2021-22 DRI Products Liability Conference Case Law Update

Prepared by:

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FIRST CIRCUIT:

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Substantive Elements and Pleading Requirements for Massachusetts Design Defect Claims – Reasonable Alternative Design

> ***Ducat v. Ethicon, Inc., et al.,* 4:21-cv-10174, --- F.Supp.3d ---, 2021 WL 1408120 (D. Mass. April 14, 2021);**
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> ***Engren v. Johnson & Johnson, Inc.,* 1:2021-cv-10333-RGS, 2021 WL 4255296 (D. Mass. Sept. 17, 2021);**
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> ***Coonan v. Ethicon, Inc., et al.*, 4:21-cv-10310-TSH, 2021 WL 5111867 (D. Mass. Nov. 3, 2021).**

One of most impactful developments in First Circuit product liability law over the past year has been the Massachusetts federal district court's ongoing interpretation and

application of the Massachusetts Supreme Judicial Court's ("SJC") seminal 2013 decision in *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411 (2013), regarding claims for design defect. In a trio of 2021 decisions (each discussed in detail below), the district court identified the essential elements and pleadings requirements for design defect claims according to *Evans*, and in separate cases identified a set of allegations that met those pleading requirements and a set that did not. Coincidentally (or not), each of these three cases involved surgical mesh medical devices.

In *Ducat v. Ethicon, Inc.*, et al., 4:21-cv-10174, --- F.Supp.3d ---, 2021 WL 1408120 (D. Mass. April 14, 2021), the plaintiff asserted claims for, inter alia, negligence and breach of implied warranty based on the theory of defective design of a surgical mesh medical device which had been implanted in her body approximately 17 years earlier. She alleged that the mesh product had eroded and compromised her pelvic organs, which resulted in significant pain and bleeding and necessitated numerous revisionary procedures.

The defendant moved for judgment on the pleadings on the basis that plaintiff had failed to plead the existence of a safer alternative design; the plaintiff opposed the motion, arguing that a safer alternative design is not a requisite element of a design defect claim under Massachusetts law, but rather one of a number of non-exhaustive, non-dispositive factors that may be considered as evidence of a design defect. The district court recognized the existence of some confusion on this issue arising from the Massachusetts state and federal courts' decisions both prior-to and since the SJC's *Evans* decision in 2013, and endeavored to resolve that ambiguity.

The court began by recognizing that Massachusetts had moved away from the consumer expectations test and adopted a risk-utility approach for design defect claims. It continued by stating that "[f]or the first time in *Evans*, the SJC departed from its prior jurisprudence and stated unambiguously that '[t]o establish a prima facie case of defect, the plaintiff must prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm.'" *Ducat*, *supra* at *3, quoting *Evans*, *supra* at 428 citing *Uloth v. City Tank Corp.*, 376 Mass. 874, 881 (1978). The *Evans* decision also signaled a move from the SJC's 1978 decision in

Back v. Wickes Corp., 375 Mass. 633 (1978), which held that a safer alternative design was merely one of a list of factors a jury may consider to determine design defect liability.

The confusion that the *Ducat* court sought to address stemmed from the fact that the SJC, on the same day that it issued its *Back* decision in 1978, also issued its decision in *Smith v. Ariens*, 375 Mass. 620 (1978), in which a snowmobile manufacturer was found liable for design defect where plaintiff had not pleaded or presented evidence of a reasonable alternative design. *Smith*, *supra* at 625. Importantly, the *Evans* court did not mention the *Smith* case in its above-referenced 2013 decision. As the *Ducat* court recognized, "[t]he First Circuit acknowledged this unresolved issue in *Osorio v. One World Technologies*, 659 F.3d 81, 86-87 (1st Cir. 2011)," stating that "*Smith* … suggests that Massachusetts product liability law may tolerate a finding of design defect in the absence of evidence supporting the existence of a feasible alternative design." *Osorio*, *supra* at 87. Importantly, however, "*Osorio* predates *Evans*, in which the SJC first clearly stated that an alternative design was a required element under its prior case law." *Ducat*, *supra* at *4. To the point, the First Circuit post-*Evans* decision in *Tersigni v. Wyeth*, 817 F.3d 364, 368-69 (2016), cited *Evans* for the proposition that under Massachusetts law "the plaintiff must offer proof of an available design modification of the product." *Tersigni*, *supra*, citing *Evans*, *supra* at 443 (internal quotations omitted).

Much of the confusion addressed in the *Ducat* decision would likely have been avoided but-for the district court's 2020 decision in *Taupier v. Davol, Inc.*, 490 F. Supp. 3d 430 (D. Mass. 2020), in which the court allowed the plaintiff's design defect claim to proceed despite the failure to plead a reasonable alternative design. There, the plaintiff argued that the pre-*Evans*, *Osorio*-*Smith* route to proving design defect without an alternative design was still good law. As the *Ducat* court recognized, however, the *Taupier* decision inexplicably omits any discussion of *Evans* and *Tersigni*.

The *Ducat* court ultimately concluded that whether the SJC's determination in *Evans* that pleading proof of a reasonable alternative design is a requisite element of a design defect claim was an extension of *Uloth* and *Back* or an abrogation of those cases was purely academic, and that the *Evans* court's holding that "[t]o establish a prima facie case of defect, the plaintiff must prove the availability of a technologically feasible and

practical alternative design" constituted the present state of Massachusetts design defect law. *Ducat*, 2021 WL 1408120, *3-*4, quoting *Evans*, 465 Mass. at 428.

With any confusion regarding the substantive requirements of Massachusetts design defect law having been removed, two additional 2021 cases addressed by the federal district court have provided insight as to how the requisite element of reasonable alternative design must be pleaded in order to survive a challenge under Rule 12(b)(6).

The case of *Engren v. Johnson & Johnson, Inc., et al.*, 1:2021-cv-10333-RGS, 2021 WL 4255296 (D. Mass. Sept. 17, 2021), is a medical device product liability action involving surgical mesh which had been implanted in the plaintiff's body and which allegedly eroded, caused injury and necessitated additional surgery. In this case, the court held that the plaintiff had sufficiently pleaded the existence of a reasonable alternative design and permitted her design defect claim to survive the defendants' motion to dismiss.

With respect to the sufficiency of the plaintiff's allegations as to reasonable alternative design, the court specifically pointed to the Public Health Notification and Safety Communication issued by the FDA regarding the serious concerns about the safety and effectiveness of surgical mesh devices for transvaginal repair of pelvic organ prolapse in the years preceding plaintiff's implantation. Notably, plaintiff alleged that the FDA noted that there was no clear evidence that the use of surgical mesh in such circumstances was more effective than traditional non-mesh repair.

The court reasoned that these statements regarding the concerns over the safety and effectiveness of surgical mesh repair (as compared to traditional non-mesh repair) combined with the potential safer alternative designs advanced by plaintiff ("sutures, an autologous fascia lata and an autologous fascia sling, an allograft sling, and a sling with less polypropylene") sufficiently pleaded the existence of a reasonable alternative design. As a brief aside, one could also take issue with these potential alternative designs as different products or procedures rather than true alternative designs of the same product. See, *Tersigni*, *supra* at 369 (2016), quoting *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995) ("A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle.").

We now juxtapose the *Engren* holding with the federal district court's decision in *Coonan v. Ethicon, Inc., et al.*, 4:21-10310-TSH, 2021 WL 5111867 (D. Mass. Nov. 3, 2021). In this medical device product liability action, the plaintiff alleged that a surgical mesh product had been surgically implanted in her body which subsequently eroded into her bladder and other organs and structures causing severe pain and requiring several additional corrective surgical procedures. Among the several claims advanced by the plaintiff from these allegations was a count for design defect. The defendants challenged the design defect claim on a Rule 12(b)(6) motion to dismiss, arguing, *inter alia*, that the plaintiff had not properly pleaded the existence of a reasonable alternative design. The court agreed and dismissed the design defect claim on this basis, as detailed below.

In dismissing the plaintiff's design defect claim, the court again recognized the decision in *Ducat* from earlier in 2021 which reinforced the SJC's holding in *Evans* that a reasonable alternative design is a requisite element of a design defect claim. The court's examination began (as it must) with the specific allegations the plaintiff advanced as to the existence of a safer alternative design. In an attempt to meet this pleading requirement, the plaintiff alleged that "[f]easible and suitable alternative designs as well as suitable alternative procedures and instruments … have existed at all times relevant to this matter" and that the defendants "had already began using the safer alternatives in their other mesh products." However, the court disagreed that these allegations met the applicable pleading standard. Rather, the court held that such allegations were merely "conclusory" and did not constitute a properly pleaded allegation of a feasible, safer alternative design. Specifically, the court stated, "[s]imply asserting that a feasible alternative design exists -- without pleading any supporting facts -- is not sufficient to plead a defective design claim or to put Defendant on notice as to what that design might be."

The court pointed to the *Engren* case (discussed above), which had recently survived a similar motion to dismiss the design defect claim. The court reasoned that the plaintiff in the *Engren* case had sufficiently alleged a reasonable alternative design because specific alternative examples were listed. As we know from our prior discussion of *Engren*, the specific alternative examples pleaded in that case were buttressed by FDA communications regarding serious concerns over the safety and efficacy of surgical mesh

in pelvic organ prolapse repair procedures. Here, the plaintiff's allegations did not include any discussion of FDA communications on the subject and did not otherwise constitute viable, non-conclusory statements as to the existence of a reasonable alternative design.

Notably, the court in *Coonan* cited to the out-of-district/circuit case *Green v. Covidien LP*, 2019 WL 4142480, at *3 (S.D.N.Y. Aug. 30, 2019), for the proposition that "[a] plaintiff need not possess specialized scientific or technical knowledge at the pleading stage." While this statement is certainly true in the technical sense, it may be less so as a practical matter, particularly in product liability involving medical devices, pharmaceuticals or other technically complex products.

SECOND CIRCUIT:

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Preemption

***Ignacuinos v. Boehringer Ingelheim Pharm.*, 2021 U.S. App. LEXIS 23348 (2d Cir. Aug. 6, 2021).**

"When does a drug manufacturer need FDA approval, and when can it act unilaterally without approval?" *Ignacuinos v. Boehringer Ingelheim Pharm.*, 2021 U.S. App. LEXIS 23348, at *1 (2d Cir. Aug. 6, 2021). The Second Circuit has now adopted the "major change" analysis set forth by the First Circuit in *Gustavsen v. Alcon Lab'ys, Inc*., 903 F.3d 1 (1st Cir. 2018) in answering this critical question. Specifically, a plaintiff's state law design and manufacturing defect claims will be preempted to the extent that they would require any "major change" requiring FDA approval, which includes, among others, "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients." *Ignacuinos, supra* at *5, *quoting* 21 C.F.R. § 314.70(b)(2).

Plaintiffs' putative class action was premised on the allegation that a prescription inhaler contained far fewer than the 120 doses represented on the product label. The defendant manufacturer moved to dismiss, arguing that plaintiffs' state law design and manufacturing defect claims required changes to the inhaler that would require FDA

approval and were accordingly preempted. Judge Underhill of the District Court for the District of Connecticut agreed.

On appeal, the plaintiffs argued that the manufacturer was required to show that the change has a "substantial potential to have an adverse effect" under 21 C.F.R. § 314.70(b)(1) to qualify as “major.” A unanimous Second Circuit panel of Judges Lohier and Bianco, joined by Judge Abrams of the Southern District of New York sitting by designation, rejected this argument, adopted the First Circuit’s reasoning in *Gustavsen*, and affirmed the holding of the District Court. Specifically, the Second Circuit held that the manufacturer could not have changed the fill volume or dosage of the inhaler without FDA approval, and the plaintiffs’ claims were therefore preempted.

In addition to its direct application in the drug and medical device context, the *Ignacuinos* opinion illustrates that in any case in which an implied preemption defense can be raised, counsel should identify regulations susceptible to broad application based on the plain language, the authorizing statute, and the legislative history.

Pleading

***Frei v. Taro Pharm. U.S.A., Inc.*, 844 F. App'x 444, 446 (2d Cir. 2021).**

Though Judge Briccetti of the District Court for the Southern District of New York dismissed the plaintiffs’ product liability complaint in *Frei* concerning off-label use of generic drugs on the basis of preemption and failure to state a claim, only the latter ground was upheld by the Second Circuit. A unanimous panel of Chief Judge Livingston and Judges Wesley and Carney held that the plaintiffs’ complaint was “fatally flawed because [it] does not plausibly allege [defendant’s] own involvement in wrongdoing.” *Frei, supra* at 446.

The plaintiffs alleged that the defendant generic manufacturer: (1) failed to make available to patients medication guides on the proper use and risks of the drug as required by regulation; (2) failed to ensure the accuracy of information regarding the drug in prescribing reference materials relied on by physicians; and (3) concealed information in its exclusive possession regarding adverse events that occurred from the use of the drug to treat atrial fibrillation.

The Second Circuit held that the plaintiff had not even pleaded allegations that would support a plausible inference that the defendants had committed any wrongdoing, finding that: (1) there was no allegation that the defendant violated the requirements of the regulation, (2) the complaint contained no allegations concerning any information that was inaccurate or false, and (3) the complaint made broad statistical allegations not tied to defendant's conduct.

Frei shows that even where there are alternate sufficient grounds for dismissal, the defendant should also raise vague and conclusory pleading that–even if accepted as true–does not allow the court to draw the reasonable inference that the defendant is liable for the alleged misconduct.

Expert Methodology

***Coning v. Bayer Pharma AG (In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.)*, 982 F.3d 113 (2d Cir. 2020).**

In *Coning v. Bayer Pharma AG (In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.)*, 982 F.3d 113 (2d Cir. 2020), the Second Circuit affirmed the propriety of a "rigorous review of each of plaintiffs' experts," including the reliability of the experts' methods and the support of their conclusions by the scientific community, in determining the admissibility of those experts' conclusions. The appeal was taken from the dismissal of the case by Judge Englemayer of the District Court for the Southern District of New York for failure to establish general causation in respect to the plaintiffs' claims of hypertension resulting from the use of an intrauterine device, after the Court precluded all of plaintiffs' experts under *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579 (1993).

The plaintiffs argued that "the district court abused its discretion by (1) focusing on plaintiffs' experts' conclusions rather than their methodologies, (2) requiring the experts to back their opinions with published studies that definitively supported their conclusions, and (3) taking a "hard look" at the experts' methodology."

The unanimous Second Circuit panel of Judges Sack, Chin, and Lohier roundly rejected each argument in turn. The Court began by concluding that a hard look was not only merited but **required**: "not only was it appropriate for the district court to take a hard look at plaintiffs' experts' reports, the court was required to do so to ensure reliability."

Second, the Court held that contrary to plaintiffs' contentions, the District Court had "provided in-depth analysis of whether the experts applied their methodologies reliably," and that accordingly "Plaintiffs may (and do) challenge whether the reliability analysis was correct, but plaintiffs have no basis to argue that the district court did not engage in a detailed analysis of their experts' methodologies." Third, the Court "was well within its discretion to consider whether plaintiffs' experts' conclusions were generally accepted by the scientific community"–indeed, as the Court notes, this is one of the four enumerated considerations in *Daubert*.

The *Coning* decision therefore stands for the principle that the District Court, in deciding whether an expert's analysis is unreliable, must take a "hard look" and conduct a review that is "searching." To that end, it bears emphasis that the District Court in *Coning* entered an early scheduling order "giving priority to the issue of whether plaintiffs have admissible evidence sufficient to establish general causation of the harms alleged." Accordingly, where possible, counsel should likewise raise this dispositive issue for the Court's consideration at the earliest juncture.

False Advertising

***George v. Starbucks Corp.*, 857 F. App'x 705, 705-07 (2d Cir. 2021).**

When is marketing puffery, when is it deceptive, and when can a reasonable consumer claim to be misled? *George v. Starbucks Corp.*, 857 F. App'x 705, 705-07 (2d Cir. 2021), makes clear that in answering all of these questions, context matters.

The plaintiffs alleged that Starbucks claimed to serve the "finest whole bean coffees," maintained a reputation for "quality" products, and made representations including that its coffee is the "Best Coffee for the Best You" and "It's Not Just Coffee. It's Starbucks," promising a "PERFECT" coffee experience." However, because Starbucks' New York City locations allegedly used commercial pesticides, Starbucks allegedly "fails to live up to its branding as a premium coffee retailer" and therefore committed a deceptive business practice under New York State law.

Judge Allison Nathan of the District Court for the Southern District of New York, dismissing plaintiffs' complaint for failure to state a claim, held in the first instance that

Starbucks' marketing was largely puffery–exaggeration and overstatement in broad commendatory measures.

The unanimous Second Circuit panel of Judges Pooler, Chin, and Lohier, Jr. agreed and went still further: even if, drawing every favorable inference, "certain statements were plausibly specific enough to be more than puffery," these statements "refer only to how Starbucks sources its products and crafts its coffee and the ingredients it uses in its baked goods. No reasonable consumer would believe that these statements communicate anything about the use of pesticide in Starbucks's stores." That is, the reasonable consumer would understand the referenced statements to "refer to Starbucks's coffee preparation methods, ethical sourcing practices, and the quality of specific ingredients used to make Starbucks's products, not whether pesticide is used within Starbucks stores."

Accordingly, when defending deceptive marketing claims, counsel must heed the Court's warning that "in determining whether a reasonable consumer would have been misled by a particular advertisement, context is crucial." Even if an alleged statement is construed to be specific enough to be more than puffery, if it would not mislead a reasonable consumer, an action premised thereon may be subject to dismissal for failure to state a claim.

THIRD CIRCUIT:

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Strict Liability – Medical Device Manufacturers

McGrain v. C.R. Bard, Inc. et al.*, --- F. Supp. 3d ---, 2021 WL 3288601 (E.D. Pa. Jul. 30, 2021).

In *McGrain v. C.R. Bard, Inc. et al.*, --- F. Supp. 3d ---, 2021 WL 3288601 (E.D. Pa. Jul. 30, 2021), the Court granted a medical device manufacturer Defendant's 12(b)(6) motion to dismiss. The Court found that Plaintiff, who had been implanted with a medical filter device designed to treat her deep vein thrombosis and pulmonary embolus, failed to

state a claim against Defendant for negligence, strict products liability, breach of express and implied warranties, fraudulent and negligent misrepresentation, fraudulent concealment, and unjust enrichment. Plaintiff was granted leave to amend her complaint, but was only permitted to assert claims for negligence, breach of express warranty, fraudulent misrepresentation, and negligent misrepresentation, as the Court determined that claims for strict liability, breach of implied warranty of merchantability, and fraudulent concealment are barred as a matter of law against medical device manufacturers, and that unjust enrichment claims are not cognizable in a products liability action as the allegations required to support the claim are not compatible with the elements of product liability tort claims.

In her Complaint, Plaintiff alleged that she was implanted in 2003 with a Bard G2 IVC filter. In 2020, Plaintiff had a CT scan that showed that two struts of the filter perforated the wall of her inferior vena cava. She contended that she suffered pain and discomfort in her abdominal area from the perforation. Plaintiff alleged strict liability claims of design, manufacturing, and warning defect; negligence claims contending negligent design, negligent manufacturing, and negligent failure to warn; breach of express warranty; fraudulent concealment; fraudulent and negligent misrepresentation; and unjust enrichment against the manufacturer of the device. Defendant filed a 12(b)(6) Motion seeking the dismissal of all of Plaintiff's claims.

In its analysis of the viability of Plaintiff's strict liability claims, the Court noted prior decisions finding that design defect and failure to warn claims against medical device manufacturers are barred under Pennsylvania law. *Lopez v. Ethicon*, 2020 WL 5569770 (E.D. Pa. Sept. 17, 2020). While recognizing a split in authority regarding the viability of claims alleging manufacturing defect, the Court determined that Pennsylvania law would also bar strict liability manufacturing defect claims. The Court, citing *Hahn v. Richter*, 543 Pa. 558, 673 A. 2d 888, 889 (1996) and *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434 (2014), found that Pennsylvania courts would apply the same public policy rationale in finding that manufacturing defect claims are prohibited against medical device manufacturers. *See Creazzo v. Medtronic, Inc.*, 903 A.2d 24,31 (Pa. Super. Ct. 2006). The Court distinguished Plaintiff's reliance on *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 104 A.3d

328 (2014), as support for the viability of manufacturing defect claims, finding that it was misplaced, as *Tincher* did not involve prescription drugs or medical devices.

The Court similarly determined that Plaintiff's claim of breach of implied warranty of merchantability was not viable against a medical device manufacturer under Pennsylvania law. In support, the Court stated that this theory of liability is largely identical to that of strict liability, and cited Pennsylvania decisions finding that "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes.'" *Makripodis ex rel. Makripodis v. Merrell-Dow Pharms., Inc*., 361 Pa. Super. 589, 523 A.2d. 374, 594 (1987). The Court further noted that sister district courts in Pennsylvania had extended the reasoning in *Makripodis* to medical devices, *Carson v. Atrium Med. Corp.*, 191 F. Supp. 3d 473 (W.D. Pa. 2016) (Medical devices are "unavoidably unsafe products" under Comment k).

Although the Court recognized that negligent manufacturing claims are viable under Pennsylvania law, the Court determined that Plaintiff had not sufficiently pled the basis for her claim in her Complaint. There were no factual allegations as to what Defendant did during the manufacturing process that Plaintiff contends was negligent. The Court rejected Plaintiff's argument that *res ipsa loquitor* should be applied, agreeing with other courts that have rejected the doctrine in examining medical device claims. *Webb v. Stryker Corp.*, 2017 WL 1406899 (W.D. Pa. Apr. 30, 2017).

The Court also agreed that Plaintiff failed to plead negligent design, determining that she had not alleged the basis for design defect or that there was a safer, feasible alternative.

The Court reached a similar conclusion as to Plaintiff's negligent failure to warn claim, finding that Plaintiff failed to provide information as to what she contends was missing from Defendant's warnings regarding the device at issue. Plaintiff did not include the precise injury posed by use of the device in her Complaint, failing to allege a nexus between her alleged injuries and Defendant's failure to warn.

Plaintiff's express warranty claim was also dismissed. Unlike Plaintiff's implied warranty claim, the Court did determine that breach of express warranty is a viable cause of action against a medical device manufacturer in Pennsylvania, but that Plaintiff had not identified what warranty was made to her, how it was communicated to her, or how she

relied upon it. Breach of express warranty claims require a level of specificity, and mere allegations that the product was warranted to be safe and fit for intended use will not survive a motion to dismiss.

The Court noted fraudulent concealment is an equitable tolling doctrine, rather than an independent tort, under Pennsylvania law.

Plaintiff's claims for fraudulent and negligent misrepresentation were also dismissed, with the Court determining that these were essentially failure to warn claims. The Court found Plaintiff did not allege any overt acts or affirmative misrepresentations made by Defendant in her Complaint. The Court restated that negligent failure to warn is the sole theory upon which a plaintiff may recover against a prescription manufacturer/medical device manufacturer under Pennsylvania law.

Finally, the Court determined that unjust enrichment claims are not cognizable in a products liability action because the elements required to plead unjust enrichment are inconsistent with those required to plead a tort claim premised on products liability.

***On August 5, 2021, two questions related to this decision were certified to the Pennsylvania Supreme Court from the United State Court of Appeals for the Third Circuit in *Ebert v. C.R. Bard, Inc*., 260 A.3d 81(Table) (Pa. 2021):**

(1) Under Pennsylvania law, must a plaintiff bringing a negligent design claim against a prescription medical device manufacturer prove that the device was too harmful to be used by anyone, or may the plaintiff also prevail on other theories of liability where appropriate?

(2) Under Pennsylvania law, are prescription implantable medical devices categorically subject to strict liability, categorically immune from strict liability, or immune from strict liability on a case-by-case basis? If they are immune on a case-by-case basis, what test should a court apply to determine whether a particular device is immune?

Admissibility of Expert Testimony – Asbestos/Talc

***Lanzo v. Cyprus Amax Mins. Co.,* 467 N.J. Super. 476, 254 A.3d 691 (App. Div.), cert. denied, 258 A.3d 355 (N.J. 2021).**

Defendants Johnson & Johnson Consumer Inc. (JJCI) and Imerys Talc America, Inc. (Imerys) appealed from a $117 million compensatory and punitive damages judgment in favor of Plaintiffs. On appeal, JJCI argued (1) the trial court erred by admitting unreliable expert testimony; (2) the court undermined its defense by refusing to grant separate trials after ruling that it would provide the jury with an adverse inference instruction regarding Imerys; (3) the jury instructions improperly constrained consideration of potential alternative causes for Plaintiff's illness; and (4) there was insufficient evidence to support the jury's verdict that Plaintiff was exposed to asbestos from J&J talcum powder, establish causation, and support the punitive damages award. Imerys argued similar grounds in support of appeal, namely that (1) the court erred by allowing plaintiffs to present unreliable expert testimony from Drs. Longo, Webber, and Moline; (2) the adverse inference instruction was unjustified and prejudicial; and (3) the punitive damage award must be vacated.

