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I. United States Supreme Court

Class Actions – “Representative” Proof


In a much-anticipated case for the class-action bar, the Supreme Court upheld the certification of a Rule 23(b)(3) class of plaintiffs against Tyson’s argument that individual questions of fact and law predominated over questions common to the class. The putative class consisted of current and former employees at a Tyson pork processing plant who were not compensated for the time spent donning and doffing various protective gear necessary for their jobs. Tyson argued that the class did not satisfy the predominance requirement because class members could prove an essential element of their overtime wage claims – that each had, in fact, worked more than 40 hours in a given week – only by relying on individualized proof. The Court rejected this argument, noting that the class had presented “representative evidence” – that is, statistical evidence – showing that the class members had spent, on average, approximately 20 minutes per day in the donning/doffing process, and that, based on this evidence, the vast majority of the class members had worked uncompensated overtime.

Central to the Court’s decision approving the use of statistical evidence were two findings. First, the Court emphasized that it was “Tyson’s failure to keep records of donning and doffing time” that put the putative class in the position of having to rely on representative rather than individualized proof. Second, and related to the first point above, the Court explained that generalized proof was admissible when such proof would be “relevant in proving a plaintiff’s individual claim.” In other words, if a single plaintiff could rely on representative evidence to support his or her individual claim, a class of plaintiffs must be able to rely on this evidence as well. Thus, even though *Bouaphakeo* is not a products liability case, it has important implications for many product manufacturers – and, therefore, for their legal counsel.

II. First Circuit

Expert Testimony

*Quilez-Velar v. Ox Bodies, Inc.*, 823 F.3d 712 (1st Cir. 2016)

In *Quilez-Velar v. Ox Bodies, Inc.*, the court held that the trial court properly admitted expert testimony concerning a feasible, safer alternative design under the *Daubert* standard. There, a motorist was involved in a car accident with a truck outfitted with an underride guard designed by the defendant. After the motorist died from injuries sustained in the accident, family members filed a products liability action against the defendant, alleging defective design of the underride guard. At trial and in spite of the defendant’s motion in limine, the plaintiff’s expert testified to deficiencies in the defendant’s underride guard design and concluded that there existed safer alternative designs. The jury found the defendant strictly liable for defective design of the underride guard.

On appeal, the First Circuit addressed whether the magistrate judge abused her discretion in concluding that the plaintiff’s expert’s testimony regarding alternative design was sufficiently reliable to survive *Daubert*’s admissibility threshold. The defendant contended that the expert’s testimony should have been excluded as unreliable under *Daubert* because the expert did not actually test the safer alternative design he testified to. The court disagreed. The court held that *Daubert* does not establish a bright-line rule, requiring that the expert must himself have tested the alternative design. Rather, the jury was able to evaluate the expert’s reliability based on the testing and research presented as foundation for his opinions, which were then scrutinized under cross-examination, presentation of contrary evidence and instruction on burden of proof. Thus, the First Circuit affirmed the trial court’s decision.
In *Milward v. Rust-Oleum Corp.*, the court affirmed the district court's decision to exclude the plaintiff’s expert’s testimony under the *Daubert* standard. In that case, the plaintiff was exposed to varying levels of benzene from paints and other products manufactured by the defendant. After being diagnosed with Acute Promyelocytic Leukemia, the plaintiff filed suit against the defendant manufacturer, alleging a toxic tort product liability claim. To prove medical causation, the plaintiff retained an expert to opine on the plaintiff’s benzene exposure, as required under Massachusetts law. However, the district court held that the expert's testimony was inadmissible under the *Daubert* standard. The plaintiff appealed.

On appeal, the plaintiff argued that his expert's testimony regarding relative risk and differential diagnosis was scientifically reliable in compliance with the *Daubert* standard; thus, the expert’s testimony was admissible to prove medical causation. The First Circuit disagreed. First, in regard to the plaintiff’s relative risk argument, the court explained that the expert's inability to articulate her reliance on conflicting studies to reach the same conclusion made it difficult for the court to ensure that her expert opinion was scientifically reliable. Second, in regard to the plaintiff’s differential diagnosis argument, the court explained that steps taken in such an analysis, ruling causes out and in, must have used scientifically valid methods and the expert did not. Because the plaintiff’s expert opinion failed under the *Daubert* standard, the court held that the plaintiff failed to establish causation under Massachusetts law and the court affirmed the district court’s decision.

**Standing**

*Hochendoner v. Genzyme Corp.*, 823 F.3d 724 (1st Cir. 2016)

In *Hochendoner v. Genzyme Corp.*, the court dismissed the plaintiffs’ class action suit for lack of Article III standing, as all of the plaintiffs failed to allege an injury suffered as a result of receiving a contaminated drug produced by the defendant drug manufacturer. There, the district court consolidated two class action suits that alleged, among other things, that the plaintiffs were harmed by their receipt of contaminated Fabryzyme, a drug that replaces enzymes to treat patients with Fabry Disease, a rare genetic disorder. The district court dismissed the plaintiffs’ contamination claim because the plaintiffs failed to provide the defendant with sufficient notice of which plaintiffs suffered harms alleged in the contamination claim. The plaintiffs appealed.

On appeal, the plaintiffs asserted that they plead concrete and particularized injuries sustained from using the defendant's contaminated drug. The court disagreed. Rather, the court held that the plaintiffs plead scattered descriptions of generalized harms. The plaintiffs merely alleged that the defendant produced contaminated doses of the drug, but failed to assert that any specific plaintiff took or received a dose of Fabryzyme that was contaminated with particulate matter. Thus, the court determined that the plaintiff class was not entitled to have the court adjudicate their claims and the court dismissed for lack of standing.

