2023 Products Liability Conference Caselaw Update

Compiled by:

YL Chair and Liaison: Xan Ingram Flowers, Butler Snow, LLP, 1819 5th Ave. N., Ste. 1000, Birmingham, AL 35205

As a member of Butler Snow's Products, Catastrophic and Industrial Litigation and Appellate practice groups, Xan focuses her practice on defending product manufacturers in complex litigation and mass tort cases. Xan's experience spans every stage of a case, whether that be a trial or final hearing in a litigated or arbitrated matter, or in immigration court, or seeking appellate relief via mandamus petitions, or interlocutory or secondary appeals. Xan has argued in front of the Court of Appeals for the Eleventh Circuit, regularly practices in both state and federal trial and appellate courts, and been selected to act as special appellate counsel, amicus counsel, pro bono counsel, and trial counsel. In addition to her product liability and appellate practices, Xan also has experience advocating for her clients in a wide range of commercial, insurance, bankruptcy, OSHA, and personal injury litigation, including recently achieving a defense verdict in a personal injury matter in Alabama state court.

YL Vice-Chair: Jason Hodge, Nelson Mullins Riley & Scarborough, LLP, 901 E. Byrd Street, suite 1650, Richmond, VA 23219

Jason focuses his practice on advanced motions, with an emphasis on products liability defense, class actions, multidistrict litigation, and appeals. He works with clients on matters in federal and state court from coast to coast. As both a principal and contributing brief writer in many of his cases, Jason authors motions at all stages of litigation, including motions to dismiss, motions for summary judgment, motions to strike, Rule 702 motions, various discovery and non-dispositive motions, and briefing on interlocutory and final appeals. He provides foundational support to the briefing and trial teams with meticulous legal research and analysis and actively participates in the development of global defense strategy. He has experience with traditional case work-up, including taking depositions and providing discovery strategy and analysis. He also works on appeals from the amicus perspective, authoring amicus briefs and promoting client interests and positions.

YL Marketing Chair: Amber Bonnell, Gowling WLG, 345 King S. W, Ste. 600, Kitchener, Ontario, N2G 0C5, Canada

Amber (she/her) is an associate lawyer, practising in Commercial Litigation within the broader Advocacy Group of Gowling WLG's Waterloo Region office. Amber's practice includes a wide variety of commercial matters, including product liability litigation, real estate litigation, property law disputes, estate litigation, collections, and various contract disputes. Amber assists a wide range of clients, from individuals to multinational businesses, across diverse sectors, including the tech, automotive, and product manufacturing sectors, as well as local establishments. Amber has successfully represented clients at a variety of levels of Court. She takes a holistic approach in assisting clients in finding creative resolutions to contentious legal issues.

YL Liaison: Frederick King, Troutman Pepper Hamilton Sanders LLP, 600 Peachtree St. NE, Suite 3000, Atlanta, GA 30308

Frederick is an associate attorney in the firm's Health Sciences Litigation Practice Group. He focuses his practice on civil litigation involving pharmaceutical companies, medical device manufacturers, and health care industry clients. He has represented clients at all stages of litigation, including trial, and enthusiastically digs into his cases, ensuring no stone is left unturned in advocating for his clients. He has argued motions in court, helped bring cases through discovery, and worked on trial teams for complex healthcare cases across the U.S. In addition to his healthcare practice, Frederick maintains an active pro bono practice representing his clients in complex civil rights litigation. Before he joined the firm, Frederick served as a law clerk to the Honorable Lisa Godbey Wood of the Southern District of Georgia.

FIRST CIRCUIT:

Christopher J. Hurst, Smith Duggan Cornell & Gollub, LLP, 101 Arch Street, Suite 1100, Boston, MA 02110

Federal law impliedly preempts state law claim that drug manufacturer should have warned of animal studies and possible link to birth defects

***In re: Zofran (Ondanestron) Prods. Liab. Litig.,* 57 F.4th 327 (1st Cir. 2023)**

The First Circuit Court of Appeals affirmed the district court's grant of summary judgment for a drug manufacturer where the MDL plaintiffs claimed that the manufacturer should have warned prescribing doctors and pregnant women of a possible link to birth defects. The district court held that the claim was preempted because federal law prohibited plaintiffs' proposed drug label changes and the First Circuit affirmed. The women took the drug off-label to treat pregnancy-related nausea and vomiting.

Applying recent Supreme Court precedent, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019), the First Circuit held that the plaintiffs' proposed warning, that "animal studies showed harm to the fetus when Zofran was ingested during pregnancy," was preempted because compliance with both plaintiffs' proposed drug label changes and with federal law was impossible, and that the manufacturer had satisfied the necessary elements of its preemption affirmative defense as a matter of law.

The First Circuit rejected plaintiffs' argument that the manufacturer could have invoked the FDA's Changes Being Effected ("CBE") procedure, which allows manufacturers unilaterally to amend an FDA-approved label and to seek after-the-fact approval for the change from the FDA. The CBE procedure is one of four pathways for the drug manufacturer, citizens, or the FDA itself to make changes to a drug's label. Manufacturers may use the CBE procedure "to reflect newly acquired information." The plaintiffs argued that three Japanese animal studies, which the manufacturer did not originally submit to the FDA as part of the new drug approval process, were sufficient "newly acquired information." The First Circuit held that the three animal studies were not "newly acquired" as a matter of law because the studies were not meaningfully different than other studies which the manufacturer submitted as part of the drug approval process. The three animal studies did not meet the definition of "newly acquired information," which is information that "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to FDA." The First Circuit found unpersuasive the opinion of plaintiffs' regulatory expert, a former FDA official, that the Japanese animal studies constituted newly acquired information. The court noted that the expert's opinion is "likely inadmissible" because the question of whether the studies constitute newly acquired information is a question of law and expert testimony on questions of law "is rarely admissible." Thus, the court concluded that there was insufficient evidence of newly acquired information to justify invoking the CBE procedure.

The First Circuit further held that even if the non-disclosed animal studies constituted "newly acquired information" based on which the manufacture could have invoked the CBE procedure, the FDA would have rejected plaintiffs' proposed change. Applying *Albrecht*, the First Circuit found that there was "clear evidence" that the FDA would have rejected the proposed

changes because in 2021, after the three Japanese animal studies had been disclosed to the FDA, the FDA approved a revised label on the drug that stated that animal data revealed "no significant effect . . . on the maternal animals or the development of the offspring." The court reasoned that "when the FDA formally approves a label stating one thing with full and obvious notice of the directly contrary position, one can read the approval as rejecting the contrary position." Therefore, there was clear evidence that the FDA would have rejected plaintiffs' proposed warning, and the district court properly awarded summary judgment.

Personal Jurisdiction: "relatedness" prong not satisfied where forum resident plaintiff eats contaminated food out of state but does not become ill from food poisoning until returning home to forum the next day; the relatedness doctrine still has teeth following the U.S. Supreme Court's 2021 Ford Decision

***Capello v. Restaurant Depot, LLC*, 21-cv-356-SE, 2023 WL 2588110 (D.N.H. Mar. 21, 2023) (appeal pending before First Circuit)**

The plaintiff, a New Hampshire resident, purchased and ate a salad from a restaurant in New Jersey. The restaurant prepared the salad using romaine that was distributed by the defendant California corporation. The plaintiff became ill the next day after he returned home to New Hampshire. The defendant distributes romaine products to major New England distributor and grocery stores with knowledge that its products will then be sold in New Hampshire.

The district court dismissed the plaintiff's complaint for lack of personal jurisdiction because the plaintiff could not meet his burden under the relatedness prong of the specific personal jurisdiction analysis. The district court rejected the plaintiff's argument that he could establish relatedness under the "more relaxed" standard of *Ford Motor Co. v. Montana Eighth Judicial Dist. Court*, 141 S. Ct. 1017, 1022 (2021). In *Ford*, the court held that the relatedness doctrine was satisfied because the plaintiffs were forum residents who were injured in the forum, and the defendant served a market for the vehicles in the forum, even though the defendant did not sell the plaintiff's particular vehicles in the forum. The plaintiff tried unsuccessfully to frame his jurisdictional facts within the framework of *Ford*, arguing that because of incubation periods, his injury actually occurred in-forum, like the *Ford* plaintiffs, not in New Jersey where he consumed the salad. The court rejected that argument, reasoning that "a jurisdictional rule driven by the length of an incubation period would be difficult to employ. It could result in a court concluding that a food-poisoning injury occurred in a state a plaintiff passed through only briefly as he traveled from the location of ingestion to his final destination. A court could do so only after it received and considered evidence regarding the bacteria's precise incubation period in a particular plaintiff." The court further reasoned that the plaintiff had offered "no legal justification for pinning the injury at the moment of the onset of symptoms rather than at the moment of consumption." An appeal of the decision remains pending before the First Circuit and will be argued December 6, 2023.

Toxic torts: summary judgment granted under admiralty law in asbestos case

***McIsaac v. Air & Liquid Sys. Corp.*, 19010282-NMG, 2023 WL 4409516 (D. Mass. July 7, 2023)**

Plaintiff alleged that her decedent was exposed to asbestos during his Navy service. The district court granted summary judgment for the defendant pump manufacturer for lack of sufficient product identification under admiralty law. The plaintiff's decedent died before being deposed, and the plaintiff's product identification evidence consisted of records demonstrating that the defendant's pumps were present on two ships that the plaintiff's decedent worked on, and the testimony of one of the decedent's former co-workers. The co-worker testified that he worked with the plaintiff's decedent on one or both ships, but that he could not recall the brand name or manufacturer of the pumps that they worked on together. Applying maritime law, the district court ruled that the plaintiff had failed to proffer sufficient facts to show that the decedent had a "high enough level of exposure" to the defendant's products to show that they were a substantial factor in causing his mesothelioma; the mere fact that the defendant's products were present somewhere at the place of work was not enough.

PFAS: denial of motion to dismiss failure to warn and strict products liability claims against paper mill suppliers

***Higgins v. Huhtamaki, Inc.*, 1:21-cv-00369-JCN, 2023 WL 6516538 (D. Me. Oct. 5, 2023)**

The Maine plaintiffs alleged that their groundwater wells were contaminated with PFAS by a paper mill operator and three chemical companies that supplied chemicals to the paper mill. The supplier defendants' motion to dismiss was denied. The district court ruled that the plaintiffs had sufficiently alleged that the supplier defendants had a duty to warn the paper mill of the risks associated with PFAS, and that their injury was proximately caused by the failure to warn. The district court rejected the supplier defendants' argument that the learned intermediary/sophisticated user doctrine barred plaintiffs' failure to warn claim because the plaintiffs could plead in the alternative that both the paper mill and the suppliers had a duty to warn and knew or should have known of the dangers of releasing residuals containing PFAS. The district court also rejected the defendants' argument that disposal of a product is not an intended use, noting that the defendants had cited no Maine case applying the intended use element, and that Maine law only required that "a plaintiff might reasonably have been expected to use, consume, or be affected by the product, which would cover foreseeable uses rather than limiting liability only to those uses that the manufacturer intended."

SECOND CIRCUIT:

Atasia Richardson, Esq., Abrams, Gorelick, Friedman & Jacobson, LLP, One Battery Park Plaza, 4th Floor, New York, New York 10004

***Buono v. Tyco Fire Prods.*, LP 2023 U.S. App. LEXIS 22331**

Plaintiff-Appellant, Franklin Buono, was severely injured during his employment when a test tank filled with compressed air exploded while he performed standard testing. Buono brought common-law claims for strict liability and negligence claims against the Defendant Tyco Fire Products, LP ("Tyco"), which through its subsidiary sold the tank to Buono's employer. Tyco moved for summary judgment, arguing that Buono's claims were preempted under the Hazardous Material Transportation Act of 1975 ("HMTA"), 49 U.S.C. § 5125(b)(1).

Buono's employer, Oprandy's Fire & Safety Inc., services, inspects, and repairs fire extinguishers, compressed air tanks, and fire suppression. In the course of his employment, Buono assisted his co-worker in assessing a fire suppression system known as "Kitchen Knight." As part of the testing, the pair used a test tank supplied by a subsidiary of Tyco and filled the empty tank with compressed air. The test tank was a DOT-type 4BW steel cylinder marked with the text "DOT 4BW 225 M453." Plaintiff checked the tank's pressure gauge and listened for air entering to the tank; however, he did not see the gauge move or hear any noise. Upon further tinkering to allow air into the test tank, the test tank ruptured, and shrapnel hit several fire extinguishers – causing an explosion.

This matter was removed from New York State Court to federal court based on diversity jurisdiction. Upon completion of discovery, Tyco moved for summary judgment on the ground that The Hazardous Materials Transportation Act of 1975 ("HMTA"), 49 U.S.C. § 5125(b)(1) preempted Buono's common law negligence claim based on failure to warn and Buono's strict products liability claim. The District Court granted Tyco's motion and held that HMTA unambiguously preempted any New York common law duties. On Appeal, Buono contended that HMTA did not preempt his common law claims.

When federal law preempts nonfederal law, the Supremacy Clause within Article VI of our Constitution requires courts to follow federal, not state laws. The courts are required to ascertain the intent of Congress by reviewing the interpretation of the statute. As a precursor, the Court determined that HMTA contained an express preemption – as opposed to a field preemption or conflict preemption – and as such the Court focused on the plain wording of the clause, which contained the "best evidence of Congress' preemptive intent."

HMTA authorized the Secretary of Transportation to designate materials as hazardous and to prescribe appropriate Hazardous Materials Regulations ("HMR"). At issue is 49 U.S.C. § 5125(b)(1), which contains two requirements for preemption – a subject-matter requirement and a substantive-similarity requirement. Under the subject matter requirement, the nonfederal law must be "about" one of the subjects enumerated in section 5125(b)(1)(A)-(E). The Court found that Buono's common-law claims for strict liability and negligence is expressly preempted under section 5125(b)(1)(E).

Section 5125(b)(1)(E) encompasses "the designing, manufacturing, fabricating, inspecting, marking, maintaining, reconditioning, repairing, or testing a package, container, or packaging component that is represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce."

While Buono conceded that the test tank qualified for use in transporting hazardous material in commerce under federal law, Buono artfully argued that there is a negative implication through the omission of the word "labeling" under section 5125(b)(1)(E), which only includes the word "marking." Specifically, Buono noted that section 5125(b)(1)(B)[1] includes the words "labeling" and "marking" while section 5125(b)(1)(E) only mentions the word "marking" which infers that Congress intended to omit "labeling" claims from section 5125(b)(1)(E)'s preemptive scope and meant to differentiate between "labeling" and "marking." The Court rejected Buono's argument.

The Court dived into the essence of Buono's common-law negligence and strict liability claims and then followed through with a robust definition review of the word "marking." The Court first determined that the essence of Buono's negligence claim concerned the "marking" of "a package, container, or packaging component." Specifically, Buono alleged:

> "The defendants had a duty to warn the general public … that the … cylinder tank in question could not be operated in a reasonably foreseeable manner without causing substantial harm and resulting injury to plaintiff, including the risk that the tank would explode … [D]efendants failed in their duty to warn that foreseeable use of the … cylinder tank would cause substantial harm, and resulting injury, including the risk that the tank would explode …. [T}he failure to warn by defendants directly and proximately caused substantial injury to plaintiff."

The Court concluded that Buono's negligence claim is based on Tyco's alleged failure to warn about the dangers of the test tank, specifically the danger of overfilling – not labeling. Next, the Court complied and analyzed various definitions of "marking." Under the ordinary meaning of marking, a marking would encompass written notations or symbols on the exterior of a container warning about known dangers. More specific to the subject matter at issue, HMTA governs the highly regulated transportation of hazardous materials and, in the HMR, the Department of Transportation has defined a "marking" as a descriptive name, identification number, instructions, cautions, weight, specifications or UN marks, or combinations thereof … on outer packages of hazardous materials. 40 C.F.R. § 171.8. "Cautions" plainly encompasses warnings. The DOT has adopted a similar interpretation of the word "markings" that encompasses warning about dangerous uses of cylinders, including overfilling. Alternatively, the meaning of "label" narrowly refers to the identification of specific contents of a container, packaging, or the like. Ultimately, the Court concluded that the word "marking" in section 5125(b)(1)(E) encompassed Buono's failure to warn negligence claim.

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[1] 49 U.S.C. § 5125(b)(1)(B), "the packing, repacking, handling, labeling, marking, and placarding of hazardous material."

The Court also concluded that Buono's strict liability claim also falls under section 5125(b)(1)(E). Before the District Court, the parties "appeared to construe" the strict liability claim solely based on a failure to warn, and the District Court deemed any design-defect theory to be abandoned, which Buono did not protest on appeal. The Court noted that even if they were to accept Buono's negative inference argument, Buono's claims were not "about" Tyco's alleged failure to label the contents of the test tank, but rather about its alleged failure to warn users about the dangers of overfilling. Thus, the subject matter requirement was fulfilled.

Shifting to the substantive similarity requirement, the Court concluded that Buono's common-law claims were based on state laws that were not "substantively the same" as the federal requirements under the HMTA and HMR. Specifically, the Court compared the culpable mental state requirements under HMTA/HMR and Buono's common-law claims. A civil violation under HMTA or HMR must be committed "knowingly," and a criminal violation must be committed "knowingly," "willfully," or "recklessly." In contrast, common-law negligence or strict liability claims based on Tyco's alleged failure to warn requires a less culpable mental state and is captured more broadly than federal law. As such, the substantive similarity requirement has also been fulfilled for HMTA's preemption requirement.

In one final attempt against preemption, Buono argued that Tyco is not subject to the substantive provisions of HMTA and HMR because the test tank was not in transit at the time of the violation and did not contain hazardous materials during transport or at arrival, therefore, HMTA's preemption clauses do not cover this matter. The Court quickly rejected Buono's argument on the ground that preemption under 49 U.S.C. § 5125(b)(1) "does not depend on whether the HMTA or HMR actually regulates the defendant's specific conduct at a given time. As long as the subject-matter and substantive similarity requirements are satisfied, a nonfederal claim is expressly preempted." Further, Section 5125(b)(1)(E) contains "no hint that preemption depends on whether a container is in transport or contains hazardous material at a specific time." In rejecting Buono's argument, the Court joined the Third Circuit in ruling that a party does not need to show that it is or may be held liable under the HMTA or HMR before raising an express-preemption defense under the HMTA.[2]

***Daniels-Feasel v. Forest Pharms., Inc.*, 2023 U.S. App LEXIS 19448 | 2023 WL 4837521 July 28, 2023 – Expert Reliability**

Plaintiff-Appellants were a group of mothers, who alleged that they ingested Lexapro, a prescription antidepression medication in the therapeutic class of selective serotonin reuptake inhibitors ("SSRIs"), during their pregnancy, and their minor children who developed autism spectrum disorder ("ASD"), allegedly as a result of their mothers taking Lexapro. The Defendant-Appellants were pharmaceutical companies involved in the design, manufacturing, and/or marketing of Lexapro.

The District Court granted the Defendants' motion to exclude evidence from the testimony regarding the causal relationship between Lexapro and ASD from three of the Plaintiffs' expert

[2] *See Roth v. Norfalco LLC*, 651 F3d 367, 370 (3d Cir. 2011).

witnesses: Dr. Lemuel Moye, Dr. Laura Plunkett, and Dr. Patricia Whitaker-Azmitia. As a result of the Plaintiffs' experts' exclusion, the District Court granted the Defendants' motion for summary judgment because the Plaintiffs were unable to prove general causation between prenatal exposure to Lexapro and ASD in the general population.

On appeal, the Plaintiffs argued that the District Court abused its discretion by excluding the Plaintiffs' experts and thereby created a false basis to grant the Defendants' motion for summary judgment. The Court noted that a decision by the District Court to admit or exclude expert scientific testimony was not an abuse of discretion unless it was manifestly erroneous. The Court then began its review of Dr. Moye's report and testimony because Dr. Moye was the only expert offered by Plaintiffs to prove the general causation requirement under state law for complex product liability (or medical) claims.

Dr. Moye used a weight of the evidence methodology and applied the standard Bradford-Hill criteria to reach his conclusions in his report that maternal use of SSRIs during gestation "is a cause of autism separate and apart from any relationship between maternal depression and autism." Dr. Moye described the weight of evidence analysis as the "process by which a body of evidence is examined component by component whereby each component is sifted and assessed using a transparent and standard method." The Bradford-Hill criteria factors "form the generally accepted set of criteria by which, when reliably applied, modern practicing epidemiologists assign causality to an association." Among others, the Bradford-Hill factors include:

1. Strength of association, which measured the degree of statistical association between cause and cause and effect;
2. Biological gradient, or "dose-response," which assesses whether more exposure to the risk factor is related to greater damage from the disease;
3. Biological plausibility, which pinpoints the mechanism by which the risk factor produces the disease; and
4. Analogy, which asks whether the proposed cause-effect association is similar to some other known cause-effect association.

To ensure that the Bradford-Hill/weight of evidence criteria is truly a methodology, rather than a mere conclusionary selection process, there must be a non-arbitrary scientific method of weighting that is used and explained within an expert's analysis in drawing causality. In determining whether an expert's opinion is reliable, a district court should undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand.

In Dr. Moye's report, he opined that the strength of association Bradford Hill factor weighed in favor of causation because he found substantial evidence demonstrating an increase in the evidence of autism associated with SSRI. In his analysis, Dr. Moye deemed studies that did not show any statistical significance between SSRI use in pregnant women and ASD in children as "unworthy of consideration" because of the lack of compliance validation[3] revealed in the

[3] The assessment and verification that an individual who is prescribed a medication or treatment is actually taking the medication or undergoing the treatment.

studies. Yet the studies cited and relied on by Dr. Moye that showed a statistically significant association between SSRI use in pregnant women and ASD in children also presented a lack of compliance validation. Dr. Moye failed to explain why the lack of compliance validation in the studies he ignored was a "big enough flaw" to render the studies irrelevant while the studies he relied on were not excluded. The District Court found the absence of that explanation concerning.

Additionally, in Dr. Moye's analysis, he disregarded meta-analysis studies that suggested that maternal mental illness was a confounding factor in the association between prenatal SSRI use and ASD in children. Dr. Moye testified that he gave meta-analysis studies no weight in his analysis because the individual studies they analyzed were not designed, collected, or intended to be combined with data from other studies.