Plaintiff husband and wife sued JJCI, Imerys, and others under the common law and New Jersey Products Liability Act (PLA), alleging that the husband developed mesothelioma from his use of Johnson and Johnson Consumer's talcum powder products, including Johnson baby powder and Shower to Shower. Plaintiffs contended that the talc products Plaintiff husband used contained asbestos.

The trial court granted Defendants' motion for summary judgment in part, dismissing all common law claims against Imerys and JJCI, but allowing the design defect and failure to warn claims under the PLA to go forward. The trial court held Defendants' motions for summary judgment as to punitive damages in abeyance.

Defendants submitted *motions in limine* seeking to bar testimony from Plaintiffs' experts William Longo, Ph.D. and James S. Webber, Ph.D. Defendants argued that Longo's testing of "vintage" containers was unreliable as there was no chain of custody for the samples tested and no guarantee that the samples weren't contaminated once they were outside of Defendants' control. Defendants sought to preclude Webber's testimony regarding the ability of non-asbestiform cleavage fragments to cause mesothelioma. The trial court denied both motions.

At trial, Defendants moved to exclude Plaintiffs' expert Jacqueline Moline, M.D., from testifying that non-asbestiform cleavage fragments cause mesothelioma. The trial

court limited the scope of Moline's testimony but permitted her to testify regarding "non-asbestiform cleavage fragments from a medical point of view."

The trial court judge also sanctioned Defendant Imerys on Plaintiffs' request, providing the jury with an adverse inference instruction as a sanction for discovery violations and spoliation of evidence. In response to the adverse inference instruction, Defendant JJCI moved to sever the claims against them and sought a mistrial, which the trial court denied. The trial court's adverse inference instruction stated that Defendant Imerys wrongfully withheld talc samples and testing data and destroyed samples. The trial court instructed the jury that it could "infer that the missing evidence may have been helpful to the Plaintiffs' case to the detriment of Imerys." The trial court further instructed that JJCI was not part of the wrongful conduct.

The jury returned a verdict against JJCI and Imerys, assigned seventy percent of responsibility to JJCI and thirty percent to Imerys. The trial court allowed the punitive damages claims against Defendants to go forward, and the jury awarded $80 million in punitive damages ($55 million against JJCI and $25 million against Imerys). The trial court denied Defendants' post-trial motions for judgment notwithstanding the verdict, new trial, and remittitur.

On appeal, the Superior Court of New Jersey, Appellate Division, reversed and remanded for a new trial against Defendants. The Court found that the trial court failed in performing its gatekeeping function under *In re Accutane Litigation (Accutane)*, 234 N.J. 340, 388, 191 A.3d 560 (2018) when it allowed Webber and Moline to testify that non-asbestiform cleavage fragments could cause mesothelioma. The Court determined that the trial court's denial of Defendants' motions to exclude Plaintiffs' expert testimony was not harmless error.

Although the *Accutane* decision was issued after trial in *Lanzo*, the Court applied its holding, noting that in civil cases judicial decisions are presumed to apply retroactively. The Court noted that *Accutane* (which reconciled the federal *Daubert* standard with New Jersey's rules of evidence) did not alter New Jersey law regarding the admissibility of expert testimony, nor would its application provide an inequitable result.

Accutane distilled the *Daubert* factors into the following general factors: (1) whether the scientific theory can be tested, or at any time has been tested; (2) whether

the scientific theory has been subjected to peer review and publication, noting that publication is one form of peer review but is not a "sine qua non"; (3) whether there is any known or potential rate of error and whether there exist any standards for maintaining or controlling the technique's operation; and (4) Whether there does exist a general acceptance in the scientific community about the scientific theory. *Accutane*, 234 N.J. at 398, 191 A.3d 560. In examining a proposed expert's methodology, the party seeking to allow the expert's testimony must demonstrate that the expert applies scientifically recognized methodology in the way that others in the field practice the methodology, and if they are unable to do so, then the expert's testimony should be excluded as unreliable.

The Court found that the trial court did not undertake the necessary evaluation in its role as gatekeeper of the proposed testimony. The trial court did not conduct a Rule 104 hearing and did not assess the experts' methodology or the data underlying their opinions. Webber did not identify any of the data underlying his opinion and did not demonstrate at trial that any of the authorities he relied upon would reasonably be relied upon by other experts in his field to reach an opinion regarding causation. Webber's opinion was untested, as he admitted that there are no studies supporting his conclusion that non-asbestiform minerals cause mesothelioma, and his opinions have not been subjected to peer review and publication. He also failed to demonstrate that his theory is generally accepted in the scientific community.

The Court found Moline's testimony should have been excluded for the same reasons, as she also failed to provide any studies or other support that non-asbestiform cleavage fragments can cause mesothelioma, despite representing that it was an opinion generally represented in the medical literature.

In reviewing for abuse of discretion, the Court found that the trial court's decisions to admit Webber and Moline's testimony were clearly capable of producing an unjust result and warranted a new trial. Although neither expert testified that Defendants' talc products contained non-asbestiform fragments, the jury could have inferred from the combination of other expert's testimony that Defendants' talc products did, or that whether a fragment was asbestiform or non-asbestiform did not matter and that both could cause mesothelioma.

In examining the adverse inference instruction, the Court found that Imerys was aware of potential claims due to alleged asbestos exposure from talc and was under an obligation to preserve evidence relevant to these claims, including the talc samples at issue. The Court disagreed with Imerys's contention that the adverse instruction was unwarranted. Although the discovery violation was unintentional, the goal in providing an adverse inference instruction is to correct any prejudice to the affected party. The Court determined that Imerys was not prejudiced by the proffered instruction, and that it was not unreasonable for the trial court to conclude that Plaintiffs were prejudiced through the destruction of the talc samples.

While the Court did not find that the adverse instruction was prejudicial to Imerys, the Court did find error in the trial court's denial of JJCI's motion to sever, as the instruction was unduly prejudicial to it. Because the jury could infer that Imerys' talc was contaminated through use of the instruction, then it necessarily flowed that the jury would infer the same for JJCI's products and the motion to sever should have been granted.

The Court did not examine Defendants' other grounds for appeal, finding it was unnecessary considering its decision regarding the admissibility of Moline and Webber's testimony, and the appropriateness of the adverse instruction.

Class Actions – Tolling of Statute of Limitations Prior to Certification of Class

Aly v. Valeant Pharmaceuticals International, Inc., 1 F.4th 168 (3d Cir. June 16, 2021).

On June 24, 2016, various class complaints filed on behalf of investors who purchased Valeant stock between February 23 and October 20, 2015, were consolidated in the United States District Court for the District of New Jersey. By December 2018, the district court had not yet ruled on class certification. In lieu of waiting on the certification ruling, certain members of the putative class filed an "opt-out" complaint in district court, bringing the same claims in their capacity as individuals.

In *American Pipe and Construction Co. v. Utah*, the United States Supreme Court held that "the commencement of a class action suspends the applicable statute of limitations as to all asserted members of the class who would have been parties had the

suit been permitted to continue as a class action." 414 U.S. 538, 554, 94 S.Ct. 756 (1974). Because a ruling regarding certification in the class action suit had not yet been issued, the district court concluded that the individual plaintiffs could not benefit from the tolling doctrine set out in *American Pipe*, and that their claims were outside of the two-year statute of limitations and time barred. The district court reasoned that judicial efficiency favored delaying individual claims until after class-certification, so that class and individual claims are not proceeding contemporaneously. Extending *American Pipe* could encourage "copy-cat" suits, which would be unnecessarily duplicative and force the court to revisit issues resolved in the class context.

On appeal, the United State Court of Appeals for the Third Circuit reversed the district court and joined the Second, Ninth, and Tenth Circuits in holding that the tolling rule in *American Pipe* applies regardless of whether a class member files an individual action before or after a decision on class certification has been issued. A contrary ruling, the Third Circuit explained, would force putative class members to delay their claims indefinitely to take advantage of *American Pipe*. The Court further noted that requiring plaintiffs to wait until ruling on class certification to permit filing of "opt-out" actions would produce "counterintuitive results," because, for example, "individual claims filed well *before* certification could be dismissed as untimely, while other claims filed at a much later date would be allowed to proceed."

Limitations on Removal – Public Readiness and Emergency Preparedness (PREP) Act

Maglioli v. Alliance HC Holdings LLC, 16 F.4th 393, 2021 WL 4890189 (3d Cir. Oct. 20, 2021).

Residents of two different New Jersey nursing homes passed away from COVID-19. Decedents' estates brought wrongful-death lawsuits against the nursing homes in state court. Defendant nursing homes removed the cases to federal court, but the United States District Court for the District of New Jersey dismissed the cases for lack of subject-matter jurisdiction and remanded them to state court. The nursing homes appealed to the United States Court of Appeals for the Third Circuit, arguing three separate grounds for

federal jurisdiction: (1) federal-officer removal, (2) complete preemption of state law, and (3) the presence of a substantial federal issue.

In 2005, Congress passed the Public Readiness and Emergency Preparedness Act ("PREP Act"), which protects certain individuals, as that term is defined in the Act, from lawsuits during a public health emergency. The Act lies dormant until triggered when the Secretary of the Department of Health and Human Services ("HHS") deems a health threat to be a public-health emergency. Covered individuals under the Act then become immune to liability from claims related to the administration of certain "covered countermeasures."

In March 2020, the Secretary declared COVID-19 to be a public health emergency and recommended certain covered countermeasures including drugs, devices, and products that are "used to treat, diagnose, cure, prevent, or mitigate COVID-19." Covered persons under the PREP Act include manufacturers, distributors, program planners, and qualified persons, as well as their officials, agents, and employees, and the broad scope of immunity extends to claims relating to things such as the design, development, manufacture, labeling, packaging, or marketing of covered countermeasures.

For claims that are blocked by PREP Act immunity, the Act established a fund to compensate eligible individuals for injuries caused by using a covered countermeasure. The Act also provides for an exclusive federal cause of action against a covered person for death or serious injury proximately caused by willful misconduct.

As a preliminary matter, the Third Circuit declined to give deference to HHS interpretations of the PREP Act, which generally favored removal of these cases to federal court. The Court stated that deference is not owed to HHS interpretations "for the simple reason that HHS is not delegated authority under the PREP Act to interpret the scope of the federal courts' jurisdiction."

The Court then rejected Defendants' claim that the district court had jurisdiction pursuant to federal officer removal. The Court reasoned that, although the nursing homes may invoke federal-officer removal if they make a showing that they were "acting under" federal officers, mere compliance with federal law is not "acting under" a federal officer for purposes of such removal. To invoke federal officer removal, Defendants must show

that their actions constitute efforts to assist or help carry out duties or tasks of a federal superior, such as a government contractor or nonprofit community defender.

The Court also rejected Defendants' argument that the district court has jurisdiction because the PREP Act completely preempts state law. The Court stated that "[w]hat matters in this case is that the nursing homes raise federal preemption as a *defense* to state law. They argue that the PREP Act displaces Plaintiffs' state-law claims, and thus courts must apply the PREP Act rather than New Jersey law. . . . [t]he issue is whether making that preemption argument gets the Defendants in federal court." Whether Plaintiffs' state law claims were completely preempted under the PREP Act could be determined by answering the following questions: "(1) Does the PREP Act create an exclusive federal cause of action? If it does, (2) do any of the Plaintiffs' claims fall within the scope of that cause of action?" The Court found that the PREP Act created an exclusive cause of action for willful misconduct, but that Plaintiffs only alleged negligent, not willful misconduct. Accordingly, Plaintiffs' negligence claims did not fall within the scope of an exclusive federal cause of action. The Court further noted that complete preemption is rare, citing the Employee Retirement Income Security Act ("ERISA"), the Labor Management Relations Act ("LMRA") and the National Bank Act.

The Court also examined whether Plaintiffs could have brought their claims under the willful misconduct cause of action contemplated under the PREP Act, and similarly found Defendants' contention that Plaintiffs' claims were fully preempted unpersuasive. The Court noted there were no common elements between Plaintiffs' state law negligence claim and the willful misconduct claim, and Plaintiffs' complaint did not contain any allegations suggesting that their claims should have been willful misconduct claims under the PREP Act and not common law negligence claims.

The Court addressed Defendants' argument that the compensation fund created by the Act completely preempts the estates' state law negligence claims. It distinguished the compensation fund from a "cause of action," and ultimately held that "(1) the estates' negligence claims based on New Jersey law do not fall under the PREP Act's narrow cause of action for willful misconduct, and (2) the PREP Act's compensation fund is not an exclusive federal action triggering removal jurisdiction."

Finally, the Court (applying the *Grable* test), noted that for Plaintiffs' claims to raise a substantial federal issue, the federal issue must be "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress". *Gunn v. Minton*, 568 U.S. 251, 133 S.Ct. 1059 (2013); *Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 125 S.Ct. 2363 (2005). Since the PREP Act was not an essential element of Plaintiffs' state law claim, a PREP Act preemption defense was not necessarily raised under Plaintiffs' Complaint. Accordingly, there was no federal issue.

The Court did note the limits of its holding, stating "only that (1) the estates' negligence claims based on New Jersey law do not fall under the PREP Act's narrow cause of action for willful misconduct, and (2) the PREP Act's compensation fund is not an exclusive federal cause of action triggering removal jurisdiction." The Court made no finding as to whether Defendants would be entitled to preemption as a defense to Plaintiffs' claims under ordinary preemption rules.

Strict Liability – Prescription Drugs (Animals)

***Foge, McKeever LLC v. Zeotis, Inc.*, --- F.Supp.3d ---, 2021 WL 4479718 (W.D. Pa. Oct. 05, 2021).**

Plaintiffs owned a racehorse that suffered a puncture wound. To treat the wound, the horse received an injection of a drug manufactured and distributed by Defendant. After receiving a recommended second dose, the horse collapsed and ultimately passed away days later. The Plaintiffs brought an action in the United States District Court for the Western District of Pennsylvania alleging, among other things, strict liability claims based on a failure to warn, defective design, and defective manufacture. Defendant moved to dismiss, arguing that such claims are not cognizable in Pennsylvania under Sec. 402A, comment k, of the Restatement (Second) of Torts. The District Court, relying on the Pennsylvania Supreme Court's prior holding that comment k bars strict liability to products such as prescription drugs, granted Defendant's motion and dismissed the strict liability claims with prejudice. The Court likewise dismissed Plaintiffs' claim for breach of implied

warranty of merchantability, observing such claims "coextensive" nature with strict liability claims.

Sufficiency of Claims – Failure to Warn and Breach of Implied Warranty

***Zuzel v. Cardinal Health, Inc.*, --- F. Supp. 3d ---, 2021 WL 4552284 (E.D. Pa. Oct. 5, 2021).**

Plaintiff sued Defendant distributor for strict product liability (design defect and failure to warn) and breach of warranty. Defendant sought summary judgment on Plaintiff's claims. The Court granted Defendants' motion for summary judgment in part, finding summary judgment appropriate on Plaintiff's failure to warn and breach of the implied warranty of fitness for a particular purpose, and denying Defendants' motion for summary judgment on all other counts.

Plaintiff purchased a Cardinal-Health brand rollator from eBay in October 2015. She did not discuss her purchase with anyone in advance and did not discuss with Defendant that she intended to use the rollator on public transportation. When she purchased the rollator from eBay, she received instructions showing her how to assemble the rollator, but no other information was provided. On November 25, 2016, the front wheels of Plaintiff's rollator became lodged in a gap between the subway car and platform. Plaintiff stated that the rollator collapsed underneath her when she attempted to dislodge the wheels, resulting in her falling and fracturing her right knee.

Plaintiff initially filed suit in November 2018, but her claims against Cardinal Health were dismissed without prejudice. She filed an amended complaint against Cardinal Health in May 2019, asserting (1) strict liability for failure to warn; (2) strict liability for defective design and manufacturer; and (3) breach of both express and implied warranties. Plaintiff's manufacturing defect and breach of express warranty claims were also dismissed at the pleading stage. Defendant later filed a third-party complaint against the alleged manufacturer of Plaintiff's rollator, and Plaintiff amended her complaint to allege claims against Cardinal Health's subsidiary that was responsible for distributing the rollator.

Defendants moved for summary judgment on several grounds. First, that Cardinal Health should be dismissed as it did not distribute the rollator, its subsidiary did. The Court determined there was a question of fact as to whether Cardinal Health could also be held liable for the rollator in addition to its subsidiary and would not grant summary judgment on that basis. Second, Defendants contended that they could not be held liable for Plaintiff's injuries as the conduct that Plaintiff contends caused her injury is attributable to the product manufacturer. Third, Defendants argued that Plaintiff's remaining claims for defective design, failure to warn, and breach of implied warranty failed on their merits.

The Court disagreed with Defendants' assertion that the manufacturer of the rollator was the "true seller" liable to Plaintiff, and that Defendants are not sellers under Pennsylvania law. The Court noted that all suppliers of a defective product under Pennsylvania law are potentially liable to the ultimate user who is injured by a defect, citing Restatement (Second) of Torts § 402A. The Court distinguished Defendants' reliance on *Musser v. Vilsmeier Auction Co*., 522 Pa. 367, 562 A.2d 279 (1989), stating that the factors in *Musser* (which involved an auctioneer) did not apply, as Defendants possessed the necessary control over the design and manufacture of the rollator.

Further, the Court also denied Defendants' motion for summary judgment on Plaintiff's design defect claim, finding that a reasonable juror could conclude that a design defect was the cause of Plaintiff's complained-of harm. The Court also did not find that Plaintiff voluntarily assumed the risk, misused the product, or was highly reckless in her use of the rollator, stating that a reasonable juror could conclude that she was not.

The Court granted summary judgment on Plaintiff's failure to warn claim, finding that no reasonable juror could conclude that insufficient warnings were the proximate cause of Plaintiff's injury. Plaintiff contended that Defendants should have included instructions regarding outdoor use and use on uneven terrain, and that the lack of these instructions caused her rollator to become stuck in the gap and collapse. The Court stated that Plaintiff, by her own testimony, knew to pick up the rollator in situations where it could become stuck.

The Court also granted summary judgment on Plaintiff's claim of breach of warranty of fitness for a particular purpose. Plaintiff did not notify anyone that she intended to use the rollator on the subway, and that her decision was based solely on the price of

the rollator. Accordingly, Defendants would have no reason to know of Plaintiff's intended use for the rollator. The Court did find that there was a sufficient question of fact as to Plaintiff's claim of breach of the implied warranty of merchantability, as use of the rollator on the subway could be considered an ordinary purpose/use for the rollator.

FOURTH CIRCUIT:

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Daubert and "Harmfulness" of Erroneously Admitted Expert Testimony

Sardis v. Overhead Door Corp., 10 F.4th 268 (4th Cir. 2021).

Evangelos Sardis died in 2016 after sustaining injuries on the job following the removal of a wooden crate from the top of a work truck. His widow, Andrea Sardis, filed this products claim against Overhead Door Corporation ("ODC"). The plaintiff contended that ODC negligently designed the crate at issue, failed to warn Sardis about the product's dangers, and breached the implied warranty of merchantability. Following a four-day trial in July 2019, a jury awarded Plaintiff in excess of four million dollars. ODC moved for a new trial and for judgment as a matter of law, which the district court denied.

On appeal, the Fourth Circuit reversed and remanded with instructions after finding that the district court had abused its discretion by abdicating its role as "gatekeepers of expert testimony" when it cursorily dismissed ODC's *Daubert* arguments regarding the experts' lack of reliability and relevance as issues of weight rather than admissibility, and by failing to make any explicit findings on the record as to the challenged preconditions of admissibility.

The Fourth Circuit further held that the testimony of Plaintiffs' expert witnesses was indeed inadmissible, and that the error was harmful. The Court acknowledged it has not previously addressed the precise parameters of when a district court's abdication of its gatekeeping function becomes harmful error and considered the facts at bar under the two commonly accepted approaches to a harmless error analysis. The first analysis focuses on whether the erroneously admitted expert testimony swayed the jury's verdict, while the second allows for a more particular harmlessness review, permitting a reviewing

court to make substantive findings if the record is sufficiently developed. The Court found that the admission was not harmless error under either analysis, and therefore declined to adopt one test versus the other as both resulted in the same outcome.

The Court also made substantive findings on the at-issue experts, and found that both experts offered irrelevant and unreliable testimony. The Court's analysis is detailed and fact intensive. It offers strong language against "borrowing" design standards for products the standard does not explicitly apply to, and admonishes an expert for testimony overstating purported requirements without citation and support. The Court also focused on the expert's failure to test his hypothesis, thereby making his opinion unreliable. Finally, the Court found that an expert's testimony was incompatible with Virginia's state law at issue in the case as it failed to incorporate the correct but uncommon standard of "reason to know" rather than "should know."

Sardis may be useful for practitioners for numerous reasons. It supports multiple paths for analyzing the "harmfulness" of erroneously admitted evidence in the 4th Circuit, reminds us of the many ways that expert testimony can be flawed and inadmissible and therefore emphasizes the importance of robust examination of expert witnesses' methods and grounds, and reinforces the importance of obtaining expert opinions that acknowledge the nuance of the applicable underlying law.

Duty & State of the Art

***Lightfoot v. Georgia-Pacific Wood Products,* 5 F.4th 484 (4th Cir. 2021).**

Christopher Lightfoot, son of a woodworker, developed nasal cancer at age 39 and asserted that the cancer was caused by exposure to wood dust when he worked in his father's shop from age 6 to 18, in 1981 to 1992. He sued the wood manufacturers in North Carolina for failure to warn that wood dust causes cancer. The defendants removed to federal court, and the district court granted summary judgment, finding that the defendants owed no duty to warn during the alleged exposure period because the "state of the art" did not indicate that wood dust causes nasal cancer.

The district court held that the fact that wood dust causes nasal cancer did not exist in the state of the art until a 1995 OSHA regulation. Plaintiffs argued that the district

court over-relied on this regulation, creating an "OSHA litmus" test that was too narrow. The Fourth Circuit disagreed, finding that the complete record demonstrated a lack of knowledge in the state of the art at the time of the alleged exposure that wood dust was a known cause of nasal cancer, which was necessary to create a duty to warn, despite some earlier writing identifying an association and increased risk of nasal cancer among workers in the furniture and cabinet making industry.

Lightfoot is a helpful case for defendants in duty to warn cases where the cause of the injury alleged is on the "edge" of the state of the art. Although the Court applied North Carolina substantive law, many jurisdictions in the Circuit will be able to show parallels between the state substantive law on negligence, duty to warn, and the state of the art defense. The Fourth Circuit's affirmation that no duty existed, despite published literature showing an increased risk of injury among similarly situated workers, reinforces the position that a duty to warn is not created by the existence of "isolated or cutting edge" studies, but rather by the application of the reasonableness standard to the existing body of literature at the time of the exposure. The Court's reliance on changes in the literature after the alleged exposure period as evidence of a lack of duty at the time of exposure also offers a roadmap for practitioners to do the same.

Preemption – Newly Acquired Information

***Knight v. Boehringer Ingelheim Pharm*., 984 F.3d 329 (4th Cir. 2021).**

In *Knight v. Boehringer Ingelheim Pharm*., 984 F.3d 329 (4th Cir. 2021), the Fourth Circuit established "goalposts" for when newly acquired information permits a pharmaceutical company to unilaterally modify their physician labels, and therefore also permits a state-law challenge to a warning label in spite of the preemption doctrine's usual prohibition of such claims.

Plaintiffs' decedent, Betty Knight, took Pradaza, a drug developed by Boehringer to help reduce the risk of stroke, for over a year before suffering a gastrointestinal bleed. Following her death, her children brought state law claims alleging that Boehringer failed to adequately warn of the risks of the drug and for fraud based on the same underlying allegations. Boehringer raised a preemption defense, and Plaintiffs responded that the

risks related to “newly acquired information” discovered after the FDA approval, such that Boehringer could have updated the warnings without FDA approval, and therefore they argued that the state-law claims were not preempted. The district court agreed with Plaintiffs, and a jury returned a mixed verdict, finding for Boehringer on the failure to warn and warranty claims, but finding for Plaintiffs on their fraud claim. The district court denied Boehringer’s post-trial motions, and Boehringer appealed, primarily on the grounds that the claims were preempted because it had not discovered “newly acquired information.”