## III. Second Circuit

**Personal Jurisdiction – General Jurisdiction**

*Brown v. Lockheed Martin Corp.*, 814 F.3d 619 (2d Cir. 2016)

Plaintiff, a personal representative of the decedent’s estate, brought suit against defendant Lockheed Martin (“Lockheed”) to recover for injuries suffered as a result of asbestos exposure. The decedent was a former U.S. Air Force mechanic who, at various times, worked on airplanes manufactured and maintained by Lockheed. The decedent was allegedly exposed to asbestos during his work in locations outside of Connecticut. After the district court dismissed the claim for lack of personal jurisdiction, Plaintiff appealed to the Second Circuit. Ultimately, the Second Circuit affirmed the dismissal of Plaintiff’s claim, holding that the district court lacked general jurisdiction over Lockheed. Though Lockheed’s contacts with Connecticut were arguably
continuous and systematic (Lockheed leased space in Connecticut, had employees in Connecticut, derived about $160 million in revenue from Connecticut-based work, and paid taxes in Connecticut), the court decided the contacts fell well below the level necessary to put the corporation essentially at home in the state. Indeed, the court held that Lockheed’s contacts fell short of establishing a “surrogate principal place of business” like the U.S. Supreme Court found in *Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437 (1952) and which the U.S. Supreme Court pointed to in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014) as the “exceptional case.” Furthermore, the act of registering to conduct business under Connecticut statutes did not constitute Lockheed’s consent to the state court’s exercise of general jurisdiction.

**Trademark Licensor**


Plaintiff, whose hand was injured while operating a table saw, filed suit against five defendants. One of the defendants, Emerson, was the trademark licensor of the table saw at issue. The table saw bore the “Rigid” trademark. The trademark was owned by Rigid, Inc., a wholly owned subsidiary of Emerson. Emerson licensed the Rigid mark to Home Depot, who used the Rigid mark to market a line of power tools that were designed and manufactured by other companies on behalf of Home Depot. All defendants moved for summary judgment as to Plaintiff’s failure-to-warn claim, including Emerson. The court granted the motion as to Emerson on the basis that Plaintiff did not produce any evidence that Emerson exercised control over the design of the saw and thus had a limited role as a trademark licensor. Under New York law, “a trademark licensor cannot be held liable for injuries caused by a defective product bearing its label where the licensor did not design, manufacture, sell, distribute or market the allegedly defective item.” However, summary judgment as to the failure-to-warn claims against the other defendants was precluded due to material issues of fact. Under New York law, failure-to-warn liability is “intensely fact-specific,” and here, factual questions remained regarding Plaintiff’s knowledge of the saw’s hazards, whether the warnings on the saw were adequate, and whether the hazard was open and obvious.

**De Minimus Exposure**


Defendant Burnham LLC (“Burnham”) successfully moved for summary judgment as to Plaintiff’s claims arising from the decedent’s diagnosis of mesothelioma allegedly caused by an asbestos-containing heater manufactured by Burnham. The court held that Plaintiff, who alleged that the decedent was potentially exposed to asbestos from the Burnham heater for three hours in one day over a fifty-five year career, failed to meet her burden of establishing that the decedent was exposed to harmful levels of asbestos from a Burnham product and that such de minimis exposure could not support a conclusion by the factfinder that Burnham’s products caused the decedent’s injuries. The court granted summary judgment.

**Loss of Parental Consortium**


Plaintiffs, a mother and her minor children, brought claims under the Connecticut Product Liability Act and the Connecticut Unfair Trade Practices Act, along with bystander emotional distress claims on behalf of her minor children and a claim for loss of parental consortium, after a defective can of cooking spray manufactured by Defendant exploded in Plaintiffs’ kitchen. Plaintiffs added the loss of parental consortium claim almost a year after filing suit and shortly after the Connecticut Supreme Court recognized this new cause of action. In the amended complaint, the new count stated, “[a]t the time of her injury the plaintiff had two minor children…who are already a party to this action. The plaintiff seeks to assert claims for loss of parental consortium,” but did not explicitly incorporate all previous paragraphs in the complaint. The court denied
Defendant’s motion to dismiss the loss of parental consortium claim on the basis that, despite Plaintiffs’ failure to incorporate preceding portions of the complaint in her allegation of loss of parental consortium, the loss of parental consortium could be inferred from the allegations regarding Plaintiffs’ serious physical injuries, and an “apparent scrivener’s error” should not prevent the parties from treating the consortium claim as if it did incorporate the preceding portions of the complaint.

Spoliation


Two of the defendants filed a joint motion for sanctions against Plaintiffs, alleging that Plaintiffs spoliated evidence when they removed “at least ten separate rolled bundles of floor covering” from their home one day before Defendants were to inspect Plaintiffs’ home. The magistrate judge granted in part Defendants’ motion for sanctions, awarding Defendants attorneys’ fees and costs incurred in bringing the motion for sanctions (but not for the costs connected with the home inspection itself) and held that Defendants were entitled to the adverse inference “that the floor covering that was removed from Plaintiffs’ home would be favorable to Defendants’ defense and unfavorable to Plaintiffs’ claims.” The magistrate judge left the other requested remedies to the discretion of the district court. Plaintiffs objected to the magistrate judge’s ruling, and the district court overruled that objection. The district court held that the magistrate judge did not rely on clearly erroneous facts or commit clear error in finding that Plaintiff had grossly understated the amount of carpeting he threw away in his affidavit and that “this fact placed in question his veracity in this matter.” The district court also rejected Plaintiff’s new excuse for throwing away the carpet: that the carpet shown in the video shot by Defendants’ private investigator of Plaintiff throwing the bundles of carpet in his truck was not carpet removed from the house one day prior to the inspection, but was carpet that had been removed several weeks earlier and had been on the porch until one day before the inspection. According to the court, even if this new explanation was true, it showed that Plaintiffs intentionally destroyed potentially relevant evidence, which they had a duty to preserve as Plaintiffs were aware that the carpeting could have been a source of volatile organic compounds (as opposed to Defendant’s products). In overruling Plaintiffs’ objection, the court also amended the remedies provided to Defendants, expanding the award of attorneys’ fees to include the costs and fees associated with Defendants’ brief in opposition to Plaintiff’s objection and clarifying that the adverse inference was a permissive inference that Plaintiffs could rebut. The court left the other requested relief for “further weighing” and allowed the parties to brief the issue of preclusion in their summary judgment motions.