The Court hinted that Dr. Moye's response ignored that the widely accepted approach amongst epidemiologists is to use a systematic meta-analysis to combine data from multiple studies to increase the power to detect an association when, on an individual level, the studies are underpowered to detect a relationship at a statistically significant level.

Finally, Dr. Moye's report failed to explicitly identify exactly how he weighed the Bradford Hill factors that he believed supported a causal relationship between maternal use of SSRIs and ASD in children. Dr. Moye's failure to explain whether each factor weighs in favor of general causation significantly hindered the replication and validation of his analysis.

Ultimately, the Court found that Dr. Moye cherry-picked only favorable studies to support his causal conclusion and did not rigorously explain the weight he attached to each Bradford-Hill factor. The District Court properly undertook a careful review of Dr. Moye's testimony and based on that review, reasonably found that his methods were not sufficiently reliable, and therefore, did not abuse their discretion to exclude his opinions.

The remaining of the Plaintiffs' experts' opinions and reports focused on biological plausibility, which alone is not enough to overcome the Plaintiffs' general causation hurdle. Therefore, with the exclusion of Dr. Moye's testimony, Plaintiffs were unable to prove general causation, and summary judgment for the Defendants was appropriate.

Nachimovsky v. Nike, Inc. **2023 U.S. App. LEXIS 17766 | 2023 WL 4504461 July 13, 2023**

Plaintiff-Counter Defendant-Appellant, David Nachimovsky, appealed an order by the District Court that granted Defendant-Cross Defendant-Appellee, Nike, Inc.'s ("Nike"), summary judgment motion, which was predicated by the exclusion of Nachimovsky's podiatrist expert opinion/testimony.

The Court noted that the district court has a gatekeeping role to "exclude expert testimony if it is speculative or conjectural or based on assumptions that are so unrealistic and contradictory as to suggest bad faith or to be in essence an apples-to-orange comparison." District courts acting in such a role may consider the gap between data and the conclusion drawn by the expert from that date and exclude opinion evidence where the court concludes that "there is simply too great an

analytical gap between the data and the opinion proffered." Thus, the district court has the discretion to determine whether the expert acted reasonably in making assumptions of fact upon which he would base his testimony.

Nachimovsky sought to admit expert testimony from a podiatrist to prove that a pair of Nike sneakers were defectively designed and caused his 2016 basketball injury. The Court hinted that the podiatrist's testimony and reports were lackluster. The one-page reports failed to explain why or how the medial longitudinal arch of the Nike shoe was excessively narrow, and how such design of the Nike shoe was a major contributing factor to Nachimovsky's injury. Nachimovsky's expert also failed to contemplate potential gaps in his report. The podiatrist did not inquire as to whether Nachimovsky modified the insoles in his shoe at the time of the incident or whether Nachimovsky had a current knee injury at the time of the incident or a prior knee injury before the incident. The podiatrist also failed to measure the medial longitudinal arch on the shoe or compare it to other similar models and failed to explain what a safe design standard would be. Instead, through testimony, the podiatrist testified that he "walked in" and "jumped in" the shoes and "twisted" them "to see what type of torsional movement there was."

The Court found that the podiatrist did not offer any basis for his opinion as to permit a meaningful review of his methods. Therefore, the Court found that the District Court did not abuse its discretion to exclude the expert evidence. Plaintiff did not make an argument that the District Court misapplied any standard for summary judgment in any way and was not discussed by the Court.

THIRD CIRCUIT:

Ryan Lucinski and Alejandro Ocasio, Hodgson Russ LLP, The Guaranty Building, 140 Pearl Street, Suite 100, Buffalo, New York 14202

***Sullivan v. Werner Co. & Lowe's Companies, Inc.*, 2023 WL 8859656 (Pa. Dec. 22, 2023)**

The plaintiff in this case brought a products liability lawsuit against a scaffold manufacturer and distributor after suffering injuries when he fell from a six-foot tall mobile scaffold, which he alleged was defectively designed.

Before trial, the plaintiff filed a motion *in limine* to preclude defendants from submitting any evidence of the scaffold's compliance with industry standards or government regulations. The trial court granted the plaintiff's motion and precluded such evidence in light of Pennsylvania Supreme Court precedent, which held the proper focus of a design defect case is on the characteristics of the product, not the conduct (including design choices) of the manufacturer. *See Lewis v. Coffing Hoist Div., Duff-Norton Co., Inc.*, 515 Pa. 334, 341 (1987). The plaintiff obtained a $2.5 million verdict at trial.

On appeal, the defendants argued the holding in *Lewis* was no longer the law of the state and that compliance evidence is admissible. In resolving prior conflicting decisions from Pennsylvania's highest court, the court disagreed: "Compliance evidence does not prove any characteristic of the product, rather it diverts attention from the product's attributes to both the manufacturer's conduct and whether a standards-issuing organization would consider the product to be free from defects." *Sullivan*, at *11.

In a plurality decision, the Pennsylvania Supreme Court maintained that evidence of compliance with industry standards is inadmissible in design defect cases to show a product is not defective under a risk-utility theory, re-affirming the rule announced in *Lewis*. The court reasoned that a manufacturer's compliance evidence is irrelevant because "[t]he duty involved in strict-liability—to produce and/or market a product without 'a defective condition unreasonably dangerous'—is different from the duty of due care in negligence." *Id.* at *10 (quoting Restatement (Second) of Torts § 402A(2)).

***Quinn v. AVCO Corporation, et al.*, 2023 WL 7547735 (3d Cir. Nov. 14, 2023)**

This case was brought on behalf of a deceased pilot who was killed while operating a Piper Saratoga aircraft, which was built and first sold in 1980. The aircraft's engine was equipped with a component called a Kelly Aerospace dual magneto, which provided electrical energy to the ignition system (the "Magneto"). The plaintiffs alleged that the Magento was defective and cause the fatal crash, which occurred on November 5, 2013. The aircraft's engine was originally manufactured by defendants AVCO and Lycoming Engines; defendant Bendix Corp. originally designed the Magneto but was acquired by defendant Continental Motors; Continental began manufacturing magnetos and rebuilt and sold the subject Magneto in 2002, which was later overhauled and installed on the Piper aircraft in June 2004.

The crux of this appeal centered on whether the General Aviation Revitalization Act of 1994 ("GARA") applied to Continental as a manufacturer or rebuilder of the Magneto. GARA contains a repose provision that bars suit against manufacturers of aircraft or aviation components brought more than 18 years after the date of delivery to an initial purchaser. Because plaintiffs brought suit more than 18 years after the original sale date of the Piper aircraft, they attempted to argue that Continental (1) was not a manufacturer under GARA but rather a "provider of maintenance services," and (2) that GARA's plain language applies only to aircraft manufacturers and not rebuilders or sellers, like Continental. *Id.* at *2.

Interpreting GARA, its legislative history, and other relevant FAA regulations, the Third Circuit determined that Continental was acting in its capacity as a manufacturer under GARA when it rebuilt the Magneto in 2002, since only such manufacturers may rebuild aircraft or related components under FAA regulations. Accordingly, GARA's 18-year statute of repose defeated plaintiffs' claims against Continental and summary judgment was affirmed.

***Hill v. Weston Solutions, Inc., et al.*, 2023 WL 5013040 (3d Cir. Aug. 7, 2023)**

Plaintiff's estate brought a products liability suit against the manufacturer of an electricity transformer. Plaintiff died from injuries sustained when he accidentally made contact with a 7,000-pound transformer during its installation/configuration at a military facility in Franklin County, Pennsylvania.

Pennsylvania has a 12-year statute of repose for construction projects that provides if a person "lawfully performs or furnishes the design, planning, supervision or observation of construction, or construction of improvements to real property, then they are immune from liability." *Id.* at *2 (quotations and citations omitted). The Third Circuit explained that "[t]he [statute] was not intended to apply to manufacturers and suppliers of products, but only to the kinds of economic actors who perform acts of individual expertise akin to those commonly thought to be performed by builders."

Despite the fact that the defendant manufactured the transformer, the Third Circuit found that the defendant was within the class protected by the statute of repose and, thus, immune from liability. Critical to the court's finding was the fact that the transformer was custom designed and built for the U.S. Army, in accord with the defendant's special expertise and onsite involvement with the installation.

***Jankowski v. Zydus Pharmaceuticals USA, Inc.*, 2023 WL 4700651 (3d Cir. July. 24, 2023)**

Plaintiffs alleged that the defendant aggressively and illegally marketed their generic drug for off-label use to treat atrial fibrillation and failed to provide adequate warnings in violation of New Jersey's Products Liability Act ("NJPLA"). Plaintiffs appealed to the Third Circuit after the district court dismissed the second amended complaint on the basis that the defendant fulfilled its duty to warn physicians by placing the FDA-approved warnings in the drug's packaging.

The Third Circuit affirmed dismissal but under a preemption analysis; the court held that plaintiffs' NJPLA claim was preempted by the Federal Food, Drug and Cosmetic Act, as amended (the "FDCA") and the federal duty of "sameness" articulated in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In essence, plaintiffs alleged that the defendant failed to further warn doctors about the potential side effects of the generic drug beyond the warnings included in the packaging. But because the brand-name manufacturer of the subject drug did not warn beyond the FDA-approved warnings in the package, the defendant was prohibited from taking different action to strengthen or alter its labeling under the FDCA. *Id.* at *3.

***Arcelik A.S. v. E.I. DuPont de Nemours & Co.*, 2023 WL 3862506 (3d Cir. Jun. 7, 2023)**

Plaintiff, a Turkish appliance distributor, sued DuPont, the Delaware-based parent company of DuPont China and DuPont India, seeking recall damages related to electric dryer fires caused by a defective plastic product used to make electrical capacitors ("Zytel FR50" or "Zytel"), which were integrated into plaintiff's clothes dryers. DuPont China produced the defective Zytel at its plant in Shenzhen, China and then sold it to DuPont India. DuPont India distributed the defective Zytel to another, unrelated company that used it to make the capacitors that were ultimately sold to plaintiff and integrated into the recalled dryers.

Plaintiff brought claims against DuPont under Delaware law for negligent manufacture and violations of the Delaware Consumer Fraud Act. To succeed on a negligent manufacture claim, a plaintiff is required to show that the defendant either directly manufactured the product or manufactured the product through an agent.

The Third Circuit maintained that plaintiff failed to present any credible evidence that DuPont was involved in the actual manufacture of the defective Zytel FR50, even though DuPont had quality control oversight and set global standards for its production. Similarly, the court found that DuPont China was not DuPont's agent in the manufacture of this product. Marketing as a collective, global network, using the universal "DuPont" name for its products irrespective of where made or by which subsidiary, approving DuPont China's suppliers, and even leading the response to complaints regarding the defective Zytel was not sufficient to evidence DuPont's control over Zytel's manufacture, or to demonstrate that DuPont China had authority to act on DuPont's behalf in its manufacturing.

This decision reinforces that Delaware undoubtedly protects the corporate form for global companies. It is a substantial feat for a party to attribute liability under Delaware law to a Delaware-based parent because of its subsidiary's (mis)conduct.

***In re LTL Management, LLC*, 64 F.4th 84 (3d Cir. March 31, 2023)**

This case involves a Johnson & Johnson ("J&J") subsidiary's attempt to file for bankruptcy to dispose of myriad talc claim liabilities. Before this lawsuit, J&J split its subsidiary—Johnson &

Johnson Consumer Inc. (“Consumer 1”)—into two new entities: LTL Management LLC (“LTL”) and Johnson & Johnson Consumer Inc. (“Consumer 2”).

Consumer 2 held virtually all Consumer 1’s productive assets while LTL held its talc liabilities. After the split, LTL filed for Chapter 11 relief in the Bankruptcy Court of North Carolina. The action was transferred to the District of New Jersey, where talc claimants moved to dismiss LTL’s bankruptcy case, alleging that it was not filed in good faith. The Bankruptcy Court denied those motions and extended the automatic stay of actions against LTL.

The Third Circuit reversed and explained that while LTL was highly insolvent, it had “access to cash to meet comfortably its liabilities as they came due for the foreseeable future.” *Id.* at 108. Further, “[b]ecause LTL was not in financial distress it [could not] show its petition served a valid bankruptcy purpose and [that it] was filed in good faith.” *Id.* at 110. Importantly, the court held that LTL’s insolvency alone was insufficient to establish financial distress.

This decision may raise the bar in the context of mass tort liabilities for target companies to establish financial distress sufficient to meet the good-cause requirement for Chapter 11 relief.

FOURTH CIRCUIT:

Jason Hodge and Marina Batalias, Nelson Mullins Riley & Scarborough, LLP, 901 E. Byrd Street, suite 1650, Richmond, VA 23219

Lemon Law & Attorneys' Fees

***Ranger v. Hyundai Motor Am.*, 885 S.E.2d 156 (Va. 2023)**

In this appeal, the Supreme Court of Virginia confirmed that pre-suit attorney's fees are not a component of the Lemon Law's statutory repurchase or buyback, and that where a manufacturer has offered a pre-suit repurchase that meets all of the statutory requirements—without attorney's fees—it has fully complied with the statute and there is no violation that would support an action.

Here, the plaintiff had purchased a new Hyundai vehicle in 2018. After the purchase, he experienced recurring problems that had to be repeatedly repaired. He retained an attorney who sent a demand letter to Hyundai demanding a refund of the purchase price of the vehicle "along with all interest paid on the finance note as well as attorney fees and incidental and consequential damages." In response, Hyundai offered to repurchase the vehicle "pursuant to the applicable statutes," as well as to pay some of the attorney's fees. The plaintiff refused the offer based on Hyundai's decision not to pay the full amount of attorney's fees requested and then filed the underlying action claiming violation of the Lemon Law.

In the trial court, Hyundai moved for summary judgment, arguing that its buyback offer complied with the Virginia Lemon Law and, accordingly, the plaintiff was barred from seeking relief under the statute as a matter of law. The trial court agreed and granted Hyundai summary judgment. The plaintiff appealed.

On appeal, the Supreme Court of Virginia explained some of the background of the Lemon Law, including the advantages it offered to both consumers and manufacturers. It echoed the purpose of the Lemon Law, as articulated in the statutory language itself, i.e., that "a good faith motor vehicle warranty complaint by a consumer should be resolved by the manufacturer, or its agent, within a specified period of time" and that "a consumer may receive a replacement motor vehicle, or a full refund, for a motor vehicle which cannot be brought into conformity with the express warranty issued by the manufacturer."

The Court then turned to the statutory language to determine what constituted a "full refund." It keyed in on the definitions of "collateral charges" and "incidental damages," which were required to be included in the "full contract price" that must be refunded to the consumer. The Court highlighted that neither definition mentioned, or even contemplated, attorneys' fees. Moreover, there was no Virginia case on point, and the "overwhelming weight of authority from other courts concludes that attorney's fees are not available under this provision of the Uniform Commercial Code." Accordingly, the Court agreed that pre-litigation attorney's fees are "not a component of collateral or incidental damages under the Lemon Law," and therefore, "when a manufacturer provides a refund, it is not required to pay pre-litigation attorney's fees to satisfy its

obligations under the Lemon Law." Likewise, the Court explained that a "manufacturer who has offered a refund that satisfies the Lemon Law requirements is not in violation of the statute."

Given these findings, the Court concluded that summary judgment in Hyundai's favor was proper. The Court reasoned that Hyundai did not violate the Lemon Law because the refund it offered complied with the Lemon Law's requirements. The Court held that the points in dispute, i.e., the payment and amount of pre-litigation attorneys' fees, were not material because the plaintiff "was not entitled to recover those fees." Thus, the trial court properly granted Hyundai summary judgment.

Takeaways. This clear and concise opinion provides automotive manufacturers with guidance in responding to Lemon Law complaints in Virginia, specifically when concerned with a demand for a refund made before the consumer files a lawsuit. Tangentially, summary judgment in Virginia state courts is more difficult to obtain than in most jurisdictions. But this case serves as a useful reminder that it should still be considered, especially where, as here, the dispute turns on a pure question of law.

Personal Jurisdiction & Medical Device Preemption

***Watters v. CooperSurgical, Inc.*, 655 F. Supp. 3d 376 (E.D.N.C. 2023)**

In this product liability action out of North Carolina, the plaintiff brought claims for products liability, negligence, and violation of North Carolina's Unfair and Deceptive Trade Practices Act (UDTPA). The claims involved a medical device called the "Filshie Clip," which is a titanium clip with a silicon rubber lining used for laparoscopic tubal ligation. The plaintiff had a procedure in 2013 using Filshie Clips, and 9 years after, she started experiencing sharp pains and cramps, at which point doctors discovered that the clips had migrated. The plaintiff's claims were based on the allegations that the defendants had evidence of the clips' "propensity to migrate" but nevertheless failed to warn the FDA, physicians, or patients of the damages that such migration could cause.

Several of the defendants moved to dismiss on grounds that the court lacked personal jurisdiction. For two of the defendants, the court quickly rejected the plaintiff's argument for jurisdiction—their market participation in North Carolina since 2019—as it was clearly not tied to the underlying controversy that gave rise to the lawsuit, i.e., the 2013 surgery.

For another defendant (Femcare), the plaintiff attempted to justify jurisdiction based on Femcare having "entered into a contract with a distributor allowing the sale of Femcare's products in the entire United States." In other words, the plaintiff argued that "because Femcare sold clips in 2013 to CSI [the distributor] and CSI in turn sold the clips in North Carolina, then Femcare has sufficient minimum contacts in North Carolina for personal jurisdiction."

The problem with this position, as the court succinctly identified, is that the "Fourth Circuit has expressly rejected Watters's stream of commerce theory, instead holding that a non-resident defendant may only be subject to personal jurisdiction under the stream of commerce theory if that

defendant engaged in some activity purposely directed at the forum state." As an example, the court explained that when a manufacturer sells products directly to a retail store that the manufacturer knows or should know has stores in the state, that could be sufficient for a court to find "purposely directed activity towards a forum state." But where, as here, manufacturer "sells a product to a distributor with no direct purpose that the product reach the forum state," that manufacturer "is not subject to personal jurisdiction even if the defendant is abstractly aware that a distributor could sell its product in the forum state." Moreover, the court noted that the distributor, CSI, and not the defendant, Femcare, controlled the sales decisions in the North Carolina market. Accordingly, personal jurisdiction was not warranted over Femcare either.

The defendants also moved to dismiss the underlying claims based on preemption. The Filshie Clip is a Class III subject to pre-market approval (PMA) by the FDA. Accordingly, established Supreme Court case law provides that certain claims regarding these devices are preempted. Here, the plaintiff ultimately admitted that she had "failed to plead specific violations of the FDA regulations," such that her claims were preempted. But, she requested "limited discovery to uncover the regulations that potentially could apply." The court did not oblige. It explained that the plaintiff had presented no argument that the requisite materials needed to show the claim were solely in the possession of defendants and, more broadly, that the court declined to "conscript defendants to find regulations for Watters to plead on her own behalf" and also to itself "hunt for FDA regulations which potentially could fit her case."

Takeaways. The Fourth Circuit jurisprudence has expressly rejected the stream of commerce theory of jurisdiction, but plaintiffs continue to make it. The unequivocal rejection provided in this case is another useful example for both evaluating the plaintiff's allegations and combatting them as necessary. As for the preemption arguments, this opinion provides a useful example of a court rejecting a plaintiff's plea for discovery to make her case, when the plaintiff has provided no basis for seeking such discovery and is instead attempting to embark on a fishing expedition to find a claim.

Exemplar Motion to Dismiss Opinion

***Blackman v. Bos. Whaler, Inc., et al.*, 649 F. Supp. 3d 142 (E.D.N.C. 2023)**

The Eastern District of North Carolina recently published an instructive opinion walking through the standard to dismiss a Complaint for failure to state a claim in the context of a product liability action. The thorough opinion offers an insightful glimpse into a court's reasoning and analysis.

In 2016, Plaintiff purchased a boat and extended service agreement from the Defendants. Over the years, the vessel allegedly suffered a variety of issues, resulting in Plaintiff bringing the vessel in for service on dozens of occasions. In 2018, Plaintiff's vessel caught fire due to the "50 Amp Shore Power Cord Connection to the shore power '1' inlet connection of the vessel." The vessel suffered extensive fire damage, although Plaintiff was not physically injured and the fire did not damage property other than the vessel itself.

Plaintiff filed suit in 2019, alleging a number of violations under the Magnuson-Moss Warranty Act and North Carolina law for breach of warranty, negligence, products liability, negligent misrepresentation, fraud, and unfair and deceptive trade practices in violation of North Carolina's Unfair and Deceptive Trade Practices Act ("UDTPA"). Plaintiff targeted three Defendants: the retailer, the manufacturer, and the extended service agreement provider. The Defendants removed the case to federal court, at which point Plaintiff amended his complaint. Defendants thereafter moved to dismiss the amended complaint under Rule 8 and Rule 12(b)(6).

Although the Court rejected the Defendants' argument that this was an impermissible shotgun pleading, the Court dismissed each count for failure to state a claim under Rule 12(b)(6).

Of note, the Court ruled that Plaintiff did not plausibly allege that Plaintiff complied with the multi-step, specific requirements the service agreement provider requires for it to fulfill its obligations under the service agreement. Plaintiff's bare allegation that he gave "all appropriate notices" to each defendant was insufficient.

The Court also dismissed each of Plaintiff's state tort law claims as barred under the economic loss rule and, in so doing, provided an instructive primer of its analysis in making this conclusion.

Finally, in dismissing Plaintiff's claim under North Carolina's UDTPA against all of the Defendants, the Court distinguishes this case from *Sain v. Adams Auto Grp., Inc.*, 244 N.C. App. 657, 665 (2016), a plaintiff-friendly decision from the Court of Appeals of North Carolina. This distinction may help other North Carolinian practitioners in future cases sort through the nuances of a successful argument to dismiss a UDTPA claim.

As a whole, *Blackman* is a useful opinion for practitioners with similar claims to reference when constructing their own arguments for a motion to dismiss.

Fed. R. Evid. 702 - Gatekeeping

CSAA Affinity Ins. Co. v. Scott Fetzer Co., 2023 WL 2714026 (D. Md. Mar. 30, 2023)

In this case, the District of Maryland provides a useful opinion emphasizing the importance of Rule 702 in gatekeeping the role of expert testimony– a reminder especially important in light of Rule 702's most recent amendment, which took effective on December 1, 2023. Though authored prior to Rule 702 taking effect, it is a prime example of how Rule 702 should be applied in a products liability case.

