensation in the litigation. Medical billing records may also be useful in discovering such relationships, particularly if there is not insurance coverage identified—medical provider billing records might disclose a third-party financing payor or other similar arrangement. Litigants should also familiarize themselves with the applicable collateral source rule in the jurisdiction to determine if there are arguments for seeking introduction of third-party payments for evidentiary purposes other than reducing the plaintiff's claimed damages award, such as to show potential bias on behalf of the treating physician.

Anne A. Gruner is a trial attorney representing clients nationally in complex products liability, mass tort and commercial litigation disputes. She regularly represents manufacturers of medical implant devices in both individual and consolidated cases and counsels clients in pre-litigation phases through resolution. She is based in Duane Morris' Philadelphia office.

Dana J. Ash is chair of the Products Liability and Toxic Torts division of Duane Morris' Trial Practice Group and serves as a team lead for the Duane Morris Life Sciences and Medical Technologies industry group. He practices in the areas of products liability and business litigation and has conducted trials in state and federal courts across the United States.

Sharon O'Reilly, an associate in Duane Morris' Trial Practice Group, also assisted in the research and preparation of this article.

Heeding the Heeding Presumption in Pharmaceutical and Medical Device Failure to Warn Litigation

By Kelly Brilleaux and Troy Bell


In litigation, legal presumptions allow a party to establish a fact without proof until the other party offers sufficient evidence to rebut it. An example specific to products liability law is the "heeding presumption," which allows for a presumption that, had the plaintiff been provided with an adequate warning by the manufacturer, the plaintiff would have read and heeded that warning. This presumption, though, is not only contrary to human behavior but also results in an inequitable shifting of the burden of proving causation from the plaintiff to the manufacturer. Many jurisdictions no longer recognize the heeding presumption; however, in those that do, it is further complicated by its potential intersection with the learned intermediary doctrine, pursuant to which manufacturing defendants' duty to warn extends only to physicians in their role as a learned intermediary between the manufac-

turer and the patient. Fortunately, in those jurisdictions that still apply it, the defendant can rebut the heeding presumption with the use of certain evidence. This article will provide a brief background on the history of the heeding presumption, identify case law addressing the complexities of its application in the context of the learned intermediary doctrine, and, finally, offer strategies for effectively rebutting the presumption.

The History Behind the Heeding Presumption

Comment j to the Restatement (Second) of Torts long recognized that when a product warning is provided, a manufacturer may "reasonably assume that it will be read and heeded" and that the product is not "unreasonably dangerous" if that product is safe for use when that warning is followed. Restatement (Second) of Torts §402A cmt. j (1965). The unfortunate corollary to this presumption, called the "heeding presumption," was introduced by the Texas Supreme Court in *Technical Chem. Co. v. Jacobs,* 480 S.W.2d 602 (Tex. 1972). The *Jacobs* Court construed the language of comment j to the Restatement (Second) of Torts as suggesting that the law "should supply the presumption that an adequate warning would have been read." *Id.* at 606 (citing Restatement (Second) of Torts §402A, cmt. j). The Court reasoned that "[w]here there is no warning, as in this case, however, the presumption that the user would have read an adequate warning works in favor of the plaintiff user." *Id.* It further held that "[t]he presumption, may, however, be rebutted if the manufacturer comes forward with contrary evidence that the presumed fact did not exist." *Id.* (internal citation omitted). In doing so, the *Jacobs* Court created an illogical corollary to this reasonable presumption in products liability law that would effectively allow future litigants to prove causation by simply relying on the heeding presumption.

In reality, however, neither the heeding presumption—nor the original presumption set forth in Comment j, for that matter—represent an accurate reflection of human behavior. Even if it can be presumed that a reasonable person would have read an adequate warning if one was provided, there is nonetheless no guarantee, or even indication, that the reasonable person would heed that warning. For example, traffic signs and the mandatory Surgeon General's warnings on both cigarette packaging and alcohol are examples of warnings that millions of "reasonable" people fail to heed daily despite their knowledge of the risks associated with the behavior against which they warn.

In fact, when Section 402A was superseded by Restatement (Third) of Torts, the drafters of the Third Restatement expressly recognized this principle, characterizing the language in §402A, Comment j as "unfortunate" and acknowledging criticism that the presumption "embodies the behavioral assumption" that "reasonable" users of a product will heed the warnings. *See* Restatement (Third) of Torts, Prod. Liab. §2, cmt. l (1998) (citing Howard Latin, *"Good" Warnings, Bad Products, and Cognitive Limitations*, 41 UCLA L. Rev. 1193 (1994)). In doing so, the Third Restatement has rejected the application of both the presumption in favor of the defendant and the heeding presumption. Hildy Bowbeer, Wendy F. Lumish, and Jeffrey A. Cohen, *Warning! Failure to Read This Article May Be Hazardous to Your Failure to Warn Defense*, 27 Wm. Mitchell L. Rev. 439, 462 (2000). Regardless, many jurisdictions continue to apply the "heeding presumption," notwithstanding the clear guidance from the Restatement (Third) of Torts.