Motions in Limine


Plaintiff crashed her 2006 Chevrolet Cobalt into a drainage ditch culvert. The front airbags did not deploy and Plaintiff was severely injured. Plaintiff claimed that the inadvertent ignition switch rotation caused her airbags to fail during the crash, exacerbating her injuries. In preparation for the bellwether trial of Plaintiff, the court addressed several motions *in limine*. First, the court granted GM’s motion to exclude certain portions of the first responders’ testimony regarding whether Plaintiff’s airbag should have deployed or whether non-deployment was caused by ignition switch rotation. GM contended such testimony constituted improper opinions. The court determined that the first responder’s familiarity with crash scenes did not equip them to offer opinions on the complex, technical, and multi-factored question of whether the airbags should have deployed or the more complicated question of what caused their non-deployment. Second, the court denied GM’s motion to exclude testimony from a first responder about whether the plaintiff may have unbuckled her seat belt prior to the arrival of the first responders, noting that the first responder’s tes-
Inadequate Warnings


Defendant successfully moved for summary judgment on Plaintiff’s failure to warn and design defect claims based on inadequate warnings. Plaintiff, a personal representative for the estate of the decedent consumer, alleged that Defendant’s medication caused the decedent to commit suicide after it allegedly caused two rare and painful skin conditions. Given that Plaintiff failed to prove that the decedent would not have ingested the medicine had there been an adequate warning, his failure to warn claim failed as a matter of law. Plaintiff’s attempt to use deposition testimony asserting the decedent’s propensity to read medicine labels was not enough to establish habit, the court reasoned. Ultimately Plaintiff could not prove that a defective warning was what in fact caused the decedent’s injuries. Furthermore, the court noted that manufacturers of non-prescription drugs have no duty to warn physicians about the risks associated with those drugs. The court also dismissed Plaintiff’s negligence and negligent design claims based on his failure to raise a genuine issue of material fact regarding whether the decedent read and relied on the warnings provided. Plaintiff also failed to show that Defendant’s alleged negligent labeling caused the deceased’s injuries. Plaintiff’s fraud and fraudulent concealment claims failed based on the same reasoning. Finally, the court determined that Plaintiff’s design defect claim, based on the premise that Defendant should have altered the chemical makeup of its drug, was preempted because federal law prohibits Defendant from substituting a different ingredient prior to FDA approval.

General Causation


Defendants successfully moved for summary judgment on claims brought by hundreds of plaintiffs arising out of injuries allegedly caused by Mirena, an intrauterine contraceptive device (“IUD”) manufactured by Defendants. The crux of Defendants’ motion was that, after the exclusion of Plaintiffs’ experts pursuant to Daubert, there was not sufficient evidence of general causation as required in products liability actions. The court agreed with Defendants that this case, due to its medical complexity, required expert testimony. The
court went on, however, to discuss Plaintiffs’ argument that even in the absence of expert testimony, alleged admissions by the Defendants could create an issue of material fact. Plaintiffs pointed to a number of alleged admissions, including IUD labels, a “Dear Health Care Professional” letter written by Defendants to Canadian healthcare providers, and statements by Defendants’ employees and internal documents. After considering Plaintiffs’ argument regarding the alleged admissions, the court held that the admissions were not sufficiently clear, concrete, or detailed to allow a jury to find general causation without speculation.


Plaintiff asserted eleven causes of action against Defendant GlobalFoundries concerning a manufacturing tool that allegedly malfunctioned and exposed him to toxic substances while working at a GlobalFoundries facility. Plaintiff developed an autoimmune disease and suffered numerous physical and emotional ailments since undergoing “extensive chemotherapy, plasmapheresis, and steroid therapy.” Defendant moved to dismiss Plaintiff’s claims for strict products liability, breach of express warranty, breach of implied warranty, and willful and wanton misconduct. The court concluded that Plaintiff’s claims failed under the first three counts because the complaint lacked any plausible allegation that he was injured by a product or good that GlobalFoundries had sold or placed in the stream of commerce. The only allegation of harm attributable to GlobalFoundries was that the chemicals used in the Fab 8 plant caused or contributed to Plaintiff’s injuries, not the components of the products after they had been placed in the stream of commerce. The fourth claim, willful and wanton conduct, was not recognized as a standalone cause of action in New York. For the above reasons, the court granted the motion to dismiss in its entirety.

**Failure to Warn – Non-English-Speaking Plaintiff**


Plaintiffs, brought an action against Defendant Delta International Machinery Corp. ("Delta") for negligence, breach of warranty, breach of implied warranty of merchantability, strict liability, and loss of services in connection with injuries Alonso Lara (“Lara”) sustained while operating a table saw designed and manufactured by Delta. At the time of Lara’s injury, the Delta saw, which had been bought used, no longer had a blade guard affixed to the machine. Further, there was no instruction manual available. Lara’s employer’s president and production manager trained Lara on use of the saw and advised him to wear protective goggles and use a “push stick” to feed material through the saw. A warning placard was affixed to the saw, but Lara stated he had never read it or recalled that the placard was affixed to the saw. On May 22, 2015, Lara’s hand came in contact with the saw blade after a piece of wood he was cutting became dislodged and he was injured. Delta moved for summary judgement.