In this subrogation action, the Plaintiff-insurer brought suit against the Defendant, a pump manufacturer, for damages allegedly incurred when a fire broke out in the basement of the insured's home. Plaintiff claimed the fire resulted from a defective sump pump, which the Defendant manufactured, and alleged three causes of action: strict liability, negligence, and breach of an implied warranty of merchantability.

The pump manufacturer moved for summary judgment, claiming that Plaintiff's single design defect theory rested on the shoulders of its purported engineering expert. Plaintiff's expert opined that "thermoset plastic or steel housing would have decreased the likelihood of the fire spreading beyond the sump pump." Plaintiff's expert, however, was unable to identify the actual material used on the pump at issue. Based on the appearance of the pump at the inspection, he presumed thermoset plastic or steel was not used. But the expert did not support this hypothesis by identifying the material with any more specificity, nor did he test or refer to industry standards or literature from the relevant field.

The Court, quoting the Fourth Circuit, excluded Plaintiff's expert and emphasized the importance of a court's gatekeeping function under Rule 702 in a products liability case: "a plaintiff may not prevail in a products liability case by relying on the opinion of an expert unsupported by any evidence such as test data or relevant literature in the field" because without it, "expert opinion testimony can easily, but improperly, devolve into nothing more than proclaiming an opinion is true 'because I say so.'" Because proof of defect was an essential element of Plaintiff's claims and Plaintiff's now-excluded expert was its only evidence to support this element, the Court granted Defendant's Motion for Summary Judgment.

Necessity of Alternative Feasible Design

***Shears v. Ethicon, Inc.*, 64 F.4th 556 (4th Cir. 2023)**

The Fourth Circuit recently certified a potentially pivotal question of law regarding the burden of proof in strict liability design defect claims under West Virginia law.

In this MDL case, Plaintiff claimed, among other counts, strict product liability design defect and negligent design for injuries allegedly stemming from implantation of a synthetic surgical mesh sling. The MDL court eventually consolidated her case and 36 others for trial. Defendant objected, claiming that under West Virginia law, plaintiffs must identify a "safer alternative design" which would have materially reduced the plaintiff's injuries" to sustain a design defect claim. This analysis, Defendant argued, requires plaintiff-specific evidence that renders these 37 cases unfit for a consolidated trial.

Initially, the MDL court disagreed, stating that no controlling West Virginia law existed on this point. As the case proceeded to discovery, however, the Supreme Court of Appeals published the *West Virginia Pattern Jury Instructions for Civil Cases*, which included the following instruction in Section 411: "There are many designs which, although they may eliminate a particular risk, are not practicable to produce. To prove that a design is defective, [name of plaintiff] must prove that there was an alternative, feasible design that eliminated the risk that injured [him/her]." Based on this instruction, Defendant successfully sought reconsideration of the MDL court's ruling; Plaintiff's case was thereafter transferred to the Northern District of West Virginia and immediately set for trial.

During the *Daubert* hearing, Defendant successfully argued to exclude Plaintiff's primary expert witness on the basis that he opined that Plaintiff's proposed alternative designs reduced but

did not – as required under Section 411 – *eliminate* the risk of injury. After a seven-day jury trial, the jury returned a defense verdict. Plaintiff timely appealed, arguing (among other points) that the trial court and MDL court erroneously relied on Section 411 in making their rulings.

Ultimately, the Fourth Circuit certified the following question to the Supreme Court of Appeals of West Virginia:

> Whether Section 411 of the West Virginia Pattern Jury Instructions for Civil Cases, entitled "Design Defect — Necessity of an Alternative, Feasible Design," correctly specifies the plaintiff's burden of proof for a strict liability design defect claim pursued under West Virginia law. More specifically, whether a plaintiff alleging a West Virginia strict liability design defect claim is required to prove the existence of an alternative, feasible product design — existing at the time of the subject product's manufacture — in order to establish that the product was not reasonably safe for its intended use. And if so, whether the alternative, feasible product design must eliminate the risk of the harm suffered by the plaintiff, or whether a reduction of that risk is sufficient.

Takeaways. West Virginia practitioners should be on the lookout for this decision in the upcoming year, and other practitioners in the Fourth Circuit should note this case as "one to watch."

FIFTH CIRCUIT:

Garret Greene, Bowman & Brooke, 2901 Via Fortuna Drive, Suite 500, Austin, TX 78746

Additional Insureds

***Weyerhaeuser Co. v. Burlington Ins.*, 74 F.4th 275 (5th Cir. 2023)**

Background:

In this case, a wood product manufacturer and its wholly owned subsidiary sued the commercial general liability (CGL) insurers of a coating company. The suit was based on the assertion that they were entitled to coverage as additional insureds under the CGL policies. This claim arose from underlying personal injury actions connected to a manufacturing agreement.

District Court Decision:

The district court dismissed the lawsuit for failure to state a claim.

Fifth Circuit Decision:

On appeal, the Fifth Circuit United States Court of Appeals upheld the district court's decision. The appellate court concluded that the insurers did not have to defend or indemnify the manufacturer and its subsidiary as additional insureds. The court reasoned that reformation of the policies to include the manufacturer as an additional insured was not justified on the grounds of mutual mistake. It was also determined that both the manufacturer and its subsidiary failed to establish breach of contract claims against the insurers as third-party beneficiaries of the policies.

Practice Points:

Parties should ensure that the insurance policies define who is considered an "additional insured." Ambiguities in policy language can lead to litigation and unintended coverage obligations.

Lawyers litigating claims in this circuit can use this case as a precedent for situations where an entity seeks coverage as an additional insured without being expressly named in the policy. They should highlight the Court's reluctance to extend coverage in such situations

Preemption

***Spano as next friend of C.S. v. Whole Foods, Inc.*, 65 F.4th 260 (5th Cir. 2023)**

Background:

This case involves a products liability claim against Whole Foods, where the plaintiffs alleged that cupcakes sold by the store were mislabeled as vegan and failed to disclose the presence

of nuts. The plaintiffs' minor son, who has a nut allergy, suffered an anaphylactic reaction after consuming one of these cupcakes.

Legal Issue:

The core issue revolved around the Federal Food, Drug, and Cosmetic Act (FDCA)'s preemption provision concerning allergen food labeling. The FDCA prohibits states from imposing food labeling requirements that are not identical to federal standards, and there is no private right of action under the FDCA.

District Court Decision:

The federal district court dismissed the case, concluding that the plaintiffs' claims were preempted by federal law.

Fifth Circuit Decision:

The Fifth Circuit overturned the district court's decision. The appellate court determined that the plaintiffs had successfully pled tort claims with an independent state-law basis, distinct from a mere violation of the FDA's regulations. The panel emphasized that if, during the progression of the case, it became evident that there was no independent state duty supporting a specific claim, such a claim would be preempted. In any event, at the pleading stage, none of the claims appeared to be exclusively reliant on FDCA violations.

Practice Points:

Defense attorneys should know that plaintiffs in this jurisdiction may strategically allege tort claims they purport as having an independent state-law basis to survive potential preemption attacks at the pleading stage. This case also highlights the importance of continual case monitoring. As the Fifth Circuit noted, if it becomes clear during a case's progression that there's no independent state duty supporting a specific claim, such a claim would be preempted. Defense attorneys should continuously evaluate the evolution of claims throughout the litigation process and press for preemption once the opportunity presents itself.

Spoliation

***Van Winkle v. Rogers*, 82 F.4th 370 (5th Cir. 2023)**

Background and Trial Court Proceedings:

In February 2018, a catastrophic accident occurred when a tire from a tractor-trailer, operated by Prime, separated and struck the vehicle of Billy Van Winkle Jr. Subsequently, Van Winkle sued Prime, its driver, and the insurance company, alleging negligence and product liability.

After the accident, Prime collected the tire, aware of its potential relevance in future litigation. But Prime later destroyed the tire, which Van Winkle argued constituted spoliation of evidence. In response, Van Winkle filed a motion for sanctions against Prime.

The trial court, after considering the circumstances, concluded that the tire's destruction resulted from negligence rather than bad faith. Consequently, it denied Van Winkle's motion for sanctions. The court also evaluated the qualifications of Van Winkle's expert witness, Roger Allen. While Allen was considered competent to discuss commercial driving and safety regulations, the court found him unqualified to testify on product liability issues specific to the tire's failure.

Ultimately, the defendants secured summary judgment in the trial court, prompting Van Winkle to appeal the decision.

Fifth Circuit Analysis and Decision

On appeal, the Fifth Circuit took a different stance. The court's analysis mainly focused on two aspects: the spoliation of evidence and the qualifications of expert witnesses under Rule 702.

Spoliation and Bad Faith

The Fifth Circuit scrutinized the circumstances of the destruction of the tire. While Prime had destroyed the evidence, the trial court saw no indication of bad faith. But the appellate court disagreed, citing several circumstantial factors:

- Prime knew that litigation might ensue due to the accident.
- The relevance of the tire as critical evidence was known to Prime.
- Lack of a formal policy at Prime for preserving such evidence.
- The intentional destruction of the tire

Based on these factors, the Fifth Circuit identified a material dispute over whether the tire was destroyed in bad faith, warranting a possible jury instruction on this issue.

Rule 702 and Expert Witness Qualifications

The appellate court upheld the trial court's decision to limit Allen's testimony. Allen, while experienced in trucking and safety, lacked specific expertise in tire mechanics, retreading processes, life expectancy, defect identification, and manufacturing defect causation.

Practice Points:

This case serves as a critical case study for defense attorneys in product liability matters, highlighting the importance of careful evidence management and the strategic use of expert testimony.

Attorneys should ensure their clients have—and enforce—strict policies for handling and preserving evidence, especially in high-risk industries.

When navigating expert testimony, counsel should assess the qualifications and background of expert witnesses to ensure they are competent in the specific subject matter relevant. Use depositions strategically to identify and restrict the scope of expertise claimed by the opposition's expert witnesses. Make sure to challenge and seek to limit testimony from experts who extend beyond their areas of specialty, as shown by the Allen testimony.

Prescription and the Discovery Rule

***Bruno v. Biomet, Inc.*, 74 F.4th 620 (5th Cir. 2023)**

Background Facts:

Andrew Bruno underwent shoulder surgery involving a Biomet-manufactured prosthetic device. Post-surgery, he experienced complications, initially believed to be due to a superficial skin infection. But a deeper infection was later discovered, leading to the device's removal. In 2019, Biomet acknowledged that certain devices, including Bruno's, might have elevated bacterial levels due to inadequate cleaning processes. Bruno filed a products liability suit under the Louisiana Products Liability Act, which was dismissed on grounds of prescription (statute of limitations). Bruno appealed.

Fifth Circuit Opinion:

The Fifth Circuit considered whether the doctrine of contra non valentem (an exception to the prescription period) applied. It held that the question of when Bruno should have reasonably discovered the cause of his injuries to sue was a matter for the jury, given the complexities of the medical evidence and the timing of Biomet's admission.

Practice Points:

The complexities surrounding the prescription period (or statute of limitations) in product liability cases, particularly involving medical devices and the effect of manufacturer communications, highlight the need for a meticulous approach in defending such cases.

Understanding Prescription and Contra Non Valentem:

Counsel should learn about state-specific prescription laws and the nuances of the discovery rule. They should also be prepared to counter the plaintiff's claims that the plaintiff was unaware of the cause of their injury, especially if there is evidence suggesting earlier awareness.

Handling Medical Device Claims:

It is important to scrutinize medical records to establish when the plaintiff could have reasonably discovered the alleged defect.

Addressing Manufacturer Notifications:

Counsel should assess how admissions by the manufacturer about potential defects can affect the prescription period and be prepared to develop strategies to mitigate the effect of manufacturer's notifications on the discovery rule.

Evidentiary Challenges:

Examine the influence of medical professionals' advice and diagnoses on the plaintiff's knowledge of the cause of injury. Be prepared to argue that the plaintiff did not act reasonably in investigating the cause of their injury, considering their education and intelligence.

Summary Judgment Considerations:

Evaluate whether the case facts present a clear-cut scenario for summary judgment, especially in light of the contra non valentem doctrine. But prepare for the possibility that the case may go to trial if reasonable minds could differ on the application of the discovery rule.

SIXTH CIRCUIT:

Katelyn Ashton, Butler Snow, LLP, 6075 Poplar Ave. #500, Memphis, TN 38119

Seller Liability

***Scruggs v. Walmart Inc.*, --- F.Supp.3d ----, No. 1:21-cv-145, 2023 WL 4777907 (E.D. Tenn. July 26, 2023)**

Plaintiff's suit arose from injuries she sustained after a candle presumably exploded, burning Plaintiff. The candle was purchased at Walmart by Plaintiff's boyfriend. Walmart moved for summary judgement. As to Plaintiff's Tennessee Product Liability Act claims, Walmart asserted that it was not a "seller" subject to liability under the TPLA. It was undisputed that Walmart sold the candle to Plaintiff's boyfriend. Walmart, however, disputed that it "exercised substantial control over that aspect of the design, testing, manufacture, packaging or labeling of the product," which is required for a seller to be liable under the TPLA. Reviewing the evidence, the Court found that Walmart's attorneys reviewed all of manufacturer Defendant Home Essentials's candles' labels to ensure they met industry requirements and consumer-protection-agency standards. Additionally, Walmart was engaged in pre-production testing, pre-shipment testing, and in-store testing of the candles. These facts indicated that Walmart may have possessed control over the manufacturer such that is necessary for Plaintiff to hold Walmart liable under the TPLA, thus defeating Walmart's motion for summary judgment.

As to Plaintiff's Tennessee Consumer Protection Act claims, the facts showed that Plaintiff's boyfriend—not Plaintiff—purchased the candle at issue. Therefore, because Plaintiff had not suffered an ascertainable loss of money or property independent from her alleged personal injuries, she did not have a cognizable TCPA claim.

Duty

***Williams v. Schneider Elec. USA, Inc.*, --- S.W.3d ----, NO. 2022-CA-0184-MR, NO. 2022-CA-0190-MR, 2023 WL 4374514 (Ky. Ct. App. July 7, 2023)**

As a matter of first impression, Kentucky's Court of Appeals held that public policy favors recognizing duty on part of employers and manufacturers of asbestos-containing products used by employers to an employee's "household members who regularly and repeatedly [come] into close contact with an employee's asbestos-contaminated work clothes over an extended period." The Court disagreed with the trial court's description of a household member as a "bystander," instead finding that the "appellees could reasonably foresee the danger to household members of workers carrying asbestos dust home." Accordingly, the Court reversed the trial court's summary judgment holding that the defendant-appellees owed no duty to an employee's daughter who, after coming in frequent contact with dust from asbestos-containing molding compounds on her father's clothing, was diagnosed with and died from mesothelioma.

***Klein v. Caterpillar, Inc.*, --- F.Supp.3d ----, No. 1:21-cv-11748, 2023 WL 4760707 (E.D. Mich. July 26, 2023)**

Klein presented the Eastern District of Michigan with an opportunity to reiterate Michigan's law that there is no post-manufacture duty to retrofit or recall a product that was not defective when manufactured. A 785B earth hauler was manufactured by Caterpillar and sold to Michigan Tractor & Machinery Company in 1994. In 2015, the hauler underwent a rebuild by an independently operating authorized dealer for Caterpillar products. In 2018, the subject hauler ran over Jill Klein's truck, resulting in her death. Plaintiff alleged negligent failure to modify the front bumper and electronic obstacle detection devices and visibility feature in 2015 (negligence) and negligence in the design and manufacture of the earth hauler in 1994 (product liability). The Court dismissed these claims because, under Michigan law, there is no post-manufacture duty to retrofit or recall a product that was not defective when manufactured.

Causation

***Frost v. Evenflo Co., Inc.*, No. 2022-CA-29, 2023 WL 8670063 (Ohio Ct. App. Dec. 15, 2023)**

Frost presented the Ohio Court of Appeals with a catastrophic fact pattern and a (presumed, for summary judgment purposes) defectively designed Evenflo car seat buckle. But there was no evidence the buckle—even if defective—proximately caused the children's deaths, dooming Appellants' claims.

The facts are undeniably tragic. In short, Ms. Frost's vehicle caught fire. She pulled over and attempted to get her daughter, who was in the back seat, out of the vehicle. Unable and on fire, Ms. Frost ran to extinguish the fire on her own body before going to the passenger side of the vehicle. In the interim, Ms. Frost's daughter, severely burned, independently got out of the vehicle. Ms. Frost then went to the passenger side to retrieve her son from his car seat. Ms. Frost was unable to unbuckle the Evenflo car seat and, again, had to abandon her efforts to extinguish the fire on her own body. Ms. Frost's son was then "exploded" from the vehicle. Ms. Frost survived; her children, sadly, did not.

Ms. Frost alleged that but for her son's defective Evenflo car seat buckle, both her children would have survived.

Reviewing the evidence, the trial court found no triable issue of fact on causation. Put simply, the evidence showed that Ms. Frost's daughter was outside the car before Ms. Frost tried to extricate her son from his Evenflo car seat; therefore, any alleged issue with the son's Evenflo car seat buckle could not have caused the daughter's injuries. As to the son's injuries, there was no evidence that the son would have survived the fire even if Ms. Frost had been able to remove him from the Evenflo car seat when she first tried; nor was there any evidence to show that the son was conscious by the time Ms. Frost tried to unbuckle the car seat.

As the Court of Appeals aptly stated, "The fact that injuries may be obvious in certain situations is not the same as concluding that an opposing party's acts proximately caused those injuries."

Manufacturing Defect

***Oetjens v. Covidien LP*, No. 22-11220, 2023 WL 3587535 (E.D. Mich. May 22, 2023)**

In *Oetjens*, the district court explained pleading requirements for manufacturing defects under Michigan law. The Oetjens alleged that a medical staple manufactured by Medtronic USA, Inc., Medtronic, Inc., and Covidien LP malfunctioned during Ms. Oejens's surgery, causing her injury. The Court explained that manufacturing defect claims—unlike design defect claims—do not require the plaintiff to plead a design defect or to identify an economically feasible alternative design. The Court also explained that manufacturing defect claims can be brought under either negligence or implied warranty theories. Additionally, plaintiffs cannot bring common law negligence claims as separate causes of action in product-liability cases.

Discovery

***Warman v. LivaNova Deutschland*, --- N.E.3d ----, Nos. C-230149, C-230150, 2023 WL 7383158 (Ohio Ct. App. Nov. 8, 2023)**

Outside of mass tort litigation, Lone Pine orders are rarely imposed. Yet the Court of Common Pleas, Hamilton County, did just that earlier this year, leading to *Warman's* ultimate dismissal. Plaintiff-appellant Warman was unable to point to any evidence in his own medical records to substantiate his claimed injury (allegedly caused by a defendant-appellee's medical device). The trial court suspended discovery and afforded Warman the opportunity to procure expert evidence that he had the relevant claimed injury. Despite assurances that proof existed, Warman was unable to produce *any* fact or expert evidence that he was injured. The trial court then dismissed Warman's case, and Warman appealed, arguing that the trial court "unfairly truncated discovery." Distinguishing the case from Ohio's most pertinent authority on Lone Pine orders, the Court of Appeals held that the trial court acted reasonably and "did not abuse its discretion in staying discovery while requiring Mr. Warman to substantiate his injury. Nor did the court err in ordering dismissal of Mr. Warman's claims after he failed to provide even basic proof that he suffered an injury, an essential element of any tort claim."

***Dreger v. KLS Martin, LP*, No. 2:20-CV-3814, 2023 WL 532012 (S.D. Ohio Jan. 27, 2023)**

Dreger is a product liability action relating to a rib plate and associated screws sold by Defendant were implanted into and explanted from Plaintiff. Plaintiff asserted manufacturing defect, design defect, failure to warn, and failure to conform to representation claims. Plaintiff sought discovery related to other similar incidents, namely Medical Device Reports, files, product complaints, and documentation of CAPA-related activities. Defendant maintained that Plaintiff was not entitled to any information related to similar incidents. The Court granted in part and

denied in part Plaintiff's motion to compel. Most notably, with respect to the discoverability of Defendant's complaint files and product complaints, the Court rejected Defendant's argument that these items are protected from discovery under applicable statutes and regulations governing FDA reporting and ordered that they be produced with respect to the relevant Rib Plate.

Experts

***Williams v. Schneider Elec. USA, Inc.*, --- S.W.3d ----, NO. 2022-CA-0184-MR, NO. 2022-CA-0190-MR, 2023 WL 4374514 (Ky. Ct. App. July 7, 2023)**

In addition to its holding regarding duty, in *Williams*, Kentucky's Court of Appeals reversed the trial court's exclusion of the plaintiff-appellant's expert's opinion on talc exposure. In his CR 26.02(4) disclosure, the plaintiff's expert opined that Union Carbide's asbestos-containing products caused the decedent's mesothelioma. But during his deposition, the expert further stated that talc, used to replace asbestos in Union Carbide's products, was also contaminated with asbestos. Materials supporting this talc claim were not disclosed until the night before the final day of the expert's deposition. Upon motion by Union Carbide, the trial court excluded the expert's talc opinions on the basis that they were not timely disclosed. The Court of Appeals disagreed, explaining that "depositions serve the same function as CR 26.02 and 26.05—to reveal evidence, information and opinions that may be used at trial." Because the expert's opinions were disclosed at a time that allowed Union Carbine a "chance to prepare for a fair trial," they should not have been excluded. The Court further held that the trial court failed to identify any prejudice that would befall the defendants as a result of the "late" disclosure—this, alone, was deemed an abuse of discretion.

***Frost v. Evenflo Co., Inc.*, No. 2022-CA-29, 2023 WL 8670063 (Ohio Ct. App. Dec. 15, 2023)**

Part of the Ohio Court of Appeals's proximate cause finding in *Frost* was based on Plaintiffs' experts' rebuttal opinions being excluded. As outlined above, *Frost* is terribly tragic—two children died after their car caught on fire. Plaintiffs-appellants attributed their deaths to one child's defective Evenflo car seat buckle allegedly rendering the mother unable to unbuckle one child and delaying her from saving the other. As set forth above, the buckle was irrelevant to one child, who had exited the vehicle before the mother ever tried to unbuckle the Evenflo car seat.