The Fourth Circuit agreed with Boehringer’s arguments and held that the claims were preempted and therefore reversed the district court’s order denying Boehringer’s post-trial motion for judgment as a matter of law.

Following its initial FDA approval, Boehringer had continued to perform testing on the drug regarding both ideal dosing, and also on increased risks of bleeding for patients with certain other risk factors. This additional research formed the basis for Plaintiffs’ claims of newly discovered information. A final paper on the additional analysis was published. The Fourth Circuit held that the publication did not contain “newly acquired information” for multiple reasons: (1) because the paper was sent to the publisher after Knight’s bleed occurred, so it could not have made any difference in her treatment; (2) because although the paper consisted of “new analysis” it did not reveal any risks of a greater type, severity or frequency than previously submitted to the FDA; and (3) the conclusion of the paper that no single concentration range was optimal for all patients on its face did not establish any new risk. The Court then turned to the more difficult question of whether the underlying research and drafts of the paper, which were different than the final publication, constituted “newly acquired information.” The Court’s analysis included evaluation of an internal email stating that the “conclusions that appear to emerge from this paper are not the ones currently wished for by marketing (that dose adjustment will optimize therapy).” A circulated draft of the paper also identified an optimized dosage range. However, Boehringer continued the research and ultimately reached a different conclusion; that conclusion was accepted by the scientific and regulatory community following peer review and publication. Accordingly, the Court held that because the new analysis did not “reveal” any new conclusions, and the initial thought and drafts did not constitute “newly acquired information,” the Plaintiffs’ claims were preempted.

After reaching its decision, the Court cautioned against a "quick trigger" regarding determinations of "newly acquired information" and reiterated the importance of open dialogue and exchange of ideas in the scientific process, and therefore "hypotheses, different viewpoints and even preliminary conclusions" should not be considered "reliable evidence of new risks."

Cases Related to Unique Issues Around Death

Wickersham v. Ford Motor Co., 997 F.3d 526 (4th Cir. 2021).

In *Wickersham v. Ford Motor Co.*, 997 F.3d 526 (4th Cir. 2021), the Fourth Circuit addressed whether death by suicide broke the causal chain in a wrongful death action, or whether a defective design can give rise to an "incontrollable impulse" which would allow the claim to survive.

Wickersham, who had a history of depression, bipolar disorder, and suicidal thoughts, was in a severe car accident that resulted in significant facial injuries, including the loss of an eye and his ability to smell or chew food. He had difficulty managing his pain and was voluntarily hospitalized for severe depression and suicidal thoughts. Following his hospitalization, due to insurance issues and his inability to maintain his employment as a pharmacist while taking pain medications, he was unable to afford out-of-pocket costs of treatment. A year and a half after the accident he died by suicide after he consumed a lethal dose of methadone.

His wife and estate filed actions against Ford in South Carolina asserting various causes of action all based on the allegation that the airbag system in the car was defective, and relying on the crashworthiness doctrine. Ford moved for summary judgment, arguing that any alleged defect could not be the proximate cause of his death by suicide under South Carolina law. The district court denied the motion and held that Plaintiffs could prevail if they proved that he suffered injuries caused by Ford's defective design that gave rise to an uncontrollable impulse, an exception to the rule that suicide breaks the chain of causation. Following a two week trial, the jury found for the Plaintiffs. Following Ford's appeal, the Fourth Circuit certified two questions of law to the Supreme Court of South Carolina regarding its treatment of the uncontrollable impulse exception

to the generally accepted rule that death by suicide severs the chain of causation. In response, the Supreme Court stated that South Carolina does not recognize the "uncontrollable impulse" exception to the general American rule that death by suicide breaks the chain of causation, but *also* stated that South Carolina does not recognize the general rule that death by suicide precludes foreseeability as a matter of law.

Accordingly, the Fourth Circuit remanded for additional proceedings in the district court to reconsider Ford's Rule 50(b) motion under the proper framework of whether Ford's conduct caused Wickersham's death by suicide and whether that death was a foreseeable consequence of Ford's tortious conduct.

This case showcases that the "American rules" cannot be assumed to be written in stone if not explicitly adopted by a state, and may indicate that as attitudes around mental health and death by suicide change, the law may bend towards allowing for recovery against manufacturers in spite of suicide as the ultimate cause of death.

***Wadsworth v. Sharma*, 215 Md. App. 159 (Md. App. 2021).**

In 2021, Maryland's Court of Special Appeals held that Maryland's wrongful death statute does not allow for recovery based on loss of time if a physician negligently failed to properly diagnose terminal illness, and Maryland's Court of Appeals recently granted *certiorari*. This case is one to watch.

Asbestos/Mass Torts

***Connor v. Covil Corp.*, 966 F.3d 143 (4th Cir. 2021).**

Applying the *Lohrman* standard for causation in a case involving an asbestos-related injury, the Fourth Circuit affirmed the district court's grant of summary judgment for a manufacturer and supplier of asbestos insulation to a site where the Plaintiff occasionally worked. Although there were disputes of fact regarding how often he was in the production plant where any asbestos products were in use, and, when he was in the plant, how often he came into contact with workers actually using the defendant's asbestos products, the district court found that taking the evidence in the most favorable light for the Plaintiff, it was insufficient to support an inference that his harm was caused by the particular defendant. The Fourth Circuit affirmed, finding that the circumstantial

evidence of exposure did not pass muster under the frequency, regularity, and proximity test, because although he testified that he saw the relevant workers "several times a day," there was no evidence of how often those workers were using the defendant's asbestos-containing products to actually constitute an "exposure" by the Plaintiff.

This case contains a detailed analysis and good holding for mass tort practitioners regarding causation where the evidence of exposure to a certain product is tenuous and speculative.

FIFTH CIRCUIT:

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Camacho v. Ford Motor Co., 993 F.3d 308 (5th Cir. 2021).

In affirming the district court's judgment that Texas' statute of repose barred the plaintiff's lawsuit, the Fifth Circuit considered how to determine the date of sale of a product. Section 16.012(b) of the Texas Civil Practice and Remedies Code establishes a 15-year statute of repose for product liability claims: "a claimant must commence a products liability action against a manufacturer or seller of a product before the end of 15 years after the date of the sale of the product by the defendant." But what does "the date of the sale of the product" actually mean in a long line of supply chain distribution?

On August 6, 2017, Plaintiff Jose Camacho and his family (including one minor son, who will become important to the analysis later) were seriously injured during a rollover accident in their 2004 Ford F-150 truck. On January 10, 2019, Plaintiff filed suit against Ford under Texas law. Ford moved for summary judgment based on the 15-year statute of repose, arguing that the statute of repose began running on October 6, 2003, the day Ford "released" the new truck to the dealership. Plaintiffs argued that the accurate

"sale" date is the date of "first sale" under the Certificate of Title Act in the Texas Transportation Code. Using that definition, they contended, the relevant sale date was either January 10, 2004, when the first consumer purchaser applied for a title to the vehicle, or January 21, 2004, when the Texas Department of Motor Vehicles issued the title. The district court agreed with Ford's interpretation and granted summary judgment on that basis.

The Camachos appealed, arguing that "the date of sale" should be interpreted using the definition of "first sale" from the Certificate of Title Act in the Texas Transportation Code. Ford argued that the definition of "sale" from the Uniform Commercial Code in the Texas Business and Commerce Code should prevail. "Not so fast," said the Fifth Circuit, concluding that both parties skipped a step in statutory analysis by immediately looking to other statutes to define "sale." Instead, the Fifth Circuit said, the "common, ordinary meaning" of the word "sale" should be assessed before looking to other statutes. Under the dictionary definition – which aligns with the UCC definition – the Fifth Circuit concluded that "the sale of the product by the defendant" happened on October 6, 2003, when Ford released the new truck to the dealership. Accordingly, the statute of repose began running on October 6, 2003, barring the plaintiffs' lawsuit which was filed more than fifteen years later.

But the Camachos also argued that at least as to their minor son's claims against Ford, the lawsuit should proceed because the statute of repose was tolled while he was a minor under Section 16.001 of the Texas Civil Practice and Remedies Code. After diving into both statutory interpretation and the purpose behind the statute of repose, the Fifth Circuit reasoned that the tolling provision in § 16.001(b) applies only to statutes of limitation, not to the statute of repose. Because the tolling provision does not apply to the statute of repose, the minor son's claim was also barred by the statute of repose.

While statute of limitations arguments are common, litigants often overlook statute of repose arguments. The Fifth Circuit's *Camacho* opinion will be helpful to Texas defendants looking to calculate the date the product-liability statute of repose begins to run as well as those arguing against applicability of certain statutory tolling provisions.

***McMillan v. Amazon.com Inc.*, 2 F.4th 525 (5th Cir. 2021).**

In a two-paragraph opinion, the Fifth Circuit resolved a question plaguing jurisdictions around the country: can Amazon be held liable as a "seller" under state product liability statutes for the third-party products sold on Amazon's website and handled through Amazon's "Fulfillment by Amazon" program? In a case arising out of Texas, the Fifth Circuit certified a question to the Texas Supreme Court, which held in response that "potentially liable sellers are limited to those who relinquished title to the product at some point in the distribution chain." Third-party sellers on Amazon do not relinquish title to their products, so the Fifth Circuit held that Amazon is not a "seller" of those products under Texas law.

This Fifth Circuit opinion is limited to Texas, and other jurisdictions have come to different conclusions based on other state's unique product liability statutes. Likewise, other e-commerce retailers may still be held liable under Texas's product liability statute if third-party sellers relinquish title to their products to the retailer. Finally, state legislatures may react to this ruling or similar rulings to change e-commerce laws and allow Amazon and similar sites to be held liable for products sold through their sites.

***In re Deepwater Horizon*, No. 20-30689, 2021 WL 3376873 (5th Cir. Aug. 3, 2021).**

In the ongoing line of cases related to the Deepwater Horizon oil spill, the Fifth Circuit affirmed the district court's order dismissing eight plaintiffs' claims with prejudice due to those plaintiffs' delay in complying with an order to produce medical records and other information. The plaintiffs each alleged they sustained medical conditions arising from exposure to the oil spill. Under the relevant MDL pretrial order, the plaintiffs were required to provide past and present medical information such as the dates their medical conditions were diagnosed and first treated, names of the diagnosing healthcare providers, and whether treatment was currently being obtained. The plaintiffs provided conflicting information, leading the district court to refer to their responses as "puzzling" and "hard to make sense of." The district court issued a show cause order, and ultimately concluded that the plaintiffs failed to comply with the pretrial order and dismissed their claims with prejudice.

On appeal, the Fifth Circuit held that the plaintiffs should have been keeping track of their claims immediately after the Deepwater Horizon oil spill. After having seven months to comply with the pretrial order, the Fifth Circuit determined that the plaintiffs' "continuous and self-imposed failure to comply" with the pretrial order amounted to "clear delay." The Fifth Circuit also notably recognized that "[n]o lesser sanction than dismissal with prejudice would serve the interests of justice." Because the district court's show cause order did not produce compliance, the appellate court reasoned that no other sanction would have achieved the pretrial order's desired effect.

The dismissal with prejudice of MDL plaintiffs' claims for failure to timely submit this information serves as a greenlight to other MDL defendants pushing to obtain information from plaintiffs via plaintiff fact sheets.

Johnson v. Novartis Pharm. Corp., 845 F. App'x 305 (5th Cir. 2021).

Though unpublished, the Fifth Circuit's *Johnson* opinion provides the latest affirmation of Texas law with regard to manufacturers of brand-name drugs. After being prescribed two generic drugs to treat certain dermatology issues, the plaintiff developed Peyronie's Disease. He subsequently sued the manufacturers of both the generic and name-brand drugs for strict liability, products liability, breach of warranty, and loss of consortium under Texas law. Under long-standing law, strict liability, breach of warranty, negligence, and product liability claims against generic drug manufacturers are preempted where the generic manufacturer complies with FDA regulations mandating the warning label be the same as the brand name's label. The plaintiff attempted to avoid dismissal based on preemption by arguing that his claim was a "strict liability marketing defect claim." But no matter the plaintiff's characterization of his claim, the Fifth Circuit concluded that plaintiff could not escape preemption under Supreme Court precedent.

As to the brand-name manufacturers, the Fifth Circuit affirmed its previous opinions, holding that "brand-name pharmaceutical companies cannot be held liable under Texas product liability law when a plaintiff ingests a generic manufacturer's drug rather than the brand-name manufacturer's drug." Reiterating the Texas Supreme

Court's holding that entities are "'manufacturers' only with respect to their own products," the Fifth Circuit determined that because the plaintiff did not allege he took the brand-name drugs, he failed to state a products liability claim against the brand-name manufacturers. Further, brand-name drug manufacturers do not owe any common law duty to those who do not take their drugs under Texas law. For those reasons, the Fifth Circuit affirmed the district court's dismissal of the plaintiff's claims.

As plaintiffs continue to try creative arguments to circumvent preemption or long-standing law on these issues, drug manufacturers can rest assured that the Fifth Circuit continues to uphold its precedent with regard to generic and brand-name manufacturers alike.

***Wages & White Lion Investments, L.L.C. v. U.S. Food & Drug Admin.*, — F. 4th _ —; 2021 WL 4955257 (5th Cir. Oct. 26, 2021)**

In 2016, the FDA generally prohibited the marketing of e-cigarettes through the combination of the Family Smoking Prevention and Tobacco Control Act ("TCA") and the "Deeming Rule." But the FDA delayed enforcement of the Deeming Rule, establishing a series of requirements and staggered deadlines that e-cigarette makers had to meet in order to keep their products on the market. The FDA required e-cigarette manufacturers to undergo a rigorous process of submitting premarket tobacco applications ("PMTAs"). The PMTAs include information on the product's health risks, ingredients, manufacturing process, samples of the product, and proposed labeling.

As relevant to the Fifth Circuit's decision, the FDA "moved its regulatory goalposts in at least two important ways." First, it extended the PMTA deadline to 2022, then moved it back up to September 9, 2020. Second, the FDA initially issued guidance stating that "in general, FDA does not expect that applicants will need to conduct long-term studies to support an application." But then the FDA reversed course and required long-term studies of e-cigarettes in conjunction with the PMTA.

The plaintiff in this case manufactured e-cigarettes before the Deeming Rule's effective date, and timely submitted a PMTA for certain flavored e-cigarettes. But on

August 26, 2021, the FDA announced it would deny the PMTAs for 55,000 flavored e-cigarettes, and indeed, issued a marketing denial order to the plaintiff two weeks later. The FDA based its denial on the lack of long-term studies in the plaintiff's PMTA, even though the plaintiff had also submitted a letter stating that it intended to conduct long-term studies of its products.

Looking closely at the FDA's rules and statements, as well as its reasons for denying plaintiff's PMTA, the Fifth Circuit called out the FDA's decision to ignore the evidence before it. The FDA plainly stated "[F]or the sake of efficiency, the evaluation of the marketing plan in applications will not occur at this stage of review, and we have not evaluated any marketing plans submitted with these applications." The Fifth Circuit analogized the FDA's reasoning to "an Article III judge saying that she stopped reading briefs because she previously found them unhelpful." In other words, the FDA's purported expertise and experience cannot substitute for the "reasoned decisionmaking" required of an agency vested with such power.

The Fifth Circuit further explained that the FDA failed to reasonably consider the plaintiff's legitimate reliance interests – plaintiff and other e-cigarette manufacturers relied on the public meetings and guidance issued by the FDA in their PMTA applications. When the FDA "pull[ed] a surprise switcheroo on regulated entities," its denial order crossed the line to arbitrary and capricious.

Ultimately, the FDA didn't even look at many aspects of plaintiff's PMTA, including plaintiff's argument that its reusable e-cigarette products aren't as popular with youth as disposable e-cigarette products – which the FDA had already concluded were preferable to minors because they're easy to hide and use secretly. The FDA failed to explain its prior disposable-reusable distinction, further demonstrating the arbitrary and capricious nature of its denial order.

Based on the FDA's treatment of plaintiff's PMTA, the Fifth Circuit granted a stay, allowing plaintiff's e-cigarette products to stay on the market pending further review. As cases involving e-cigarettes continue to be litigated across the country, the Fifth Circuit's decision signals to the FDA that it cannot remove products from the market without affording manufacturers a meaningful opportunity to comply with ever-changing regulations.

***In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 994 F.3d 704 (5th Cir. 2021).**

Defendant Sanofi U.S. Services, Inc. continues to find success in the *In re Taxotere* MDL pending in the Eastern District of Louisiana, including on appeal. In this particular appeal, the Fifth Circuit faced the question of whether a physician's warning of permanent hair loss, as opposed to temporary hair loss, would have affected the prescribing physician's decision to prescribe Taxotere to the plaintiff. Taxotere is a chemotherapy medication, frequently used to treat breast cancer. In this case, the plaintiff was prescribed Taxotere to reduce the risk of cancer recurrence after the plaintiff had surgery to remove breast cancer. At that time, Taxotere did not include any mention of a risk of potentially permanent hair loss, but the prescribing physician discussed Taxotere's potential side effect of temporary hair loss with the plaintiff. The plaintiff did not ask about alternative treatments in light of that risk, and consented to the treatment.

After the plaintiff experienced potentially permanent hair loss, she filed suit and joined the MDL against the drug manufacturer. Yet the treating physician testified that hair loss is a common and widely known side effect of Taxotere and other chemotherapy drugs, and whether such hair loss was permanent or temporary would not have changed his prescribing decision in this case. In fact, the prescribing physician had explained to the plaintiff why available alternatives were inadequate treatments for her.

Based on that evidence, the district court granted summary judgment to the defendant on plaintiff's failure-to-warn claim under Louisiana law. To prove causation in this context, the plaintiff must prove that but for the inadequate warning, the prescribing physician would not have prescribed the product. Given the prescribing physician's testimony, there was simply insufficient evidence to create a genuine issue of material fact as to whether a warning that hair loss could be permanent rather than temporary would have changed the doctor's prescription. Because an adequate warning "would have been futile under the circumstances," the Fifth Circuit affirmed summary judgment in favor of the defendant.

Several thousand individual actions remain pending in the MDL, but the defense has now won two consecutive bellwether trials and prevailed on issues of label adequacy

and medical causation, which are sure to have significant implications in the broader litigation.

SIXTH CIRCUIT:

Kaitlyn Hawkins-Yokley, Frost Brown Todd LLC, 301 E. 4th St., Suite 3300, Cincinnati, OH 45202

Failure to State a Claim

***Christian v. Altaire Pharmaceuticals, Inc.*, No. 20-6360, 2021 WL 3578812 (6th Cir. Aug. 10, 2021).**

Plaintiff brought this Products Liability action under Kentucky law claiming that she suffered severe and permanent ophthalmological damage after using Defendant's lubricant Eye Ointment. Plaintiff alleged that the product was subject to a Food and Drug Administration ("FDA") recall and incorrectly claimed in her pleadings that the recall was due to bacteria in the product that could lead to an infection. The District Court reviewed the actual recall announcement, which did not state the recall was due to contamination of the eye ointment. Plaintiff relied solely on the recall to allege that the eye ointment was contaminated. The District Court granted Defendant's motion to dismiss because Plaintiff's complaint did not plausibly allege a product defect.

Plaintiff filed a motion for reconsideration relying on an FDA warning letter citing violations of good manufacturing practice regulations at Defendant's manufacturing facility. The District Court pointed out the warning letter was available prior to the

dismissal of the Plaintiff's claims and that the warning letter addressed violations at a facility where various products were manufactured and did not identify any specific issue connected to the eye ointment used by Plaintiff. Therefore, the District Court denied Plaintiff's motion for reconsideration.

The 6th Circuit affirmed the District Court's dismissal of Plaintiff's claims and denial of Plaintiff's motion for reconsideration for the same reasons expressed by the District Court.

Pleading Standard: Motion for Judgment on the Pleadings

***Genaw v. Garage Equipment Supply Co.*, 856 F.App'x. 23 (6th Cir. 2021).**

In this Products Liability dispute, Plaintiff appeals the District Court's grant of judgment on the pleadings in favor of Defendant because Plaintiff failed to allege sufficient factual matter to plausibly state a claim for relief on all five counts in the complaint. Plaintiff appealed to the Sixth Circuit.

Plaintiff alleged that Defendant's vehicle lift was defective because it suddenly and unforeseeably slid across a garage floor when a vehicle was driven onto it, striking her husband in the head and back with lethal force. Plaintiff brought the action on behalf of her husband's estate claiming: (1) negligent production; (2) breach of implied warranty; (3) gross negligence/actual knowledge, (4) breach of express warranty, and (5) failure to warn under Michigan law.

The Defendants pointed to a line of Michigan cases where the pleadings specifically identified the defect in the product, and noted that a specific defect was not alleged in Plaintiff's Complaint. The Sixth Circuit pointed out that those cases had the benefit of discovery to identify a particular defect. The Sixth Circuit held that to survive the pleading stage, it was sufficient for Plaintiff to show that the lift malfunctioned by violently sliding across the floor.

The Sixth Circuit reversed the District Court's grant of Defendant's motion for judgment on the pleadings because Plaintiff pled sufficient facts in her complaint to state a plausible claim to relief on all counts. The Sixth Circuit found that the allegations that Plaintiff's husband suffered fatal injuries while using the lift permit the reasonable

inference that the lift was defective. Additionally, the Sixth Circuit found that the complaint sufficiently asserts that a properly designed and manufactured lift would not have caused such serious injuries to an ordinary user. Finally, the Sixth Circuit found that the complaint contained sufficient facts that the lift was defective under Michigan law because it malfunctioned during ordinary use.

Tennessee Products Liability Statute of Repose

Clabo v. Johnson & Johnson Health Care Systems, Inc., 982 F.3d 989 (6th Cir. 2020).

In this Products Liability Action, Plaintiff asserted claims under the Tennessee Products Liability Act ("TPLA") based on a TVT transvaginal mesh device that allegedly caused additional pain and revision surgeries after implantation. Defendants moved for and were granted summary judgment based on Tennessee's statute of repose for products liability cases.

In 2003, Plaintiff underwent a surgery implanting a TVT transvaginal mesh device to treat pelvic organ prolapse and urinary incontinence. By 2006, Plaintiff began experiencing additional discomfort including pelvic pain, urinary issues, scarring, and pain during sexual intercourse. After being notified by her doctor that the mesh had eroded through her vaginal canal, Plaintiff had a second procedure in 2006 to remove the mesh implant. Approximately one month later, Plaintiff had surgery to implant another similar mesh sling. In 2011, Plaintiff had yet another surgery due to mesh erosion. Although Plaintiff had several revision surgeries, she claimed that she did not know that her pain and discomfort was due to the devices until 2012 while speaking with a physician. The District Court found that Plaintiff's original claims were time-barred because her initial injury occurred in 2006. Tennessee's statute of repose for product liability cases is six years and Plaintiff filed her action in 2013.

The Sixth Circuit upheld the grant of summary judgment to Defendants because Tennessee Courts have explicitly held that Tennessee's statute of repose is not tolled due to the discovery rule. Additionally, Plaintiff did not sufficiently plead how her 2006 surgery differed significantly from her 2011 surgery as to defeat Defendant's claims of

untimeliness. Therefore, the Sixth Circuit agreed that Plaintiff's original injury was in 2006 and therefore the statute of repose had run at the time of her 2013 filing.

Fraudulent Joinder

***Hall v. Orthomidwest, Inc., et al*., 1:21-cv-00897; --- F. Supp. 3d --- (N.D. Ohio May 24, 2021).**

Plaintiff brought this Products Liability action in connection to injuries he sustained following hip replacement surgery using Johnson & Johnson's metal-on-hip replacement device. Plaintiff sued both the product manufacturer and distributors in state court under the Ohio Product Liability Act ("OPLA"). Defendants moved to remove the case to Federal Court claiming that the Ohio-based Distributor Defendants were fraudulently joined for the purpose of defeating diversity jurisdiction. Fraudulent joinder occurs when a complaint names a party against which there is no colorable cause of action.

Plaintiffs alleged that the distributor defendants were responsible for informing and educating the medical providers as well as marketing/selling the product at issue. Although the Court determined that the distributors fell under the definition of "supplier" in the OPLA, liability under the OPLA requires a supplier to make a representation or act negligently. Although the Distributor Defendants could be held liable under the OPLA, the Court determined that there is no reasonable basis to support Plaintiff's claims because: (1) there was no evidence that the distributor defendants designed the product, had any role in creating the label, or had any knowledge of any alleged defect in the product; and (2) Plaintiff's claim that distributors selectively provided their knowledge of revision

surgeries to the manufacturers which in turn impacted future warnings for the product, did not equate to proximate cause under the OPLA.