The court addressed Plaintiffs’ claims concerning: (1) defective design; (2) failure to warn; (3) breach of implied warranty; (4) breach of express warranty; (5) strict liability based upon an alleged manufacturing defect; and (5) loss of services. The court found that Plaintiffs failed to adequately allege a feasible alternate design after their expert’s testimony was barred and the fact that table saws have been found by law not to need an interlock if the blade guard was off. As to the failure to warn claim, the court acknowledged that because Lara could not read English and the only warnings were in English, the accident would have occurred in any event. The court then addressed whether the failure to warn was a substantial factor in Lara's injuries. While the court acknowledged that Lara never asserted he would read the warning if it was printed in Spanish, New York law allows a plaintiff to recover if he can demonstrate that adequate warnings would have come to the attention of a third party that could have informed him of the warnings. The court denied the motion to dismiss the failure to warn claim because reasonable minds could disagree as to whether adequate warnings would have come to the attention of Lara’s co-workers.
The court dismissed the breach of implied warranty claim because the statute of limitations accrues four years from the date the original purchaser of the saw takes possession. Because more than four years had accrued, this claim was barred by the statute of limitations. As to the claims for breach of express warranty, strict liability upon an alleged manufacturing defect, and loss of services, Plaintiff’s failure to address those claims in their opposition to Delta’s motion for summary judgment rendered them abandoned.

Expert Testimony & Daubert


This case arose in connection with an automobile accident in which M.R.O. died. Plaintiffs alleged, among other claims, that GM violated Connecticut’s product liability statute by distributing the 2004 Suburban in a defective condition and by not providing adequate instructions or warnings. Plaintiffs had two experts: Sgt. O’Brien (the officer in charge of investigating the incident), who Plaintiffs contended was an expert in the field of accident investigation and reconstruction, and McCracken, an engineer, who was to testify regarding the reconstruction of the collision as well as the design and function of the brake transmission shift interlock (“BTSI”). GM moved to exclude the experts and moved for summary judgment, based on its allegations that Plaintiffs’ expert testimony was inadmissible.

GM moved to exclude O’Brien’s testimony, asserting that it was unreliable because the analytical gap between the data and opinion proffered was too great and relying on the facts that O’Brien did not interview M.O., assumed, rather than concluded based on measurements that M.R.O. could not reach the brake pedal, and assumed that M.R.O. did not turn on the engine, without adequately considering the alternative. The court denied the motion to exclude because O’Brien had relied on sufficient facts and data, finding that his report was the product of the same method he had used in countless other accident investigations, and because he applied his method reliably to the facts of the case.

GM also moved to exclude McCracken’s product defect testimony. The court characterized McCracken as offering 3 product defect opinions: (1) that the automobile industry was aware of the particular risk; (2) that GM was capable of manufacturing the 2004 Suburban with a BTSI function that was active in the accessory position; and (3) that GM was capable of retrofitting the 2004 Suburban so as to make the BTSI function active in the Accessory position. GM characterized McCracken’s conclusion as stating that “emerging technology in motor vehicle design renders defective all vehicles which do not have the technology,” and asserted that opinion was inconsistent with substantive product liability law. The court rejected GM’s characterization of McCracken’s testimony. GM also argued that his opinion conflicted with applicable federal law because federal regulations in place in 2004 did not require that automobiles include a BTSI function that was active in all ignition positions. Again, however, the court did not read McCracken’s product defect opinion as standing for that proposition. The court also rejected GM’s argument that McCracken’s reliance on an occurrence in 2003 constituted reliance on subsequent remedial measures. GM also contended that McCracken’s opinions were unreliable. The court concluded McCracken’s first two opinions were based on reliable methodologies but that his third opinion was based on unreliable methodology, as his alternative design and the GM representative testimony did not provide a reliable basis for his conclusion. GM also sought to exclude McCracken’s causation opinion on the ground that it was unreliable. The court determined that McCracken could rely on O’Brien’s report. Additionally, the court held that McCracken was not required to rule out every possibility. The court also relied on the fact that McCracken did consider the possibility that the key had been turned to the run position but ultimately concluded based on his technical analysis that it had not been. Finally, the court did not find it dispositive that McCracken did not plot the car’s travel path or trajectory or calculated its speed as it rolled.
Because Plaintiffs’ expert testimony was admissible, the court rejected GM’s motion for summary judgment on the product defect claim. As to the failure to warn/inadequate warning claim, GM argued that summary judgment was due to be granted because Plaintiff did not offer an expert on the adequacy of the warning. The court however was not aware of any authority in which a court applying Connecticut law had held that expert testimony was required, as a matter of law, in order to prevail on an inadequate warning claim. Indeed, the court decided it would not go beyond the ordinary knowledge and experience to ask a lay person to look at the warnings contained in the owners’ manual and determine if the warnings were sufficient.