As to the other child, Plaintiffs' experts' "rebuttal" opinions were linchpins for the Court's proximate cause analysis. Applying the "sham affidavit" rule, the trial court refused to consider the experts' rebuttal opinions, which, in one instance, was not at all connected to the expert's former testimony (relating to a different person), and, in the other instance, contradicted the expert's original report and deposition testimony. As to the latter, the Court agreed with the trial court's conclusion that the opinions offered on rebuttal should have been offered as part of Plaintiffs' case in chief, that the expert's opinions improperly contradicted his deposition testimony, and that any contradictions should have been addressed and explained.

***Bardin v. Nissan Motor Co., Ltd.*, NO. 1:21-CV-00144-GNS-HBB, 2023 WL 6392743 (W.D. Ky. Sept. 28, 2023)**

Bardin is another manufacturing defect case—this time out of Kentucky. Plaintiff was driving his friend/landlord's truck when it suddenly caught fire, allegedly due to defective wires and wiring harnesses. Plaintiff asserted claims for strict liability, negligence and breach of warranty. The parties moved to exclude each another's experts under Federal Rule of Evidence 702 (pre-2023 amendment) and *Daubert*. While the Court undertook a full expert analysis, a notable takeaway from *Bardin* is the Court's analysis as it pertained to the evidence on which the experts could rely. Of course, the plaintiff must show that an identifiable defect probably caused the accident and injury. But *Bardin* is a recent example of Kentucky law allowing a plaintiff to establish that a defect probably caused his injuries with only circumstantial evidence.

***In re Flint Water Cases*, No. 5:16-cv-10444 (E.D. Mich.)**

In a series of opinions this year, the Eastern District of Michigan ruled on Defendants' motions to exclude opinions of nine of Plaintiffs' retained experts in the *Flint Water* litigation. Most of Defendants' motions were denied. *See* 2023 WL 6036662 (E.D. Mich. Sept. 15, 2023) (denying motion to exclude Plaintiffs' environmental and natural resource economics expert); 2023 WL 5844730 (E.D. Mich. Sept. 11, 2023) (denying motion to exclude Plaintiffs' expert in water quality assessments, corrosion mitigation, and the behavior of materials exposed to drinking water); 2023 WL 6147255 (E.D. Mich. Sept. 20, 2023) (denying motion to exclude Plaintiffs' expert retained to opine on professional, ethical and standard of care obligations related to the identification, communications, and response to threats to human health and property posed by corrosive water conditions and the absence of corrosion control in the Flint water distribution system); 2023 WL 6147348 (E.D. Mich. Sept. 20, 2023) (denying motion to exclude Plaintiffs' expert retained to opine on whether the corrosive water conditions allegedly caused in part by VNA could cause harm to Flint residents); 2023 WL 6215336 (E.D. Mich. Sept. 25, 2023) (denying motion to exclude Plaintiffs' expert retained to opine on whether the corrosive water conditions allegedly caused by VNA were capable of causing harm to Flint residents, properties, and businesses);

The Court granted in part and denied in part Defendants' motion to exclude certain testimony and opinions Dr. Daryn Reicherter, retained to offer general causation opinions on whether the water contamination in Flint could harm Flint residents' mental health and emotional well-being. 2023 WL 6279521 (E.D. Mich. Sept. 26, 2023). The Court deemed that Reicherter's opinions about community trauma as a collective harm to the community in the abstract or about community trauma as a type of individual harm were not admissible in this case. However, his opinions about community trauma as a cause of *individual* mental health disorders were admissible.

The Court also granted in part and denied in part Defendants' motion to exclude most of the testimony and report of Dr. Howard Hu, who was retained by Plaintiffs to opine on what medical harms—if any—could have resulted from Flint residents' exposure to lead. 2023 WL 6939234 (E.D. Mich. Oct. 20, 2023) The Court rejected most of Defendants' arguments as to Dr.

Hu. But the Court held that he could not opine about the risk of impaired cognitive development babies face when their mothers are exposed to lead during pregnancy. The Court deemed this opinion irrelevant because the evidence does not point to harms suffered by the *class members*, who are adult Flint residents.

Finally, the Court granted Defendants' motion to exclude Dr. Robert A. Simons, who was retained to opine on whether "the contaminated water conditions" could cause "harm to Flint businesses," and he concluded that they "in fact did cause such harm." 2023 WL 6624685 (E.D. Mich. Oct. 11, 2023). The Court held that Dr. Simons's quantitative opinions and economic theories were unreliable and excluded his opinions and testimony in their entirety.

Defenses

Cash-Darling v. Recycling Equip., Inc., 62 F.4th 969 (6th Cir. 2023)

In *Cash-Darling*, the Sixth Circuit assumed—without holding (as the issue was waived)—that Tennessee recognizes the contract-specification defense to TPLA claims. The Court explained that the defense requires "that the customer provide the manufacturer with detailed plans or specifications directing how the product should be built." But here, the evidence showed that the customer and manufacturer collaborated in designing and assembling a shredder system. While the customer certainly conveyed its needs to the manufacturer and provided proposed drawings for the system, the manufacturer was left to identify the components needed and the precise assembly of the system. In fact, the manufacturer contemplated incorporating a dust-collection bin in the design of the system but ultimately did not incorporate this component—and the absence of a dust-collection system was the likely cause of the explosion that killed Paul Cash. Because the testimony and documentary evidence in the record did not foreclose the possibility that the manufacturer made design determinations in the way the system was assembled, the Sixth Circuit reversed the trial court's holding that no genuine dispute of material fact existed as to the *viability* of the contract-specification defense.

Thompson v. Ryobi Ltd., No. 22-1228, 2023 WL 1961228 (6th Cir. Feb. 13, 2023)

Thompson presented the Sixth Circuit with two Michigan defenses: misuse (treated as an affirmative defense for the purposes of this summary) and impairment. Plaintiff resided in an apartment complex that often used a generator as its power source. The generator at issue was installed on the roof of Plaintiff's building. Plaintiff testified that he had read the operator's manual for a prior generator and at least some of the operator manual for the generator at issue. He also understood the risks of gasoline, used to power the generator. Unable to start the generator one day, Plaintiff—intoxicated—removed the gas cap, tilted the generator using the handle, and shined his flashlight inside to see the gas. Plaintiff then caught fire and sustained injury. Michigan law provides that a product "manufacturer or seller is not liable in a product liability action for harm caused by misuse of a product unless the misuse was reasonably foreseeable." Mich. Comp. Laws § 600.2947(2). Relying on Defendants' experts, the trial court found that Plaintiff misused the generator by tipping it while the cap was off and by operating it while impaired. Defendants

showed that this misuse was not foreseeable, and Plaintiff put forth no evidence or argument to the contrary. Accordingly, the Sixth Circuit affirmed the trial court's finding that Plaintiff misused the generator and his misuse was not reasonably foreseeable.

Michigan also recognizes the affirmative defense of impairment, requiring the defendant to show that the plaintiff was legally "impaired" and, due to the plaintiff's impairment, plaintiff was 50% or more the cause of the injury-causing accident. Relying on Defendants' experts, the trial court found that Plaintiff was impaired, and Plaintiff failed to present any evidence to rebut the presumption that he was impaired. However, the Sixth Circuit did not reach the second prong of the impairment defense; i.e., that Plaintiff was 50% or more the cause of the accident.

Preemption

***Farson v. Coopersurgical, Inc.*, No. 3:22-CV-716, 2023 WL 5002818 (N.D. Ohio Aug. 4, 2023)**

Plaintiff Farson filed a product liability suit related to the Filshie Clips used during her tubal ligation surgery. Following the surgery, the Filshie Clips migrated and became embedded in her abdomen and pelvic artery, such that they could not be removed. Migration was a known risk associated with Filshie Clips, a Class III medical device. Defendant CooperSurgical moved to dismiss Plaintiff's claims against it, as preempted both expressly and impliedly by the FDCA. The Court held that plaintiff's design-defect and failure-to-warn claims were preempted—expressly preempted by 21 U.S.C. § 360k(a) inasmuch as they would impose state-law design and warning requirements different from or in addition to those imposed by the FDA through the PMA process, and impliedly preempted by 21 U.S.C. § 337(a) insofar as they were premised on the manufacturer's purported failure to supply the FDA accurate data during the pre-market approval process.

***Arnold v. CooperSurgical, Inc.*, No. 2:22-CV-1951, 2023 WL 4552154 (S.D. Ohio July 10, 2023)**

The facts in *Arnold* are similar to those in *Farson*. Plaintiff Arnold underwent a tubal ligation, during which Filshie Clips were used. One Clip subsequently migrated, causing Plaintiff pain. The Court held that Plaintiff's design defect claim was impliedly preempted by Medical Device Amendments to the FDCA. The Court held that Plaintiff's manufacturing defect claim was expressly preempted. But because Plaintiff carefully pleaded her failure-to-warn claim to *avoid* alleging that Defendants failed to provide warnings "beyond" those required by the FDA, thus limiting her FDCA failure-to-warn allegations to those that parallel Ohio's product liability laws, her failure-to-warn claim evaded preemption and survived the motion to dismiss.

Jurisdiction

***Sullivan v. LG Chem, Ltd.*, 79 F.4th 651 (6th Cir. 2023)**

LG Chem manufactured lithium-ion batteries. Plaintiff obtained these particular batteries from a vape store in Michigan to use for his electronic cigarette. The batteries exploded in Plaintiff's pocket, injuring him. Accordingly, Plaintiff brought product liability claims against Defendant. Defendant, a South Korean company, opposed personal jurisdiction, arguing that exercising personal jurisdiction over it in Michigan would be improper under Michigan's long-arm statute and the Due Process Clause because, not only had Defendant never sold the batteries to the Michigan vape store where Plaintiff purchased them, but it had also never sold the batteries for individual consumer use in Michigan. The Sixth Circuit revered the district court, holding that the Michigan district court had personal jurisdiction over Defendant because Defendant directly shipped the batteries into Michigan and entered into two supplier contracts with Michigan companies for the batteries.

***Adams v. 3M Co.*, 65 F.4th 802, 803 (6th Cir. 2023)**

The issue in *Adams* was the Class Action Fairness Act of 2005's extension of federal diversity jurisdiction to certain "mass action[s]" involving "100 or more persons." 28 U.S.C. § 1332(d)(11)(B)(i). Two plaintiffs—Adams and Mounts—wore respirators to protect their lungs from coal dust while they mined coal in Kentucky. Despite their respirator use, they both developed pneumoconiosis. They then sued 3M and other manufacturers and distributors, alleging the respirators were defective and were the cause of their pneumoconiosis. Adams' complaint named more than 400 co-plaintiffs, demanded "judgment" against all defendants "jointly, severally, and/or individually," and sought "a trial by jury on all issues so triable." Mounts' complaint named more than 300 co-plaintiffs and mirrored Adams' in substance. 3M removed the cases on CAFA, federal question, and diversity grounds. Upon Plaintiffs' motion, the district court remanded the cases to state court. 3M's interlocutory appeal followed. Looking at the plain language of CAFA and Plaintiffs' own pleadings, the Sixth Circuit explained that the federal court had jurisdiction and reversed the trial court's decision to remand.

***Michigan Dep't of Env't, Great Lakes, and Energy v. Gerald R. Ford Int'l Airport Auth.*, No. 1:23-cv-01068, ECF No. 13 (W.D. Mich. Dec. 4, 2023)**

Plaintiff filed suit in state court on behalf of the People of the State of Michigan against Gerald R. Ford International Airport Authority for violations of Michigan's Natural Resources and Environmental Protection Act, arising from the Airport Authority's release of PFAS substances into the environment. Defendant removed the action to federal court under 28 U.S.C. § 1442(a)(1), which provides for a case's removal if it is against an "officer"—or any person acting under that officer—of the United States for any act "under color of such office." Plaintiff moved to remand, asserting that Federal Officer Removal was inapplicable. The Court agreed, applying a three-part test to determine whether such removal was proper. The Court first found that the Airport Authority met its burden of showing that the government contractor defense is plausible. But then the Court went on to find that the Airport Authority had not met its burden of establishing that it was "acting under" a federal officer within the meaning of § 1442(a)(1). In doing so, the Court

explained that the Airport Authority's "compl[iance] with a [federal] regulation is insufficient to show an acting-under relationship, even if the regulatory scheme is highly detailed and the defendant's activities are highly supervised and monitored." The Court continued in its analysis, furth finding that the Airport Authority had not met its burden to show a relation between the FAA's regulation of Aqueous Film-Forming Foams and the Airport Authority's release of PFAS; i.e., the Airport Authority did not show how the federal regulations mandated its release of PFAS in a way that establishes that it was acting under the color of federal office in doing so. Because the Airport Authority did not carry its burden as to two of the three prongs necessary for Federal Officer Removal, the Court remanded the case to state court.

Class Actions

In re E. I. du Pont de Nemours & Co. C-8 Pers. Inj. Litig., 87 F.4th 315 (6th Cir. 2023)

In November, the Sixth Circuit vacated the Southern District of Ohio's order certifying a class of more than 11 million Ohio residents claiming that ten manufacturers of per- and polyfluoroalkyl substances (PFAS) endangered their health.

Most (if not all) Americans interact with PFAS-containing materials on a regular basis—these materials are ubiquitous. In fact, thousands of companies have manufactured chemicals of this general type over the past half-century. And thousands of different compounds fall under the heading of PFAS.

Plaintiff Hardwick, a firefighter, submitted to testing that revealed trace quantities of five particular PFAS compounds in his blood. He did not know what companies manufactured the particular PFAS in his bloodstream or from what materials the PFAS originated. He was not sick or showing symptoms of any illness connected to PFAS. Indeed, he does not know whether the PFAS will *ever* make him sick. Yet he sought to represent a class comprising nearly every United States resident in his action against ten PFAS manufacturers. The Southern District of Ohio limited its certification to a class of every Ohio citizen. Reviewing the trial court's ruling, the pleadings, and some undisputed facts, the Sixth Circuit held that Hardwick did not have standing to proceed with his suit, aptly stating, "Seldom is so ambitious a case filed on so slight a basis."

In Re Ford Motor Co., 86 F.4th 723 (6th Cir. 2023)

Also in November, the Sixth Circuit vacated the Eastern District of Michigan's order certifying five statewide classes of Ford F-150 owners who sued Ford for alleged design defects in the trucks' brake system. The Sixth Circuit stated that the district court's "cursory treatment of commonality, one of the four necessary class action ingredients, failed to meet Rule 23's stringent requirements" and instructed the trial court to more thoroughly analyze whether the drivers had common enough claims concerning a purported defect.

***In re Fam. Dollar Stores, Inc., Pest Infestation Litig.*, No. 222MD03032SHLTMP, 2023 WL 7112838 (W.D. Tenn. Oct. 27, 2023)**

This MDL arose from allegations that Defendants deceptively, negligently, recklessly, and/or intentionally sold products that were contaminated by a rodent infestation in Family Dollar stores throughout Mississippi, Arkansas, Louisiana, Alabama, Missouri, and Tennessee. Following mediation, Plaintiffs sought conditional certification of a class of persons who resided in these states from January 1, 2020, through February 18, 2022, and purchased any product from an affected Family Dollar Store. The Western District of Tennessee conditionally certified the class and granted preliminary approval of the settlement agreement, which would award a $25 Family Dollar Gift Card for each eligible Settlement Class Member who submits an approved claim. The Court noted that such recovery "covers a 'significant portion' of the maximum possible damages."

***Hawes v. Macy's Inc.*, No. 1:17-CV-754, 2023 WL 8811499 (S.D. Ohio Dec. 20, 2023)**

A proposed nationwide class sued Macy's and textile manufactures alleging that Macy's misrepresented the thread count in some of the bed sheets it sells, in violation of consumer protection laws. This year, the Parties agreed to a global class action settlement that creates a $10,500,000 common fund to settle all claims of a nationwide class of bedsheet purchasers. But the Southern District of Ohio rejected the Parties' Motion to approve the settlement, ruling that the selected cy pres recipient of any undistributed funds—non-party Public Interest Research Group—was not related directly enough to the case to receive settlement funds.

Other

***Berkheimer v. REKM, LLC*, 206 N.E.3d 90 (Ohio Ct. App. 2023)**

Berkheimer presented the Ohio Court of Appeals with another opportunity to consider whether the "foreign-natural" test or the "reasonable expectation" test is properly applied in cases involving injuries in meat dishes. Plaintiff-appellee Berkheimer and his family were at a restaurant, when Berkheimer choked on a bone in a "boneless" chicken wing, injuring his esophagus. The Court of Appeals summarized Ohio case law in similar circumstances, explaining that aspects from both the "foreign-natural" and "reasonable expectation" tests appear in courts' analyses. Applying the reasoning from those cases, the Court affirmed the trial court's dismissal, concluding that the chicken bone was natural to the chicken wing and that a reasonable person could have anticipated and guarded against a similarly large-sized bone concealed in a bite-size piece of chicken.

***Colfor Mfg., Inc. v. Macrodyne Techs., Inc.*, --- F.Supp.3d ----, No. 5:22-CV-01658, 2023 WL 2866028 (N.D. Ohio Apr. 10, 2023)**

This case stems from a fire at a metal forming plant, which housed a hydraulic draw press that Plaintiffs alleged was defective and caused the fire. Plaintiffs brought thirteen claims, including claims under the Ohio Product Liability Act and common law claims for negligence and breach of warranty. Defendant Bosch moved to dismiss the common law claims, asserting that

the OPLA abrogates all products liability claims pleaded outside of it. The Court disagreed: the OPLA abrogates all common law product liability claims, but such claims are only those seeking to recover compensatory damages "for death, physical injury to person, emotional distress, or physical damage to property other than the product in question." Where, as here, the common law claims seek only economic damages, those claims are not abrogated by the OPLA. However, these common law theories are alternative claims—Plaintiffs cannot recover on both their OPLA claims and common law claims under the same set of facts.

SEVENTH CIRCUIT:

Cody Paschall, Dentons US LLP, 2000 McKinney Ave #1900, Dallas, TX 75201

Duty to Warn Extension

***Johnson v. Edward Orton, Jr. Ceramic Foundation*, 71 F.4th 601 (7th Cir. 2023)**

Plaintiff, the Estate of Bruce Johnson, brought this suit after Bruce contracted mesothelioma due to exposure of asbestos in vermiculite used in cone packaging. Bruce's Estate brought this suit as a products liability action that was pursued in state court and later removed to federal court. The Defendant, Edward Orton, Jr. Ceramic Foundation, ("Orton") manufactures and sells pyrometric cones. These cones were shipped to the consumers in a cardboard box with packaging intended to prevent the cone from breaking in transit.

Beginning in 1975, Orton began using packaging material from a different company which allegedly used vermiculite from mining sites that contained asbestos. It wasn't until 1981 that the cone manufacturer became aware that their product could contain asbestos. Being a ceramics artist and teacher from 1971 to 1984, Bruce would heavily use products manufactured by Orton. In 1981, Orton received a Material Safety Data Sheet that stated that the vermiculite contained less than 0.1% by weight of asbestos from 1963-1975 and 1979-1981. However, it is unclear whether this sheet contained any warning regarding the dangers of asbestos.

The trial court granted Orton's motion to dismiss because Bruce's Estate "did not establish that Orton knew, or should have known, that W.R. Grace [the supplier] was supplying vermiculite from Libby or that Libby vermiculite was contaminated with asbestos." However, the Seventh Circuit, applying Illinois law, reversed the lower court, and found that because Orton manufactured and sold the ceramic cones, that there was a duty to prepare their product for safe transportation and to not expose consumers to unreasonable danger. Despite not mining or creating the material and not knowing about the packaging contents until later, there was still a failure to warn.

The Seventh Circuit concluded that under Illinois product liability law, it is what a manufacturer either knew or should have known at the time of the harm. The manufacturer, therefore, has a duty to warn if they either have actual knowledge of a risk of harm relating to the product or reasonably should know of an expected risk of harm from the product. Here, Orton was held to an expert standard of knowledge in making the determination of whether it had constructive knowledge of asbestos in its packaging materials. The Seventh Circuit determined there was a fact issue to whether Orton had constructive knowledge of asbestos prior to the Material Safety Data Sheet and thus would have a duty to warn.

There are two key insights from *Johnson*. First, a company may be held liable for failure to warn relating to a product that it does not manufacturer or produce due to a dangerous propensity in its packaging that could harm consumers. Second, under Illinois law a company can expect the knowledge standard to be the same for duty to warn cases, whether in negligence or strict liability cases.

Expert Opinion on Design

***Anderson v. Raymond Corp.*, 61 F.4th 505 (7th Cir. 2023)**

Plaintiff, Adelaida Anderson, brought a diversity suit in federal court against the Raymond Corporation, a forklift manufacturer, on a claim of negligent design. Adelaida was a forklift operator at a FedEx warehouse in Illinois who hit a bump and fell on the warehouse floor while operating the machinery. The forklift continued to operate and ran over her leg which required amputation.

The key dispute as the parties headed to trial was over the admissibility of Dr. John Meyer, one of Plaintiff's expert witness. Dr. Meyer's contention was that Defendant could have implemented numerous changes to its machinery design that would have prevented Adelaida's injury. He proposed that if the Defendant had equipped its forklifts with a door that would enclose the operating compartment, it would stop an operator from falling to the ground and thus being in the forklift's pathway. While Defendant provides it as an option to equip the forklift with a door, the standard model did not come equipped this way.

Defendant contended that it did not provide their standard model with the doors because it could prevent an operator from making a quick exit if the forklift were to run off the loading dock or tip over. The key ruling then from the district court was that Dr. Meyer's opinion over the absence of a door was inadmissible because it did not meet the standard of Federal Rules of Evidence 702 or the test established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Thus, when the jury determined the forklift was not defectively designed and returned a verdict in Defendant's favor, Adelaida appealed. Specifically, she contended that the erroneous exclusion of Dr. Meyer's opinion substantially prejudiced her case.

The Seventh Circuit on appeal agreed and reversed the lower court. On review, the Seventh Circuit gave the district court no deference on their determination of Dr. Meyer's admissibility because the district court failed to conduct the requisite analysis and provided a mere conclusion. The Seventh Circuit concluded that Dr. Meyer's opinion should have been permitted.