Therefore, the court held that the Distributor Defendants were fraudulently joined and the case could proceed because the District Court had diversity jurisdiction.

Failure to Warn

Seaton v. Black & Decker, Inc., No. 2:20-CV-124, 2021 WL 1395560 (E.D. Tenn. Apr. 13, 2021).

Plaintiff brought this Products Liability action against Defendant alleging negligence, implied warranty of fitness, implied warranty of merchantability, and strict liability under the Tennessee Products Liability Act ("TPLA") after injuring his hand on a hedge trimmer. While Plaintiff was unpacking the hedge trimmer from its original packaging, Plaintiff attempted to move the hedge trimmer by picking up the trimmer by the blade. Plaintiff unknowingly engaged the power switches, injuring his hand.

Defendant moved for summary judgment by stating that Plaintiff failed to prove that the hedge trimmer was defective or unreasonably dangerous. The Court disagreed that Plaintiff failed to identify a defect in the trimmer in regards to a failure to warn because Plaintiff pled that he was unaware that the battery was connected to the trimmer and charged in the original packaging. The Court granted Defendant's Summary Judgment on all claims based on design or manufacturing defect.

The Court also looked to whether the hedge trimmer was unreasonably dangerous by using two main tests: the Prudent-Manufacturer Test and the Consumer-Expectation Test. Under the Prudent-Manufacturer Test, the Court examines whether a reasonably prudent manufacturer would market the product if it had knowledge of the dangerous condition. The test requires the plaintiff to offer expert testimony as to the prudence of the defendant's decision to market the product. Under the Prudent-Manufacturer Test, the Court granted Defendant's Motion for Summary Judgment because Plaintiff did not make any expert disclosures which were necessary to prove their claims under the TPLA.

However, the Court denied Defendant's Motion for Summary Judgment under the Consumer-Expectation Test. The Consumer-Expectation Test holds that a product is not

unreasonably dangerous if the ordinary consumer would appreciate the condition of the product and the risk of injury. The Court found that Plaintiff's expectation, on its own, that having an attached battery that was partially charged in the original packaging was unreasonably dangerous, is sufficient to survive summary judgment.

Assumed Duty to Warn

***State Farm Fire & Cas. Co. v. Amazon.com, Inc.*, 528 F. Supp. 3d 686 (W.D. KY 2021).**

In this Products Liability action, Plaintiffs alleged several causes of action against Amazon related to the sale of a hoverboard through Amazon's third-party marketplace. Plaintiff claimed: (1) negligence, (2) strict products liability, (3) negligent failure to warn, (4) common law strict liability, (5) strict liability, (6) assumed duty to warn, (7) a strict liability against one unknown manufacturer, and (8) another strict liability claim against a second unknown manufacturer. The Court granted Amazon's Motion for Summary Judgment related to Counts 1-5, and 7-8 because on Amazon's third-party marketplace, Amazon never takes possession or title of the product, nor does Amazon set any of the prices. Amazon's website is simply used as a vehicle to connect consumers with third-party retailers who handle the details of the sale. However, the Court found there was an issue of fact as to whether Amazon assumed a duty to warn.

Plaintiff's insured claimed that a hoverboard caused a house fire that led to the loss of their home and personal property. Prior to the fire, Amazon sent an email to individuals who purchased hoverboards from the listing on its website warning the customers of safety issues involving hoverboards. The Court examined Restatement (Second) of Torts §32 (A) which states:

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third

person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if

(a) his failure to exercise reasonable care increases the risk of such harm, or

(b) he has undertaken to perform a duty owed by the other to the third person, or

(c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

The Court relied on Sixth Circuit precedent holding that that when Amazon previously sent out an email to customers concerning the dangers of Hoverboards, it assumed a duty to warn buyers of the risks. In the case at hand, there was a question of fact as to whether the insured received the email and if the insured did receive the email, whether the failure to include certain information in the email amounted to negligence on the part of Amazon. Therefore, the Court denied summary judgment on this count.

This case presents a warning to online marketplaces that they can create a duty to warn through communications with customers even if they don't take physical control of the product or control the details of the sale.

Preemption

***Smith v. ZOLL Medical Corporation*, 505 F. Supp. 3d 787 (E.D. Tenn. 2020).**

In this Products Liability action, Plaintiff claimed that Defendants were liable for strict liability and negligence under the Tennessee Products Liability Act ("TPLA") regarding an allegedly defective medical device that ultimately caused injury and death to Plaintiff's husband. Defendants claimed that Plaintiff's cause of action was preempted under the Medical Device Act.

Plaintiff alleged that her husband was using a wearable cardioverter defibrillator that was designed to sound an alarm and provide electric shock when the patient experienced an arrhythmia. The decedent was wearing the vest, experienced an arrhythmia, and the vest did not sound an alarm or provide an electric shock. The decedent subsequently died. Upon inspection of the device, it was determined that the battery was not properly connected at the time of the decedent's arrhythmia and the inadequate connection contributed to the lack of an alarm and electric shock treatment.

Plaintiff sued Defendants for strict liability and negligence due to their alleged defective manufacture, production, refurbishment, and distribution of the device in violation of the FDA-approved design and manufacturing requirements for the device.

The Court denied Defendant's motion to dismiss, holding that Plaintiff's claims were not preempted. Applying the two-step test from *Riegel*, the Court determined that, although the federal government established requirements applicable to the medical device, the state law claims brought by Plaintiff did not impose requirements that were different from or in addition to federal requirements. Plaintiff alleged that Defendants violated the FDA's requirements by failing to manufacture, produce, refurbish, and distribute the device with a properly functioning battery. Plaintiff alleged that these violations rendered the device defective and unreasonably dangerous for its designed use. Because Plaintiff's product liability claims were based on a parallel duty under state law, they were not expressly preempted.

Additionally, because the duties that Plaintiff sought to enforce are traditional state law duties Defendants owed as manufacturers of the device, not duties that Defendants owed to the FDA, Plaintiffs claims were also not impliedly preempted.

SEVENTH CIRCUIT:

BreAnna Davis, Adam Ira, Haley A. Johnston, and Jordan Slusher, Frost Brown Todd LLC, 201 N Illinois St #1900, Indianapolis, IN 46204

Adequacy of Product Warnings under Indiana Product Liability Act

Anderson v. Procter & Gamble, 2021 WL 2223791, (S.D. Ind. June 2, 2021).

The plaintiff brought a product liability action against Procter & Gamble (P&G), the manufacturer of Tide PODS, claiming he sustained a chemical burn to his right foot from exposure to a partially dissolved Tide POD inside his sock, which he wore after a load of laundry. Plaintiff initially asserted defective design and failure to warn claims against P&G, but later abandoned the design claim, leaving only the failure to warn claim at issue. The plaintiff claimed P&G failed to provide three warnings on the Tide PODS package: (1) that

the liquid contained in the PODS could cause cell death or burns to the skin; (2) that users should inspect clothing after washing and before wearing clothes; and (2) that failing to inspect clothing after washing, but before wearing the clothes, could cause burns to the skin from residual undissolved PODS liquid.

P&G moved for summary judgment asserting the warnings on the package were adequate and it did not breach its duty to warn under the Indiana Product Liability Act (IPLA). The plaintiff argued summary judgment was inappropriate because there was a genuine issue of material fact about the adequacy or lack of specific warnings. The court disagreed.

In undertaking its analysis, the court first noted a manufacturer's duty to warn under the IPLA is twofold: (1) to provide adequate instructions for safe use and (2) to provide a warning as to dangers inherent in improper use." citing Citing *Ford Motor Co. v. Rushford*, 868 N.E.2d 806, 810 (Ind. 2007). It further noted that "[t]he product label must make apparent the potential harmful consequences" and "[t]he warning should be of such intensity as to cause a reasonable man to exercise for his own safety caution commensurate with the potential danger." Citing *Jarrell v. Monsanto Co.*, 528 N.E.2d 1158, 1162 (Ind. Ct. App. 1988). Lastly, the court noted that "[a] warning's adequacy is measured by its factual content, the manner in which it is expressed, and the method of conveying these facts."

The crux of plaintiff's argument was that the warnings on the packaging were inadequate because they did not warn against the specific harm at issue – that PODS liquid could cause burns to skin. The court disagreed, relying on *Weigle v. SPX Corp.*, 729 F.3d 724, 734 (7th Cir. 2013).

The court found that, although the PODS packaging did not contain warnings specific to burns, the package contained several warnings from which a reasonable person could infer that PODS liquid can harm skin. For instance, one of the warnings stated: "if detergent gets ... on skin, call your local Poison Control Center" and "[i]mmediately rinse ... skin with water for 15 minutes." The court found *Weigle v. SPX Corp.*, 729 F.3d 724, 734 (7th Cir. 2013) particularly instructive, noting a manufacturer is not required to explain in detail the physics of the product to satisfy its duty. Rather, it is

enough that the manufacturer instructs users how to use the product and warn users of the inherent dangers of not following those instructions.

Relying on *Weigle*, the court found it was not necessary for P&G to warn of the scientific mechanism of harm that could occur if detergent contacted skin. Indeed, the court found that such a detailed instruction would be distracting surplusage. In doing so, the court pointed to reasoning in *Weigle* that "[e]xtended warnings present several difficulties, first among them that, the more text must be squeezed onto the product, the smaller the type, and the less likely is the consumer to read or remember any of it… only pithy and bold warnings can be effective." The court also pointed to *McMahon v. Bunn-O-Matic Corp.*, 150 F.3d 651, 656 (7th Cir. 1998), recognizing that "Indiana courts have expressed considerable reluctance to require ever-more detail in warnings."

Accordingly, the court concluded as a matter of law that P&G's warnings were adequate and that it did not breach its duty to warn. Summary judgment was therefore granted.

Indiana Product Liability Statute of Repose

***Wiesehan v. FCA US, LLC*, 2021 WL 4398789, (N.D. Ind. Sept. 27, 2021).**

This action arose from a February 2019 vehicle accident in which the plaintiff's decedent was driving a 2002 Jeep Liberty and was rear-ended by a Ford Explorer. The impact ruptured the Jeep's fuel tank and caused a fire. The Jeep Liberty had been the subject of a recall in 2013 stemming from a National Highway Transportation Safety Association (NHTSA) investigation into Jeep fires. As a result of the investigation, the manufacturer, FCA, voluntarily recalled several model year Jeeps, including the 2002 Jeep Liberty, to address certain low-speed rear impact accidents by providing a trailer hitch manufactured by Defendant Northern Stamping as a guard for the rear placed fuel tank. The Jeep plaintiff's decedent was operating was equipped with a Northern Stamping trailer hitch.

Plaintiff's decedent filed a product liability action against FCA, claiming the trailer hitch and fuel tank location were defects in the Jeep which caused decedent's death. FCA moved for judgment on the pleadings, arguing plaintiff's actions were barred by Indiana's

10-year statute of repose for product liability claims. FCA argued that because the action was commenced more than ten years after the 2002 Jeep was first delivered, and there is no exception for subsequent product modification, Plaintiffs' entire cause of action was barred. FCA relied on the Indiana Supreme Court's decision in Court in *Estabrook v. Mazak Corp.*, 140 N.E.3d 830 (Ind. 2020).

In *Estabrook*, the Indiana Supreme Court addressed whether the statute of repose can be extended by post-sale repair/refurbishment/reconstruction of the product. The Indiana Supreme Court answered the question in the negative, holding there is no exception that extends the statute of repose for post-sale repair/refurbishment. The Indiana Supreme Court stated that "[b]ecause the statute has no other exceptions…its ten-year limitation period cannot be extended for any other reason – including a manufacturer's post-sale repair, refurbishment, or reconstruction of a product."

Plaintiff argued the trailer hitch was not a manufacturer's post-delivery repair or refurbishment, but instead was an entirely separate product, so *Estabrook* was not controlling. The plaintiff therefore contended that, because the trailer hitch was first delivered in 2014 at the earliest, plaintiff's claim was not time barred.

The court held that under *Estabrook*, plaintiff's claims as to the Jeep itself were barred by the statute of repose. However, the court held plaintiff's claims regarding the trailer hitch were not barred because the trailer hitch was a separate product carrying its own 10-year statute of repose commencing in 2014 at the earliest. The court found that *Estabrook* was not controlling as to the trailer hitch because the Indiana Supreme Court did not address the issue of whether new parts installed on a product were distinct products with their own statute of repose. The court therefore denied FCA's motion for judgment on the pleadings and permitted plaintiff's product liability claims with respect to the trailer hitch to continue.

No Personal Jurisdiction Over Foreign Manufacturer of Firearm Under New Ford Motor Co. United States Supreme Court Standard

***Patterson v. Chiappa Firearms, USA, LTD,* No. 1:20-CV-01430-JPH-MG, 2021 WL 4287431 (S.D. Ind. Sept. 21, 2021).**

Plaintiff Jacob Patterson brought a product liability action against Chiappa Firearms USA, LTD ("Chiappa USA") (a distributor) and Chiappa Firearms, S.R.I. ("Chiappa Italy"), the Italian manufacturer of a revolver. Patterson alleged the firearm exploded in his hand, causing injuries. The firearm was manufactured in Italy by Chiappa Italy, and distributed in the USA by Chiappa USA. Chiappa USA distributed the firearm to a retailer named Williams Shooters Supply based in Illinois. An online retailer named Bud's Gun Shop, based in Kentucky, purchased the firearm from Williams Shooters Supply, which then sold the firearm to the Plaintiff. Plaintiff received the firearm from a local federal firearms licensee in Indiana named Indy Arms (a requirement for sale of firearms). Chiappa Italy did not sell firearms directly to Williams Shooters Supply or Bud's Gun Shop.

Chiappa Italy moved to dismiss for lack of personal jurisdiction, arguing the Indiana court lacked general and specific jurisdiction over it. The court first examined whether general personal jurisdiction existed over Chiappa Italy. The court found that Chiappa Italy was an Italian corporation with its principal place of business in Italy, and there were no allegations that Chiappa Italy had continuous and systematic contacts with Indiana. The court thus found Chiappa Italy was not subject to general jurisdiction.

Turning next to the question of specific jurisdiction, Chiappa Italy argued the court lacked specific jurisdiction because there was no evidence that Chiappa Italy directed any activities toward Indiana or purposefully availed itself of the privilege of conducting business in Indiana. The plaintiff responded by arguing that the court had specific jurisdiction because Chiappa Italy placed its products in the stream of commerce, expecting that they would be marketed and sold in Indiana. The court began its analysis by addressing the recent United States Supreme Court Decision of *Ford Motor Co. v. Montana Eighth Judicial District Court*, 141 S.Ct. 1017 (2021). The court noted that the *Ford* case addressed the requirement that the injury must "arise out of or relate to" the defendant's forum contacts.

The court found that while American consumers could buy some products directly from Chiappa Italy's website, all firearms must be transferred through a federal firearms licensee dealer. Chiappa Italy's website had a "dealer locator" function that returned 24 Indiana dealers with federal firearms licenses within 100 miles of Indianapolis. However, Mr. Patterson bought the firearm from Bud's Gun Shop, and not Chiappa Italy's website. Patterson alleged that Chiappa Italy's website listed Bud's Gun Shop as an available "Web Shop," but he did not allege that he saw or used that link, or that Chiappa Italy's contacts with Indiana otherwise motivated his purchase or caused his injury. Thus, the court found that the "arise out of" part of the test did not support specific personal jurisdiction.

As to the "relate to" half of the test, the court distinguished the *Ford* case by pointing out that Chiappa Italy had not "invaded Indiana's market 'by every means imaginable' as Ford did in Montana and Minnesota." (Quoting, *Ford Motor Co., Id.).* The were no Indiana "billboards, TV and radio spots, print ads, and direct mail" from Chiappa Italy. And Plaintiff did not allege Chiappa Italy "works hard to foster ongoing connections" to its guns' owners. The court found that Chiappa Italy's closest contact to Indiana is that Hoosiers can buy some of its products through its website and use the website to find Indiana gun dealers who sell or can transfer firearms. Plaintiff did not allege that Chiappa Italy had a relationship with Indiana gun dealers similar to the relationship between a car manufacturer and its dealers, like in *Ford Motor Co.* Chiappa Italy's website merely provided contact information for Indiana gun dealers, with a disclaimer that "Not all dealers carry our firearms in stock. Any dealer can order our products."

The plaintiff attempted to raise the "stream of commerce" theory to establish jurisdiction, but the court found that a single isolated sale from a distributor to a customer in the forum state has never been sufficient to establish minimum contacts. As a result, the court found no basis for exercising personal jurisdiction over Chiappa Italy, and the court dismissed Chiappa Italy for lack of personal jurisdiction.

Specific Personal Jurisdiction Under Illinois Law Over Non-Manufacturing, Non-Selling, and Non-Distributing Marketer of Product

***Hernandez v. Oliveros,* 2021 IL App (1st) 200032 (Not yet released for publication in the permanent law reporters).**

The plaintiffs, a husband and wife, filed a product liability action against GMAX, LLC, which branded and marketed motorcycle helmets, alleging strict products liability based on manufacturing defects and failure to warn after they crashed their motorcycle, causing head injuries. GMAX was incorporated in Michigan with its principal place of business in Idaho. GMAX filed a motion to dismiss for lack of personal jurisdiction. GMAX submitted an affidavit stating it did not design, manufacture, sell or distribute the motorcycle helmets the plaintiffs were allegedly wearing, as it does not design, manufacture, sell or distribute any products. GMAX's affidavit further stated it has never had any customers in Illinois and that it "has no connection to the State of Illinois with respect to the motorcycle helmets alleged in the [c]omplaint."

The plaintiffs responded to GMAX's motion to dismiss by pointing out that they purchased the helmets through RevZilla, which is an online, authorized retailer for GMAX products. While the GMAX helmet worn by plaintiff husband was shipped through RevZilla, the GMAX helmet worn by plaintiff wife was shipped directly from WPS (a member of GMAX, LLC) to plaintiff husband at his home address in Chicago. Plaintiffs argued that Illinois does have personal jurisdiction over GMAX because: GMAX participated in the design of GMAX helmets, GMAX has authorized retailers in Illinois to sell its products, GMAX has an exclusive distribution agreement with the Taiwanese manufacturer of the helmet and WPS, WPS is a member of GMAX, LLC, and their injuries arose out of using GMAX's products in Illinois.

GMAX argued that its only involvement in the design of the helmets was "helmet aesthetics." GMAX further argued that although WPS was its sole distributor, GMAX had no involvement in the sale of the helmets. GMAX also argued it has no affiliation with RevZilla, and that the activities of WPS and RevZilla in selling the helmet could not be imputed to GMAX.

The trial court found sufficient facts to establish specific jurisdiction over GMAX. GMAX appealed, arguing the trial court erred in finding specific personal jurisdiction based on the stream of commerce theory, claiming it was not the prevailing law in Illinois. GMAX also argued it did not have sufficient minimum contacts with Illinois, arguing that the acts of the third-party sellers, WPS and RevZilla could not be imputed to it for purposes of personal jurisdiction.

The Appellate Court of Illinois began its analysis by finding the Illinois Long Arm Statute permitted Illinois courts to exercise personal jurisdiction to the full extent allowed by the state and federal constitutions. The parties did not dispute that general personal jurisdiction did not exist in the case. The court then examined the state of the "stream of commerce" theory in Illinois. It found that the Illinois Supreme Court declined to adopt the theory without more definitive guidance from a majority of the United States Supreme Court, but noted that the theory was still valid (this case predated the recent United States Supreme Court decision in *Ford Motor Co.*, 141 S.Ct. 1017 (2021)).

The court rejected GMAX's reliance on the fact that it did not manufacture, distribute or sell the helmets. The helmets were GMAX products, and GMAX was aware the products were being marketed and sold in Illinois. The court focused on the fact that GMAX had authorized retailers for GMAX products throughout Illinois. The court also found that the purposeful availment requirement could be achieved through another entity (i.e. WPS), as long as the other entity makes contact with the form state bilaterally rather than unilaterally. The court found bilateral contact through WPS, as WPS was GMAX's sole distributor and distributed its products on GMAX's behalf throughout North America, including Illinois.

The court then examined whether the cause of action arose out of GMAX's contacts with Illinois. The court found that it did because the helmets were purchased and used in Illinois. Accordingly, the court affirmed the denial of GMAX's motion to dismiss for lack of personal jurisdiction.

Use of OSHA Standards in Informing Expert Opinion on Design Defect

***Gillespie v. Edmier*, 2020 IL 125262, reh'g denied (Jan. 25, 2021) (Not yet released for publication in the permanent law reporters).**

The plaintiff truck driver injured himself after he fell off the step of a mulch trailer during the course and scope of his employment. He brought a product liability action against the manufacturer alleging strict liability for negligent design, manufacturing, and selling an allegedly defective and unreasonably dangerous product. The plaintiff further argued the manufacturer failed to warn consumers about foreseeable dangers from unsafe modifications. The trailer had been modified with an after-market tarp and cap.

Plaintiff's expert provided deposition testimony opining that the steps on the dump trailer were defective and unreasonably dangerous because the spacing and width of the steps, as well as the lack of side rails on the dump trailer, did not comply with the recommended practices of the Occupational Safety and Health Administration (OSHA), the American National Standards Institute, the Federal Motor Carrier Safety Regulations, and the Truck Trailer Manufacturers Association.

The manufacturer moved for summary judgment, which the trial court granted, ruing that OSHA does not apply to trailers and that industry standards are not mandatory. The trial court also found that the trailer met industry custom and practice because it was built to the purchaser's specifications, and the purchaser had the trailer modified by a third-party that installed the tarp cover and cap. Because the tarp cover and cap played a role in the plaintiff's injury, the trial court found the trailer was not in a defective condition when it left the manufacturer's control. The appellate court reversed and remanded, reasoning that the plaintiff's expert deposition testimony was sufficient to raise a genuine issue of material fact as to whether the trailer was unreasonably dangerous.

The manufacturer appealed to the Illinois Supreme Court, arguing the trial court properly granted summary judgment. The Illinois Supreme Court began its analysis by noting plaintiffs may demonstrate that a product is defectively designed by presenting evidence that the product fails to satisfy the "consumer-expectation test" or the "risk-utility test." The manufacturer argued that summary judgment was proper under the risk-utility test, and that the plaintiff's expert opinion that the trailer was dangerous was based upon inapplicable governmental standards and industry regulations. The Illinois Supreme

Court disagreed, pointing out that the governmental standards were not admitted as substantive evidence, but rather formed the basis for the expert's opinion that the product was unreasonably dangerous. Thus, the issue was whether it was appropriate for the expert to rely upon such standards in forming his opinion. The court found that it was, and affirmed the intermediate appellate court's reversal of the grant of summary judgment in favor of the manufacturer.

Operator of Online Marketplace for Third-Party Sellers not a "Seller"

***Great N. Ins. Co. v. Amazon.com, Inc.,* 524 F. Supp. 3d 852 (N.D. Ill. 2021).**

This case was a subrogation action brought by an insurer after a hoverboard sold by third-party sellers on Amazon caused fire damage to its insureds' home.

Amazon operates a marketplace where third-party sellers can sell products on its platform. Third-party sellers are responsible for sourcing their products from manufacturers or upstream distributors and communicating their offers on a detail page for each product. A third-party seller's identity is twice communicated to customers—first, in the "sold by" line on the product detail page, and second, on the order confirmation page before the customer clicks the "place your order" button. When communicating an offer, a third-party seller must provide a product description and pricing information. Third-party sellers set the prices of their products and may offer warranties of their choosing. Third-party sellers entered into an agreement with Amazon to sell their products at least as favorable to Amazon users as the seller's own sales channels. Amazon had the authority to remove, in its sole discretion, any content uploaded by third-party sellers.

Amazon was responsible for processing payment, and would remit the payments to third-party sellers after it took a negotiated fee. Third-party sellers must properly package their products, and for "seller-fulfilled products" the third-party seller must ship them directly to the buyer. Third-party sellers agree in their contract with Amazon that third-party sellers are responsible for any non-conformity or defect in, or any public or private recall of, any of the third-party seller's products.

Customers can opt to file a dispute with either the third-party seller or Amazon. Amazon retains "broad ability" to investigate returns, credit card chargebacks, customer complaints, and other customer disputes. If Amazon engages in such an investigation, it can withhold the third-party seller's remittance. Amazon's "A-to-Z Guarantee" also applied to third-party sellers, meaning if a third-party seller does not respond to a customer complaint to the customer's reasonable satisfaction, Amazon would refund the customer's purchase. Absent fraud, for which Amazon assumes responsibility, the third-party seller must reimburse Amazon for any refunds pursuant to the "A-to Z guarantee."