Plaintiff alleged she was injured (suffering frostbite) by leaking oxygen when she attempted to disconnect a portable unit for an oxygen reservoir tank. Plaintiff brought claims for strict product liability and negligence against Lincare, which leased the oxygen system to Plaintiff but did not manufacture the system. On the day of the incident, a representative of Lincare provided instructions to Plaintiff, via telephone, of how to remove the portable unit from the reservoir unit. Lincare contended that the temperature of the oxygen vapor was not low enough to freeze skin and that the oxygen tank could not have caused Plaintiff’s injury. Plaintiff offered expert testimony from a certified safety professional. The court excluded the expert’s opinion that the manufacturer’s instructions were inadequate, because “the question of whether a manufacturer provided adequate warnings about foreseeable danger is a question of fact properly left to the jury.” The court also excluded the expert’s opinion that the Lincare representative’s advice to Plaintiff was in defiance of the manufacturer’s instructions, because that opinion intruded on the province of the factfinder as it was a matter capable of being understood and decided without an expert’s help. The expert opined that the Lincare representative’s advice was the cause of Plaintiff’s injury, based on his acceptance of her version of facts. The expert never inspected or tested the unit and conceded that the unit had never been tested, and as such, the reason why it leaked is unknown. Thus, the court determined that the expert was simply “acting as a conduit for another witness’s testimony in the guise of an expert’s opinion.” Finally, the court excluded certain opinions that had not been previously disclosed.

The court granted summary judgment in favor of Lincare on the strict product liability claim, finding that Plaintiff had presented no evidence of a defect in the system. The court relied on the fact that the system had functioned for four years without issue. For the same reason, the court granted summary judgment in favor of Lincare on the negligence claim alleging failure to inspect and/or discover a defect. However, the court determined there was an issue of triable fact as to Plaintiff’s claim that she would not have been injured but for the Lincare representative’s unreasonable advice that put her in close proximity to the leaking system.

**Preemption**


Plaintiff alleged that Essure (a permanent contraceptive device manufactured by Beyer Corp. and related defendants) caused her injuries. The FDA issued premarket approval of Essure in 2002. Plaintiff alleged that the FDA cited Defendants for numerous violations of regulations on various dates from 2003 to 2013, including that Defendants were producing devices at an unlicensed facility, that Defendants had used a non-conforming material in at least one facility, and that Defendants had failed to report adverse events to the FDA. Plaintiff also alleged that Defendants inadequately trained doctors to perform the Essure insertion procedure. Plaintiff’s complaint did not allege any facts to indicate that her device was improperly implanted, that it broke, or that it had any other manufacturing defect, or that Plaintiff or her doctor relied on any particular information or warnings about the device.
Defendant moved to dismiss Plaintiff’s complaint, arguing that many, if not all, of Plaintiff’s claims were preempted by the Food, Drug, and Cosmetic Act (“FDCA”), as well as the Medical Device Amendments (“MDA”) to the FDCA. According to the court, a plaintiff’s state law claim arising from the use of a medical device must fit into a “narrow” gap to avoid express or implied preemption: “the plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by §360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such claim would be implied preempted under Buckman Co v. Plaintiff's Legal Comm., 531 U.S. 341, 353 (2001)).” First, Plaintiff brought claims for strict products liability and for negligent manufacturing, principally relying on Form 484 (an FDA violation report) indicating that Defendants had used a nonconforming material in production of Essure at least one plant. According to the court, to avoid preemption, Plaintiff must allege that her device was not manufactured in conformance with the specifications approved by the FDA. However, Plaintiff did not allege any plausible reason to think that her device came from the non-conforming batch or that it suffered from any other manufacturing defect. In any case, Plaintiff did not allege sufficient facts to establish causation. Therefore, the court dismissed the claims. Second, Plaintiff also alleged that Defendants were liable because they failed to report certain adverse events to the FDA, which they were required to report. The court dismissed this claim, concluding that Connecticut law did not create any parallel duty to report such events to the FDA. Therefore, the failure-to-warn claim arose solely based on the MDAs reporting requirements and was therefore subject to implied preemption. Third, the court determined that even assuming there was a cause of action under Connecticut law for negligent training, there is no dispute that it would require Plaintiff to show a causal connection between the violation of a duty and the harm she suffered, which Plaintiff’s complaint did not plausibly suggest. Fourth, the court determined that Plaintiff’s negligence per se claims were impliedly preempted because they arose directly and not wholly derivatively from the violation of federal law. Finally, as to Plaintiff’s negligent misrepresentation and breach of express warranty claims, the central issue was whether any of the misrepresentations were not approved by the FDA during the PMA process. As to the statements that Plaintiff did argue were not approved by the FDA, the court concluded that those statements were not actionable because the claim was either so similar to the approved language so as to be substantively the same or Plaintiff had not properly alleged any actual misrepresentation or that she was actually deceived or that she relied on the alleged warranty.


Plaintiff asserted claims against the manufacturer of hip implant parts, asserting claims under the Connecticut Product Liability Act. There were several devices at issue. The R3 Acetabular System consists of an Acetabular Cup and one of several possible liners. It is used with Defendants’ Echelon Hip Stems, Modular Femoral Heads, and Modular Head Sleeves. Defendant also manufactured the Birmingham Hip Resurfacing System (“BHR”), as well as the R3 Acetabular Liner. Prior to Plaintiff’s surgeries, Defendant received 510(k) approval from the FDA for the R3 Acetabular System and the components it was used with. Also prior to Plaintiff’s surgery, Defendant received FDA premarket approval for marketing the BHR. In 2008, the R3 Acetabular Liner became a Class III component to be used with the BHR System. As of February 2009, Defendant manufactured the R3 Acetabular Liner for use with the R3 Acetabular System. Plaintiff underwent left and right hip implants on August 25 and November 10, 2009. Plaintiff alleged that the implanted devices (the R3 Acetabular Liners, Modular Femoral Heads, Modular Head Sleeves and Echelon Hip Stems) caused the accelerated release of metal ions and debris into her body, causing her injury.