First, they considered Dr. Meyer qualified to give an opinion based on his extensive training and professional experience. The Defendant's attempt to discredit his experience, based on a lack of experience with forklifts, did not move the needle because that focus is misplaced. The lack of specialization, instead "typically goes to the weight to be placed on [her] opinion, not its admissibility." *Hall v. Flannery*, 840 F.3d 922, 929 (7th Cir. 2016). Thus, Dr. Meyer's overall experience with accident reconstruction and engineering background allowed him to render opinions on what Defendant could have done differently to prevent the accident.

Second, the Seventh Circuit found Dr. Meyer's methodology to be sound. The Court reiterated that an expert need not conduct hands-on testing to have their testimony be admissible. Likewise, the court rejected Defendant's argument that Dr. Meyer's methodology does not meet the bar because it has been excluded elsewhere. As the Court stated, the inquiry focuses on the methodology of the expert, not whether they agree with the expert's conclusions. Additional arguments by Defendant of decades of experience in designing forklifts and the American National Standards Institute agreeing with it's position did not require exclusion of Plaintiff's expert. Therefore, given that Dr. Meyer was qualified, his methodology was sound, and his opinion was

relevant, his testimony over the design should have been admitted. Because Dr. Meyer's opinion could have affected the jury's verdict, a new trial was ordered.

Deceptive Labeling

***DeMaso v. Walmart Inc.*, 655 F. Supp. 3d 696 (N.D. Ill. 2023)**

A consumer brought a putative class action against Walmart arguing that Walmart's labeling of its cookies as "fudge mint" was deceptive. Plaintiff argued that the Great Value brand cookie was deceptive because the cookies were made with vegetable oil instead of dairy fat and was not made with mint. Plaintiff sued under the Illinois Consumer Fraud and Deceptive Business Practice Act (the "ICFA"), 815 Ill. Comp. Stat. 505/2, the state consumer fraud laws of the other 25 states, breaches of express warranty, implied warranty of merchantability, the Magnuson Moss Warranty Act (the "MMWA"), 15 U.S.C. § 2301, and common law claims for negligent misrepresentation, fraud, and unjust enrichment. He also sought class-wide injunctive relief as well as damages and restitution. Walmart, Inc. moved to dismiss, and the U.S. District Court for the Northern District of Illinois granted the motion.

The Walmart Great Value cookies at issue contained labeling describing the cookies as made with real cocoa and had a mint leaf and green packaging. Plaintiff argued that a reasonable consumer, seeing the statement of "Fudge Mint Cookies" and the cookies appearing coated with fudge would be misled by these representations. Rather, the reasonable consumer would expect fudge to mean that the cookies were made from dairy ingredients. Plaintiff asserted that the product instead of containing dairy ingredients or milk fat, consisted of vegetable shortening for its fat content. Regarding the placement of the mint leaf and green packaging, Plaintiff contended that the absence of terms like "Mint-flavored" and "Artificial Mint Flavored" would lead a consumer to believe the cookies contained mint ingredients. Plaintiff here also alleged that the mint flavor was a synthesized blend extracted in a laboratory from artificial sources. Therefore, combined with the fact that the product is made with real cocoa and labeled as such, a reasonable consumer's expectation that the product is made with mint is further enhanced.

The Plaintiff's contention was that Walmart's labeling strategy allowed it to gain an advantage against similar companies by misleading consumers to purchase a product that they believed contained fudge and mint ingredients—essentially, that the consumers received a product that was materially less than represented by Walmart through their packaging. Plaintiff's last allegation was that Walmart was able to sell their product at a higher price than they would have if they had labeled their product in a more appropriate manner. Walmart argued that their labeling was not deceptive or misleading and that Plaintiff therefore failed to state a claim under the ICFA and other related state consumer fraud statutes. Additionally, that Plaintiff's fraud, negligent misrepresentation, and unjust enrichment claims should be dismissed. Lastly, Walmart argued that Plaintiff lacked standing to seek injunctive relief.

The Court, in assessing the ICFA claim, evaluated the allegations regarding fudge and mint in separate sections. In assessing the fudge allegations, the court brought up how Plaintiff's own complaint asserted that fudge could contain vegetable oils, which ran contrary to Plaintiff's reliance on academic definitions. The court also brought up the lack of extant case law indicating that consumers seeing the term "fudge" brings with it an expectation that the product will contain

specific ingredients. Instead, the court cited several cases to the contrary. In discussing the mint, the dispute was whether the product promised a flavor or an ingredient and here the court agreed with Walmart that it promises a flavor. The court ruled that Plaintiff did not sufficiently plead that a reasonable consumer would have been misled by the label which required dismissal of the ICFA claim. Likewise, because Plaintiff's state consumer fraud act claims and the common-law fraud claim are based on a similar "unreasonable" interpretation of the products label, they do not survive the motion to dismiss.

Finally, in discussing the Warranty and MMWA, negligent misrepresentation, and unjust enrichment claims, the court found dismissal of the claims was warranted. Here, Plaintiff did not sufficiently identify an actionable "affirmation of fact or promise." Likewise, the cookies were not unfit for their ordinary purpose (eating). Thus, the same findings that applied to the ICFA claim apply to the warranty claims because a reasonable consumer would not be misled. Because the state law warranty claim failed, the MMWA claim also failed. Similarly, the negligent misrepresentation and unjust enrichment claims failed because they were based on the same theory.

This decision provides another illustration for whether there is an expectation of a flavor or ingredient. Here, this case can be seen as an expansion to earlier cases involving vanilla where courts have ruled that the ice cream products are identified by their flavors rather than their ingredients. *See Wach v. Prairie Farms Dairy, Inc.*, No. 21-cv-2191, 2022 WL 1591715, at *3 (N.D. Ill. May 19, 2022).

No Personal Jurisdiction

Webber v. Armslist LLC, 70 F.4th 945 (7th Cir. 2023)

Plaintiffs, the legal representatives of two deceased individuals, sued Defendants, Armslist LLC and Jonathan Gibbon, on negligence and Wisconsin state law claims arising from the deceased individuals' shooting deaths. Specifically, Plaintiffs argued that Defendants designed their websites in a manner that would both encourage and assist individuals in circumventing federal and state law regulating firearms. Defendants contended that the Plaintiffs failed to state a claim for relief that could be granted because Armslist providing third-party offers to sell firearms does not constitute a tort or other liability under Wisconsin law. The district court dismissed both negligence claims ruling that the Plaintiffs had failed to plausibly allege the website's design caused the deaths. On appeal, the Defendants argued that the district court lacked personal jurisdiction over Jonathan Gibbon, Armslist LLC's member manager.

Armslist operates as an online marketplace for firearms and is registered as a Pennsylvania limited liability company. Gibbon, the member manager is a Pennsylvania resident as well. Armslist does not engage in directly selling firearms, rather they are a website that allows users to post for sale and requests to purchase advertisements. This suit emerged in Illinois because a private seller from Wisconsin listed a Glock 26 9mm handgun for sale on armslist.com and it was purchased by a Milwaukee resident. Later, the Milwaukee resident resold the gun where it entered a criminal market that was later used by Shomari Legghette to shoot and kill Chicago Police Commander, Paul Bauer.

Plaintiff's contention was that Armslist allows persons to engage in the selling of firearms without a license and circumvents the relevant federal and state laws governing firearms. Allegedly, Armslist did this through their design and content features on their website. Plaintiff contended that the filter function on the website provided a pathway for the private sale of firearms without background checks to individuals who were prohibited from having firearms. Plaintiff's argue that Armslist and Gibbon should have implemented certain design features that had been adopted by other online firearm marketplace to prevent illegal transactions.

The Seventh Circuit was tasked with handling the *Bauer* and *Webber* decisions that had contrary rulings regarding personal jurisdiction. The long-arm statute at issue were Wisconsin Statute § 801.05(3) and (4)(a). Plaintiff alleged that specific jurisdiction was present over Gibbon because under § 801.05(3), Wisconsin courts have personal jurisdiction in an action "claiming injury to person or property within or without this state arising out of an act or omission within this state by defendant." The *Webber* court found personal jurisdiction could exist under § 801.05(4)(a), where personal jurisdiction exists when "claiming injury to person or property within this state arising out of an act or omission outside this state by the defendant, provided in addition that at the time of the injury…[s]olicitaiton or service activities were carried on within this state by or on behalf of the defendant." Plaintiff argued that Gibbon subjected himself to person jurisdiction in the forum because they designed armslist.com to solicit business in several states, including Wisconsin.

The Court, analogizing to the *Pavlic v. Woodrum*, 169 Wis.2d 585, 486 N.W.2d 533, 534 (Wis. Ct. App. 1992) decision, found that Gibbon's activities did not constitute actions that would allow for the exercise of personal jurisdiction over him within Wisconsin. Missing from Plaintiff's pleadings was that Gibbon anticipated receiving a financial benefit from persons in Wisconsin just because he decided to solicit business in Wisconsin. As the Court described, "in other words, the plaintiffs do not allege that Gibbon was responsible for Armslist LLC's decision to target the forum. Instead, plaintiffs plead only that Gibbon 'played a role in the design, architecture, and administration of Armslist.com' and 'controls its operations.'" Therefore, there was nothing pled that could bring Gibbon within the reach of the Wisconsin long-arm statute.

No Expert Testimony Needed

***Hakim v. Safariland, LLC*, 79 F.4th 861 (7th Cir. 2023)**

Plaintiff, a former Special Weapons and Tactics ("SWAT") team member brought a diversity action in federal court alleging that Plaintiff manufactured a defective shotgun shell made for door breaching. Plaintiff asserted a strict product liability and negligence claim for manufacturing defect, design defect, and failure to warn under Illinois law. The allegations emerged from an incident where a SWAT member was shot by the door-breaching shotgun round during a training exercise where the round failed to disintegrate upon impact with the target. After the jury returned a $7.5 million verdict on the failure-to-warn claim, The United States District Court for the Northern District of Illinois denied all of the manufacturer's motions for judgment as a matter of law, new trial, and reduction in damages.

The Seventh Circuit reviewed the issue of whether expert testimony was required to demonstrate inadequacy of warning given by manufacturer. Safariland's argument was that expert

testimony was required because the shotgun breaching rounds are a specialty product that is beyond the understanding of a typical lay juror. The special characteristics include the rounds having a complex design, the usage by trained law enforcement rather your average citizen, as well as the rounds having to be fired in a specific, correct manner for effectiveness.

The Seventh circuit, however, found none of these arguments to be relevant to Hakim's failure-to-warn claim. This is because while the round might be complex in certain regards, it does not necessitate expert testimony being required for every products liability claim regarding the rounds. However, the Court elaborated that expert testimony might be needed where a Plaintiff claimed that the rounds were designed defectively. In that case, expert testimony from a ballistics expert or design engineer would be necessary. *Citing Show*, 569 F.3d at 587. In fact, the jury found for Safariland on Hakim's design-defect claim and Hakim has not appealed that verdict.

The issue that the Seventh Circuit determined was factually relevant was whether Safariland's product literature adequately warned consumers of the risk that the breaching rounds could remain live after striking wood. They determined that this did not require expert testimony. What the Seventh Circuit found is that the jury's role in this situation is to examine the warnings and assess whether they were adequate. Therefore, this did not require any specialized knowledge or expertise by the jury.

This case was distinguished from the line of cases that require expert testimony for design-defect claims involving complex products. The Seventh Circuit made clear that it "is not the characteristics of the audience to whom the warning is directed that is dispositive, but whether a lay juror would understand the nature of the relevant risk and the substance of the warning at issue absent expert testimony." Thus, this decision by the Seventh Circuit is helpful in illustrating what exact issue the jury needs to analyze and assess in determining whether expert testimony is essential.

EIGHTH CIRCUIT:

Ann Motl, Greenberg Traurig, 90 South 7th St., Minneapolis, MN 55402

***Cantrell v. Coloplast Corp*., 76 F.4th 1113 (8th Cir. 2023)**

Plaintiff sued Defendant Coloplast for injuries allegedly caused by implantation of its vaginal surgical mesh device. The scheduling order required the plaintiff to disclose her expert witness by May 20, 2021, and for the parties to complete discovery by August 31, 2021. Plaintiff timely disclosed her expert's opinion, but the expert described the specific causation in only three brief sentences. When the defendant moved to exclude, the plaintiff responded by including a supplemental declaration by the expert with a lengthy analysis and a differential diagnosis after the August 31, 2021 deadline.

The district court (District of Minnesota) excluded portions of the plaintiff's expert opinions and testimony, concluding that the expert's original report lacked reasons for his opinions and the supplemental declaration was untimely. The district court granted the defendant's motion for summary judgment. Plaintiff appealed, arguing that the deadlines did not apply because the court's scheduling order required the parties to "fully supplement all discovery responses" according to Federal Rules of Civil Procedure Rule 26(e). The plaintiff argued that she had thirty days before the trial to disclose the expert's supplemental declaration.

The Eighth Circuit affirmed the district court's conclusion. The court reasoned that the Rule 26 timing provision only applies if the court does not order otherwise. Because the court set deadlines in its scheduling order, those deadlines supersede any default timing rules provided in Rule 26. Thus, the plaintiff's expert's supplemental declaration was untimely. The court also concluded that the district court did not abuse its discretion in excluding the expert's supplemental declaration, finding that the supplemental declaration attempted to clarify methodology that was not included in his original report.

***In re Stryker Rejuvenate & ABG II Hip Implant Prod. Liab. Litig*., 2023 WL 6514996 (D. Minn. Oct. 5, 2023) – NOTE: appeal pending**

Plaintiff brought this action in the Superior Court for the State of Connecticut against Connecticut Orthopedic Specialists ("Health Care Defendants") and Howmedica Osteonics Corp ("HOC") for an allegedly defective hip replacement component. Defendant HOC removed the action to the United States District Court of Minnesota under diversity citizenship. Additionally,

the District of Minnesota currently has an MDL with claims on the same bases (MDL No. 13-2441 (DWF/DJF)). Plaintiff filed a motion to remand the action back to Connecticut, arguing there was no subject matter jurisdiction because there was not complete diversity between the parties. HOC asserted that removal was appropriate because the plaintiff improperly misjoined the Health Care Defendants.

Under the fraudulent misjoinder doctrine, a plaintiff sues a diverse defendant in state court and joins a viable claim involving a nondiverse party or resident defendant, even though the plaintiff has no reasonable procedural basis to join them in one action because the claims bear no relation to each other. Federal Rules of Civil Procedure Rule 20 allows permissive joinder of multiple defendants in one action if: (1) any right to relief asserted against them arises out of the same transaction or occurrence, and (2) there is a common question of law or fact that arises out of the action. If the defendants have been misjoined, Rule 20 allows the defendants to be severed.

The District of Minnesota concluded that the Healthcare Defendants were misjoined in this case. The joinder of any malpractice or negligence claim against the Healthcare Defendants with other products liability claims was inappropriate because the claims did not involve common questions of law or fact, nor did they arise out of the same transaction or occurrence. Here, the medical negligence claims against the Healthcare Defendants arose out of the plaintiff's care, treatment, and services provided by the Healthcare Defendants. In contrast, the claims against HOC were based on alleged manufacturing and design defects associated with the hip replacement device. Any liability that arises from the Healthcare Defendants or HOC would not be a basis for liability to the other defendant. Thus, the court severed the action against the Healthcare Defendants to preserve the HOC's right to removal in the remaining action.

***Hunt v. Home Depot, Inc.*, 71 F.4th 673 (8th Cir. 2023)**

Decedent's wife, as representative of the decedent's estate, brought a claim against Home Depot alleging that a defect in the ladder the decedent was using to change a light bulb caused the decedent to fall to his death. Plaintiff submitted expert testimony, which concluded that although the ladder was fully locked at the time of the accident, the ladder was inherently wobbly and exceeded the maximum height according to the American National Standards Institute. The district court granted Home Depot's summary judgment motion, holding that the plaintiff's

position was supported only by mere speculation. The court further determined that there was no evidence to suggest that the ladder was defective.

On appeal, the Eighth Circuit viewed the facts in the light most favorable to the plaintiff, but affirmed the decision that there was no causation. Both experts agreed the ladder was fully locked at the time of the accident, and the plaintiff's allegation that this was not obvious was insufficient to establish causation. The court reiterated previous holdings that alleged violations of ANSI standards are not sufficient to establish causation. The court also concluded that the plaintiff failed to rule out other causes of the accident, including a possible electrical malfunction from exposed live wires where the decedent was working, or a sudden cardiac event.

***Knapp v. FAG Bearings, LLC*, 69 F.4th 513 (8th Cir. 2023)**

Plaintiff brought an action against the defendant, alleging that its improper disposal of trichloroethylene ("TCE") at their manufacturing facility caused him to develop multiple sclerosis ("MS") as a child between 1975 to 1981. His parents had previously participated in a class action lawsuit against the defendant for the alleged contamination during that time. In 2017, the plaintiff moved to Texas, where he started experiencing increased numbness in his body and was later diagnosed with MS. The same year, the plaintiff received an article discussing the possible link between exposure to TCE and the development of autoimmune diseases. Importantly, in winter 2017, the plaintiff also spoke with an attorney regarding his claims. In 2018, a doctor located in Missouri concluded that the plaintiff's exposure to TCE likely caused his MS, and then in 2021 the plaintiff filed suit for negligence and strict liability. The case was removed to federal court under diversity jurisdiction. The district court granted the defendant's motion for summary judgment on the ground that the plaintiff's negligent claim originated in Texas under Missouri's borrowing statute and was time-barred by Texas's two-year statute of limitations.

Under Missouri's borrowing statute, a cause of action will be fully barred in the state where it *originated*. The state in which a claim *originates* is where a reasonably prudent person received notice of a potential injury. The Eighth Circuit concluded that the plaintiff's claim originated in Texas because a reasonably prudent person in the plaintiff's position would have been on notice of a potential actional injury in Texas no later than December 2017 when he began experiencing numbness, read the articles linking TCE to MS, and spoke with an attorney. Because the plaintiff

filed his lawsuit in February 2021, his negligence claim was barred by Texas's two-year statute of limitations.

***Brunts v. Walmart, Inc.*, 68 F.4th 1091 (8th Cir. 2023)**

Plaintiff filed a putative class-action lawsuit against the defendant arising from allegedly misleading and deceptive marketing practices by selling cough drops containing dextromethorphan hydrobromide ("DXM") along with a "non-drowsy" label. Plaintiff asserted that the non-drowsy label was misleading because DXM is known to cause drowsiness. The defendant filed a timely motion to remove the case to the United States District Court for the Eastern District of Missouri. The plaintiff subsequently filed a motion to remand the case to state court, arguing that the defendant failed to show that the Class Action Fairness Act jurisdictional requirement of $5 million dollars was in controversy. The district court remanded the class action to state court, concluding that defendant did not provide sufficient detail to show that its total sales exceeded $5 million dollars, or that plaintiffs could recover the full cost of the sales.

The Eighth Circuit noted that when the amount of controversy after removal is at issue, the party seeking to remove the case must establish the amount in controversy by a preponderance of the evidence. Applying this analysis, the court held that the defendant's declaration from the Senior Manager of Regulated Product Development, who confirmed its sales of more than $5 million dollars in cough suppressants, was sufficient to satisfy the amount in controversy requirement. The Eighth Circuit reiterated previous holdings that the total amount of sales could be a measure of the amount in controversy. The Eighth Circuit noted that it wished the declaration included additional detail because that could have helped avoid the appeal, but nonetheless found it to be sufficient, especially since a company the size of Walmart could have sold more than $5 million of cough suppressant in Missouri over five years. Accordingly, the Eighth Circuit reversed the district court's order remanding the case to state court.

***Rey v. Gen. Motors, LLC*, 76 F.4th 1125 (8th Cir. 2023)**

A husband and wife sued the Defendant General Motors for injuries sustained after their vehicle was involved in a rollover crash driving from Mexico to the United States border. Plaintiffs alleged that the vehicle's design and performance of the vehicle's roof and other features were

defective. The district court determined that although plaintiffs' domicile was Missouri, the accident occurred in Mexico, and Mexico's law would govern the claims. Pursuant to the plaintiffs' amended complaint to replead their claims under the law of Coahuila, Mexico, the district court held that Coahuila does not recognize "indirect" moral injuries and granted the defendant's motion for summary judgment.

On appeal, plaintiffs first argued that the defendant waived the application of foreign law under Federal Rule of Civil Procedure 44.1 by failing to raise the issue in a timely manner. The Eighth Circuit concluded that although the defendant could have provided earlier notice, it did not mean such notice was so unreasonable that it waived its rights to request an application of foreign law.

The plaintiffs also alleged that Missouri law should govern the claims because Missouri had a more significant relationship with the parties and the occurrence than Mexico did. Under Missouri's "most significant relationship" test in the Second Restatement of Conflict of Laws, the state with the most significant relationship is the state where the injury occurred, absent any overriding interest of another state. The Eighth Circuit determined that although the plaintiff is a long-time resident of Missouri, and their claim would be more successful in Missouri, Missouri's interest in the plaintiff's "right of recovery" did not outweigh Mexico's interest in determining the "right of remedy." The court was also unpersuaded by the plaintiffs' attempt to reduce Mexico's interest, noting that the plaintiff had been in Mexico for over a month and intended to stay there for an extended amount of time at the time of the accident. Accordingly, the court concluded that Mexico, as the place of injury, had the most significant relationship to the parties and the occurrence.

***Tucker v. Gen. Motors LLC*, 58 F.4th 392 (8th Cir. 2023)**

Plaintiffs brought a putative class action suit against defendant General Motors in the Eastern District of Missouri, arising from an alleged oil consumption defect in the defendant's vehicles. Under the Missouri Merchandising Practice Act ("MMPA"), a right of action is created for any person who sustains ascertainable loss in connection with a purchase of personal, family, or household merchandise as a result of unlawful practices. The plaintiffs alleged that the defendant engaged in unlawful conduct under the MMPA when it concealed, suppressed, or omitted a material fact in connection with the sale of vehicles affected by the oil defect. The district

court granted the defendant's motion to dismiss, holding that the defendant's advertising constituted "mere puffery," which was insufficient to form the basis of a fraud claim.

The Eighth Circuit reversed. The court held that the plaintiffs plausibly stated their claims, based on the class action complaint containing numerous pages of specific allegations relating to the defendant's knowledge of oil consumption issues, as well as numerous examples of how the defendant "trumpeted the performance" of the affected vehicle's engines. Further, the court determined that that the plaintiffs' fraudulent omission claims were more than "mere puffery," because the oil consumption defect was a deficiency that the average consumer would be unlikely to know or would be able to research.