Amazon's terms and conditions applicable to purchasers included the following language:

> Parties other than Amazon operate stores, provide services, or sell product lines through the Amazon Services.... We are not responsible for examining or evaluating, and we do not warrant the offerings of, any of these businesses or individuals or the content of their Web sites. Amazon does not assume any responsibility or liability for the actions, product, and content of all these and any other third parties.

The plaintiff's insureds purchased hoverboards from third-party sellers on Amazon's platform. The third-party sellers shipped the hoverboards directly to the plaintiff's insureds at their home in Chicago. The hoverboards caught fire the day they arrived and caused significant property damage to the home insured by the plaintiff insurer. The plaintiff insurer brought suit against Amazon, alleging it sold, distributed, and/or played an integral role in the marketing and distribution of the hoverboards alleging design defect.

The court began its analysis by noting Illinois has adopted Restatement (Second) of Torts § 402A, which subjects manufacturers and "sellers" of a product to strict liability for product defects. Illinois courts have defined "sellers" to include "all persons in the distributive chain" of a defective product, "including suppliers, distributors, wholesalers, and retailers." Illinois law also includes entities that might not otherwise be "sellers" of a product but have "integral involvement in the overall producing and marketing enterprise that placed the dangerous product in the stream of commerce, and ... participat[e] in the profits from the distribution of the product." The court found that the Illinois Supreme

Court had not addressed whether a defendant can be liable and subject to strict product liability where it operates a platform where others can sell their own products.

Amazon argued it was never in the chain of distribution of the hoverboards because it never sourced, owned, possessed, or offered the hoverboards for sale. The plaintiff responded by pointing out that Amazon maintained control over the third-party's interaction with customers. The court examined § 402A and found that in Illinois, the key criterion for being a "seller" is exercising control over the product itself, and not the purchasing process. The court determined that it was likely the Illinois Supreme Court would not find Amazon to be a "seller" within the meaning of § 402A.

The court then turned to the issue of whether Amazon could be the kind of actor not otherwise a "seller" that could still be liable for strict product liability. Plaintiff's only argument on this point was that the third-party sellers of the hoverboards could only be served in China, making Amazon the only entity "reasonably available to an injured plaintiff." The district court declined to take this expansive approach to existing case law, and thus granted summary judgment in favor of Amazon because it was not a "seller" of the product or an entity otherwise subject to strict product liability under Illinois law.

Expert Testimony Required to Support Strict Liability Manufacturing Defect Claim

Kirk v. Clark Equipment Company, 991 F.3d 865, Prod. Liab. Rep. (CCH) P 21101, 114 Fed. R. Evid. Serv. 2334 (7th Cir. 2021).

Plaintiff, employee of a steel company, brought a strict liability manufacturing defect claim against Defendant, manufacturer of a skid-steer loader, for foot and ankle injuries he sustained while the loader he was operating tipped over. The Seventh Circuit held the District Court (applying Illinois law) did not abuse its discretion in excluding, as unreliable, the opinion of plaintiffs' expert that the loader was defective in design when equipped with a 62-inch bucket. Because Plaintiff's strict liability claims related to a skid steer loader design, which was not a simple product commonly saw or used by jurors, but was a specialized piece of industrial equipment that fell outside of a juror's common understanding and experiences, expert testimony was required to support his claims.

Plaintiff's design expert opined that based on his calculations and the company engineer's calculations, it was "highly likely" that a heaped load would exceed the skid-steer loader's rated operating capacity and, combined with its short wheelbase, would cause a propensity for the skid-steer loader to tip forward. The District Court excluded the expert's opinion because it was based on speculation and lacked data from similar accidents, generally accepted industry standards, and peer review. The expert did not test his opinions on the skid-steer loader or similar equipment, did not view or test the loader, did not visit the accident scene, did not interview the employee, and did not rule out alternative causes. The expert also relied on the employee, who admitted he did not know the weight of the load in the buck at the time of the accident or whether it exceeded the capacity. The Seventh Circuit held that expert testimony was required to support Plaintiff's strict liability claims because the skid-steer loader was not a simple product that lay jurors commonly saw or used but was a specialized piece of industrial equipment that fell outside of a juror's common understanding and experiences.

Evidence of Defect at the Time the Product Left Manufacturer's Control

***Horne v. Electric Eel Manuf. Co., Inc.,* 987 F.3d 704 (7th Cir. 2021).**

The Seventh Circuit affirmed summary judgment in favor of the manufacturer of a rodding machine because there was no evidence of a defect at the time it left the manufacturer's control or that the manufacturer's actions caused Plaintiff's injuries. A consumer was injured while using a rented rodding machine when the power toggle switch failed and a cable became wrapped around his hand. He filed suit against the manufacturer of the machine and the company that rented him the machine. The manufacturer presented evidence that the rental company modified the allegedly defective foot pedal and toggle switch on the rodding machine and received complaints about a leak prior to the accident. The undisputed evidence was that the rodding machine had been modified and was in poor condition.

The Seventh Circuit affirmed summary judgment, holding that there was no evidence of design defect in the drain rodding machine at time that it left manufacturer's control, that in an absence of abnormal use or reasonable secondary causes the product

failed to perform in a reasonably expected manner, or that manufacturer's actions or omissions caused Plaintiff's injury. Under Illinois law, in order to survive summary judgment, plaintiff must prove that the purported defect existed when the product left the manufacturer's control and must come forward with evidence justifying an inference of probability as to causation.

Dismissal of Class Action under Rule 12(b)(6)

***Brame v. Gen. Motors LLC*, No. 20-C-1775, 2021 WL 1599186 (E.D. Wis. Apr. 23, 2021).**

The class action in *Brame* arose from the purchase of vehicles manufactured by General Motors LLC ("GM"). The plaintiffs alleged that the engine's piston rings failed to keep oil in the crankcase because GM coated the rings with an inappropriate anti-friction and anti-wear material, causing the vehicle to consume an unusually high volume of oil. The complaint asserted claims for breach of express limited warranty, unjust enrichment, and fraudulent omission.

Plaintiffs alleged that GM made express warranties to each owner and subsequent owner of a GM vehicle and the warranty was governed by Wisconsin Statute § 402.313. GM contended its express warranty did not apply because it applied only to defects in "materials and workmanship," which, excludes design defects such as the oil consumption defect. Furthermore, GM contended that even if the defect was within the scope of the warranty, the plaintiffs did not adequately plead notice of the alleged breach pursuant to Wisconsin Statute § 402.607(3)(a).

Plaintiffs also alleged that GM made fraudulent misrepresentations by failing to disclose, in its advertisements and other statements, that the engines of the affected vehicles would consume excessive amounts of oil. GM argued that common-law fraud claims were barred by the economic loss doctrine. "The economic loss doctrine is 'based on an understanding that contract law and the law of warranty, in particular, is better suited than tort law for dealing with purely economic loss in the commercial arena." *Daanen & Janssen, Inc. v. Cedarapids*, Inc., 216 Wis. 2d 395, 403–04, 573 N.W.2d 842 (1998).

Lastly, Plaintiffs alleged that GM was unjustly enriched by Plaintiffs' purchase of their defective vehicles by independent dealers. GM argued that the doctrine of unjust enrichment does not apply to the facts in this matter. *Brame v. Gen. Motors LLC,* No. 20-C-1775, 2021 WL 1599186, at 6 (E.D. Wis. Apr. 23, 2021).

GM moved to dismiss the complaint under Rule 12(b)(6) and the court granted the motion with prejudice. As to plaintiffs' count one, breach of express warranty, the court reasoned that the claim fails because Plaintiffs had not alleged that they asked GM to repair their vehicles during the warranty period. As to count two, fraudulent misrepresentation, the court reasoned that the inducement exception could not apply because the alleged fraud was not extraneous to the contract but rather related to the quality and characteristics of the product. As to count three, unjust enrichment, the court reasoned that the doctrine of unjust enrichment did not apply because the plaintiffs received something in exchange for the benefit they conferred.

The court also acknowledged that often when a district court dismisses a complaint for failure to state a claim upon which relief can be granted, the court should grant the plaintiff leave to amend. However, in this instance, Plaintiffs failed to request an opportunity to amend their complaint. Furthermore, the Court was certain, just from the face of the complaint, that any amendment to the complaint would be futile.

***Allen v. Am. Cyanamid*, 527 F. Supp. 3d 982 (E.D. Wis. 2021).**

The *Allen* suit arose from injuries that were allegedly caused by ingesting paint that contained white lead carbonate (WLC) when they were young children. Plaintiffs alleged that the white lead carbonate pigment manufactured, processed, marketed, promoted, supplied, distributed and/or sold by the defendants was defective and unreasonably dangerous and sough to hold defendants liability under the contribution theory of liability. Plaintiffs moved for summary judgment on the Defendant's affirmative defense, intervening superseding cause, statute of limitations, statute of repose, violations of the Due Process Clause, the Commerce Clause, the Taking Clause, the First Amendment, and misuse.

The court denied plaintiffs' motion for summary judgment on intervening superseding cause and deferred consideration until after the jury had reached a verdict

and the affirmative defenses regarding the statute of limitations and the statute of repose had been withdrawn. Therefore, the court considered Plaintiffs' motion for summary judgment on the remaining affirmative defenses: violations of the Due Process Clause, the Commerce Clause, the Taking Clause, the First Amendment, and misuse. Plaintiffs argued that the Seventh Circuit's decision in *Gibson v. American Cyanamid*, 760 F.3d 600 (7th Cir. 2014) foreclosed all constitutional affirmative defenses. The court reasoned that although bound by Seventh Circuit precedent, the court was unwilling to pass preemptive judgment on issues that have not yet been raised or briefed. Accordingly, the court denied Plaintiff's summary judgment on the defendants' constitutional affirmative defenses.

The court granted Plaintiffs' motion as to misuse and held as a matter of law that poor maintenance of paint constituted a "use" of WLC other than "the purpose for which it was intended." *Burton v. Am. Cyanamid,* 341 F. Supp. 3d 941 (E.D. Wis. 2018). The court denied Plaintiffs' motion for partial summary judgment on the affirmative defense of mitigating damages.

Defendant Armstrong Containers ("Armstrong") moved for summary judgment and argued that plaintiffs' identified only one brand of paint containing WLC, as being sold in the Milwaukee market during the relevant time period and thus there was no genuine dispute of fact as to whether any WLC produced or sold by John R. MacGregor Company or the MacGregor Lead Company (together, "MacGregor"), Armstrong's predecessors, could reasonably have contributed to plaintiffs' injuries. Plaintiffs contended that Armstrong bore the burden of proving its product was not sold in Milwaukee market during the relevant time period. The court sided with Plaintiffs and reasoned that under *Thomas ex rel. Gramling v. Mallett*, 2005 WI 129, 285 Wis. 2d 236, 701 N.W.2d 523 the burden of proof shifts to each defendant to prove by a preponderance of the evidence that it did not produce or market white lead carbonate either during the relevant time period or in the geographical market where the house is located.

Defendant Sherwin-Williams moved for summary judgment and argued that plaintiffs are not entitled to proceed on the theory of risk-contribution because that theory is available only when a plaintiff shows by evidence that "insurmountable obstacles" foreclose his or her ability to identify the manufacturer of the product that cause him or

her harm. The court explained "it would be illogical and repetitious to require WLC plaintiffs to perform the kind of testing Sherwin-Williams describes as a prerequisite to proceeding on risk-contribution theory." The Wisconsin Supreme Court has established the basis for liability in risk-contribution cases; that is a showing that the defendant "reasonably could have contributed in some way to the actual injury." *Collins,* 116 Wis.2d at 191, 342 N.W.2d 37; *Thomas*, 2005 WI 129 at ¶164, 285 Wis.2d 236, 701 N.W.2d 523. The court considered each of the defendants' arguments in turn and held:

(1) There was sufficient evidence on the record for a jury to find the product was defective and plaintiffs had no obligation to present evidence of what warnings defendants ought to have given to render the product not unreasonably dangerous. Accordingly, the motion for summary judgment on the issue of product defect was denied.

(2) Plaintiffs adduced evidence sufficient for a reasonable jury to find that WLC and products containing WLC were dangerous to an extent beyond that which would be contemplated by an ordinary consumer. Accordingly, the motion for summary judgment on the issue of duty to warn and duty of ordinary care was denied.

(3) Because such a misuse was foreseeable, a reasonable jury could find that Sherwin-Williams breached its duty of ordinary care. Accordingly, the motion for summary judgment on the issue of breach of duty was denied.

(4) Given that WLC is inherently toxic, and that paint inevitably deteriorates, a reasonable jury could find that these changes were not material. Accordingly, the motion for summary judgment on the issue of substantial change was denied.

(5) The necessary inference did not require an expert with specialized technical, scientific, or medical knowledge, but may be made based on common understandings of human behavior. Accordingly, the motion for summary judgment on the issue of causation was denied.

(6) A reasonable jury could further infer that a more complete warning would have prevented the use of the paint in the plaintiffs' homes. Expert testimony was not needed because specialized technical, scientific, or medical knowledge was not necessary to make these inferences; they may be made on the basis of common

understandings of human behavior. Accordingly, the motion for summary judgment on the issue of evidence of inadequate warnings was denied.

(7) The Federal Hazardous Labeling Substances Act ("FHSA") explicitly preempted state law warning requirements for lead paints. Plaintiffs did not identify any evidence that defendants' warning labels violated the FHSA. Accordingly, the motion for summary judgment on the issue of federal preemption was granted.

EIGHTH CIRCUIT:

Baxter D. Drennon, Hall Booth Smith, P.C., 500 President Clinton Ave., Suite RL 20, Little Rock, AR 72201

Learned-Intermediary Doctrine Recognized in Nebraska

***Ideus v. Teva Pharmaceuticals USA, Inc.*, 986 F.3d 1098 (8th Cir. 2021).**

Teva Plaintiff Ideus brought a suit against Pharmaceuticals claiming that she was not adequately warned about risks associated with Teva's intrauterine contraceptive product. A piece of the product broke off and embedded in Ideus' uterine wall during removal by her physician. Ideus underwent surgery to remove the broken piece.

Ideus sued Teva for breach of its duty to warn her of the potential risks associated with the device. Teva moved for summary judgment at the District Court level arguing that the learned-intermediary doctrine applied and that it satisfied its obligation to warn Ideus by warning her treating physician. On appeal, the parties agreed that Nebraska law applied to the claim and that Teva adequately warned Ideus' physician. The question on appeal was whether Nebraska law recognized the learned-intermediary doctrine.

Nebraska state courts had not previously adopted the learned-intermediary doctrine in a medical device case. But, in *Freeman v. Hoffman-La Roche, Inc.*, 260 Neb. 552, 618 N.W.2d 827 (2000), a case involving a prescription drug, the Nebraska Supreme Court adopted § 6(d) of the Third Restatement of Torts, which involves the application of the learned-intermediary doctrine. Because the Third Restatement treats prescription drugs and medical devices no differently, the Eighth Circuit determined that the Nebraska Supreme Court, if faced with the question, would apply the learned-intermediary doctrine

to cases involving medical devices. The Circuit Court, then, affirmed the trial court's grant of summary judgment in Teva's favor.

Standing Requires Allegations of Actual Harm

In re: Polaris Marketing, Sales Practices, and Products Liability Litigation, 9 F.4th 793 (8th Cir. 2021).

Plaintiffs were a group of fourteen purchasers of off-road vehicles that brought a class action against Polaris alleging that a design defect in the vehicles caused the vehicles to produce excessive heat. Plaintiffs made claims for violation of the Magnuson-Moss Warranty Act and state law claims for breach of warranty, fraud, and violations of consumer fraud statutes. Seven of the plaintiffs owned vehicles that had caught fire and were destroyed. The other seven owned vehicles that had not experienced a fire. Polaris moved to dismiss the claims of the "no-fire" purchasers for lack of standing.

The no-fire purchasers claimed that they suffered economic damages because they would not have purchased the vehicles or would have purchased them at significantly lower prices if they had known about the alleged defects. And, while they all alleged that operating the vehicles put them at risk of injury or property damage, none of the purchasers alleged that they stopped using the vehicles because of the alleged defects. Polaris moved to dismiss the no-fire purchasers' claims because they did not allege any manifest defect in their vehicles. Thus, they failed to allege an injury that would establish Article III standing to sue. The district court found that the no-fire purchasers alleged no facts "as to how the defect manifests in their respective" vehicles, and therefore failed to "allege a particularized and actual injury."

Article III standing requires a plaintiff to establish that they have "suffered an 'injury in fact' – an invasion of a legally protected interest" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). In evaluating standing, courts treat as true the factual allegations in the complaint and give no effect to conclusory allegations of law.

The no-fire purchasers argued that they suffered particularized and actual injuries because they overpaid for the vehicles with a manifest defect at the time of purchase. Polaris countered arguing that the no-fire purchasers only asserted a risk that their vehicles will develop a defect in the future. Citing *Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025 (8th Cir. 2014), the Circuit Court found that it is not enough for a plaintiff to allege that a product line contains a defect or that a product is at risk for manifesting this defect; rather, the plaintiffs must allege that their product actually exhibited the alleged defect. Otherwise, they lack standing to pursue a claim of product defect.

Potential Economic Injury Insufficient for Jurisdiction Under CAFA

***Penrod v. K&N Engineering, Inc.*, 14 F.4th 671 (2021).**

Plaintiffs, nationwide buyers of oil filters for motorcycles, brought an action against the manufacturer of the filters, seeking to represent a nationwide class and asserting claims for breach of warranty, fraud, negligence, and strict liability. Plaintiffs alleged damages in excess of $5 million to invoke federal jurisdiction under the Class Action Fairness Act. Defendant K&N Engineering moved to dismiss the case for lack of subject matter jurisdiction arguing that Plaintiffs failed to plausibly allege damages in excess of $5 million.

Under CAFA, federal courts have jurisdiction over class actions in which the amount in controversy is plausibly in excess of $5 million in the aggregate. 28 U.S.C. § 1332(d)(6); *see also Raskas v. Johnson & Johnson*, 719 F.3d 884, 888 (8th Cir. 2013). The proponent of federal jurisdiction must plausibly explain how the damages exceed $5 million.

The named plaintiffs, three motorcycle owners, purchased K&N designed oil filters that failed. Two plaintiffs experienced failures that caused oil to leak onto the rear tire of their motorcycles. The third experienced a failure that caused catastrophic damage to the engine of his motorcycle. To establish jurisdiction under CAFA, Plaintiffs estimated that 2.5 million oil filters were sold during the class period. Of those, .03% failed, which meant that there were only 750 alleged defective oil filters. With that limited number of defective

filters, the damages must have exceeded $6,666.66 per failed filter to satisfy the CAFA jurisdictional requirements.

Because only one of the three failures experienced by the named plaintiffs caused actual damages, the Circuit Court found Plaintiffs did not plausibly explain how the alleged damages exceeded $5 million. The Court also rejected the argument that the proper measure of damages is the monetary difference between what the proposed class members paid for the filters and what they actually paid, in light of the filter's design defects, because it was contrary to the long-standing rule that no tort claim for economic damages lies when the product is simply at risk for failing.

NINTH CIRCUIT:

Alexi Layton, Esq. and Paige Silva, Esq., Evans Fears & Schuttert LLP, 6720 Via Austi Parkway, Suite 300, Las Vegas, NV 89119

Negligent Product Design & CDA Immunity

***Lemmon v. Snap, Inc.*, 995 F.3d 1085 (9th Cir. 2021).**

In *Lemmon*, parents of teenagers who died in a fatal car accident brought claims for negligent product design against Snap, Inc., the creators of Snapchat, a social media app. The two teenage boys died in a car accident when their vehicle hit a tree after one of the teenagers posted from his cellphone to his Snapchat account using the app's "Speed Filter." Snapchat's Speed Filter allows users to superimpose and/or overlay a depiction of their driving speed on a photo or video image, which they can then share on the social media app. The district court dismissed the parents' action and held that Snap, Inc. was immune from liability under the 47 U.S.C. § 230, the Communications Decency Act ("CDA"), which provides companies immunity from being "treated as the publisher or speaker of any information" provided by third parties who use their platforms.

The parents appealed, arguing that they were not treating Snap, Inc. as the publisher or speaker of their children's information, but rather that the company knew or should have known that its Speed Filter incentivized Snapchat users, the vast majority of

whom are teenagers, to use the app on their cell phone while traveling at high speeds, and that many users believe the app offers "achievements" for hitting speeds over 100 miles per hour.

The Ninth Circuit reversed and remanded the district court, holding that Snap, Inc. was not immune from liability for a tort claim of negligent product design under the CDA. The Ninth Circuit reasoned that the CDA's immunity did not apply to this case because the Appellants were not suing Snap, Inc. as a speaker or publisher of third-party content on the app, but were instead suing Snap, Inc. for the design of the app itself. Correspondingly, the Court acknowledged that Snap, Inc.'s duty to produce a safe product was discrete and separate from its duty to monitor third-party publishing on the app.

Application of *Ford v. Mont. Eighth Jud. Dist. Ct.* in California

***Ayla, LLC v. Alya Skin Pty. Ltd.,* 11 F.4th 972, 982 (9th Cir. 2021).**

In Ayla, LLC the Ninth Circuit found general personal jurisdiction over an Australian beauty supply company, in part relying on *Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.,* 141 S. Ct. 1017 (2021), and reversing the United States District Court for the Northern District of California order granting Defendant's motion to dismiss for lack of personal jurisdiction; however. The Plaintiff sued Ayla, LLC, an Australian skin care company, in California for trademark infringement. The Ninth Circuit determined that Ayla met the first prong of the specific jurisdiction test and that it purposefully availed itself of the privilege of conducting business in the United States based on the following activities: the company hired US influencers, listed US dollars as currency on the website, had an Idaho distribution center that promised shipping throughout the U.S. in five days, advertised for Black Friday sales on its Facebook page, touted approval by the FDA for its products, had been featured in American magazine, and advertised on an Instagram page "ATTENTION USA BABES WE NOW ACCEPT AFTERPAY."

As to the second prong—the "nexus" analysis at the center of *Ford*—the Ninth Circuit determined the action both arose out of and related to Alya's contacts with the U.S., finding that Ayla "sought to capture the attention of an American audience and

thereby sell allegedly infringing products to that audience with advertisements addressed to “USA BABES[.]” Because the advertisements and sales to U.S. customers occurred with the allegedly infringing products, the second prong was established. Finally, the court found that Ayla could not prove that jurisdiction would be unreasonable and would not violate due process.

Statute of Limitations, Equitable Estoppel and Choice of Law

***Rustico v. Intuitive Surgical, Inc.*, 993 F.3d 1085 (9th Cir. 2021).**

In *Rustico*, a Connecticut resident underwent a robotically assisted hysterectomy in Connecticut and sued the robotic surgical system’s manufacturer on theories of negligence and strict products liability for injuries incurred during the surgery. The surgical robot was designed and manufactured in California. Pre-litigation, Plaintiff agreed to an agreement to “toll the applicable statute of limitations,”; however, when she entered into the agreement, California’s 2-year statute of limitations has expired but Connecticut’s 3-year statute of limitations had not. The Plaintiff filed suit in California anyway, and the district court granted Defendant’s motion for summary judgment on the basis that the California statute of limitations had expired. On appeal, the Ninth Circuit held that (1) the district court was required to consider whether Connecticut had an interest in seeing its own three-year statute of limitations applied before deciding that California’s applied; (2) California’s two-year statute of limitations applied based on the ‘governmental interest test’ and barred Plaintiff’s claims; (3) Plaintiff did not show that her case represented a rare situation where the forum would entertain a claim that was barred by its own statute of limitations but not by that of some other state; and (4) the doctrine of equitable estoppel did not apply to Plaintiff’s product liability claim to avoid California’s two-year statute of limitations period because Plaintiff knew the facts, was represented by counsel, and Defendant expressly stated it would not waive previously available defenses.

Practice pointer: the *Rustico c*ourt found that, even though the tolling agreement was offered before the statute of limitations expired, it was signed after the statute ran. Besides the obvious practice pointer of taking care to file cases prior to statutory

deadlines, parties should be aware that the 9th Circuit held that a tolling agreement becomes effective when signed and not before, even if the parties agreed to execute the agreement at an earlier date.