Defendant moved to dismiss based on preemption, pursuant to the Medical Device Amendments to the Food, Drug, and Cosmetic Act. According to the court, “common law tort claims are expressly preempted
to the extent that such claims impose a standard different from or in addition to federal requirements, and
to the extent that such claims relate to the safety and effectiveness of Class III devices subject to premarket
approval.” However, claims related to medical devices approved through the 510(k) process are not subject to
preemption. With respect to implied preemption, the court provided that a state law parallel claim can exist
where the conduct on which the claim is premised is the type of conduct that would traditionally give rise to
liability under state law, even if the FDCA had never been enacted. With regard to the claims involving the A3
Acetabular Liner the court found as follows. First, the court found that Plaintiff’s strict liability and negligence
claims asserted on the basis of an alleged defect with the R3 Acetabular Liner were expressly preempted as
those claims cast doubt on the FDA’s findings concerning safety of the device’s design. Second, the court found
plausible parallel claims sounding in negligence for failure to warn or failure to report in volition of federal
requirements. Third, the court held that Plaintiff’s claims alleging breach of implied warranty based on the
A3 Acetabular Liner and innocent and negligent misrepresentation were preempted because they implicate
the FDA’s review of the safety and effectiveness of the Class III Liner and impose standards different from the
federal requirements. However, the breach of express warranty claims were not preempted, because the MDA
does not prohibit a manufacturer from imposing upon itself contractual standards that differ from federal
requirements (even for Class III devices).

The court then addressed the claims asserted by Plaintiff based on the combination of components.
Defendant argued that Plaintiff’s claims asserting injuries based on the A3 Acetabular System should be dis-
misseased due to the System’s inclusion of the R3 Acetabular Liner (a Class III device). The court determined
that, unlike the cases cited by Defendants, the instant action involved injuries stemming from the combina-
tion of the component parts. Thus, the court declined to separate the device into its component parts to cre-
ate express preemption and therefore denied the motion to dismiss. With regard to the claims by Plaintiff that
Defendant perpetrated fraud on the FDA, the court found those claims were preempted. Finally, Defendant
argued that Plaintiff’s claims were due to be dismissed for failure to state a plausible claim. The court dis-
missed the breach of express warranty claim finding the pleadings were not sufficient but permitted Plaintiff
to replead the claims to state a plausible claims for relief. The court found Plaintiff had adequately alleged that
the hip implant system contained defects and caused complications and thus refused to deny on that basis
(with the caveat that to the extent the claim was premised on the R3 Acetabular Liner’s federally-approved
design, such claim was preempted).


Defendant, which manufactured the hip-replacement device that was implanted in Plaintiff, suc-
cessfully moved to dismiss Plaintiff’s claims on the basis that they were preempted by federal law and, alter-
atively, that Plaintiff failed to state a claim for relief. The hip-implant manufactured by Defendant required
the use of a liner component which, in the device implanted in Plaintiff, was normally composed of a polymer
plastic. Plaintiff’s physician, with Plaintiff’s consent, chose a metal liner to implant instead. Plaintiff subse-
quently developed severe complications, including significant pain and the growth of a pseudotumor. Con-
sistent with the failure of a metal liner, lab testing revealed a high metal content in Plaintiff’s blood. The FDA
approved the system that Plaintiff’s physician implanted through the streamlined §510(k) approval proce-
dure; however, it was approved with use of the polymer liner rather than the metal liner that was ultimately
implanted in Plaintiff. The metal liner was originally approved through the more demanding premarket
approval process as a part of a different hip replacement system. After approval of the metal liner, the FDA
instructed manufacturers to conduct post-marketing surveillance following recalls of other unrelated metal-
on-metal hip implants. Defendant voluntarily recalled the metal liners one year later after finding a higher
than expected number of revision surgeries in patients with those liners. Plaintiff asserted a variety of claims
under the Connecticut Product Liability Act, and Defendant moved to dismiss all claims as preempted by federal law and because Plaintiff failed to state a claim for relief.

Federal law largely protects medical device manufacturers from state law tort claims if that manufacturer has complied with federal regulatory requirements. The Medical Device Amendments to the Food, Drug, and Cosmetic Act (FDCA) contains an express preemption clause that prevents application of state law that would impose requirements “different from, or in addition to” federal requirements. 21 U.S.C. §360k(a). The Supreme Court has also held that state law claims are impliedly preempted under the FDCA if the sole grounds for liability under state law is based on a violation of the FDCA. See Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 349 (2001). The scope of federal preemption varies widely depending on whether a device was approved through the stringent premarket approval process or the more streamlined §510(k) approval process. Courts within the Second Circuit disagree as to the scope of the preemption where, as here, a component that is subject to the more stringent review is later used in a device that was approved through the §510(k) approval process.
The court, in granting Defendant’s motion to dismiss, noted that where a component has been approved through the premarket approval process, it should not lose the protection of express preemption simply because a physician later chooses to use that component with a §510(k)-approved device.

IV. Third Circuit


Third Circuit, applying Wisconsin law, reversed a trial court grant of summary judgment in favor of asbestos defendant based on holding of Frankenberger v. CBS Corp. (In re Asbestos Prod. Liab. Litig. (No. VI)), 837 F.3d 231 (3d Cir. 2016). In Zellner, similar to the prior Frankenberger decision, the Third Circuit found that expert testimony to the effect that a “switchgear’s asbestos-containing parts would likely deteriorate and release asbestos dust during maintenance” combined with the decedent’s former co-worker’s testimony that they worked in close proximity to the switchgear and were exposed to dust when maintenance was performed was sufficient to establish a question of fact as to the decedent-plaintiff’s exposure to asbestos, even though the decedent did not himself perform the maintenance. In effect, the Court held that “evidence of deterioration and asbestos exposure was sufficient [for plaintiff] to survive summary judgment” especially in light of additional expert testimony to the effect that normal wear and tear of the switchgear causes deterioration that often causes “some asbestos containing materials to flake off, break, or crumble” such that the defendant had an internal memorandum that “explicitly states that cleaning switchgear components could cause asbestos to become airborne and that protective equipment should be worn.