***McDougall v. CRC Indus., Inc.*, 2023 WL 5515827 (D. Minn. Aug. 25, 2023)**

A decedent's surviving spouse brought a claim against CRC Industries, Inc. ("CRC") after his wife was struck and killed in a car accident. The driver of the other vehicle was allegedly intoxicated from ingesting compressed gas from a cannister of dusting spray manufactured by CRC. The driver lost control of his vehicle and drove into oncoming traffic, hitting the decedent's vehicle head on.

CRC's compressed gas duster spray contains a hydrocarbon gas called difluoroethane, which can cause intoxicating side effects when inhaled or ingested, including hallucinations, drowsiness, suffocation, loss of consciousness, cardiac arrest, and death. To deter consumers from misuse, CRC advertised a bittering agent in the CRC Duster to prevent inhalation abuse. Between 2012 and 2017, CRC revised its Safety Data Sheet product label for its CRC, warning consumers that deliberately inhaling the product could lead to death, depending on the concentration and duration of exposure.

CRC filed a motion to dismiss. The district court granted the motion with respect to the plaintiff's public nuisance claim and alleged Minnesota Deceptive Trade Practices Act violations but denied the motion regarding the remaining claims.

The defendant then brought a motion for summary judgment, asserting that the plaintiff's strict liability design defect and failure to warn claims contained no triable issues regarding duty, breach, or proximate causation. The District of Minnesota rejected CRC's motion for summary judgment, finding that there were genuine disputes of material fact regarding CRC's duty and proximate case claims. Generally, a person does not owe a duty of care to another if the harm is

caused by a third party's conduct. However, the court explained that an exception exists when the defendant's own conduct creates a foreseeable risk of injury to a foreseeable plaintiff. The plaintiff produced evidence which demonstrated CRC's knowledge of the product's misuse, introduction of its bittering agent, and revision to its warning labels. The court determined that the plaintiff's evidence could lead a jury to reasonably infer that CRC's conduct created a foreseeable risk of injury.

The court further rejected CRC's argument that making and selling the CRC Duster were not substantial factors in the decedent's actions. The court explained that proximate cause is satisfied if the injury was the natural and probable consequence of the defendant's acts, following an unbroken sequence without an intervening cause, from the original negligent act. An intervening cause is not superseding unless it "actively worked to bring about a result which would not otherwise have followed from the original negligence and was not reasonably foreseeable." The court found that although the third-party driver's actions "actively worked to bring about a result that would not otherwise have followed from the original negligence," a jury could conclude that, based on CRC's actions and prior knowledge of the product's misuse, the events leading to the decedent's death were a reasonably foreseeable risk.

NINTH CIRCUIT:

Alexi Layton and Brennen Marshall, Evans Fears Schuttert McNulty Mickus, 6720 Via Austi Parkway, Suite 300, Las Vegas, NV 89119

***Yamashita v. LG Chem, Ltd.*, 62 F.4th 496 (9th Cir. 2023)**

Summary: In *Yamashita v. LG Chem*, 62 F.4th 496 (9th Cir. 2023), the plaintiff brought a product liability case involving a South Korean manufacturer and a Delaware distributor with a principal place of business in Georgia. The plaintiff alleged that a battery used to power an electronic cigarette exploded in his mouth, and defendants challenged personal jurisdiction in the underlying United States District Court for the District of Hawai'i. The distributor shipped their products through the port of Honolulu and sold residential solar batteries in Hawai'i. The batteries in question, however, were only found in products sold in Hawai'i through third party sellers and there was no evidence that either the manufacturer or distributor introduced or distributed these batteries to Hawai'i.

In analyzing the U.S. Supreme Court's most recent personal jurisdiction case, *Ford Motor Co. v. Montana Eighth Judicial District Court*, 141 S. Ct. 1017, 209 L.Ed. 225 (2021), the Ninth Circuit determined that the district court lacked both general and specific jurisdiction. As to specific jurisdiction, the Court reasoned that the manufacturer was an out-of-state company with various forum contacts but does not sell the product in question to residents of Hawaii. The Court found that there was no general jurisdiction because neither the manufacturer or distributor defendants were domiciled in Hawaii and their only contacts with Hawaii were "random, fortuitous, [and] attenuated." *Id.* at 503. The Court further found that the district court lacked specific jurisdiction because, under the stream-of-commerce-plus test, the manufacturer must do more than place the product into the stream of commerce and the plaintiff's claims lacked causation as they did not arise out of the few contacts the defendants had with Hawaii, stating that "*Ford* makes clear that 'relate to' 'does not mean anything goes.'" *Id.* at 506. This case shows the Ninth Circuit's willingness to distinguish cases from the fact pattern of *Ford*, potentially chipping away at certain aspects of the Court's prior analysis. The Courts are sure to continue to analyze *Ford* and practitioners should continue to monitor the Court's application of this case.

***McGinity v. Procter & Gamble Co.*, 69 F.4th 1093 (9th Cir. 2023)**

Summary: In *McGinity v. Procter & Gamble Co.*, 69 F.4th 1093 (9th Cir. 2023), the Ninth Circuit tackled the issue of an ambiguous, but not necessarily misleading, label on a shampoo packaging that displayed the phrase "Nature Fusion." The back label of the shampoo referenced avocado, a natural ingredient, and a list of artificial ingredients that were fused with the natural one. The plaintiff brought claims under California's Unfair Competition Law, California's False Advertising Law, and California's Consumers Legal Remedies Act, alleging the "Nature Fusion" moniker was misleading. Applying the reasonable consumer standard, the Court found that, although the phrase "Nature Fusion" was ambiguous, such ambiguity can be resolved by referencing the contents of the back label and a reasonable consumer would see that the term "Nature Fusion" is a sort of fusion of natural and artificial ingredients and not, as plaintiff alleged, a fusion of only natural ingredients. While this case establishes precedent that ambiguous front

labels can be mitigated by back labels, the concurring opinion warns manufacturers against the dangers of "greenwashing" in similar situations: the misrepresentation or exaggeration that a product has a positive environmental impact, which goes against the FTC's Green Guides.

***Davis v. Cranfield Aerospace Solutions, Ltd.*, 71 F.4th 1154 (9th Cir. 2023)**

Summary: In *Davis v. Cranfield Aerospace Solutions, Ltd.*, 71 F.4th 1154 (9th Cir. 2023), the Ninth Circuit affirmed the Idaho District Court's decision that it lacked personal jurisdiction over an English aerospace company because the case involved an out-of-state plane accident brought by out-of-state plaintiffs against an out-of-state defendant with no minimum contacts in Idaho. A jet crashed in Indiana and killed all occupants aboard, and the plaintiffs from Indiana and Louisiana alleged that the crash resulted from the on-flight ATLAS system, which was manufactured and installed by a Washington defendant with its principal place of business in Idaho. In addition, the plaintiffs also brought action against Cranfield, an English consultant company that helped with obtain the necessary certification to install the ATLAS system. Other than two trips by Cranfield employees to Idaho, all of Cranfield's work over a period of six years was conducted in Washington or England, not in Idaho.

Determining that the only issue before the Court was whether there was specific jurisdiction, the Court found neither purposeful direction nor purposeful availment in Idaho because there was no injury in Idaho and any contacts with Idaho were too attenuated to establish the necessary minimum contacts for specific jurisdiction. Specifically, Cranfield's contract negotiations, the terms of the contract, the consequences of the contract, and the course of dealing with the ATLAS manufacturer did not constitute purposeful availment. Essentially, Cranfield had not purposefully availed itself by seeking out or benefiting from the manufacturer's Idaho residence. Furthermore, the two trips by employees to Idaho were too random, fortuitous, and attenuated to create the required minimum contacts for an exercise of specific jurisdiction. This case provides an interesting example of the Ninth Circuit finding no jurisdiction where an out-of-state consultant defendant was engaged in a long-term contract with an in-state defendant, essentially conducting work remotely but never gathering sufficient minimum contacts to be subject to specific jurisdiction in Idaho.

***Faulk v. JELD-WEN, Inc.*, 650 F.Supp.3d 803 (D. Alaska 2023)**

Summary: In *Faulk v. JELD-WEN, Inc.*, 650 F.Supp.3d 803 (D. Alaska 2023), plaintiffs filed a putative class action lawsuit in Alaska state court against three defendants, proposing a class of Alaskans who own structures with allegedly defective windows. The defendants removed the case to federal court under the Class Action Fairness Act ("CAFA") and the plaintiffs attempted to remand the case back to state court, arguing that the CAFA's local controversy exception applied. The local controversy exception attempts to ensure that cases involving a controversy involving one specific locality are tried in that state's court instead of federal court. Plaintiffs attempted to limit the class to only include Alaskans so they could argue that the local controversy exception applied because all the class members would be individuals in Alaska, there was an Alaskan defendant, and the complaint limited the injuries to only those that occurred in Alaska.

While the court noted that the damages sought against the Alaskan defendant were most likely significant, it determined that the Alaskan defendant was not significant to the complaint because the other defendants were the focus of the complaint and the allegations against the Alaskan defendant were non-specific. Additionally, the court saw through the plaintiffs' attempt to take a nationwide controversy and squeeze it into a local one, considering that the windows in question were distributed nationwide and would have allegedly injured consumers across the country. This case stands for the proposition that a plaintiff cannot force a class action to fall under the local controversy exception of the CAFA by artificially limiting the class and to one state where the product is distributed nationwide and the claims against the only in-state defendant do not form a significant basis for the action.

***Elorreaga v. Rockwell Automation, Inc.*, 2023 WL 2769146 (N.D. Cal. Mar. 31, 2023)**

Summary: In *Elorreaga v. Rockwell Automation, Inc.*, No. 21-cv-05696-HSG, 2023 WL 2769146 (N.D. Cal. Mar. 31, 2023), a decedent plaintiff alleged that he developed mesothelioma from exposure to asbestos-containing equipment while he worked aboard Navy vessels and in Navy shipyards. The district court denied the defendants' motions for summary judgment on liability, despite acknowledging the general weakness of plaintiff's evidence of exposure. The court held that the government contractor defense did not apply to the claims based on federal maritime law. The plaintiffs' proffered evidence on liability was mainly the deposition testimony of the decedent plaintiff, which centered around which asbestos-containing products were attributable to each defendant he worked for. Finally, reasoning that plaintiffs' experts did not rely on the "every exposure" theory of liability, which the Ninth Circuit has rejected, the court found sufficient evidence to raise at least one genuine dispute of material fact regarding whether the alleged exposure was a substantial factor in causing the mesothelioma. This case shows the difficulty of summary judgment motions in mesothelioma and other exposure cases, where the plaintiff's weaker causation and exposure evidence can still be sufficient to survive summary judgment.

***L.W. through Doe v. Snap Inc.*, 2023 WL 3830365 (S.D. Cal. June 5, 2023)**

Summary: *L.W. through Doe v. Snap Inc.*, 2023 WL 3830365 (S.D. Cal. June 5, 2023) involves several cases of adult perpetrators approaching and abusing minors on Snapchat and plaintiffs alleging multiple claims against Snapchat, Google, and Apple, including strict liability claims under theories of defective design and failure to warn, and negligence and negligence per se. The district court found that under § 230(c)(1) of the federal Communications Decency Act ("CDA"), defendants were entitled to immunity on each of plaintiffs' claims because this section of the CDA provides broad federal immunity that would make service providers liable for information that originated from third parties on the service. The Ninth Circuit's three-prong test for determining whether immunity from liability exists, requiring (1) that the defendant be a provider or user of an interactive computer service, (2) who the plaintiff seeks to treat as a publisher or speaker, (3) of information that is third party content. Because all three defendants satisfied this test, the court held that they were entitled to immunity under CDA Section 230 for the actions of the third-party, adult perpetrators.

***McCarthy v. Amazon*, 2023 WL 4201745 (W.D. Wash. June 27, 2023)**

Summary: In *McCarthy v. Amazon*, 2023 WL 4201745 (W.D. Wash. June 27, 2023), the parents of two teenagers who committed suicide after ordering and ingesting sodium nitrate from Amazon sued Amazon, alleging negligent and strict product liability claims, common law negligence claims, and a negligent infliction of emotional distress claim. Amazon filed a motion to dismiss, which the district court granted. The district court held that, under the Washington Product Liability Act ("WPLA"), Amazon was a seller, not a manufacturer, and neither Amazon's negligence nor intentional concealment of information proximately caused the children's deaths. Amazon was also absolved of liability because the product was not defective and there was no duty to warn because the dangers of sodium nitrate were known to the children, who deliberately sought it out for its lethal properties, and additional warnings would not have prevented their deaths. The children knew about the dangers of the product and deliberately disregarded the warnings, breaking any chain of proximate causation between the defendant's conduct and the plaintiff's injury.

As for intentional concealment, the court found that, under the broad immunity of the Communications Decency Act ("CDA"), Amazon was not liable for reviews or concealment of reviews created by third parties. Finally, the court found that the plaintiffs' common law negligence and NIED claims were preempted by the WPLA and, attempting to convert their preempted claims into claims under the WPLA, the court found that plaintiffs failed to state a plausible claim for relief against Amazon under any claim.

TENTH CIRCUIT:

A. Alexander DeMasi, Lewis Brisbois Bisgaard & Smith LLP, 4600 Madison Avenue, Suite 700, Kansas City, Missouri 64112; alexander.demasi@lewisbrisbois.com

Illegality Defense

***Messerli v. AW Distrib., Inc.*, 2023 U.S. Dist. LEXIS 113946 (D. Kan. Jun. 30, 2023)**

The District of Kansas recently applied the illegality defense to dismiss a case based on the decedent's own behavior. The plaintiff filed his lawsuit against four defendants who design and/or manufacturer computer dusters, claiming that each of the dusters designed and/or manufactured by the defendants contributed to his son's huffing addiction and eventually led to his death. The plaintiff asserted claims of negligence, strict liability, and breach of implied and express warranties under Kansas law.

One of the defendants' moved to dismiss the plaintiff's claims under the *in pari delicto* doctrine because the claims were based on the decedent's own violations of Kansas law, specifically Kan. Stat. Ann. § 21-5712, which criminalized the unlawful abuse of toxic vapors. The district court held the *in pari delicto* doctrine and the illegality defense as analogous to the wrongful-conduct doctrine in *Inge v. McCelland*, 725 F.App'x 634 (10th Cir. 2018) because Kansas courts have recognized that "a party who consents to and participates in an illegal act may not recover from other participants for the consequences of that act" and that the illegality defense has been applied by Kansas courts "if the evidence shows that plaintiff freely and voluntarily consent to participate in the illegal act, without duress or coercion." *Messerli*, 2023 U.S. Dist. LEXIS 113946, at *12-13 (citing *Parker v. Mid-Century Ins.*, 25 Kan. App. 2d 329, 962 P.2d 1114, 1116 (Kan. App. 1998)).

In applying this rule to the plaintiff's complaint, the district court ruled that the plaintiff's son had voluntarily engaged in an illegal act, i.e., huffing computer dusters, which barred his claims. In dismissing the claim, the District of Kansas made two rulings.

First, the district court rejected the argument that Kansas's codification of comparative fault impliedly overruled the *in pari delicto* doctrine. The plaintiff argued the son's contributory negligence did not bar recovery if his negligence was less than the defendants' negligence and that his damages award should be reduced by the negligence attributed to the son. The plaintiff cited several cases involving negligent conduct by a plaintiff, but none of them involved illegal conduct. The district court emphasized that Kansas courts have continued to apply the illegality defense to claims arising from a plaintiff's illegal conduct without citing to the comparative fault rule.

Second, the district court became the first court in Kansas to rule that the illegality defense applies in products liability cases. The plaintiff argued that the court should not apply the illegality defense to plaintiff's claims because no Kansas court had applied the defense in a products liability case and that the public policy underlying products liability actions did not support this defense. The district court disagreed and predicted that Kansas courts would apply this defense to plaintiff's claims just as it applied it to non-products cases heavily cited to in its ruling. The district court

also recognized similar rulings in products cases in Kentucky, Mississippi, Alabama, Pennsylvania, and Florida.

Certification to State Supreme Court

Messerli v. AW Distrib., Inc., No. 22-2305-DDC-TJJ, 2023 U.S. Dist. LEXIS 188974 (D. Kan. Oct. 20, 2023)

Following the district court's dismissal in *Messerli* based on the decedent's illegal conduct, the remaining defendants filed "me too" motions seeking to apply the ruling to the claims against them as well. In response, the plaintiff sought certification from the Kansas Supreme Court about the applicability and requirements of the Kansas illegality defense in the context of a products liability claim.

In denying the plaintiff's request for certification, the district court noted that "while Kansas law allows a federal court to certify, Tenth Circuit precedent does not require it" and reiterated the notion that a federal does not have to certify "every time an arguably unsettled question of state law comes across [its] desk." *Messerli*, 2023 U.S. Dist. LEXIS 188974, at *10 (quoting *Spurlock v. Townes*, 594 F. App'x 463, 466 (10th Cir. 2014)). The district court noted the discretion to certify "rests in the sound discretion of the federal court" and that the federal court "should consider should consider state court decisions, decisions of other states, federal decisions, and the general weight and trend of authority" even when the state's highest court has not addressed the issue before it. *Id.*

The District of Kansas refused to certify because it had already considered decisions from multiple other jurisdictions as well as the Kansas case law recognizing the illegality defense. The plaintiff was also unable to provide any signal that Kansas courts would have considered the question unsettled. The district court also noted that requests to certify are particularly disfavored after the requesting party has received an adverse ruling.

Munoz v. FCA US LLC, No. 22-2077, 2023 U.S. App. LEXIS 13502 (10th Cir. June 1, 2023)

The 10th Circuit recently denied certification to the New Mexico Supreme Court after the district court ruled against the moving party. Like the *Messerli* case cited above, the 10th Circuit indicated that the appellant did not seek certification until after the district court entered judgment against him and because neither question of state law presented by the appellant was determinative on the appeal.

Expert Testimony

Munoz v. FCA US LLC, No. 22-2077, 2023 U.S. App. LEXIS 13502 (10th Cir. June 1, 2023)

In *Munoz*, a driver was injured when his airbags did not deploy after he struck two elk at highway speeds. The driver filed claims for defective manufacturing and breach of warranty

against the manufacturer. The district court granted summary judgment to the manufacturer, ruling that the driver failed to provide expert testimony to establish the presence of a defect that caused his injuries. On appeal, the driver argued that the district court erred in (1) requiring expert evidence and (2) overlooking other evidence the driver provided.

In applying New Mexico substantive law, the 10th Circuit found that expert testimony was necessary because "the intricacies of occupant protection systems and their potential design or manufacturing defects are outside the realm of the everyday experience" and the functionality of this system was highly technical. *Munoz v. FCA US LLC*, No. 22-2077, 2023 U.S. App. LEXIS 13502 (10th Cir. June 1, 2023) (citing *Ruminer v. Gen. Motors Corp.*, 483 F.3d 561, 565 (8th Cir. 2007)). The 10th Circuit went on to state that "common experience does not dictate that if an individual is injured in a car accident, the injury is most likely a result of a defect in the automobile's occupant protection system." *Id.*

The 10th Circuit emphasized that if the driver had presented evidence of the defect, he failed to provide expert evidence of causation, which was required under New Mexico law.

Minimum Contacts for Personal Jurisdiction

***Stuart v. Petzl Am., Inc.*, No. 1:23-cv-00595-CNS-SKC, 2023 U.S. Dist. LEXIS 144535 (D. Colo. Aug. 17, 2023)**

The District of Colorado dismissed a products liability action against an alleged manufacturer of a safety equipment used by a rock climber because the rock climber could not show the minimum contacts necessary to exercise personal jurisdiction—either general or specific—over the manufacturer in Colorado. The rock climber, a Colorado resident, suffered near-fatal and life-altering injuries after using the equipment while rock climbing in West Virgina. The alleged manufacturer argued that even if it were the correct manufacturer (which it denied), as a Utah company, the court lacked personal jurisdiction over it since the rock climber purchased the equipment from a retailer in the United Kingdom.

The district court concluded that the manufacturer's contacts did not render it at home in Colorado. The rock climber argued that the exercise of general jurisdiction in Colorado was proper because the alleged manufacturer had (1) consented to being sued in Colorado in a related lawsuit and (2) counsel for the manufacturer suggested that the underlying matter be filed in Colorado as a matter of convenience. The district court did not find this argument persuasive and declined to exercise general jurisdiction over the manufacturer based on "case-linked" jurisdiction.

The court further declined to exercise specific jurisdiction over the manufacturer in Colorado because the lawsuit did not "arise out of" or "relate to" the manufacturers contacts with Colorado. Specifically, the court found that even if the manufacturer distributed the equipment in Colorado generally, the rock climber purchased the equipment at issue from a retailer in the United Kingdom, meaning that the rock climber's injuries did not "arise out" of the manufacturer's business activities in Colorado. The court also found the rock climber's alter ego arguments unavailing because even if the manufacturer's parent company sold the equipment that failed, a

parent company's minimum contacts do not suffice to establish personal jurisdiction over its alter ego subsidiary.

ELEVENTH CIRCUIT:

Gabrielle C. Broders, Irwin Fritchie Urquhart Moore & Daniels, 400 Poydras Street, Suite 2700, New Orleans, LA 70130

***Carson v. Monsanto Company,* 72 F.4th 1261 (11th Cir. 2023) (en banc)**

Plaintiff brought suit against the herbicide manufacturer, Monsanto, alleging that the herbicide, Roundup, was carcinogenic and that his exposure thereto caused his malignant fibrous histiocytoma. Plaintiff asserted claims under Georgia law for strict liability for design defect, strict liability for failure to warn, negligence, and breach of implied warranty of merchantability. On appeal, the Eleventh Circuit answered the question of whether the Environmental Protection Agency's ("EPA") decision to register herbicide without a cancer warning, along with the EPA's repeated scientific conclusions about its active ingredient, glyphosate, preempted the consumer's claim. Specifically, whether, in express preemption cases, the court must consider if the agency actions that are claimed to preempt the state law have the force of law.