Uber Drivers as Independent Contractors

***Capriole v. Uber Technologies, Inc.*, 7 F.4th 854 (9th Cir. 2021).**

In *Capriole,* Uber drivers brought a class action, alleging Uber misclassified them as independent contractors rather than as employees under Massachusetts law. Before becoming Uber drivers, all potential drivers were required to sign Uber's 2015 Technology Services Agreement, which contains a mandatory arbitration provision. Uber brought a motion to compel arbitration, which the district court granted. Plaintiffs appealed, arguing they were exempt from mandatory arbitration under Section 1 of the FAA because they were a "class of workers engaged in foreign or interstate commerce." The Ninth Circuit disagreed, holding that Uber drivers as a class of workers do not fall within the "interstate commerce" exemption of the FAA. The court held that Uber drivers "are not engaged in interstate commerce" because their work "predominantly entails intrastate trips," even though some Uber drivers undoubtedly cross state lines in the course of their work and rideshare companies do contract with airports "to allow Uber drivers . . . to pick up arriving passengers." The court added that "interstate trips, even when combined with trips to the airport, represent a very small percentage of Uber rides, and only occasionally implicate interstate commerce."

Class Action Attorneys' Fees Award Versus Awards to Plaintiffs

***Kim v. Allison,* 8 F.4th 1170 (9th Cir. 2021).**

The Ninth Circuit now requires a more probing inquiry for approval of class action settlement where the attorneys' fees dwarf anticipated monetary payout to the class. Plaintiff brought a putative class action under California's Unfair Civil Rights Act and Unfair Competition Law (UCL) based on the allegation that Tinder offered reduced pricing to subscribers under 30 years old. Following compelled arbitration, the parties reached

a settlement that applied to the putative class. Several class members objected, arguing the settlement terms offered too little in cash payouts, credits that premium Tinder subscribers did not need, and subscriptions that former subscribers did not want. The district court rejected the objections and certified a settlement class, awarding Plaintiff a $5,000 incentive payment and $1.2 million in attorneys' fees to Plaintiff's counsel.

The Ninth Circuit reversed, holding that although the district court applied the correct fairness factors under Fed. R. Civ. P. 23(e)(2), it understated the strength of Plaintiff's claims and substantially overstated the settlement's worth given that (a) Tinder's agreement to eliminate age-based pricing going forward only applied to new California-based subscribers (which did not include the class members), (b) the claims rate at the time of final approval was 0.745% (which meant Tinder stood to pay less than $45,000 to the class members, not the $6 million claimed by Plaintiffs), and (c) most importantly, the district court failed to consider evidence of collusion in the form of a request for attorneys' fees that dwarfed the anticipated payout to the class.

Supplier Immunity Under the BAAA

***Connell v. Lima Corporate*, 988 F.3d 1089, 1089 (9th Cir. 2021).**

In *Connell*, a patient and his wife sued a medical device manufacturer and the manufacturer's supplier for injuries suffered when the femoral stem portion of the patient's hip implant fractured just three years after his surgery. The manufacturer settled the claims, resulting in a voluntary dismissal. The district court held that the remaining Defendant, the Italian supplier, who supplied the manufacturer with a portion of the hip implant, was entitled to summary judgment because it was immune to suit under the Biomaterials Access Assurance Act ("BAAA"). The Plaintiffs appealed.

The Ninth Circuit affirmed the summary judgment, holding that the supplier was a biomaterials supplier and was immune under the BAAA. Importantly, as a matter of first impression, the Court of Appeals found that, if an entity provides a part that must be combined with other items to create a final, independently functional implant, that entity is a biomaterials supplier under the BAAA. The Court found that Congress meant for

Plaintiffs to recover from either the statutory manufacturer or the direct seller of an implant instead.

Practice pointer: the Court explicitly stated that "future plaintiffs are now on notice that absent negligent or intentionally tortious conduct, recovery from an entity that provides part of an implant will not be available."

FAA & GARA Preemption

Specter v. Texas Turbine Conversions, Inc., 519 F. Supp. 3d 576 (D. Alaska Feb. 12, 2021).

Representatives of passengers who died in an airplane crash sued the airplane manufacturer under a theory of product liability based on the manufacturer's failure to warn passengers about a defective short takeoff and landing kit and engine conversion which the manufacturer installed on the subject airplane. The Defendants argued that the Plaintiffs' claims were preempted by federal law, specifically by regulations under the Federal Aviation Administration ("FAA") and the General Aviation Revitalization Act ("GARA").

The United States District Court for the District of Alaska held that (1) FAA regulations did not preempt the Plaintiffs' claims because adherence to the general federal certification process was not enough to find federal preemption barring warning defect claims as to particular parts of the airplane; and (2) that GARA did not bar the Plaintiffs' claims because GARA's eighteen-year statute of repose for civil actions against aircraft manufacturers restarts when the injury at issue is caused by a new, replacement, or additional component that was not part of the original aircraft.

PLCAA & Constitutional Considerations

Travieso v. Glock Incorporated, 526 F. Supp. 3d 533 (D. Ariz. Mar. 10, 2021).

In *Travieso*, the Plaintiff was shot in the back with a handgun while on his way back from a church camping trip in a vehicle with fellow church members. One occupant was a fourteen-year-old girl who found the gun in the car and believed that it was empty

because there was no magazine in it. The girl discharged the gun and a live round in the chamber and caused injuries to Plaintiff's spine and organs, rendering him a paraplegic.

Plaintiff did not bring charges against the girl but brought strict products liability and negligence actions against the handgun manufacturer, Glock Incorporated, arguing that the gun was defectively and negligently designed and should have been equipped with safety features and warnings on the product. The Defendant argued that Plaintiff's claims were barred by the Protection of Lawful Commerce in Arms Act ("PLCAA") because the shooting was caused by a criminal act of a third party. Plaintiff argued that the PLCAA was inapplicable to his case, but even if it applied, his claims were permitted under the PLCAA's "product defect exception." In the alternative, Plaintiff argued that if the PLCAA did bar his claims, then it was unconstitutional under the Fifth and Tenth Amendments.

The United States District Court for the District of Arizona held that (1) the PLCAA did apply to generally bar common law claims like Plaintiff's; (2) the products liability exception of the PLCAA did not apply to the victim's claims because the shooter's volitional acts--including the being a juvenile in possession of a gun and pulling the trigger while the gun was pointed at another person--were criminal offenses sufficient to bar the products liability exception from applying; (3) the PLCAA did not violate the Plaintiff's procedural due process rights under Ninth Circuit precedent; and (4) the PLCAA did not violate the Tenth Amendment because Congress enacted the PLCAA as a constitutional exercise of its power to regulate interstate commerce.

Arbitration Clause Unenforceable in California Lemon Law Cases

***Kalasho v. BMW of North America, LLC*, 520 F. Supp. 3d 1288 (S.D. Cal. Feb. 22, 2021).**

In *Kalasho*, Plaintiffs leased a 2019 BMW M5. Plaintiffs alleged that during the lease period, the vehicle showed various defects which BMW of North America failed to service. Plaintiffs brought suit against BMW of North America in state court, alleging that it violated California's Song-Beverly Consumer Warranty Act ("Song-Beverly Act") and California's Unfair Competition Law ("UCL"). Defendants removed the case to federal

court and filed a motion to compel arbitration under the arbitration provision contained in the subject lease agreement.

The United States District Court for the Southern District of California found that, because the California Arbitration Act ("CAA") was enacted to benefit the public, it could not be waived by private agreement. Accordingly, the Court held that the arbitration clause contained in the lease agreement was void because it improperly waived Plaintiffs' right to a neutral arbitrator under the CAA.

TENTH CIRCUIT:

Kate Mercer-Lawson, Partner, Wheeler Trigg O'Donnell LLP, 370 17th Street, Suite 4500, Denver, Colorado 80202

Daubert Standard

***Harris v. Remington Arms Co.*, 997 F.3d 1107 (10th Cir. 2021).**

Harris affirmed a defense-friendly district court opinion articulating the Tenth Circuit's understanding of a trial court's *Daubert* gatekeeping responsibility. This appeal revisited the propriety of excluding a rifle expert for offering an opinion that did not fit undisputed material case facts. In blessing the district court's analysis, the Tenth Circuit reiterated that it views *Daubert* as imposing a two-part gatekeeping test. As understood by the Tenth Circuit, the first prong of *Daubert* assays whether the expert is adequately qualified to offer the proposed opinions. The second step is in itself a two-part inquiry: whether the expert's opinion is sufficiently reliable and relevant to assist the factfinder. Here, the Tenth Circuit focused on the relevance sub-prong of reliability and underscored that the issue turns on "fit." The decision will be helpful for practitioners who, like the plaintiff here, attempted to elude the "fit" requirement by arguing that the excluded opinion was methodologically sound.

Judge Bacharach left no room for doubt that (i) a reliable method can still be utterly irrelevant; (ii) the proponent of an expert must establish fit to withstand a *Daubert* challenge; and (iii) fit can be a highly technical inquiry. The case is also a useful citation

for anyone arguing that it is improper to admit late-breaking (i.e., post-disclosure/discovery) opinions offered to show fit.

***Peterson v. Raymond Corp.*, 994 F.3d 1224 (10th Cir. 2021)**

Peterson should benefit defendants challenging expert methodology in design defect actions. This lawsuit involved a forklift incident and the plaintiff's contention that the forklift was defective for lack of a door. To support his burden of proof, the plaintiff tendered an expert who stated vaguely that any door in the forklift's open compartment would have prevented his injury. However, the expert refused to commit to a particular type of door that would have cured the claimed defect. The district court held numerous evidentiary hearings and ultimately found that the expert's opinion was unreliable because it purported to attack a design defect without offering a specific safer alternative design for the forklift. The Tenth Circuit affirmed.

Although the opinion speaks to Utah law, the following points should prove useful in expert challenges across the country: (i) design concepts or possibilities are not enough to show reliability of a design defect expert's opinion; (ii) at least one testable, definitive product design should be offered to support design defect claims; and (iii) without at least one definite alternative design, there is no way for the factfinder to meaningfully compare the expert's opinion to the facts and design of the product at issue (a finding that arguably goes to fit as well). Multiple alternative designs are not required, but one that rises above the equivalent of "there should have been a door" is necessary.

***Wurm v. Ford Motor Co.*, 849 F. App'x 766 (10th Cir. 2021)**

Last year's Tenth Circuit DRI update reported on this truck-rollover case at the district court level, noting that the ruling was pending appellate review. This year, the Tenth Circuit affirmed the district court's exclusion of two plaintiff experts on the qualification prong of *Daubert*. The first expert, despite having a graduate degree in anatomy and physiology, was deemed unqualified to provide opinion testimony regarding occupant kinetics and biomechanics. The second, despite being a biomechanical engineer with thirty-three years experience, was deemed unqualified to opine regarding truck design and rollovers—i.e., general car-design experience did not pass muster. This

case not only reminds practitioners not to push experts outside their narrow lane, but also provides support for challenging opposing experts who do so.

Discovery Rule

Nowell v. Medtronic, Inc., No. 19-2073, 2021 WL 4979300 (10th Cir. Oct. 27, 2021).

In October 2010, Janice Nowell had a hernia surgically repaired with a Medtronic-manufactured mesh implant. A second surgery to reinforce the mesh was necessary just six months later. Over the next three years, Ms. Nowell experienced pain and discomfort in the area of the implant. Finally, on March 1, 2014, she became so concerned about the safety of the implant that she sought a CT scan—one that revealed cysts.

Ms. Nowell sued Medtronic in the U.S. District Court for the District of New Mexico on October 5, 2017—more than three and a half years after the abnormal CT result. Medtronic subsequently moved for dismissal and succeeded. In granting the motion, the district court concluded that Ms. Nowell's claims were time-barred under New Mexico's three-year statute of limitations for personal injury claims.

The Tenth Circuit exercised jurisdiction to predict whether the New Mexico Supreme Court would apply the state's "discovery rule" to personal injury cases involving products. Pursuant to this rule, a claim accrues when the plaintiff either knows, or with reasonable diligence should know, of her injury and its cause. In the Tenth Circuit's view, the New Mexico Supreme Court would follow the majority of jurisdictions that have utilized similar discovery rules in other tort contexts. The court cited policy considerations such as fairness and late manifestation of injuries in reaching this result. In the end, the court found that even under this more liberal discovery rule, Ms. Nowell's claims from extinction were still time-barred.

Duty to Warn

Boynton v. Kennecott Utah Copper, LLC, 2021 UT 40, 2021 WL 3418401 (Utah Aug. 5, 2021).

Larry Boynton was a career electrician who alleged work on and around asbestos-containing products at various locations throughout Utah in the 1960s and 1970s. He filed suit against multiple product manufacturers and premises operators after his wife, Barbara Boynton, developed malignant mesothelioma (allegedly from "take-home" exposures sustained while laundering his clothing). Two of the premises defendants were successful at the summary judgment stage: the district court concluded that they had no duty to prevent "take-home" exposure to asbestos emanating from products or equipment located at their respective facilities. Finally the Utah Supreme Court addressed an issue long-debated in the state, and reversed these rulings instructing that the prior *Jeffs-Herland* standard no longer applies. In the wake of *Boynton*, there is now a categorical duty imposed on Utah premises operators where asbestos-containing products have the potential to harm plaintiff-workers and those who may be exposed in a "take-home" manner (namely, the worker's co-habitants).

While imposing this new duty, the court issued multiple findings that practitioners will need to consider in asbestos litigation. Notably, the court defined an affirmative act of misfeasance that imposes a duty broadly: as anything that launches the instrument of harm by directing, requiring, or causing an individual to contact asbestos. Examples of such an act include instructing a worker to handle asbestos, instructing a nearby worker other than the plaintiff to handle asbestos, placing asbestos at the jobsite, or sending a worker to a different jobsite where asbestos is present. The court rejected defense arguments in favor of imposing a "special relationship" rule between the premises operator and the person exposed in a "take-home" fashion. It likewise rejected the concept that anyone other than the premises operator is best situated to prevent exposure and loss. Further, the court left the concept of foreseeability wide open: "foreseeability will counsel in favor of finding a duty of care if any circumstances within that category would have included a foreseeable harm."

The Utah Supreme Court confidently asserted that this decision would not have far-reaching public policy considerations. It will be interesting to follow the court's prediction over the next few years as litigation will surely increase in Utah.

Federal Preemption in Medical Device Cases

***Brooks v. Mentor Worldwide*, 985 F.3d 1272 (10th Cir. 2021).**

Dissatisfied with their allegedly leaking breast implants, Plaintiffs in this case brought claims asserting (i) ordinary negligence in terms of failure to warn and manufacturing defect; (ii) negligence per se; and (iii) strict liability. Their case was dismissed for failure to state a claim, and they appealed. The Tenth Circuit declined to revive the lawsuit, affirming the district court's dismissal. The key aspect of the appellate ruling is the finding that Plaintiffs' negligence per se and failure to warn claims (whether sounding in ordinary negligence or strict liability) were preempted by the Federal Food, Drug, and Cosmetic Act (FDCA). Writing for the court, Judge Carson disagreed with Plaintiffs' averment that a narrow preemption exception could apply. The opinion clarifies that it is permissible to sue under state law for conduct that violates the 1976 Medical Device Amendments to the FDCA (as Plaintiffs should have done), but it is impermissible to do so if the sole reason is that the conduct violates state law (as Plaintiffs did). Going forward, similarly situated plaintiffs must plausibly allege that the complained-of conduct violated state law without regard to the FDCA—because only the United States may enforce that statute.

Negligent Infliction of Emotional Distress

***Robinson v. Grove US, LLC*, No. 19-CV-0025-F, 2021 WL 5235548 (D. Wyo. Nov. 10, 2021).**

Cora Robinson filed a wrongful death action after her husband died in 2015 in a crane tire explosion. Mr. Robinson, who owned a repair company, was not trained in the servicing of multiple-piece-rim assemblies like the one on the subject crane, and he had never reviewed any manuals for the crane. The accident ultimately occurred because Mr. Robinson attempted to switch the tire assembly before first deflating the tires. Because Ms. Robinson was present at the time of the explosion, she sued several entities for negligent infliction of emotional distress (NIED). Defendant, Grove, designed the subject crane and then sold it in 1999 and never exercised possession or control over it thereafter.

Grove moved for summary judgment on seven theories as to why it should not be found liable on Ms. Robinson's NIED claim. The applicable Wyoming standard for NIED required that: (1) the primary victim (Mr. Robinson) die or suffer serious bodily injury; (2) the plaintiff (Ms. Robinson) observe either the infliction of the harmful blow or observe the aftermath, assuming no material change in the condition and location of the victim; and (3) afterward, the satisfaction of a normal negligence rubric.

No one disputed that the failed tire-rim assembly was a replacement part that Grove did not manufacture or supply. Thus, Grove argued that it owed a duty only for products it made or provided in the crane at the time of sale. In other words, Grove advanced the "bare-metal defense" disputed in the 2019 *DeVries* decision of the U.S. Supreme Court. Ms. Robinson pursued the simple foreseeability standard. Noting that Wyoming has not yet articulated whether Plaintiff's, Defendant's, or the "middle" standard from *DeVries* applied, Judge Freudenthal predicted how the Wyoming Supreme Court would rule. She concluded that for negligence-based claims like this NIED claim, the Wyoming Supreme Court would adopt a middle approach resembling that of *DeVries*. The standard Judge Freudenthal found persuasive comes from the following asbestos case out of the U.S. District Court for the District of Wyoming:

> [A] product manufacturer [is] liable in negligence for failing to warn about asbestos hazards of aftermarket parts used with its product which it neither manufactured nor supplied if the manufacturer: (1) knew that its product would be used with an asbestos-containing component part, (2) knew asbestos was hazardous, and (3) failed to provide an adequate and reasonable warning. . . . The Court finds that if the three elements outlined above are satisfied, the manufacturer did not merely create the condition or occasion for exposure to asbestos, but designed a product that *required or specified* the use of a known-to-be hazardous aftermarket replacement part.

Robinson v. Flowserve, No. 14-CV-161-ABJ, 2015 WL 11622965, at *12 (D. Wyo. Oct. 9, 2015).

The court then predicted that the Wyoming Supreme Court would impose a duty to a manufacturer that "designed a product that required or specified the use of a known-

to-be hazardous aftermarket replacement part or additional part." Because Grove's design of the crane at minimum specified wheels with multi-piece rim assemblies (part of what made the product potentially hazardous), the court found that Grove owed a duty with respect to the failed aspects of the crane despite the fact that the explosion involved replacement parts not ascribable to Grove.

Another aspect of the ruling was the court's assessment of Grove's warning defense. Grove argued both that it had no duty to warn a person in Mr. Robinson's shoes and that it had fulfilled its duty to warn about known dangers concerning the tire assembly. But the court disagreed, noting that a reasonable jury could find Mr. Robinson's conduct a foreseeable improper use triggering a duty to warn. The court found persuasive Grove's failure to provide evidence that tire service persons always read manufacturers' manuals. Summary judgment was denied on this basis as well. The court also rejected Grove's argument that Mr. Robinson was a "learned intermediary," making the point that the learned-intermediary doctrine does not weaken the standard for adequacy of warnings.

Personal Jurisdiction

***Growcentia, Inc. v. Jemie B.V.*, No. 20-cv-2619-WJM-NYW, 2021 WL 3510764 (D. Colo. Aug. 10, 2021).**

Plaintiff, Growcentia, a Delaware corporation with its principal place of business in Fort Collins, Colorado, is the manufacturer of a fungicide/pesticide (CANNCONTROL) used by cultivators of cannabis and hemp. Defendant, Jemie, is a Dutch limited liability company with its principal place of business in the Netherlands. Because Jemie claims to own multiple "CANNA-" trademarks for goods and services in the cannabis industry, Jemie sent a cease-and-desist letter demanding that Growcentia abandon its CANNCONTROL mark. Growcentia instead sought a declaratory judgment that it had not infringed upon Jemie's trademark. Jemie responded to the complaint by moving for dismissal pursuant to Fed. R. Civ. P. 12(b)(2) for lack of personal jurisdiction.

There being no legally cognizable debate regarding general jurisdiction, the court focused on specific jurisdiction and whether or not (i) Jemie's conduct constituted adequate minimum contacts to support it reasonably anticipating being sued in Colorado

court; and (ii) if so, whether the court's exercise of personal jurisdiction over Jemie would contravene traditional notions of fair play and substantial justice. Of note to practitioners is the court's determination that sending a single cease-and-desist letter did not confer personal jurisdiction in a declaratory judgment action. The court also refused to deem actions of Jemie's trademark licensee sufficient to confer personal jurisdiction: the licensee did not market with a Colorado focus and the licensee did not retain a degree of control sufficient to impute its Colorado contacts to Jemie. Finally, other enforcement actions brought by Jemie outside of Colorado did not qualify for the exercise of personal jurisdiction in this case. The court determined that it lacked personal jurisdiction over Jemie and granted the motion to dismiss.

Public Nuisance

Oklahoma ex rel. Hunter v. Johnson & Johnson, 499 P.3d 719, 2021 OK 54 (Okla. Nov. 9, 2021).

On November 9, 2021, Johnson & Johnson (J&J) obtained reversal of a bench-trial verdict of $465 million in a public nuisance lawsuit. The district court had held J&J liable under Oklahoma's public nuisance statute for its marketing and selling of Duragesic (fentanyl patch), Nucynta/Nucynta ER (tapentadol tablets), and Ultram/Ultram ER (tramadol tablets). At trial, Plaintiff contended that when promoting these products, J&J overstated the benefits of opioid use, minimized the hazards, and did not disclose an alleged lack of evidence supporting sustained use of the products at issue—all in the interest of putting profits over people. But the Oklahoma Supreme Court assigned error, concluding that the district court had extended the statute too far and invaded the legislature's domain.

At the outset, the court held that public nuisance and product liability have boundaries that do not overlap. The court found persuasive an Eighth Circuit decision refusing to extend a North Dakota public nuisance law to harm caused by asbestos-containing products. Adopting many principles of that case's analysis, the Oklahoma Supreme Court identified three reasons why the district court should not have extended public nuisance law to cover advertising by an opioid manufacturer. First, the manufacture

and distribution of products will rarely cause the violation of a public right (one key element of a public nuisance claim). Even the public right to be free from the threat of others' opioid abuse did not qualify. The court stated that an alternative holding would inappropriately impose liability for all types of use and misuse of prescription medications. Second, the court reversed on the ground that at the relevant time, J&J did not control the instrumentality alleged to produce a nuisance. The court held that there is no common law duty to monitor how a consumer uses or misuses prescription drugs. Third, the court was concerned by the possibility that under the district court's ruling, J&J could be held liable for its products in perpetuity. Oklahoma has rejected endless liability in other traditional tort cases, and it did so again here. In conclusion, the court stated:

> This case challenges us to rethink traditional notions of liability and causation. Tort law is ever-changing; it reflects the complexity and vitality of daily life. The State presented us with a novel theory-public nuisance liability for the marketing and selling of a legal product, based upon the acts not of one manufacturer, but an industry. However, we are unconvinced that such actions amount to a public nuisance under Oklahoma law.
>
> The Court has allowed public nuisance claims to address discrete, localized problems, not policy problems. Erasing the traditional limits on nuisance liability leaves Oklahoma's nuisance statute impermissibly vague. The district court's expansion of public nuisance law allows courts to manage public policy matters that should be dealt with by the legislative and executive branches; the branches that are more capable than courts to balance the competing interests at play in societal problems.

Oklahoma ex rel. Hunter v. Johnson & Johnson, 499 P.3d 719, 731 (Okla. Nov. 9, 2021).

Settlement Agreements in Class Action Suits

***In re Samsung Top-Load Washing Machine Mktg., Sales Prac. & Prod. Liab. Litig.*, 997 F.3d 1077 (10th Cir. 2021).**

This class action washing machine case presented the Tenth Circuit with an issue of first impression involving the proper level of scrutiny a district court must apply when reviewing a class action settlement that includes both a "kicker" and a "clear-sailing" provision?

Defendant, Samsung, agreed to a class action settlement involving its top-loading washers wherein it agreed to pay fees and costs up to a maximum of $6.55 million. By the terms of the agreement, any difference between this figure the court's award would revert, or "kick" back, to Samsung instead of the plaintiff class. Additionally, the agreement obligated Samsung not to dispute the class counsel's request for fees and costs up to the agreed-upon $6.55 million—i.e., to allow class counsel "clear sailing." Over an objector, the district court approved the settlement and awarded class counsel approximately $3.8 million. Thereafter, the objector appealed, claiming error in the adequacy of the settlement agreement because of the presence of the "kicker" and "clear-sailing" provisions.

Rather than simply addressing case-specific facts, the Tenth Circuit decided to set forth a rubric for district courts to employ in the future. The court proposed four potential levels of scrutiny for similarly situated district courts: (1) a per se rule against agreements with both provisions; (2) a presumption against the fairness and reasonableness of agreements with both provisions; (3) the standard imposed by Fed. R. Civ. P. 23(e)(2) of a "fair, reasonable, and adequate" settlement informed by four factors in the text of the rule; or (4) a heightened level of scrutiny altogether—the option selected and the rule of this case. This solution, in the court's view, would best prevent collusion between defense and class counsel while not jettisoning "kicker" and "clear-sailing" provisions—which do facilitate settlement.