Third Circuit affirmed trial court granting of summary judgment on behalf of replacement hip manufacturer on the grounds that plaintiff failed to present triable issue of fact related to breach and causation in negligent design and negligent warning claims (the only claims left at the time of summary judgment). The Court rejected plaintiff’s attempt to use proof of another failed hip replacement on a different patient as such evidence is not admissible, given that it does not involve the same product and could not inform notice related to the danger presented to this plaintiff. The Court noted plaintiff’s various contentions with respect to the allegedly malfeasant design, but rejected plaintiff’s argument for failure to adduce evidence that the design decisions made by defendant were unreasonable. The Court also agreed with the trial court that plaintiff failed to present evidence that the warning were insufficient, notwithstanding that plaintiff presented evidence that
another manufacturer issued a contraindication for the product that may have included plaintiff had it been a part of the warning for the product at issue, i.e. plaintiff presented no evidence that the "weaker warning was unreasonable."

_Frankenberger v. CBS Corp. (In re Asbestos Prod. Liab. Litig. (No. VI)), 837 F.3d 231 (3d Cir. 2016)_

A precedental case in which the Third Circuit, applying Indiana law, rejected the trial court's grant of summary judgment for an asbestos defendant and ruled that there were triable issues of fact where plaintiff presented evidence that: (1) the product allegedly linked to plaintiff's asbestos exposure in fact contained asbestos and was supplied by the defendant; (2) a co-worker testified that dust was blown out of the product during maintenance; (3) the defendant admitted that some of the products contain asbestos; and (4) plaintiff's expert testified that the asbestos-containing portion of the product will likely deteriorate and in so doing release asbestos dust during maintenance.

_In re Asbestos Prod. Liab. Litig. (No. VI), 822 F.3d 125 (3d Cir. 2016)_

The court reversed dismissal of the plaintiff's complaint on the grounds that the district court erred by considering extrinsic evidence and that a fact issue regarding preemption precluded summary judgment. The plaintiff had filed suit alleging state law cause of actions based on her husband's exposure to asbestos while working for a railway company. The defendants moved to dismiss, on the plaintiff's claims as preempted by the Locomotive Inspection Act and the Safety Appliance Act. The district court granted the motion, and plaintiff appealed.

The court reversed, finding that the district court had erroneously relied on extrinsic evidence to establish that plaintiff's decedent's work on asbestos-insulated pipes were joined to "create a 'system of pipes'" that was an "essential and integral part of the completed locomotive" and thereby covered under the LIA and SIA. The court found that nowhere in plaintiff's complaint did she use the term "locomotive" and that only by relying on extrinsic evidence could the district court have reached this conclusion.

The Court then found that dismissal of the case was also inappropriate under summary judgment. First, the defendants did not produce any evidence supporting their assertion that the pipes that caused the decedent's asbestos exposure were part of an "interconnected system" with the locomotive. Second, even if there was evidence in the pleadings, it was contradicted by the plaintiff's affidavit that the pipes were connected to "power cars" and not the locomotive of the train, thereby creating a genuine dispute of material fact precluding summary judgment on the basis of preemption. Accordingly, the court reversed the district court's ruling and remanded the case for further proceedings.

_Sikkelee v. Precision Airmotive Corp., 822 F.3d 680 (3d Cir. 2016), cert. denied sub nom. AVCO Corp. v. Sikkelee (U.S. Nov. 28, 2016)_

In _Sikkelee_, the court ruled that issuance of a type certificate by the Federal Aviation Administration ("FAA") did not preempt a plaintiff's state law products liability claims of defective design or manufacture. The plaintiff brought a wrongful death claim alleging that the defendant's product was defectively designed and manufactured, causing the plane crash that killed her husband. The defendant moved for summary judgment arguing that the FAA issued type certificate, which is intended to serve as federal governmental confirmation that an aviation product meets FAA design standards, preempted the plaintiff's state law products liability claims. The district court granted summary judgment and the plaintiff appealed.

On appeal, the Third Circuit reversed on several grounds and remanded the case to the district court. The court found that its prior decision in _Abdullah v. American Airlines_, 181 F.3d 363 (3d Cir. 1999), which had stated that the Federal Aviation Act "preempted the field of aviation safety," was limited only to "in-air operations." The court ruled that the "catch-all" regulation that had provided for preemption in _Abdullah_ did
not apply to the manufacture and design of aircrafts or aviation products. Further, the court found that there was insufficient evidence of congressional intent to support field preemption, based on its review of the Federal Aviation Act, the Federal Aviation Regulations, and the statute of repose in the General Aviation Revitalization Act of 1994. In particular, it noted that the Federal Aviation Act set only “minimum standards” and provided that its remedies were “in addition to any other remedies provided by law.”

In further support of its ruling, the court reasoned that the Supreme Court has been hesitant to extend field preemption in the area of transportation law. It also noted that other circuits have either found that the entire field of aviation safety is not preempted or have excepted product liability claims from preemption. Although the court found that field preemption was not applicable, it acknowledged that conflict preemption could occur where a “manufacturer’s compliance with both the type certificate and a state law standard of care is a physical impossibility.”