Monsanto contended that a provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") expressly preempted the consumer's suit, or, in the alternative, the suit was impliedly preempted by the EPA's previous approval of Roundup's labeling. Plaintiff asserted that FIFRA could neither expressly nor impliedly preempt the state law because a federal agency rule that does not have the force of law cannot preempt a state law rule that does. Relying upon ordinary principles of statutory interpretation, the en banc Eleventh Circuit held that whether the agency acted with the force of law is relevant to express preemption only if the express preemption provision makes it relevant.

Accordingly, where Congress has enacted an express preemption provision, courts are to identify the state law that is subject to preemption according to ordinary principles of statutory interpretation. The relevant inquiry is not simply whether the agency has acted with the force of law, but rather whether the express preemption provision of the federal statute in question requires a force of law analysis. Here, the Eleventh Circuit therefore left it to the panel to evaluate whether the express preemption language in FIFRA mandates a force of law analysis prior to determining whether the EPA's actions with respect to Roundup indeed have the force of law, and if so, whether a Georgia cancer warning for Roundup would be in addition to or different from those requirements, and hence expressly preempted.

***Cates v. Zeltiq Aesthetics, Inc.*, 73 F.4th 1342 (11th Cir. 2023)**

Plaintiff, who experienced paradoxical adipose hyperplasia ("PAH") following cryolipolysis ("CoolSculpting") treatments, brought action against cryolipolysis device manufacturer, Zeltiq, asserting claims for strict products liability based on defective design, strict products liability based on failure to warn, negligence, negligent misrepresentation, and fraudulent misrepresentation and concealment. On appeal, Plaintiff challenged the district court's granting of summary judgment in favor of the manufacturer. Specifically, (1) on failure to warn, the district court concluded that Zeltiq's warnings about PAH were adequate as a matter of law, and (2) on

design defect, the court determined that the patient failed to provide expert testimony that the risk of CoolSculpting outweighed its utility.

First, as to the failure to warn claim, the Eleventh Circuit determined that Zeltiq warned medical professionals, under the learned intermediary doctrine, about PAH and its potential consequences in both its CoolSculpting user manual and its training session materials. Notably, and important to remember, is that the assessment of the adequacy of the warning is objective. It is not dispositive that the medical professional at issue did not have a subjective appreciation of the danger of PAH because a reasonable medical provider would have. When the warning is legally adequate to inform the *objective* learned intermediary, the actual learned intermediary's failure to warn the patient does "not give rise to a duty in the manufacturer."

Second, as to the design defect claim, the Eleventh Circuit declined to determine which of the two tests that Florida law applies for design defect claims, (1) the consumer expectations test and (2) the risk utility test, applies to CoolScuplting, but instead assessed Plaintiff's claims under both. The Court found that Plaintiff had not identified a defect in the design of CoolSculpting, but he had merely pointed to a known, but rare, side effect. More specifically, under the risk utility test, the Court found that Plaintiff failed to present any evidence of an alternative design for the CoolSculpting system that could have reduced or avoided PAH and its effect. And regarding the consumer-expectations test, which for medical devices like CoolSculpting assesses the expectations of a learned intermediary rather than an end user, "PAH was within the realm of known (albeit rare) side effects of CoolSculpting."

***Henderson v. Ford Motor Company,* 72 F.4th 1237 (11th Cir. 2023)**

Estate of driver who died in roll-over accident brought action against vehicle manufacturer, Ford, for wrongful death and products liability alleging that vehicle's faulty seatbelt design, which resulted in excess slack, caused driver's fatal injury. Plaintiff tried to introduce 50,829 warranty claims that purportedly showed thousands of reports filed with Ford regarding seatbelt issues in the vehicle at issue. On appeal, the Eleventh Circuit affirmed the district court's suppression of the warranty claims, finding that the court appropriately applied the substantial similarity doctrine in determining that the over 50,000 prior warranty claims that purportedly showed thousands of reports filed with Ford regarding seatbelt issues, from the same model of vehicle that was manufactured during same time frame as the vehicle decedent was driving, were not "substantially similar" to the claims at trial.

Moreover, the Eleventh Circuit affirmed the district court's ruling that allowing Plaintiff's experts to review the inadmissible warranties did not open the door to the admission of the evidence on cross examination. The Court reasoned that admission of the warranties on cross examination would be "inadmissible evidence disguised as expert opinion."

Finally, Ford cross-appealed the admission of Plaintiff's expert, and the Eleventh Circuit used this cross-appeal to clarify their precedent: prevailing parties lack standing to appeal absent some prejudice by the collateral estoppel effect of the district court's order. Accordingly, the Court

found that, since Ford was the prevailing party, its injury is "merely anticipatory," and the cross appeal was dismissed.

***Bayless v. Coloplast Corp.*, No. 21-14397, 2023 WL 1466607 (11th Cir. Feb. 2, 2023)**

Patient who underwent surgical operations in which two polypropylene meshes—including Coloplast Corporation's Restorelle Y—were inserted into her pelvic region brought suit against Coloplast and the other manufacturer attributing her post-operation injuries to the products inserted during surgery alleging, among other claims, that Restorelle Y was defectively designed. After a trial, the jury found in her favor against Coloplast, and Coloplast appealed arguing, in part, that Plaintiff did not present sufficient evidence to establish general causation.

The Eleventh Circuit reasoned that Plaintiff had presented sufficient evidence to establish general causation because "the record contains significant testimony about the potential harmful effects of polypropylene mesh." Based upon the materials science expert's testimony, the jury could have believed that, as a polypropylene product, Restorelle Y could undergo oxidative degradation after it is implanted in vivo. And based upon the medical causation expert's testimony, the jury could have believed that oxidative degradation leads to injuries such as mesh exposure and vaginal erosion. Even though the medical causation expert did not testify about the general effects of Restorelle Y, he did testify about the general effects of polypropylene mesh, and a sufficient basis existed for the jury to connect them. Accordingly, the Eleventh Circuit opined that the jury could have relied on the medical causation expert's testimony about specific causation—combined with the materials science expert's testimony about polypropylene—to infer that the general causation requirement was satisfied.

The good news: this case is unpublished. The bad news: it is apparently proper for a jury to take specific causation evidence and combine it with non-medical scientific testimony and "infer" general causation.

DC CIRCUIT:

Jason Hodge, Nelson Mullins Riley & Scarborough, LLP, 901 E. Byrd Street, suite 1650, Richmond, VA 23219

Ariel Redfern, Nelson Mullins Riley & Scarborough, LLP, 750 B Street, Suite 2200, San Diego, CA 92101

Removal Strategy and Opposition to Motion to Remand

***Chem. Toxin Working Grp. Inc. v. Johnson & Johnson*, 2023 WL 2631492 (D.D.C. Mar. 24, 2023)**

The District of D.C. provided clear guidance on the standards for removal under the Class Action Fairness Act (CAFA), which can also be translated into any opposition to a plaintiff's motion to remand.

The plaintiff, a non-profit public interest organization based in California, filed a putative class action in the D.C. Superior Court against Johnson & Johnson and Johnson & Johnson Consumer Inc. (collectively, "defendants"), both of whom were based in New Jersey. The putative class action was brought on behalf of D.C. consumers under the D.C. Consumer Protection Procedures Act ("CPPA"), alleging that defendants deceptively labeled, marketed, and sold five different baby hygiene products. Defendants removed to the D.D.C., on the basis of diversity jurisdiction under CAFA, pursuant to 28 U.S.C. § 1332(d), which requires that "the parties are minimally diverse, the class-wide amount in controversy exceeds $5 million, and there are more than 100 putative class members."

Plaintiff filed a motion to remand. In considering, and denying, the plaintiff's motion, the court systemically considered whether each of these elements were met. Because they were, the court correctly concluded it had diversity jurisdiction under CAFA, that removal was proper, and that the motion to remand should be denied.

The "minimal diversity" prong was easily met and, indeed, not disputed by the plaintiff—i.e., "neither shares common citizenship that would lend to extinguish diversity between them."

The plaintiff did challenge the prong—amount in controversy. The Court provided useful instruction on the appropriate standards for assessing this prong in the context of a removal. Specifically, the Court explained that the "amount in controversy is an estimate of the total amount in dispute; not a prospective assessment of a defendant's liability," which thus affords the defendant "some latitude in estimating the amount in controversy in the early stages of litigation." Importantly, the estimate of the amount in controversy need not be established by concrete evidence or to a legal certainty; rather, just as with the evaluation of whether a plaintiff's complaint sufficiently states a claim, there need only be "plausible factual allegations, accepted as true, [that] establish federal jurisdiction." In making this assessment, the court is allowed to "make common-sense inferences."

In demonstrating the amount in controversy in this case, the defendants provided an estimate that it sold 27,551 units of the products at issue during the class period—a figure derived

by taking the number of sales relative to the size of the population of D.C. compared to the United States as a whole, i.e., 0.2% of sales of the product throughout the entire United States. The defendants then multiplied this figure by the relief sought, which could be up to $1,500 per violation, to arrive at an amount in controversy of $41,326,500 in statutory damages (the DC CPPA considers it a "violation" each time a customer purchases an allegedly mislabeled product). The plaintiff argued that this amount in controversy was speculative, but the Court disagreed. Referencing the appropriate standard, the Court explained that because the defendants had "offered an estimate of the amount in controversy and its theory in developing that conclusion," coupled with the "legal latitude in estimating the amount in controversy" at that "early stage of this litigation," the Court could accept the good-faith allegations regarding the "amount in controversy allegation without requiring evidentiary submissions to validate it."

As for the final prong, the putative class size, the defendants simply referenced the plaintiff's complaint alleging that the putative class "consists of at least hundreds, if not thousands, of consumers." The plaintiff challenged this showing, claiming that because it was the defendant's burden, they could not "carry that burden simply by relying on the allegations in [the plaintiff's] complaint." The Court also rejected this position. It explained that while the D.C. Circuit had not addressed this precise question, "numerous circuits have held that a plaintiff is bound by allegations in a state-court complaint that go to CAFA's jurisdictional requirements." This conclusion required the Court to "break with *Wexler*, a case decided by another court in this District" in 2007. The Court explained that the Supreme Court's *Dart Cherokee* decision, handed down after *Wexler*, had "severely undermined [Wexler's] reasoning."

Takeaways. The language in this case provides clear guidance on the appropriate standard for removal under CAFA, which should be considered when evaluating removal, as well as when opposing remand. In short, the allegations of a notice of removal under CAFA are evaluated under the same general standard as a plaintiff's allegations in a complaint, so removal is still an option to consider even if you do not have a precise figure for the amount in controversy and/or the numerosity elements. Likewise, such allegations need not be supported with evidence and shown to a legal certainty. Finally, this case directly breaks with previous precedent in the District, i.e., *Wexler*, which, although it had been implicitly overruled since *Dart Cherokee*, is now directly refuted by this case.

Motions to Compel Arbitration

Gambo v. Lyft, Inc., 642 F. Supp. 3d 46 (D.D.C. 2022)

In this case, the District of D.C. compelled arbitration based on the plaintiff's assent to Lyft's terms of service, which contained an arbitration provision. The plaintiff was using a Lyft scooter through the Lyft application and alleged that while riding the scooter, "the stem detached from the deck, causing [the plaintiff] to fall and seriously injure himself." He brought several claims for product liability, negligence, and implied warranty, based on alleged design and manufacturing defects. Lyft removed the case to federal court and subsequently moved to compel arbitration, which the plaintiff opposed.

In moving to compel arbitration, Lyft submitted a declaration from one of its "staff engineers." The declaration established when the plaintiff had created an account with Lyft and how many times he used the account to rent a Lyft scooter. The declaration also comprehensively set forth the process for creating a Lyft account, including imaging to show what setting up an account would have looked like to the plaintiff at the time he signed up. This account-creation process included a "clickwrap" agreement, which required the plaintiff to affirmatively check a box that read "I understand and agree to Lyft's Terms of Service and Privacy Policy," which were hyperlinked next to the box, before being able to continue with creating the account. The staff engineer declaration also included the pertinent language from the Terms of Service itself setting forth the arbitration agreement. The declaration included pertinent screen grabs of what the plaintiff would have seen in creating his account.

In considering the motion to compel arbitration, the Court identified the applicable standard as "whether or not there had been a meeting of the minds on the agreement to arbitrate," which was a question that the Court could not postpone. Thus, the Court had to "consider arbitrability at the outset of litigation." The Court also noted that it was Lyft's burden to show evidence of an enforceable agreement to arbitrate, after which the burden shifts to the non-moving party to "raise a genuine issue of material fact as to the making of the agreement, using evidence comparable to that identified in Rule 56."

Here, the Court acknowledged that the "present dispute between the parties is a narrow one." Specifically, although the plaintiff did not dispute that he clicked the "agree" button on the Terms of Service and that these Terms of Service contained an arbitration clause, he nonetheless argued that this agreement "did not form an enforceable agreement to arbitrate." The Court disagreed. It explained that the present case was "on all fours with *Selden*," an opinion by the D.C. Circuit that had compelled arbitration based on a "sign-in wrap" agreement (where there was a statement to the effect that by proceeding with an action, the party was agreeing to the terms of service). The Court emphasized that the Terms of Service and the agreement to arbitrate was a contract and should be analyzed as such. Specifically, it looked at D.C. law, which "requires mutual consent to create an enforceable contract, and mandates that, absent fraud or mistake, one who signs a contract is bound by a contract which he has an opportunity to read, whether he does so or not." The Court also cited to "numerous other judicial decisions" concluding that "clickwrap and similar electronic agreements are enforceable." It thus rejected the plaintiff's "argument that the arbitration is unenforceable because he was not on reasonable notice of it," and stayed the case pending the outcome of arbitration.

Takeaways. Motions to compel arbitration often arise in the class action context in products liability cases, but this case serves as a good reminder that they can also be useful in the context of an individual action as well. To maximize chances for success, it is a good practice to include a thorough declaration setting out how an arbitration agreement was conveyed to the user, how it was accepted, what it looked like to the user, and then juxtapose those facts with comparable scenarios in cases compelling arbitration.

Regulatory / Agency Opinions vis-à-vis Products

***Fontem US, LLC v. United States Food & Drug Administration*, 82 F.4th 1207 (D.C. Cir. 2023)**

In this decision, the D.C. Circuit invalidated the FDA's denial of premarket approval of Fontem's unflavored vaping products, based on the agency's failure to follow its own guidance. This opinion can be useful for identifying and structuring challenges to premarket approval denials.

Fontem appealed the FDA's order denying premarket approval for its flavored and unflavored vaping products under 21 U.S.C. § 387*l*(a)(1). Before addressing the substance of Fontem's challenge, the Court clarified two procedural points for challenging an FDA determination made under the Tobacco Control Act. First, the Court instructed that the FDA's denial of premarket approval was a final order reviewable by the Court, and Fontem's administrative rehearing request within the FDA did not strip the Court of jurisdiction. Second, the Court confirmed that because Fontem filed its petition for judicial review within 30 days of denial, the petition was timely and reviewable.

Fontem challenged the FDA's denial for both its flavored and unflavored vaping devices. The Court found the FDA denial of flavored vaping devices proper. The Court noted that the higher risk to youth and the danger of hooking new users outweighed the extent to which flavored products would aid current smokers in quitting. The Court rejected Fontem's arguments and concluded that because the FDA put forth a valid reason for its decision, the Court will nevertheless uphold the agency's decision even if there were also invalid reasons for the denial.

As for the denial of Fontem's application for its unflavored products, however, the Court found the FDA failed to follow its own guidance and thus improperly denied the application. Specifically, the FDA has not used "its regulatory authority to promulgate tobacco product standards or manufacturing regulations." Instead, it evaluates premarket approval for vaping devices through a holistic public health framework—requiring the agency to balance the benefit to the public as a whole on a case-by-case basis. In denying Fontem's application for its unflavored products, the FDA did not perform a comprehensive analysis, but instead made a wholesale denial based on its findings regarding Fontem's flavored products. The Court emphasized that the FDA could not set a case-by-case review standard for evaluating applications and then deny an application based on a regulatory standard it chose not to set. In doing so, the Court invited the FDA to promulgate tobacco product standards or manufacturing regulations to alleviate the need for a holistic review.

The Court further criticized the FDA for departing from guidance it provided in a deficiency letter to Fontem. The Court explained that when the FDA issued this deficiency letter detailing what Fontem could do to resolve the issues with its application, the FDA represented that such information would be sufficient to secure approval. When Fontem provided this information, and the FDA nevertheless denied its application, it "shifted the regulatory goalposts without explanation," resulting in an arbitrary and capricious determination. Ultimately, the Court vacated the FDA's denial of premarket approval for Fontem's unflavored vaping devices.

***Takeaways*.** The D.C. Circuit took issue with the FDA's moving target evaluation of vaping devices. This case demonstrates the Court's reluctance to rubber stamp the FDA's denial of premarket approval for vaping devices. Additionally, this case shows that FDA deficiency letters can, and should, be used as roadmaps for securing approval—it is authority that the FDA cannot outline the requirements for premarket approval, then shift and "pull a surprise switcheroo" on the applicant without notice. This case also confirms that a denied application under the Tobacco Control Act is reviewable despite an internal FDA administrative rehearing.

***Window Covering Manufacturers Association v. Consumer Product Safety Commission*, 82 F.4th 1273 (D.C. Cir. 2023)**

With proper representational standing, the Window Covering Manufacturers Association ("WCMA"), brought suit on behalf of similarly situated window covering businesses against the Consumer Product Safety Commission ("CPSC") for a promulgated rule impacting the design and manufacture of corded stock and custom window covering products.

The CPSC determined that corded window coverings pose a deadly risk to children. Both WCMA and the CPSC have taken steps to make window coverings safer for children. The WCMA adopted a voluntary safety standard to reduce the risk of child strangulation. The CPSC nevertheless expressed concerns that the voluntary safety standard was not sufficient. The CPSC then promulgated and adopted a Final Rule regarding custom window coverings.

The WCMA challenged the CPSC's rule and argued that it: (1) violated notice-and comment requirements under the Administrative Procedure Act ("APA"); (2) engaged in an erroneous cost-benefit analysis by not giving sufficient weight to the WCMA's voluntary standard; (3) set an arbitrary 180-day effective date for the Final Rule; and (4) had no authority to promulgate the Final Rule because the CPSC's members are subject to a for-cause removal provision. The Court did not address the constitutional challenge to the Final Rule, but it agreed with WCMA's position on its other three challenges.

The Court took issues with several steps in how the CPSC achieved the Final Rule. First, the Court highlighted the CPSC's failure to properly disclose underlying data supporting the Final Rule, reasoning that this failure led to an erroneous decision and deprived challengers of the ability to fully refute the CPSC's position. Next, the Court found the CPSC's cost-benefit analysis flawed because the CPSC improperly compared the economic consequences of the Final Rule on stock window coverings versus custom window coverings. Finally, the Court rejected the CPSC's 180-day effective date for the Final Rule because the CPSC based its effective date on the single comment of one manufacturer indicating a 180-day compliance deadline would be appropriate, despite there being 401 industry commenters supporting a contrary position.

Thus, the Court vacated the Final Rule and remanded the matter to the CPSC for further proceedings.

Takeaways. This is another example of the D.C. Circuit not merely rubber stamping agency action. Outside of the specific context, the opinion provides a useful reminder that agency action can be successfully challenged on appeal, even after a final rule is promulgated.

SUPREME COURT OF THE UNITED STATES:

Trent Mansfield, Butler Snow, LLP, 1819 5th Avenue N. #1000, Birmingham, AL 35203

***Abitron Austria GmbH v. Hetronic Int', Inc.*, 600 U.S. 412 (2023)**

The Supreme Court explained the high burden one faces when arguing in favor of extraterritorial application of federal law.

Hetronic, a manufacturer of radio remote controls for construction equipment, sued Abitron for selling Hetronic-branded products in violation of 15 U.S.C. § 1114(1)(a) and § 1125(a)(1). Hetronic argued that the broad definition of "commerce" should be interpreted to cover sales that occurred outside of the United States. This was a winning argument at the trial level, and a jury awarded Hetronic approximately $96 million in damages, an amount that included foreign sales of products that did not end up in the United States. The Tenth Circuit affirmed, holding that "the Lanham Act extended to all of Abitron's foreign infringing conduct because the impacts within the United States were of a sufficient character and magnitude as would give the United States a reasonably strong interest in the litigation." The Court granted certiorari to resolve a Circuit split over the extraterritorial reach of the Lanham Act.

The Court explained the well-established presumption against extraterritoriality and applied a two-step framework to determine whether the law extended to foreign conduct. The first step, which determines whether a provision is extraterritorial, turns on whether "Congress has affirmatively and unmistakably instructed that the provision at issue should apply to foreign conduct. . . . If Congress has provided an unmistakable instruction that the provision is extraterritorial, then claims alleging exclusively foreign conduct may proceed, subject to the limits Congress has (or has not) imposed on the statute's foreign application."

If it is determined that the law is not extraterritorial, the second part of the test is applied, and a determination is made as to whether the suit seeks a permissible domestic or impermissible foreign application of the provision. To make this determination, courts must look to the primary congressional focus underlying the provision at issue. Courts must then ask whether the conduct relevant to that focus occurred in United States territory. If it is determined that "the conduct relevant to the statute's focus occurred in the United States, then the case involved a permissible application of the statute, even if other conduct occurred abroad." However, "if the relevant conduct occurred in another country, then the case involves an impermissible extraterritorial application regardless of any other conduct that occurred in U.S. territory."

Hetronic argued that both statutes, § 1114(1)(a) and § 1125(a)(1), should have extraterritorial application because of the broad definition of "commerce" that applies to both provisions. "Commerce" is defined as "all commerce which may lawfully be regulated by Congress," which would include foreign conduct under the Foreign Commerce Clause. However, the Court has "repeatedly held that even statutes that expressly refer to foreign commerce when defining commerce are not extraterritorial."

The Court, emphasizing the "territorial" nature of trademark law, ultimately held in favor of Abitron and remanded the case for further proceedings consistent with the opinion. "It thus

bears repeating our longstanding admonition that United States law governs domestically but does not rule the world."

***Mallory v. Norfolk Southern Railway Co.*, 600 U.S. 122 (2023)**

Mr. Mallory, a former employee of Norfolk Southern, sued the company in Pennsylvania state court for injuries he sustained from asbestos and other chemical exposure during his employment.