Of course, the heightened scrutiny is multi-factorial and far from clear cut. First, the standard imposes two mandatory requirements on district courts assessing settlements with both challenged provisions: the court must (i) "take special care to assure that" class plaintiffs are adequately compensated "based on record evidence of their actual damages and the likelihood of success at trial"; and (ii) carefully scrutinize the

litigation/settlement as a whole for evidence of collusion between class and defense counsel. Next, the district court should "consider the fees and costs award" in the settlement "in comparison to the value of the settlement to the class." Finally, the district court may assess various aspects of the negotiations process (e.g., timing and whether the parties engaged a mediator).

Two other aspects of the *Samsung* holding are noteworthy. The court also held that before awarding fees and costs in class action settlements, district courts are required to issue specific findings as to both the value of the settlement to the class and the financial impact the settlement will have on the defendant. The court also held that for agreements containing "clear-sailing" provisions, discrepancies as to attorneys' hourly rates and hours billed must be construed against defense counsel.

ELEVENTH CIRCUIT:

Angel A. Darmer, Esq., Carr Allison, 100 Vestavia Parkway, Birmingham, AL 35216

Eleventh Circuit Court of Appeals Cases

Learned Intermediary Doctrine

***Salinero v. Johnson & Johnson*, 995 F.3d 959 (11th Cir. 2021).**

Plaintiff Charlotte Salinero had surgery to correct her pelvic organ prolapse. As part of the correction, Dr. Jaime Sepulveda implanted Artisyn Y-Mesh, a polypropylene mesh designed and manufactured by Ethicon, Inc. A few years after the surgery, Plaintiff experienced new health problems that she attributed to the mesh implant. Plaintiff had the implant removed, and she and her husband sued Ethicon and its parent company, Johnson and Johnson. Plaintiffs argued the mesh implant's Instructions for Use ("IFU") failed to properly and adequately warn of the risks related to the implant. Defendants moved for summary judgment and argued that (1) under the learned intermediary doctrine, medical device manufacturers have a duty to adequately warn physicians (not patients) of the risk of their products, and (2) Defendants fulfilled that duty.

The district court granted Defendants' motion for summary judgment on the basis of the learned intermediary doctrine. The court rejected Plaintiffs' argument that there should be a "financial basis" exception to the learned intermediary doctrine that would make the defense unavailable where the physician has a financial relationship with the manufacturer. Plaintiffs argued that such an exception should exist because it is unreasonable to expect manufacturers to adequately communicate the risks of their products to physicians who are financially invested in those products. Dr. Sepulveda had a long relationship with both Ethicon and Johnson and Johnson in which he served as an expert witness and product consultant. Dr. Sepulveda admitted that he had earned approximately $2 million in these roles throughout his career.

The Eleventh Circuit affirmed the district court's grant of summary judgment. Dr. Sepulveda testified that he believed he was fully informed of the risks of the implant prior to Plaintiff's surgery, he believed the use of the implant was the correct decision even after learning of Plaintiff's post-surgery issues and complications, and he would continue to use the implant in future surgeries. Thus, the court reasoned Defendants fulfilled their duty to warn Dr. Sepulveda, as the informed intermediary, of the risks of the implant, and held the learned intermediary doctrine was a complete defense to Plaintiffs' failure to warn claim. The Eleventh Circuit agreed with the district court that it could not create a "financial basis" exception to the learned intermediary doctrine because no courts in Florida (or elsewhere in the Eleventh Circuit) had recognized such an exception. Moreover, to succeed on a failure to warn claim under Florida law, a plaintiff must prove that an inadequate warning proximately caused his or her injuries. And an inadequate warning could not have proximately caused Plaintiff's injuries because Dr. Sepulveda would have used the implant in her surgery even if the IFU Plaintiffs sought had been provided. *See also Swintelski v. Am. Med. Sys.*, 521 F. Supp. 3d 1215, 1221 (S.D. Fla. 2021) (finding an experienced physician does not necessarily lose his or her learned intermediary status because a manufacturer provided allegedly insufficient product warnings).

Practitioners should be mindful of the learned intermediary defense and consider whether it could logically extend to product liability lawsuits outside of the manufacturer-physician context.

Expert Qualifications

Moore v. Intuitive Surgical, Inc., 995 F.3d 839 (11th Cir. 2021).

Plaintiff Tamanchia Moore had a robotically assisted laparoscopic hysterectomy. As part of the surgery, her surgeon used a pair of miniature electrified scissors manufactured by Defendant. After the surgery, Plaintiff began experiencing abdominal pain and other related symptoms. She eventually learned her left ureter was burned during the hysterectomy. She also learned that the electrified scissors her surgeon used were recalled after her procedure because Defendant discovered they could develop cracks that cause thermal damage to the patient's surrounding tissues. Plaintiff brought a product liability lawsuit claiming, among other things, that the scissors were defective and Defendant failed to adequately warn of their dangers.

Plaintiff retained Dr. Michael Hall as her medical causation expert. Dr. Hall testified that Plaintiff's burned ureter was likely caused by a micro-crack in the scissors. Defendant moved to exclude all of Dr. Hall's testimony. Defendant primarily argued that Dr. Hall was not qualified to testify because he does not use the scissors at issue in his practice, and he did not perform robotically assisted hysterectomies. The district court agreed and, because Dr. Hall was Plaintiff's only medical causation expert, entered summary judgment for Defendant.

On appeal, the Eleventh Circuit held that the district court abused its discretion by applying an incorrect legal standard. The district court applied the "exacting analysis" standard to the question of Dr. Hall's qualification as an expert on this issue. However, the Eleventh Circuit held that this "exacting analysis" inquiry applies only to an expert's methodology, and not to his qualification. The Court emphasized that *Daubert*'s qualification prong and reliability prong answer two separate questions—whether a witness is qualified as an expert, versus whether his opinion is reliable based on valid scientific methodology—and conflating the two is legal error. The correct inquiry was whether Dr. Hall was familiar with the possible causes of Plaintiff's injury during the operation based on his knowledge, training, skill, experience, or education.

The Court applied the correct qualification standard and found that Dr. Hall was, in fact, qualified to testify. Dr. Hall was a board-certified gynecologist who had performed at

least four thousand hysterectomies, he had served on committees tasked with determining the cause of injuries sustained during gynecological procedures, he had reviewed medical literature on the scissors, and he had even received some training on the scissors and Defendant's robotic system when they were marketed to his hospital. Both Dr. Hall and Defendant's causation expert also testified that laparoscopic hysterectomies are substantially the same regardless of whether a robot is used. The Court reasoned that whether Dr. Hall had used the scissors at issue, and whether he had used a robot in performing laparoscopic hysterectomies, was only relevant to the reliability of his opinion. The Court specifically rejected a bright line rule that an expert is qualified to testify regarding an injury only if he has personally used the allegedly defective product.

Practitioners asserting challenges under *Daubert* should be careful to not conflate the qualification, reliability, and/or helpfulness inquiries. In framing *Daubert* challenges, they should consider that some of these inquiries (i.e., reliability) are more stringent than the others.

Expert Reports

***Pierre v. Intuitive Surgical, Inc.*, 854 F. App'x 316 (11th Cir. 2021).**

Plaintiff Elmitha Pierre had a robotically assisted hysterectomy. Like in *Moore*, her surgeon, Dr. Yat-Min Chen, used a pair of electrified scissors and forceps manufactured by Defendant. Dr. Chen noticed that Plaintiff's bowel was burned during the surgery, and shortly thereafter she began experiencing related symptoms. Plaintiff learned that an older version of the scissors Dr. Chen used had been recalled when Defendant discovered they could develop cracks that cause thermal damage to the patient's surrounding tissues. Although Dr. Chen used a newer, non-recalled version of the scissors in Plaintiff's surgery, she brought suit and argued the new version had the same type of insulation defect as the older version.

Plaintiff retained Dr. Chen as her medical causation expert. Dr. Chen testified that Plaintiff's injury was likely caused by arcing, which may be—but is not necessarily—caused by an insulation failure. Dr. Chen also determined that it was more likely that Plaintiff's bowel had been burned by energy from the electrified forceps rather than the

scissors. The district court excluded Dr. Chen's testimony and granted Defendant's motion for summary judgment on the ground that Plaintiff had not presented sufficient medical causation evidence.

The Eleventh Circuit affirmed and held that summary judgment would have been appropriate even if the district court had admitted Dr. Chen's testimony. The Court noted that an expert's testimony is required to establish causation when complex medical or scientific issues are present. It reasoned that, although Dr. Chen's testimony was not inconsistent with Plaintiff's claim that an insulation defect in the scissors caused her injury, it did not directly support that conclusion either. The Court held that the mere possibility that Plaintiff's medical causation theory was correct was insufficient. A jury verdict for Plaintiff, based on Dr. Chen's medical causation testimony, would have required the jury to engage in speculation and conjecture.

Practitioners should work with their experts to ensure that the expert does more than exclude alternative causes in their reports. It is important that the expert's report also discuss and emphasize any findings that directly support the party's theory of causation.

District Court Cases

Statute of Limitations and Judicial Estoppel

***Boneta v. Am. Med. Sys.*, 524 F. Supp. 3d 1304 (S.D. Fla. 2021).**

In April 2006, Defendant's transvaginal mesh was implanted in Plaintiff Deborah Boneta to treat her grade two cystocele. Plaintiff began experiencing problems related to the mesh in the following months and years, and she had her first mesh excision surgery in March 2008. By August 2015, her doctors determined the mesh was eroding and not functioning properly, and she had the entire mesh surgically removed. Plaintiff and her husband brought suit on December 31, 2015. Defendant moved for summary judgment on the grounds that (1) Plaintiffs' claims were barred by the statute of limitations, and (2) Plaintiffs were judicially estopped from recovering because they did not disclose the lawsuit in their joint bankruptcy proceeding.

First, with respect to the statute of limitations, Defendant argued Plaintiffs' claims accrued when Plaintiff had her first mesh revision surgery in March 2008, and were thus

barred by the four (4) year statute of limitations. Plaintiffs argued their claims did not accrue until Plaintiff's doctor informed her the entire mesh should be removed in August 2015. Under Florida's discovery rule, the statute of limitation for a product liability claim begins to run when the facts giving rise to the claim were discovered or should have been discovered in the exercise of due diligence. FLA. STAT. **§** 95.031(2)(b).

The district court held that, in medical device cases, this means that the patient plaintiff was experiencing symptoms that would not naturally occur from the implantation procedure or the medical device itself—and instead must be attributed to medical negligence or a product defect. Plaintiff only knew that she had negative symptoms related to the mesh in 2008, and she attributed those symptoms to naturally occurring scar tissue from the implantation surgery. Plaintiff did not know that her symptoms could be due to a *defect* in the mesh until August 2015. Thus, the court found her claims did not accrue until that later date, and they were not untimely.

Second, with respect to the issue of judicial estoppel, Defendant argued Plaintiffs should be prevented from recovering for failing to disclose these claims in their bankruptcy filings. On December 31, 2015, Plaintiffs' bankruptcy trustee filed their Notice of Plan Completion verifying that they had completed all payments under the Plan. That same day, Plaintiffs filed the transvaginal mesh lawsuit against Defendant. Plaintiffs did not disclose the existence of their product liability lawsuit at any point while the bankruptcy case was pending.

The Court found that Plaintiffs took an inconsistent position by pursuing their mesh implant lawsuit while the bankruptcy proceeding was pending, and such an inconsistent position can be grounds for judicial estoppel under the federal law standard promulgated by the Eleventh Circuit. But because the case was before the court based on diversity jurisdiction, Florida's judicial estoppel standard applied. Under Florida's standard, judicial estoppel is only appropriate if the inconsistent position prejudices the defendant in the civil lawsuit. The Court found Defendant was not prejudiced because it was not involved in Plaintiffs' bankruptcy proceeding or one of Plaintiffs' creditors, and it thus held Plaintiffs' claims were not barred by judicial estoppel.

When a plaintiff alleges injuries or symptoms over a period of time, practitioners should carefully consider when the plaintiff's claim actually accrued and identify any

discovery rules that may apply. Practitioners should also determine whether a plaintiff has been involved in any bankruptcy matters that could affect the lawsuit as part of their initial and ongoing investigations.

Deposing Experts

***Altidor v. Carnival Corp.*, No. 20-CV-21516-COOKE/GOODMAN, 2021 U.S. Dist. LEXIS 139433 (S.D. Fla. July 27, 2021).**

Plaintiff Marie Altidor was injured on Defendant's cruise ship when she attempted to sit on a barstool and fell. Plaintiff retained Paul Tucker as an expert engineering witness regarding the barstool and Dr. Roberto Moya as a medical causation expert. Tucker was a licensed professional engineer (including in Florida) with a Master of Science in Structural Engineering. He determined that Defendant failed to repair and maintain the barstool based on the type and length of screw in the stool and damage to the screw and the barstool. He also determined that Defendant knew about issues with the stool based on lubricant he observed on the stool. Dr. Moya received his medical degree in Spain, completed five (5) years of graduate education in the United States, worked for ten (10) years as an orthopedic surgeon, and worked for ten (10) years as a solo practitioner. He determined that Plaintiff "may incur" certain medical costs in the future for physical therapy, pain medication, and possibly surgery.

Defendant filed *Daubert* motions to exclude all of Tucker's testimony and the portions of Dr. Moya's testimony relating to Plaintiff's future medical expenses. Defendant did not depose either expert prior to filing the *Daubert* motions. In denying both motions, the district court noted that it cannot exclude an expert on the grounds that the expert lacks personal credibility, and a less-than-perfect expert opinion with "gaps" may still be admissible.

Regarding Mr. Tucker, the court rejected Defendant's argument that he was not qualified to opine on the stool because all his experienced pertained to "land-based engineering." The Court reasoned that a barstool's engineering does not become unique simply because it is placed on a ship. The Court was also not persuaded by Defendant's argument that Tucker could not know for sure whether there was lubricant on the barstool

because he did not touch, feel, or smell it. If that were the rule, experts could never offer opinions about things they observed or viewed through a video.

Regarding Dr. Moya, the court rejected Defendant's argument that testimony regarding possible future expenses was too speculative. Defendant did not provide any cases holding that medical expense testimony is only admissible if those expenses are guaranteed to occur. The Court also rejected any suggestion that Dr. Moya was not qualified to testify about medical expenses. Although Dr. Moya was not a billing or medical coding professional, the court reasoned that he could not work as a solo practitioner without general knowledge of patients' medical costs. The fact that other professional specialties may be more qualified to render an opinion on a topic does not necessarily make less qualified professionals *not* qualified to offer such an opinion.

Finally, although the court held that Defendant was not *required* to depose Tucker or Dr. Moya prior to filing a *Daubert* motion, it heavily emphasized throughout its opinion that many of the issues and questions Defendant raised in its *Daubert* motions could, and probably should, have been addressed in the experts' deposition(s).

Practitioners should remember that a court is less likely to strike an expert or limit the expert's testimony without first giving the expert an opportunity to explain and elaborate on his or her qualifications and opinions (such as in a deposition).

Standing and Notice

Carder v. Graco Children's Prods., No. 220-CV-00137-LMM, 2021 U.S. Dist. LEXIS 165492 (N.D. Ga. Aug. 31, 2021).

Plaintiffs from fifteen states claimed Defendant falsely and misleadingly represented that certain car seats it manufactured and sold (1) significantly reduced the risks associated with side-impact collisions and (2) were safe for children of a certain age and weight. Plaintiffs argued they either would not have purchased the car seats, or would have paid less for the car seats, absent these representations. Defendant moved to dismiss Plaintiffs' claims on the ground that Plaintiffs lacked standing and otherwise failed to adequately state a claim for relief.

Regarding standing, Defendant argued Plaintiffs had not suffered a legally cognizable "injury in fact" because their children had not suffered any physical injuries related to the car seats. The district court disagreed and held Plaintiffs had sufficiently alleged an economic injury by arguing they did not get what they thought they paid for when they purchased the car seats. The Court rejected Defendant's argument that under *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1086 (11th Cir. 2019), a plaintiff must prove that the product he or she purchased is entirely worthless to establish standing. The Court interpreted *Debernardis* as recognizing that lesser allegations—such as that a product failed to perform as advertised, or that a plaintiff paid a premium for a product due to a misrepresentation—are sufficient for standing purposes.

The Court distinguished the Eleventh Circuit's decision in *Doss v. Gen. Mills, Inc.*, 816 F. App'x 312, 314 (11th Cir. 2020). In *Doss*, the plaintiff alleged a cereal manufacturer's cereal contained a harmful herbicide, and the Eleventh Circuit held her alleged injuries were merely hypothetical. The district court reasoned that *Carder* was different because Plaintiffs actually purchased the allegedly inferior car seats, while the *Doss* plaintiff never alleged that she purchased cereal boxes actually containing herbicide. However, the court did agree with Defendant that Plaintiffs lacked standing to seek injunctive relief. The Court reasoned that Plaintiffs had not plead a risk of actual and imminent future harm because they did not claim they would purchase the car seats again in the future.

Defendant also argued Plaintiffs' breach of warranty claims failed under the laws of various states (including Alabama and Florida) because certain Plaintiffs did not provide the notice required in those states. Plaintiffs alleged that they sent Defendant a letter dated November 5, 2020 regarding Defendant's breach. This letter was issued five months after Plaintiffs filed the initial lawsuit but one month before Plaintiffs filed their amended complaint (in December 2020). Defendant argued the November letter could not constitute "pre-suit" notice for the Plaintiffs who were first named in the amended complaint because those Plaintiffs effectively joined the pre-existing suit, not a new lawsuit filed in December. However, Defendant did not provide authority from Alabama, or Florida, or elsewhere to support this position. Thus, the court reasoned it could not hold that the newly added Plaintiffs provided insufficient notice as a matter of law.

Practitioners should remember that standing arguments may effectively eliminate some, even if not all, of a plaintiff's claims. Practitioners should also stay apprised of the nuances of the notice requirement for breach of express and implied warranty claims, particularly in cases involving multiple plaintiffs who join the litigation at different times.

Failure to Warn

Cates v. Zeltiq Aesthetics, No. 6:19-cv-1670-PGB-LRH, 2021 U.S. Dist. LEXIS 88208 (M.D. Fla. April 19, 2021).

Plaintiff Terrance Cates sued the manufacturer of CoolSculping, a medical device that intensely cools targeted areas of the body to induce fat breakdown, after experiencing Paradoxical Hyperplasia ("PH"—tissue enlargement and hardening) in the treated areas. Plaintiff brought claims for strict product liability based on defective design and failure to warn, negligence, negligent misrepresentation, and fraudulent misrepresentation and concealment.

Defendant argued Plaintiff's failure to warn claim failed because its warnings were adequate as a matter of law, and even if they were not, inadequate warnings were not the proximate cause of Plaintiff's injuries. Defendant also argued Plaintiff's other claims failed because they were predicated on inadequate warnings. The district court agreed.

The Court noted that under the learned intermediary doctrine, Defendant had a duty to warn Plaintiff's doctor—not Plaintiff—of the risk of HP. Defendant provided Plaintiff's CoolSculpting providers with a User Manual discussing the risk of PH, provided in-person training to Plaintiff's CoolSculpting providers that contained a slide exclusively devoted to the risks of PH, and even provided Plaintiff's CoolSculpting providers with a sample patient consent form describing the risk of PH (which Plaintiff's doctor distributed and Plaintiff signed). The Court found the warnings in these materials accurately discussed the risk of PH based on the medical literature, and it held Defendant provided adequate warnings as a matter of law.

As for Plaintiff's defective design claim, Plaintiff's experts were required to show that CoolSculpting was "unreasonably dangerous" under Florida's risk utility test. However, no expert involved in the case opined that the CoolSculpting device was defectively designed, and one of Plaintiff's experts even testified that he had provided, and would continue to provide, CoolSculpting treatment to his patients. The Court agreed with Defendant that this claim, as well as Plaintiff's other claims, were simply "repackaged" claims premised on an inadequate warning. Accordingly, the court granted summary judgment on all counts.

Practitioners should remember that failure to warn claims may be dismissed as a matter of law where the manufacturer provided substantial and truthful warnings about its product.

Economic Loss Rule and Implied Warranties

***Elder v. Reliance Worldwide Corp.*, No. 1:20-cv-1596-AT, 2021 U.S. Dist. LEXIS 194414 (N.D. Ga. Sept. 27, 2021).**

Plaintiffs from Florida and seven other states sued Defendants for manufacturing and distributing an allegedly defective water heater connector. They claimed the rubber lining in the connector deteriorated during normal use and resulted in flooding, leakage, and rubber flakes in Plaintiffs' water supply. Plaintiffs brought claims for, among other things, negligence and breach of implied warranties, and Defendants moved to dismiss.

First, Defendants argued that the economic loss rule barred Plaintiffs' negligence claims. The economic loss rule generally applies when a product causes only economic damage (as opposed to personal injury). The rule bars recovery for damage to the product itself, but it does not bar recovery for damage to other property. Defendants argued that the economic loss rule barred all of Plaintiffs' claimed property damages because the connectors were "integrated" into Plaintiffs' appliances and plumbing systems that were damaged. Applying Georgia law, the district court rejected this "integrated system approach" to the economic loss rule. The Court identified Florida and Georgia case law that allowed plaintiffs to recover for damage to property that was arguably connected to the product at issue. Thus, the court reasoned that Georgia courts would likely reject Plaintiffs' integrated system approach, and it held the economic loss rule did not bar Plaintiffs' claims for damage to property other than the connector itself.

Next, Defendants argued that Plaintiffs' (1) implied warranty of merchantability and (2) implied warranty of fitness for a particular purpose claims should be dismissed. Defendants claimed that the implied warranty of merchantability does not guarantee a product will perform indefinitely, and the fact that the connectors eventually began to deteriorate simply meant that they did not last as long as Plaintiffs would have liked. The district court rejected this argument and reasoned that the implied warranty of merchantability can be breached both (1) when the product is not capable of performing its ordinary function, and (2) even if the product is capable of performing its ordinary function, when it nonetheless fails in a way the consumer would not expect. The Court held that an unexpected side effect—such as rubber flakes in Plaintiffs' water supply—is enough to render a product unmerchantable.

Defendants argued that Plaintiffs could not recover based on the implied warranty of fitness for a particular purpose because Plaintiffs used the water heater connector for its *ordinary* purpose—connecting water lines. The district court agreed and reasoned that Plaintiffs could not state a claim for breach of implied warranty of fitness for a particular purpose when they only used the product for its ordinary purpose. The Court emphasized that the implied warranty of fitness for a particular purpose requires, as its name suggests, that the plaintiff use the product in a specific, peculiar way. The defendant must also be aware of the plaintiff's intended use of the product. Because Plaintiffs did not allege that

they used the connectors for a particular purpose or allege that Defendants knew that they planned to use the connectors for a particular purpose, the court granted Defendants' motion to dismiss this claim.

Practitioners should consider the economic loss rule as a potential bar to recovery in product liability cases that do not involve personal injury, and they should specifically consider how the subject product's relationship to other property may affect the rule's application. When confronted with an implied warranty of merchantability claim and an implied warranty of fitness for a particular purpose claim in the same lawsuit, practitioners should determine whether the plaintiff used the product for an ordinary versus unique and specific purpose. They should then consider whether the plaintiff can logically maintain those claims simultaneously.

SUPREME COURT OF THE UNITED STATES:

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Personal Jurisdiction

***Ford Motor Co. v. Montana Eighth Jud. Dist. Ct*., 141 S. Ct. 1017, 209 L. Ed. 2d 225 (2021).**

Last year, we reported on the Ford Motor cases which have since been decided by the court. Ultimately, the Supreme Court affirmed the lower courts' decision. It held specific jurisdiction did not require a strict causation-only approach and Ford's substantial business in the forum states supported specific personal jurisdiction citing a host of reasons it availed itself of the forum states.

Ford Motor Co. v. Montana Eight Judicial District Court involved a wrongful death suit involving a 1996 Ford Explorer which experienced a tire belt and tread separation on a Montana interstate. Plaintiff's estate sued Ford in Montana state court, and asserted claims for design defect, failure to warn, and negligence. Ford moved to dismiss for lack of personal jurisdiction based on a lack of contact with the subject forum because Ford designed, manufactured, and sold the car outside of Montana.