In jurisdictions that recognize the heeding presumption, the plaintiff must initially prove only that "the manufacturer owed a duty to warn and failed to adequately do so: it is then presumed the user would have followed an adequate warning." *Id.* at 462. If the defendant successfully rebuts the presumption, the plaintiff must meet his original burden of proof—that the manufacturer's failure to warn was the proximate cause of his injury by a preponderance of the evidence. *Id*. If the manufacturer fails to introduce evidence to rebut the presumption, however, the plaintiff is relieved of this burden and can rely on the presumption to establish the essential element of causation. Historically, the heeding presumption is rebutted by introducing three different categories of evidence: the plaintiff's knowledge of the risk of which the allegedly absent warning was supposed to warn; the circumstances surrounding the plaintiff's use of the product that would "call into question whether the plaintiff would have noticed a warning if provided and would have been motivated to heed the warning if he had noticed it"; and, finally, plaintiff attitudes and any conduct that "demonstrates an indifference to safety warnings generally." *Id.* at 463.

Recognizing the Problem of Applying the Heeding Presumption in the Context of the Learned Intermediary Doctrine

In addition to the issues with applying the heeding presumption in traditional products liability cases, the application of the heeding presumption alongside the learned intermediary doctrine is particularly problematic, as it seemingly refuses to consider both the weight of the

learned intermediary's risk-benefit calculation and the relative nature of the alleged injury compared to the product's benefit. Under a traditional reading of the heeding presumption, "heeding" the warning would mean that the plaintiff would necessarily avoid the risk altogether. The application of the heeding presumption under these circumstances, however, runs afoul of the well-known principle that all pharmaceutical and medical device products have inherent risks and benefits, as recognized by Comment k to the Restatement (Second) of Torts, which states that certain products are "unavoidably unsafe." *See* Restatement (Second) of Torts §402A cmt. k (1965). This, of course, is the very foundation of the learned intermediary doctrine: that the physician, as a learned intermediary standing between the manufacturer and the patient, is in the best position to evaluate those risks and benefits and to advise the patient accordingly in order to maximize the chance that the patient will avoid potential injury. *See Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).

The United States Court of Appeal for the Tenth Circuit analyzed the complexities of applying both the learned intermediary doctrine and the heeding presumption in *Eck v. Parke, Davis & Co.,* 256 F.3d 1013, 1018 (10th Cir. 2001). In *Eck,* the manufacturing defendants filed for summary judgment on the plaintiffs' failure to warn claims. Pursuant to Oklahoma law, the Tenth Circuit applied the heeding presumption in the plaintiffs' favor, noting that it could be successfully rebutted by proving that, "although the prescribing physician would have 'read and heeded' the warning or additional information, this would not have changed the prescribing physician's course of treatment." *Id.* at 1019. The court disagreed with plaintiffs' definition of "heed," which, according to plaintiffs, meant that the prescribing physician would have both read *and given* the warning to the patient. *Id.* at 1021. Rather, the court reasoned, in the context of the learned intermediary doctrine, the word "heed" means "only that the learned intermediary would have incorporated the 'additional' risk into [her] decisional calculus." *Id.* (internal citations omitted).

Notably, however, the Tenth Circuit declined to go so far as to hold that the "physician's conduct automatically acts as an intervening cause relieving the manufacturer of liability," but rather recognized that Oklahoma law shifts the burden back to the plaintiff "to allow him to controvert the physician's testimony." *Id.* at 1023. The *Eck C*ourt found, however, that plaintiffs failed to controvert the defendant's evidence and that the patient's prescribing and treating physicians would not have changed their course of treatment if provided with the additional risk information. *Id.* at 1024. The court ultimately affirmed the district court's summary judgment ruling in favor of defendants, holding that the plaintiffs could not establish causation. *Id.*

In *Nall v. C. R. Bard, Inc.,* an MDL court specifically recognized the problem of applying the heeding presumption in the context of the learned intermediary doctrine when the defendant manufacturer sought summary judgment on plaintiff's failure to warn claims. No. 2:13-CV-01526, 2018 WL 521791 (S.D.W. Va. Jan. 23, 2018). Pursuant to Missouri law, which the court applied under the applicable choice-of-law provisions, the court recognized that both the learned intermediary doctrine and the heeding presumption applied to the claims. *Id.* at *3-4. The defendant sought to rebut the presumption by presenting the treating physician's testimony that he did not rely on the product's "instructions for use" before recommending the product to the plaintiff. *Id.* at *3. The court acknowledged that, based on the physician's testimony, whether the plaintiff could prove that an adequate warning would have affected the physician's conduct was "of course, speculative." *Id.* Reasoning that Missouri law had not yet determined the application or scope of the heeding presumption in the context of a learned intermediary, the Court ultimately reserved the defendant's motion on those points for trial. *Id.* at *4. The Court held that the issue of "[w]hether the heeding presumption transfers to a physician" was a determination for the court on remand, and that whether the physician would have "altered his recommendation" of defendant's product had it "provided an adequate warning" was a question for a jury. *Id.*

These decisions articulate just a few of the many issues raised by applying the heeding presumption into the framework of the learned intermediary doctrine. *Eck* highlights the problem with interpreting the meaning of the word "heed" in the context of the learned intermediary doctrine, which may not be consistent across jurisdictions that apply the presumption. Further, *Nall* demonstrates the overall difficulty in determining the scope of the presumption while also applying the learned intermediary doctrine—after all, by definition, the learned intermediary must analyze a warning label that is both sophisticated and highly technical, assess the relative risks and benefits of a product based on his or her knowledge and experience, and then advise patients of a recommendation within his or her medical judgment.