Norfolk Southern moved to dismiss Mr. Mallory's suit on the grounds that the Pennsylvania court lacked specific personal jurisdiction over it because Mallory's complaint alleged exposure to carcinogens in Ohio and Virginia, not Pennsylvania. Further, Norfolk Southern argued that general personal jurisdiction was not applicable either because it was incorporated, and had its headquarters in, Virginia, not Pennsylvania.

The Pennsylvania Supreme Court agreed with Norfolk Southern and held that a Pennsylvania law requiring out-of-state companies registered to do business in Pennsylvania to appear in its courts on "any cause of action" against them violated the Due Process Clause of the U.S. Constitution. *See* 42 Pa. Cons. Stat. § 5301(a)(2)(i), (b).

The Supreme Court of the United States disagreed and held in favor of Mallory. The Court identified several categories of laws that require corporations to consent to personal jurisdiction as a cost of doing business within the forum state. Some states require all out-of-state corporations registered to do business within the forum to agree to defend themselves there against any manner of suit. Other states applied "this all-purpose-jurisdiction rule to a subset of corporate defendants, like railroads and insurance companies." Mallory presented the Court with a list of statutes falling within these two categories that were enacted between 1835 and 1915.

The Court ultimately relied on a case decided over 100 years ago, *Pennsylvania Fire Ins. Co. of Philadelphia v. Gold Issue Min. & Mill Co.*, 243 U.S. 93 (1917). The Court explained that "all-purpose-jurisdiction" statutes, such as Pennsylvania's, have always comported with the Due Process Clause. The Court rejected Norfolk Southern's argument that the Court's *International Shoe* decision established only two types of personal jurisdiction: general and specific. The Court explained in this case that *International Shoe* did nothing more than introduce a "novel" way of securing personal jurisdiction and did not replace traditional ways such as the consent by all-purpose-jurisdiction statute method at issue in *Pennsylvania Fire*.

The Court then spent time discussing the substantial business Norfolk Southern conducts, and "boasts" about, in its marketing materials. However, the Court did not seem to indicate that this affected the analysis. In other words, if a state has one of these all-purpose-jurisdiction statutes in effect, a corporation consents to personal jurisdiction as a cost of doing business in that state to be weighed alongside the potential benefits.

CANADA:

Sunny Rehsi, Bowman and Brooke LLP, 101 West Big Beaver Road, Suite 1100, Troy, MI, 48084, sunny.rehsi@bowmanandbrooke.com

Noah Boudreau and Nicolas-Karl Perrault, Fasken Martineau DuMoulin LLP, 800 Square Victoria, Suite 3500, Montréal, Québec, H3C 0B4 nboudreau@fasken.com nperrault@fasken.com

2023 Cases

Plaintiff Not Entitled to Pierce Litigation and Solicitor-Client Privilege to Obtain Yamaha's File Relating to Investigation Performed by Outside Counsel in a Product Liability Action

***Belanger et al. v. Avalon et al*., 2023 ONSC 5816**

On July 18, 2016, Plaintiff was out wakeboarding with family and friends on the Detroit River. Plaintiff left the helm unattended, with the twin outboard motors idling, to urinate from the back of the boat. There was some horseplay and a friend pushed Plaintiff into the water. While Plaintiff was in the water, other occupants were storing a wakeboard on a wakeboard rack that was mounted adjacent to the captain's chair and throttles. During this process, there was contact with the throttles and the boat went into reverse. One of the outboard motors made contact with Plaintiff, resulting in a below the knee amputation.

Plaintiff sued numerous parties, including the manufacturer of the outboard motors and throttle control and its distributor in Canada: Yamaha Motor Co. Ltd., Yamaha Motor Corporation, U.S.A., and Yamaha Motor Canada Ltd. (collectively "Yamaha"). After Yamaha's corporate representatives were examined, Yamaha provided more than 182 undertaking responses. Included in these undertakings was an inquiry as to what steps Yamaha took to investigate the accident and what instructions were provided to its outside counsel. Yamaha refused to answer these undertakings on the basis of litigation and solicitor-client privilege. Plaintiff brought a motion to compel and argue Yamaha was shielding relevant documents on unfounded claims of privilege, and that the real purpose of its investigation was a design related concern.

The Court dismissed Plaintiff's motion to compel. The evidence was clear that the investigation file and instructions to outside counsel were protected by the litigation and solicitor-client privileges. Justice Howard found the threat of Plaintiff commencing litigation was very likely approximately a week after his injury and that Yamaha satisfied its onus. Justice Howard further held "*the attempts by plaintiffs to pierce the litigation privilege and solicitor-client privilege, in demanding the production of external counsel's retention letter, external counsel's investigation file, Yamaha's investigation file, and the related documents in question, must fail*."

Motion for Summary Judgment Granted in a Simplified Procedure Action for the Manufacturer of a Tankless Water Heater

***Ahmed v. Rheem Canada, et al*. 2023 ONSC 3340**

Plaintiffs sued Rheem Canada Ltd. ("Rheem") and Reliance Home Comfort ("Reliance") following a carbon monoxide incident in November 2013. After several years of ongoing litigation, Rheem brought a motion for summary judgment, arguing there was no evidence the tankless water heater was defective or that it caused or contributed to the carbon monoxide leak. Justice Leibovich agreed and held "*…this is an appropriate case to issue summary judgment and dismiss the claim against Rheem. There is simply no evidence that the water heater they supplied was defective in any way…*" Plaintiffs had no expert evidence to substantiate their defect claims against Rheem.

Justice Leibovich further held that "*plaintiffs have not, in their material or in oral submissions, pointed to <u>any</u> evidence that supports their contention that this particular water heater was defective or that the design of the water heater was defective*." The crux of Plaintiffs arguments to substantiate a defect with the tankless water heater rested on an email from Reliance to Plaintiffs, that the tankless water heaters were being swapped out sooner than expected. The Court disposed of this argument, stating the email "*in no way supports the assertion that the water heater, which was used for five years, after the carbon monoxide incident was defective in November 2013. Rather, the email seems to simply indicate that the water heater's shelf life is not as long as first thought*." The claim against Rheem was dismissed.

<u>Summary Disposition Can be Heard at the Same Time as Class Certification</u>

***Dussiaume v. Sandoz Canada Inc*., 2023 BCSC 795**

The British Columbia Supreme Court dismissed a class action against the manufacturers, distributors and retailers relating to the negligence and failure to warn of the risks associated with a heartburn medicine containing ranitidine, sold as Zantac (and other generic formulations).

In particular, the Court was tasked with deciding whether it was permissible, just and convenient to hear summary disposition applications brought by Defendants at the same time as the class certification. It was appropriate, and in the interest of justice for summary disposition to be heard in conjunction with a class action certification application – as a proposed class proceeding has "*no special status and, until certified, it is to be treated as any other individual action*."

Plaintiff sought to certify a national class pursuant to the *Class Proceedings Act*, for individuals who purchased Zantac, by alleging that ranitidine transforms over time, and under certain conditions becomes N-Nitrosodimethylamine ("NDMA"), a carcinogen, which can increase the risk of cancer. In particular, Plaintiff sought the following claims:

- Negligent design claims against the GlaxoSmithKline Inc.;
- Negligence, failure to warn, strict liability, battery, deceptive acts and practices under the *Business Practices and Consumer Protection Act*, by reason of knowingly or recklessly making materially false or misleading representations under the *Competition Act* against the remaining defendant manufacturers; and

- Breach of implied conditions under the *Sale of Goods Act*, and other similar legislation or otherwise breach of contract against all defendant retailers.

On behalf of the class, Plaintiff sought damages for mental health distress (due to learning of the recall), medical monitoring, recovery of health care costs, economic loss for the purchase price of the product, and general damages for increased risk of harm and cellular change.

Plaintiff's Negligence, Failure to Warn and Psychological Injury Claims Fail

Plaintiff's claim for potential future harm is not compensable and is not a complete tort. Essentially, without there being a harm, there can be no actual loss. Additionally, the law does not recognize claims for being upset, disgust, anxiety, agitation or other mental states that fall short of being an actual injury. Thus, Plaintiff's claims for negligence, failure to warn and psychological injuries fails because they disclose no reasonable claim.

Plaintiff's Medical Monitoring Claim, and Claims that NDMA causes Cancer and Battery due to Alleged Cellular Damage Also Fail

Plaintiff sought damages for past and future costs of medical monitoring of the class members. The Court found this claim would fail, as no imminent and serious threat was pleaded, and the Plaintiff has the burden of proving either economic or physical injury. With respect to NMDA causing cancer, the Court agreed with the Defendants experts that given "*the uncontroverted evidence that neither ranitidine nor NDMA are reliably associated with increased cancer risk, and the absence of evidence that ranitidine or NMDA cause cancer in humans*," Plaintiff failed to raise a *bona fide* triable issue. Plaintiff's battery claim suffered a similar fate. The Court found humans are exposed to cellular changes on a regular basis in their lives. Plaintiff failed to adduce evidence of any actual genetic mutation for the proposed class members and thus, compensation for this injury has no prospect of success and is dismissed.

Class Certification Denied for Failing to Meet Evidentiary Burden

***Larsen v. ZF TRW Automotive Holdings Corp.*, 2023 BCSC 1471**

The British Columbia Supreme Court dismissed a class action against the designer, manufacturer and installer of Airbag Control Units ("ACU") in automobiles. Originally the Plaintiff had framed the action in negligent design and/or manufacture, unjust enrichment, failure to warn, breach of express warranty, and statutory causes of breach of the implied warranty under the *Sales of Goods Act*, and breach of the *Business Practices and Consumer Protection Act* and for deceptive acts or practices and breach of the *Competition Act*. However, at the certification stage, Plaintiff abandoned several of her claims and the remaining causes of actions were framed in negligence and breaches of the *Competition Act*. The Court held Plaintiff failed to meet her evidentiary burden and dismissed her application.

Plaintiff alleged the defect in the ACU's prevented the airbag and seatbelt pretensioners in numerous vehicles from deploying in rare collisions. However, Plaintiff alleged no damages from injuries to persons or property, rather her damages were fixated solely on pure economic loss. The

Court also acknowledged that various vehicle manufacturers had implemented safety recalls to remove the risk of airbag failure in potentially affected vehicles – despite this recall constituting "*some acknowledgement of a defective design or manufacturing*," Plaintiff failed to identify a common defect with the vehicles. Primarily, there was no evidence from Plaintiff that repaired vehicles remained defective. The Court went onto hold "*[t]hese claims are entirely derived from the existence of the alleged ACU defect. Having found no basis in fact for its existence, there is no concordant misrepresentation and no risk of dangers that the defendant failed to disclose*." Thus, there were no common issues for certification and Plaintiff's claim for punitive damages alone "*cannot support class certification*."

Class Certification Abandoned After Recent Update in Canadian Product Liability Actions

Piccolo v. General Motors of Canada Limited, 2023 ONSC 3018 and *Baggio v. General Motors of Canada Ltd.*, 2023 ONSC 3019

The Court was faced with a motion from the Plaintiff to discontinue a nationwide putative class on a without prejudice basis (in order to allow any individuals to commence their own action) against General Motors of Canada Limited and General Motors Company, due to the recent developments in case law that have placed limits on the compensation available in product liability cases and the increased risks associated with same.

Piccolo dealt with the negligent and dangerous design, manufacture and installation of the Body Control Module ("BCM") in Defendants' vehicles and Plaintiffs alleged defendants failed to warn them and the public about the BCM's defects. *Baggio* on the other hand, dealt with allegations of negligent and dangerous design, manufacture and installation of defective transmission shift cable in Defendants vehicles.

The Court in both actions discussed the recent product liability developments resulting from two Supreme Court of Canada decisions: *Atlantic Lottery Corp Inc. v. Babstock*, 2020 SCC 19, and *1688782 Ontario Inc. v. Maple Leaf Foods Inc*., 2020 SCC 35. The Supreme Court of Canada has clarified the law delimiting the recoveries for pure economic losses for dangerous defective products:

> "*establishing that: (a) apart from a few exceptions, tort law leaves pure economic losses to be addressed by the law of contract; (b) there is no right to compensation for a threat of injury unless the product defect presents an imminent threat; (c) the scope of recovery is limited to mitigating or averting the danger presented by the defective product; and (d) to the extent that it is feasible for the plaintiff to simply discard the defective product, the danger to the plaintiff's economic rights as well as the basis for recovery fall away*."

Thus, these changes affected the recoveries for pure economic losses arising from the dangerous products, curtailing the prospect of a substantial award for the class members. When this class action was commenced, a substantial award was possible, but that is not the case any longer. The Defendants consented to Plaintiffs request to have the action dismissed.

New Evidence Not Allowed on Appeal in a Nationwide Multi-Jurisdictional Class Action

***Evans v. General Motors of Canada Company*, 2023 SKCA 86**

The Saskatchewan Court of Appeal was tasked with determining whether the lead Plaintiff's application should be granted to adduce additional evidence (seven affidavits) in response to her appeal brought by General Motors. The Court denied Plaintiff's application.

This case involves a nationwide multi-jurisdictional class action against General Motors for individuals who purchased or leased a 2011 or newer Chevrolet Cruze. The Plaintiff alleged General Motors breached various common law and statutory duties in designing, manufacturing, marketing and selling the Cruze, causing her and the class members economic loss. Plaintiff's allegations related to the Cruze's cooling system and there were defects with these components that caused overheating and low coolant warning lights to remain illuminated and entry of noxious and foul-smelling emissions. Shortly after the class was certified in April 2019, General Motors was given leave to appeal and for unexplained reasons, Plaintiff did not file her materials until November 2022.

In determining whether to permit Plaintiff to adduce additional evidence, the Court utilized the test set forth in *Palmer v. R.*, 1 S.C.R. 759, which takes into account the following factors:

> "*(i) the evidence could not by the exercise of due diligence, have been obtained for the trial (provided that this general principle will not be applied as strictly in a criminal case as in civil cases); (ii) the evidence is relevant in that it bears upon a decisive or potentially decisive issue; (iii) the evidence is credible in the sense that it is reasonably capable of belief; and (iv) the evidence is such that, if believed, could have affected the result at trial.*"

The Court held the newly adduced evidence did not meet the test for admission under *Palmer* – as it failed to satisfy the due diligence criteria. The Court also considered General Motors argument that the evidence is not credible, as General Motors never had an opportunity to cross-examine the affiants. The new evidence was excluded.

No Class Certification for an Emissions Defeat Device Case

***Tress v. FCA US LLC*, 2023 SKKB 186**

The Court had to decide whether a class action was the preferable procedure and whether the representative Plaintiff was a resident of Saskatchewan when the class was commenced. Plaintiff brought a class certification against both FCA US LLC and FCA Canada Inc. (collectively "FCA") arising out of alleged emission defeat devices in a 2015 Dodge Ram pickup truck. Plaintiff and the proposed class sought damages for misrepresentation, negligence, breach of contract and violation of regulatory standards. In response FCA argued there was no evidence of compensable harm to Plaintiff or any member of the proposed class, as the vehicles fitted with defeat devices

were recalled and repaired. The Court agreed with FCA and dismissed the application for certification.

The burden was on Plaintiff to establish some evidence of compensable harm before the proposed class is certified. The Court held after considering the evidence and submissions of the parties, "*there is no minimum evidentiary basis for compensable harm established through any of the five general themes of loss claimed by plaintiff*." Thus, the Court dismissed the application for certification. Additionally, Plaintiff was not a resident of Saskatchewan when he commenced the claim, which was in violation of the *Class Actions Act*.

The Quebec Court of Appeal Authorizes a Class Action Alleging a Product Defect Despite the Absence of Recall Notices

Hand v. *Denso International America Inc*., 2023 QCCA 546

The Quebec Court of Appeal overturned a judgment of the Superior Court which had dismissed an application for authorization (certification) of a class action for damages allegedly suffered in connection with a defect in low-pressure fuel pumps resulting in the issuance of recall notices in the United States and Canada. The affected fuel pumps had been installed in different vehicle models sold or leased by the defendants, Toyota Sales Canada, Honda Canada Inc., and Subaru Canada Inc. The recall notices indicated that the problem involved a component known as an impeller and that manufacturing conditions in certain production lots could result in impellers being more susceptible to fuel absorption, causing them to become warped and restricting the supply of fuel to the engine.

The representative Plaintiff had leased a 2019 Acura TLX. While certain vehicles of this make and model were the subject of a recall notice issued by Honda Canada Inc., the Plaintiff's was not.

While the judge would have authorized the class action for persons who had received recall notices, it refused to authorize the class action for persons who had not received recall notices. The judge held that it would be an error to infer from the evidence that just because certain fuel pumps identified as defective were installed in vehicles of a particular make and model, that all such vehicles must be recalled. In his view, the evidence demonstrated that the defendants proceeded methodically and diligently to limit the number of recalls to only those vehicles with a defective fuel pump. He concluded that the Plaintiff – as well as all potential members of the second sub-group - failed to demonstrate an arguable case that the fuel pumps in their vehicles were defective or that they should have received a recall notice. Since the Plaintiff had not received a recall notice, the first judge dismissed the authorization application entirely.

In granting the appeal, the Court of Appeal held that the first instance judge erred by concluding that the Plaintiff had not established an arguable case that the fuel pump in his vehicle was defective. The Court referred to evidence submitted by the Plaintiff that motorists who had not received recall notices still experienced problems associated with the alleged defect. The Court also found that the first instance judge erred in finding that the Plaintiff did not personally experience problems with his vehicle's fuel pump as the defendants had acknowledged that not all

motorists who had received recall notices had experienced problems with their fuel pumps and that the Plaintiff benefitted from the presumption of prejudice associated with alleged violations of the requirements of Quebec's *Consumer Protection Act*. Finally, the Court of Appeal held that the first instance judge erred in accepting the Defendants' argument that the Plaintiff failed to demonstrate an arguable case as he could not even confirm whether his vehicle's fuel pump housed a low-density impeller since the Defendants in fact had access to this information and either failed to provide it or failed to verify it. Given the informational imbalance between the parties, the Court found that the Defendants' argument in this regard could not be relied upon to refuse authorization.

The Court of Appeal thus granted the appeal and authorized the class action without distinction between the members who received recall notices and those who did not.

Professional Sellers held Liable for to Failure to Warn of Risks Inherent to Products

La Capitale assurances générales inc. v. *Construction McKinley inc.*, 2023 QCCS 419

The Plaintiff La Capitale brought a subrogation claim for water damage resulting from the rupture of a flexible stainless steel hose connected to a bathroom sink against the general contractor, the seller of the sink and hose and the manufacturer of a Lysol brand product which was stored near the hose. The evidence revealed that the rupture of the hose resulted from corrosion caused by its prolonged exposure to emanations from the Lysol cleaning product. The sink had been purchased by the general contractor as part of building of the house in 2012. The rupture occurred on February 2, 2017.

The Court held that the hose was not defective as the legal warranties of quality only covered normal use and that prolonged exposure to corrosive products did not constitute normal use for this type of product. Accordingly, the case rested on the allegation that the defendants failed to warn the insureds about the risks inherent to the storage of this type of cleaning product in the vicinity of flexible stainless steel hoses pursuant to the *Civil Code of Quebec*.

The Court found that the duty to warn provided by the *Civil Code of Quebec* did not apply to the general contractor as it was not the manufacturer, distributor or supplier or the sink or hose. The contractor also successfully rebutted the presumption of knowledge imposed on professional sellers as it was found not to be a specialized professional seller of plumbing products and could not have known about the potential risk at the time of the construction work.

As for the distributor of the sink, the Court found that it could not have been aware of the risk invoked since there was no evidence that anyone was aware of this risk in 2012. However, the Court noted that the duty to warn was continuous and subsists even after the sale. In this case, the evidence showed that the risk became progressively known as of 2014 and the distributor had started including a warning regarding this risk in its installation booklets as of 2015. However, the Court found that the warning was not complete and was not appropriately made to customers as it was mainly targeted to installers. It was thus held that the distributor should have sent a notice to customers who had already bought sinks equipped with this type of hose and that a sticker including a clear warning should have been attached to the hoses.

The Court also held that the manufacturer of the Lysol product failed to comply with its duty to warn buyers once it became aware of this risk as the warnings stated in the product label were not sufficient to inform buyers that vapors emanating from the product could significantly degrade metals in its immediate environment. The Court also dismissed the argument that the incident would not have occurred if the insureds had completely closed the lid of the bottle each time as recommended in its instructions as the insureds' conduct did not significantly differ from the conduct of the average consumer. The Court invoked the established principle established that manufacturers may not invoke the buyer's failure to read instructions or labels as a valid defense if the relevant warnings did not appear in such instructions and labels (see *Mulco inc.* v. *Garantie, compagnie d'assurance de l'Amérique du Nord*, 1990 CanLII 3279 (QC CA).

Ultimately, it was found that the manufacturer of the cleaning product and the distributor of the sink were jointly and severally liable towards the Plaintiff for the damages claimed and that the manufacturer was to bear the larger share of the liability (75%).

Failure to Warn Claim Dismissed due to full Disclosure to a Learned Intermediary (Pharmacist)

***Fortin* v. *Teva Canada Ltée*, 2023 QCCQ 1336**

The Plaintiff Ghislaine Fortin claimed damages from Teva Canada Ltée as manufacturer of the drug Alendronate for having allegedly caused her to lose her hair. Teva submitted that hair loss was a known risk associated with Alendronate which is appropriately disclosed. At the suggestion of her pharmacist, the Plaintiff had started using Alendronate for the treatment of osteoporosis. She started suffering from significant hair loss two weeks after starting the treatment.

The Plaintiff sought Teva's liability on the basis of the manufacturer's duty to warn buyers of the inherent risks associated with the use of their products pursuant to the *Civil Code of Quebec*. The Court noted that manufacturers may satisfy such duty by disclosing the risks to a learned intermediary, as recognized by the Supreme Court of Canada in *Hollis* v. *Dow Corning Corp.*, 1995 CanLII 55, par. 27 (CSC), and that this rule notably applies to disclosures made to physicians and pharmacists for prescription medication.

It was found that the product monograph and the leaflet included in the product packaging of Alendronate mentioned the risk of hair loss. Pharmacists who sell individual flasks of Alendronate were also instructed to provide a copy of the leaflet to patients. Accordingly, it was found that Teva had fulfilled its duty to warn buyers, through the information provided to pharmacists, of the inherent risk of hair loss associated with the use of Alendronate, such that it could not be held liable for the damages claimed by the Plaintiff.