Ford Motor Company v. Bandemer involved a 1994 Crown Victoria rolling after rear-ending a snowplow. Plaintiff sued Ford alleging that the air bag failed to deploy raising claims of products liability, negligence, and breach of warranty in Minnesota state court. Ford moved to dismiss for lack of personal jurisdiction again arguing the trial court lacked specific personal jurisdiction because Ford did not design the airbag system, assemble the vehicle, or sell the vehicle in Minnesota. In both cases, Ford originally sold the vehicles outside the forum states and the vehicles were resold to subsequent owners in those states.

Ford's arguments did not prevail on appeal. The Supreme Court affirmed the decisions of the lower courts in Montana and Minnesota courts finding that personal jurisdiction existed over Ford. Ultimately, the court noted Ford as a global company exploited the market in each forum to such a level to warrant specific jurisdiction. "The contacts must be the defendant's own choice and not 'random, isolated, or fortuitous.'" *Id*. at 1025. Additionally, the court noted Ford clearly availed itself to the respective forums by marketing, selling its products, and servicing its vehicles in the forum. The Court noted, that in the respective forums, the plaintiffs were residents of their respective forums, used the products in those forums, and suffered injuries in the forum. *Id.* The Court reiterated that federalism supports the respective forums interest in providing a convenient forum for their residents to address disputes.

The Supreme Court noted the *Bristol-Myers Squibb v. Superior Court* case agrees with the affirmance of the lower court's orders in that that specific jurisdiction exists only where the defendant "purposefully avails itself of the privilege of conducting activities within the forum" and the plaintiff's claims "arise out of or relate to" the defendant's forum conduct. *Bristol-Myers Squibb v. Superior Court*, 137 S. Ct. 1773, 1785–86 (2017). Ford's central argument was that the incidents lack a direct relation to its conduct in Montana or Minnesota. This argument relied on a limited interpretation of the phrase "arise out of or relate to." However, the court did not agree with this argument and held that Ford "purposefully availed" itself of both forums through its sales of vehicles, marketing, sale of its auto parts, and servicing or offering maintenance on its vehicles. Therefore, *Bristol-Meyers* did not support the central argument of Ford.

The majority opinion held the “relate to” analysis is a step for finding jurisdiction but it “never framed the specific jurisdiction inquiry as always requiring proof of causation—*i.e.,* proof that the plaintiff ’s claim came about because of the defendant's in-state conduct.” *Id*. at 1026. After analyzing *World-Wide Volkswagen*, the court found the outcome in this matter aligns with the existing case law. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 299, 100 S. Ct. 580, 581, 62 L. Ed. 2d 490 (1980). In the concurrence with the judgement, Justice Alito noted that the “relate to” analysis was without real limits which likely will not be helpful to lower courts in the future. In the second concurrence with the judgment, Justices Gorsuch and Thomas discussed the two elements for jurisdiction: first, “the defendant must “purposefully avail” itself of the chance to do business in a State and second, the plaintiff ’s suit must “arise out of or relate to” the defendant's in-state activities.” *Id*. at 1034. The Justices noted this is not the clear outcome based on the majority opinion and foresee complications for future cases without guardrails to show the criterion for “purposeful availment.”

A key takeaway from the court’s opinion is that it sought to leave the law in the same position as it was before these cases were heard. The actions taken by Ford were found to purposefully avail itself to the forum states which leads to new considerations when analyzing the viability of a motion to dismiss on grounds of personal jurisdiction grounds.

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Automotive Product Liability Class Action Certification – Parts Supplier Liability – Preferable Procedure– Claims under Consumer Protection Statutes

***Kett v. Mitsubishi Material Corporation.,* 2020 BCSC 1879.**

The plaintiff sought to certify a class action against parts suppliers. The plaintiff alleged that he paid a higher price for his Honda vehicle because the defendants, who failed to carry out proper testing, charged auto manufacturers more than they should have for parts. The plaintiff advanced causes of action under, among other things, British Columbia's *Business Practices and Consumer Protection Act*, SBC 2004, c.2 ("BPCPA"). The plaintiff argued that a class action would be the preferable procedure for the resolution of the claimed common issues because the class members would be able to "share the costs of the experts and counsel" and because it would enable joint discoveries.

The British Columbia Supreme Court rejected this argument because of "expansive" manageability concerns. The automotive supply chain is vast and involves three separate tiers of part suppliers who provide parts, either directly or indirectly, to each other and to a variety of automotive manufacturers. The automotive supply chain is further complicated because suppliers may operate in different tiers at the same time and automotive manufacturers may source different parts from multiple locations around the world. In addition: (1) the defendants each conducted different operations; (2) the extent to which their component were present in vehicles in Canada was unknown; and (3) the breadth of products the plaintiff sought to cover was "staggering".

The Court noted that preferability must be considered with a view to enhancing access to justice, judicial economy and behaviour modification. In this case, access to justice was limited by the small value of any possible recovery, and behaviour

modification had already been fulfilled by criminal proceedings and reputational damage. Regarding judicial economy, the court found that:

> [T]he risk of the proceeding collapsing under its own weight is simply too great. This risk will not only be visited upon the court, but also upon the defendants and individual class members, who expect and deserve prompt access to justice once the proceeding has been certified. The court should avoid certifying an action where the proceeding will inevitably over-promise and under-deliver.

The plaintiffs also advanced a cause of action under section 5 of the BPCPA, which prohibits representations by a "supplier" that "goods" have components that they do not have. The Court refused to certify this cause of action. The Court held that, where consumers purchase fully assembled vehicles from dealerships, those vehicles are the "goods", rather than any individual parts in those vehicles. Accordingly, the defendants were not suppliers of "goods", and could only supply "goods" to a consumer if that consumer bought specific replacement parts from the defendants, separate and apart from the purchase of any vehicle.

Product Liability Class Action – Food Products

***Durand v. Subway Franchise Systems of Canada*, 2020 QCCA 1647.**

The *Durand* case presents a Quebec class action authorization decision wherein the proposed plaintiff alleged that the Subway restaurant chain misrepresented the contents of its chicken sandwiches. The plaintiff was a consumer who had purchased and consumed a Subway sandwich at least twenty-five times in the previous three years, the majority of which were grilled chicken. In support of these allegations, the plaintiff relied upon a news article reporting the results of a DNA analysis conducted by a researcher at Trent University which reported that the chicken found in the sandwiches sold by Subway contained only about 50% chicken DNA, with the rest being soy.

From these allegations the plaintiff claimed that Subway made misrepresentations and violated various provisions of the *Consumer Protection Act* and the *Competition Act*.

In refusing to authorize the class action, the Quebec Superior Court judge found that the syllogism proposed by the plaintiff did not hold water for three reasons:

1) The respondents had no legal relationship with the consumers since they did not manufacture or sell the sandwiches;
2) The evidence did not support the allegation that the respondents represented that Subway's sandwiches were 100% chicken; and
3) No facts were alleged to suggest that the plaintiff's decision to purchase the chicken sandwiches was influenced by the representations made by the respondents.

The Court of Appeal reversed the decision and authorized the class action. The Court explained that at the authorization stage, the evidence presented by the respondents must be essential, indispensable and limited to what can demonstrate without question that the facts alleged by plaintiff are implausible or false. It must not have the effect of forcing an adversarial debate on a substantive issue or leading to a trial before the trial. The judge must remember that he or she should only take for granted the facts alleged by the plaintiff and not those alleged by the respondents, even if the respondents' evidence establishes a *prima facie* case.

On the three reasons raised by the first judge to refuse to authorize the class action, the court of Appeal concluded that:

1) The question of whether a franchisor may have incurred liability by making false or inaccurate representations to consumers about the products sold in its franchise network has an important factual dimension and, thus, should be reserved for the trial judge.
2) The suggestion that the respondents represented that their sandwiches contain "real chicken" is not frivolous and is sufficient at this stage. It may not be sustained at trial, but the appellant did not have to convince the judge of its merits. The analysis to be followed in assessing the truthfulness of a commercial representation was established by the Supreme Court in *Richard v. Time*. That assessment should be done at trial.
3) Since the plaintiff specifically alleges that he purchased the chicken sandwiches because he believed they were made with chicken, there was is a sufficient basis

to conclude that the representation had an impact on his decision to purchase a Subway chicken sandwich. He will have to prove this later.

In this decision, the court of Appeal sent a clear reminder to avoid deciding the merits of the case at the authorization stage.

Manufacturer's Liability – Fencing Machinery – Duty to Warn after the Time of Sale

***St. Isidore Co-op Limited v. AG Growth International Inc.*, 2020 ABCA 447.**

This was an appeal from the decision of the Alberta Court of Queen's Bench in *St. Isidore Co-op Limited v. AG Growth International Inc.*, 2019 ABQB 763. The respondent purchased a "heavy hitter" fence post pounding machine from the appellants which broke, killing a person in 2012. The respondent paid damages to the estate of the person who was killed and sought full indemnity from the appellants.

The respondent alleged, among other things, that the appellants breached their duty to warn by failing to warn the respondent of: (1) an alleged defect in the "heavy hitter" fence post pounding machine that caused it to malfunction; and (2) the availability of a "Stop Tilt Kit", implemented in 2005, which would have prevented the accident.

At trial, the appellants argued that no warning was required because "the fatal accident was an anomalous event… outside the range of what would be reasonably foreseeable". The trial judge rejected this argument and found that the appellant breached its duty to warn because it knew, or ought to have known of the "substantial likelihood of harm" in light of: (1) a "near miss event" that occurred prior to the implementation of the "Stop Tilt Kit" in 2005; and (2) other evidence of similar incidents.

The appellants on appeal argued that the trial judge erred by failing to apply the correct legal test for failure to warn. The Alberta Court of Appeal rejected this argument, adopting the reasons of the trial judge and holding that the defendant had recognized the safety defect and was obliged "to consider the seriousness of the consequences to the end user" even where the risk of an accident occurring was small. Accordingly, the defendant was required to warn past purchasers of the defect, the danger it caused, and the availability of the Stop Tilt Kit.

The appellants also argued that the trial judge erred in holding them to an "industry standard" which had not been proven. Specifically, the appellants took issue with the trail judge's finding that documents in the appellants' possession from Flexi-Coil (one of the appellants' competitors) had constituted "compelling direct evidence of a standard industry practice relating 'to safety changes to post pounding machines'" and the need to warn past purchasers of these changes.

The Court of Appeal rejected this argument, finding that, while the trial judge considered the Flexi-Coil documents to be persuasive, they did not constitute the sole basis for the finding that the appellants owed a duty to warn the respondent. The trial judge considered many factors in concluding that there was a foreseeable risk of substantial harm, including: (1) the Flexi-Coil documents; (2) the "near miss event"; (3) the implementation of the Stop Tilt Kit; and (4) other evidence of defective "Heavy Hitter" components. Accordingly, the court dismissed the appeal.

Product Liability Motion to Dismiss – Gun Manufacturer's Liability – Duty of Care – "Goods Dangerous Per Se" Category

***Price v. Smith & Wesson Corp.*, 2021 ONSC 1114.**

The defendants brought a motion to strike the Plaintiff's Statement of Claim and to dismiss the Plaintiffs' action. The action itself arose out of the "Danforth Shooting", where a Smith & Wesson handgun, which did not utilize "authorized user" technology, was used to shoot and kill pedestrians. The Plaintiffs claimed, among other things, damages for negligent design.

To succeed on the motion, the defendant needed to demonstrate that the plaintiffs' claims were doomed to fail. The defendant argued that the plaintiffs' claims in negligence were doomed to fail because the proximate cause of the damage was the conscious criminal acts of the shooter, not the alleged negligence of the defendant.

The Ontario Superior Court of Justice rejected this argument by relying on an old and rarely used duty to care relationship referred to by the court as the "goods dangerous per se" relationship, which requires that manufacturer of a good "dangerous in itself" take precautions when it is "necessarily the case that innocent parties will come within the proximity of the dangerous article." Accordingly, the proximate cause of the damage was

the defendant's failure to take the precaution of implementing authorized user technology, which would have allowed the defendant to "avail itself" against the volition of the shooter.

The defendant argued that extending the duty of care relationship in this manner would have "industry shattering consequences" because many goods can be used by criminals to cause harm to innocent persons. The Court rejected this argument:

> I am not persuaded by this argument because there is no extension of liability in the immediate case. The impact of extending a duty of care to introduce authorized user technology to weapons is a drop in the bucket to the extension of liability already introduced by Donoghue v. Stevenson, where the Law Lords heard similar in terrorem arguments, which arguments did not impress the majority judges. And for that matter the arguments were irrelevant to the minority, which accepted that there was already a duty of care for manufacturers of goods that were dangerous as such… Similarly, I am also not persuaded that the recognition of a duty of care in the immediate case raises concerns of indeterminate liability any more than did the enormous extension of liability introduced by Donoghue v. Stevenson.

Finally, the defendant argued the plaintiffs' claim was doomed to fail because its weapons, which are intended for police officers, would be dangerous to police officers if they were designed with authorized user technology. The Court rejected this as an argument on the merits of the negligent design claim, which was inappropriate for the motion. Accordingly, the court did not strike the plaintiffs' pleadings or dismiss the action.

Automotive Product Liability Class Action Certification – Car Manufacturer Liability – Claims under Multiple Consumer Protection Statutes – Negligence Claims for "Pure Economic Loss"

***Bhangu v. Honda.*, 2021 BCSC 794.**

The plaintiff alleged that certain Acura vehicles, which were made, distributed and sold by the defendants, contained defective Bluetooth systems that drained the vehicles of their battery and damaged other electronic components such that the vehicles could stall in a dangerous manner.

To certify a cause of action, plaintiffs must demonstrate that it is not "plain and obvious" that the causes of action will fail by pleading material facts that, if true, would make out the cause of action. Among other things, the plaintiff pled causes of action under consumer protection statutes in all Canadian jurisdictions except Quebec, based primarily on alleged misrepresentations. In particular, the plaintiff plead material facts relating to section 5 of the *BPCPA*, which prevents "suppliers" from engaging in deceptive acts or practices. Pursuant to section 4 of the *BPCPA*, a deceptive act or practice can include a representation by a supplier that "has the capability, tendency or effect of deceiving or misleading a consumer." However, the plaintiff did not plead material facts relating to the similar causes of action under the other consumer protection statutes.

The Court refused to certify the claims under consumer protection statutes other than the *BPCPA*, because the plaintiff failed to plead material facts related to those specific statutes. The Court noted significant differences in the elements of the statutory causes of action between the *BPCPA* and the other consumer protection statutes, including "the meanings of key terms (such as 'consumer' and 'supplier'), the transactions to which the statutes apply, differences in requirements for privity, when the misrepresentations must be made in order to be actionable, whether reliance must be shown, and notice requirements." The plaintiff failed to advert to these differences, in particular by failing to plead material facts showing (1) contractual privity between the putative Ontario class members and Honda; (2) reliance for putative Saskatchewan class members; and (3) notice of the statutory actions given to Honda by putative class members in Alberta and Ontario. The Court did, however, grant the plaintiff leave to amend her Notice of Civil Claim in order to properly plead material facts sufficient to make out the consumer protection causes of action, holding that the amendments were more "technical than fundamental".

The plaintiff also sought to certify various causes of action in negligence for "pure economic loss" by claiming the costs of replacing the allegedly dangerous Bluetooth systems defect. The plaintiff argued that the defect posed a "substantial risk of harm", as required by *Maple Leaf*, because the it could cause vehicles to stall on the road or prevent vehicles from starting during an emergency. The Court accepted these arguments and certified the causes of action.

Automotive Product Liability Class Action Certification – Car Manufacturer Liability – Some Basis in Fact Standard for Certification Criteria – No evidence of "Compensable Loss"

***Maginnis v. FCA Canada Inc*., 2021 ONSC 3897 (Divisional Court).**

This was an appeal from a decision dismissing a motion to certify a class action against FCA Canada Inc. and other related entities (the "FCA Defendants"). The appellants alleged, among other things, that the FCA Defendants installed emissions "defeat devices" in certain vehicles in order to permit those vehicles to cheat government emissions tests. The vehicles at issue were recalled and subject to a repair that ameliorated the alleged problems.

The appellants claimed negligent misrepresentation and alleged that they suffered two kinds of damages: (1) the payment of a higher price for a clean vehicle they did not receive; and (2) the reduced resale value of the vehicle, or alternatively, the loss caused by increased fuel prices and/or reduced vehicle performance.

The motions judge denied the motion for certification, finding that there was no evidence of compensable loss following the recall of the vehicles, and holding that a class proceeding is not the preferable procedure for the resolution of common issues. At issue on appeal before the Divisional Court was, among other things, the question of whether the motions judge erred by requiring the appellants to provide some basis in fact of compensable loss in order to meet the certification criteria.

The Divisional Court upheld the motion judge's decision, holding that evidence of compensable loss is required to demonstrate that there is "some basis in fact" that a class proceeding would be the preferable procedure for the resolution of the common issues. In coming to this conclusion, the court cited *Atlantic Lottery Corporation Inc. v. Babstock*, 2020 SCC 19, where the Supreme Court of Canada held that class actions do not enhance judicial economy, behaviour modification or access to justice where plaintiffs do not suffer compensable loss and instead pursue nominal damages.

The appellants argued that it was improper to require them to provide some basis in fact for compensable loss at the certification stage since they gave evidence of a methodology to prove such loss, relying on the Supreme Court of Canada's decision in

Pro-Sys Consultants Ltd. v. Microsoft Corporation, 2013 SCC 57. The Divisional Court rejected this argument:

> Pro-Sys was an indirect purchaser action. In the sections of the reasons the appellants relied on, the Supreme Court of Canada was discussing whether there was a basis in fact to show that loss-related issues were capable of resolution on a common basis. The Court was not focused on the issue in this case – namely, whether there was some basis in fact for finding that any compensable loss at all had been suffered by the plaintiffs. The Court observed that the plaintiffs were not required to prove actual loss by indirect purchasers. Rather they must show that there was a methodology capable of establishing that overcharges had been passed on to the indirect purchasers to as to satisfy the common issues criterion… [T]he motion judge's approach is consistent with Pro-Sys. He was not requiring quantification of damages suffered in the present case, which is a case involving direct purchasers, not indirect purchasers. Rather, he found that the was no evidence that there were any compensable damages suffered by any members of the class once the AEM repair was made.

The Divisional Court further upheld the motion judge's finding of fact that there was no evidence of compensable harm in light of: (1) the defendant's uncontroverted evidence that the repair fixed the problems at issue without affecting overall fuel economy or vehicle performance; and (2) the insufficiency of the plaintiffs' proposed methodology to prove any compensable loss.

Automotive Product Liability Class Action Certification – Car Manufacturer Liability – Negligence Claims for "Pure Economic Loss" – Breach of Warranty – Unjust Enrichment

***Carter v. Ford Motor Company of Canada.,* 2021 ONSC 4137/2021 ONSC 4138.**

In this Ontario Superior Court of Justice case, the plaintiffs alleged that the defendants manufactured, designed, distributed, sold and leased vehicles with defective water pumps that created a propensity for dangerous engine failure after "moderate mileage". The plaintiffs sought to certify a class action on behalf of three groups: (A) putative class members who experienced water pump failure and suffered personal injury from a car accident; (B) putative class members who experienced water pump failure that caused vehicle damage; and (C) putative class members who had not experienced water pump failure, but who allegedly required a repair to avoid future water pump failure.
The plaintiffs sought to certify a cause of action in negligence for "pure economic loss", by claiming damages for the diminution in value of the vehicles containing the alleged defect, on behalf of Group C. The plaintiffs sought to certify other causes of action in negligence for Groups A and B. The plaintiffs also sought to certify the causes of action of breach of warranty and unjust enrichment.

With respect to the negligence claim for "pure economic loss" on behalf of Group C, the court applied the Supreme Court of Canada's *1688782 Ontario Inc. v. Maple Leaf Foods Inc.*, 2020 SCC 35 ("*Maple Leaf*") decision, which clarified that negligence claims for "pure economic loss" require an "imminent threat" of "real and substantial danger" to person or property, and that recovery in such cases is limited to the costs of averting that threat.

The Court refused to certify the negligence claim for "pure economic loss" for Group C because the plaintiffs failed to plead an "imminent threat". Instead, the plaintiffs pled that the defect may arise "at some indeterminate time in the future", which the court characterized as a "yet to be borne danger… that may never be borne" and as a matter of "durability rather than inevitability". Thus, the plaintiffs failed to plead material facts that, if true, would make out the negligence claim for "pure economic loss", as is required to certify a cause of action. The Court also held that diminution in value of the vehicles

containing the defect would not be recoverable, because such an award was not connected to averting an "imminent threat" of "real and substantial danger".

It is worth noting that the plaintiff in *Bhangu v. Honda Canada Inc.*, 2021 BCSC 794 ("*Bhangu*") was successful even though he did not plead that the defect in question posed an "imminent threat" of danger. In this regard, the *Bhangu* decision stands in contrast with this decision. However, the court distinguished *Bhangu* on the basis that the alleged defect in that case was more about inevitability than durability, unlike the alleged defect in this case.

The plaintiffs also sought to certify a claim for breach of the express warranty. The Court refused to certify this cause of action for several reasons. First, the court rejected the plaintiffs' argument that Ford warranted that the water pumps would be free of design defects, since the warranty covered only defects in "materials or workmanship", not design. Second, the court rejected the plaintiffs' argument that Ford warranted that the water pumps would be free of the risk of the alleged design defect, since the warranty covered "actualities" rather than "potentialities". Third, the court held that the question of whether Ford breached its obligations under the warranty by refusing to repair or replace the alleged defect was an individual issue rather than a common issue shared by the class.

The plaintiffs also sought to certify claims in breach of implied warranty under various consumer protection statutes, including breaches of the warranties of fitness and merchantability. The Court refused to certify these causes of action because the claims lacked commonality for several reasons. First, the putative class members were not all consumers and the defendant did not "supply" vehicles to second-hand purchasers. Second, the requirement for privity varied between different consumer protection statutes. Finally, the question of whether a vehicle was reasonably fit for its purpose or of merchantable quality was an individual issue. In addition, the warranty claims under Ontario's *Consumer Protection Act, 2002*, S.O. 2002, c. 30, Sched. A, were doomed to fail because the only direct contracts between the parties were the express warranties, which are agreements to supply services rather than goods.

The Court refused to certify the plaintiffs' unjust enrichment claim because the defendant was only enriched by putative class members when those putative class

members purchased vehicles directly from the defendant, rather than from Ford dealers (who were not agents of the defendant) or from some other party. In addition, if a legal relationship did exist between the putative class members and the defendant, the relevant contracts of purchase and sale provided a juristic reason for the defendant's enrichment. Finally, the court also refused to certify the disgorgement remedy for the already certified claim of negligent design because the "elements of causation and the determination of damages" must be determined at individual issues trials, and the election of disgorgement as a remedy is a matter for individual class members

Automotive Product Liability Class Action Certification – Car Manufacturer Liability – Some Basis in Fact Standard for Certification Criteria – No Evidence of "Compensable Loss"

***MacKinnon v. Volkswagen.,* 2021 ONSC 5491.**

The plaintiff sought to certify a class action on behalf of owners and lessees who had sold or returned vehicles marketed as "clean diesel" that contained emission "defeat devices", before the emissions violations were made public. The plaintiff advanced causes of action in negligent misrepresentation, negligence, breach of warranty, breach of consumer protection legislation and unjust enrichment, and claimed damages on the basis that he had paid for, but had not received, a clean diesel vehicle.

Like in *Maginnis v. FCA Canada Inc.*, 2021 ONSC 3897, the Ontario Superior Court of Justice refused to certify the class proceeding because the plaintiff was unable to provide evidence of compensable loss or of a plausible methodology to measure that loss on a class-wide basis, both of which are required on certification where the core issue that could advance the litigation was related to the existence of a loss and the quantification of damages.

Specifically, the court found that there was no evidence of compensable loss because the plaintiff was unable to show that any premium had been paid for the clean diesel feature. Instead, the plaintiff relied entirely on evidence of the effect that the emissions violation disclosure had on the value of clean diesel vehicles as evidence of the value of the clean diesel feature at the time of the original sale or lease. The court found this evidence insufficient on the following basis:

> The post-disclosure drop in value cannot be used to calculate initial overpayment in the pre-disclosure context because the market's post-disclosure reaction/drop in value included brand effects that did not exist when class members disposed of their vehicles in the pre-disclosure market before the fraud was made public.

Relatedly, the plaintiff was unable or failed to provide a plausible methodology to measure the alleged loss on a class-wide basis.

In light of these findings, the court held that the plaintiff was unable to demonstrate that there was "some basis in fact" for the requirements that: (1) there be an identifiable class; (2) the claims raise common issues; (3) a class proceeding would be the preferable procedure for the resolution of the common issues; and (4) there be a suitable representative plaintiff. Accordingly, the court refused to certify the action.