Yet another issue is that many of the traditional evidentiary bases used to rebut the presumption—such as demonstrating whether the plaintiff was motivated to heed the warning, for example, or establishing a general indifference to safety warnings—simply don't translate

neatly when the learned intermediary doctrine also applies. The presumption can be rebutted, though, in the context of the learned intermediary doctrine by producing evidence that may break the causal link between the manufacturing defendant and the plaintiff.

Rebutting the Heeding Presumption

Generally, in pharmaceutical and medical device litigation, the heeding presumption may be rebutted with evidence that additional warning information would not have changed the learned intermediary's treatment decision. This can be accomplished with evidence that the inclusion of additional warning information would have been futile, because the physician would not have read it, or that the inclusion of such information would not have changed the treatment decision of the learned intermediary, because the physician had already considered the risk and factored it into the risk-benefit analysis. Thus, when deposing a prescribing or treating physician, it is particularly important to ask specific questions that may further these arguments, including whether the physician was aware of the alleged risk independent from the product label; whether the physician based treatment decisions on medical training rather than relying on product labels; whether the physician failed to read any labels for a particular product after a certain date; or whether the physician would have made the same treatment decision even if the additional warning information had been included in the product labeling. And although such testimony is key in nearly every case in which the learned intermediary doctrine applies, it is especially critical to elicit testimony that is precise and unequivocal when rebutting the heeding presumption.

For example, in *Baker v. App Pharms, LLP,* the District of New Jersey applied the heeding presumption when considering defendant's summary judgment motion under New Jersey law, finding that the presumption permits a finding "that the plaintiff's physician would not have prescribed the drug to the plaintiff if there had been an adequate warning." No. 09-05725, 2012 WL 3598841, at *8 (D.N.J. Aug. 21, 2012). It noted that the presumption could be rebutted by the manufacturer, however, with a showing that the prescriber "was aware of the risks of the drug that [he] prescribed, and having conducted a risk-benefit analysis, nonetheless determined its use to be warranted." *Id.* (internal citations omitted). The court further recognized that "a manufacturer who fails to warn the medical community of a particular risk" may be relieved of liability under the learned intermediary doctrine if "the prescribing physician either did not read the warning at all, . . . or if the physician was aware of the risk from other sources and considered the risk in prescribing the product," as this would constitute a "superseding or intervening cause that breaks the chain of liability" between the manufacturer and plaintiff. *Id.* (internal citations omitted).

In *Baker*, the physician's testimony revealed that he regularly used the product at issue, did not read the labels of pharmaceutical products that he "prescribed often" (which included the product at issue), stood by his decision to use the product under the circumstances, and was familiar with both the risks and benefits of the product—including the risk at issue. *Id.* at *9. Further, the court recognized that the plaintiff failed to introduce any evidence that the physician would have consulted additional warnings. *Id.* Therefore, it held that a different warning would not have made a difference in the plaintiff's treatment or outcome because her physician "would not have reviewed it." *Id.* The court ultimately concluded that "no reasonable jury could conclude that a different label" would have changed the physician's decision and thus granted the defendant's motion for summary judgment. *Id.* at *10.

There are many arguments in favor of abandoning the heeding presumption altogether and, indeed, many jurisdictions have adopted this approach. In jurisdictions that continue to apply the heeding presumption in pharmaceutical and medical device failure to warn cases, it is necessary to take steps early in the litigation in order to sufficiently protect the interests of your client. An important first step is to determine whether the presumption applies in the jurisdiction in which your case is pending and, if it does, review the applicable case law on the evidence necessary to rebut the presumption. Whatever you do, be sure to heed the heeding presumption and its potential effect on the outcome of your opponent's failure to warn claims.

Kelly E. Brilleaux is a member at Irwin Fritchie Urquhart & Moore, LLC, and practices primarily in the areas of products liability, pharmaceutical and medical device litigation, and mass tort litigation. She is a member of the Association of Defense Trial Attorneys, the Federation of Defense and Corporate Counsel, and has appeared on the Rising Star list of Louisiana Super Lawyers in the area of Products Liability. Kelly attended Louisiana State University Paul M. Hebert Law Center, where she served as a Senior Editor of the Louisiana Law Review.

Troy L. Bell is an associate attorney at Irwin Fritchie Urquhart & Moore, LLC in New Orleans, LA. He practices primarily in the areas of products liability, mass torts litiga-

tion, and medical device and pharmaceutical litigation. He is a member of DRI. He has 20 years of experience working in the medical device and pharmaceutical industry. Troy attended Southern University Law Center.