**DISTRICT OF NEW JERSEY**


District Court granted pre-answer motion to dismiss product liability/toxic tort complaint associated with alleged exposure to formaldehyde-based embalming products on grounds that plaintiffs failed to adequately plead causes of action and on failure to adequately plead personal jurisdiction. Specifically, plaintiff failed, under *Twombly/Iqbal*, to adequately plead “when, where, of even if” plaintiff was exposed to defendants’ products, and also failed to plead any facts indicating that the defendants were present in and thus subject to jurisdiction in New Jersey. The Court granted plaintiff the right to re-plead. In addition, despite dismissing the complaint, the Court ruled that formaldehyde-based embalming products are “merchandise” under the New Jersey Consumer Fraud Act.


Defendant motion to dismiss granted in part for claims arising from plaintiff-decedent’s death after being caught in conveyer belt. Among the part of the motion granted was a motion to dismiss the Product Liability Act claim act with respect to plaintiff-decedent’s heirs (including the executrix of the estate who sued in her individual capacity). The Court ruled that, although it is unclear whether a plaintiff needs to allege physical harm for a products liability claim, it is clear that the law requires that each plaintiff allege harm specific to the plaintiff bringing the claim, something the heir-plaintiffs did not do. Thus, the product liability claims could not be asserted by the heirs.


Court dismissed plaintiff’s Product Liability Act claims (with leave to re-plead) for failure to allege cognizable harm under the statute; the claim asserted various defects, but no statutorily recognized harm. The Court sustained the Consumer Fraud Act claim.


Under Rules 12(b)(6) and 8(a)(2), the Court dismissed plaintiff’s complaint that gas cans sold by defendant were defective because the complaint failed to allege the gasoline can’s intended purpose, a requirement of a product liability claim. Dismissal was without prejudice.


Defendant moved to dismiss the amended complaint that now addressed the Court’s concern regarding the gasoline can’s intended purpose; the Court granted dismissal, without prejudice, for plaintiff’s failure to allege that plaintiff was a reasonably foreseeable user.

In an MDL involving 1900 plaintiffs who ingested olmesartan containing prescription drugs to alleviate hypertension, allegations included that defendants designed, manufactured, and sold the drugs at issue, and certain defendants marketed the drugs. The Court denied Plaintiffs’ request to file Summary Judgment Motion on Submitted Exhibits, based on the Minera rule that plaintiffs in products liability cases must offer admissible expert testimony regarding general causation and specific causation. Plaintiffs attempted to proffer purported admissions as substitutes for expert testimony, and the Court ruled in denying the use of those admissions that they must be “clear, unambiguous, and concrete” and suffice to prove, without speculation, the mechanism by which the drugs at issue may generally cause the injuries at issue (i.e. general causation). No exhibit or combination of exhibits could resolve the jury speculation as to the complex biochemical, biological, and epidemiological information that accompanies the causation question absent expert testimony.

The insufficient evidence submitted by plaintiffs included, among others: (1) excerpts from physician depositions that could not sufficiently show causation; (2) emails from physicians that did not detail the causal link between the drugs and the injuries; and (3) excerpts from the deposition of a defendant’s employee who collaborated on the development of the chemical that also does not demonstrate causation.


Plaintiffs brought a putative class action alleging defendant’s inability to cure a defective fuel tank in certain Ford F-Series Super Duty trucks and E-Series Vans under theories of breach of express warranty, breach of the implied contractual covenant of good faith and The Court’s granted summary judgment in part based on plaintiff’s inability or refusal to specify the type of defect present in the fuel tanks (design or manufacture), in part because it found Ford was not contractually obligated by its warranty to cover design defects and its replacements of the fuel tanks could not have violated the customer’s legitimate expectations and deprived customers of the fruits of the contract, and in part because plaintiff provided no arguments showing defendant’s duty to disclose (and NJ Courts will not impose a duty to disclose on manufacturers).


Plaintiff alleged defendant's vacuum product was defective, did not work properly, caused his home electrical outlet to catch on fire, and prevented him from using the outlet as a result of defects and product malfunctions that defendant was aware of and failed to disclose to consumers. Defendant argued for dismissal on the grounds that the CFA claim is subsumed by the PLA since the core issue of the action is not the harm to the defective product but rather the harm to plaintiff’s other property. The Court ruled that the CFA claim is not subsumed by the PLA because the core issue or “heart” of the lawsuit is still the defect in the product and the additional damages are only mentioned sporadically in the complaint, not discussed in the relevant harms and damages section, and therefore do not cause the CFA claim to be subsumed by the PLA. However, the Court accepted defendant’s alternative argument that the CFA claim should be dismissed because plaintiff failed to plead the “ascertainable loss” element of a CFA claim for lack of demonstrating either out-of-pocket loss or demonstrated loss in value. The Court ruled that plaintiff’s allegation of loss of the purchase price of the product does not meet the ascertainable loss requirement, because it is the replacement cost that constitutes ascertainable loss, and none of plaintiff’s other potential expenses had cost estimates.

**EASTERN DISTRICT OF PENNSYLVANIA**


In _Shuker_, following complications from a total hip replacement, plaintiff brought suit against the manufacturer of a hip replacement system alleging parallel state-law claims for negligence, fraud, and loss of consortium arguing that they were not preempted by the Federal Food, Drug, and Cosmetic Act (“FDCA”)
based on the manufacturer’s alleged off-label promotion of a particular component. Plaintiff relied on a press release issued by the manufacturer which he alleged actively marketed the component at issue in such a way as to lead his surgeon to believe that the component was safe for use with the system that was installed in plaintiff, even though it had only been approved for installation with another hip replacement system. Defendant moved to dismiss the plaintiff’s claims on the grounds they were preempted by the Medical Device Amendments (“MDA”) to the FDCA.

The court granted dismissal finding that the press release did not sufficiently support plaintiff’s claims of off-label promotion as the press release disclosed that the component had multiple uses and nowhere affirmatively recommended the component for use in hip replacement, “much less suggest[ed] [it] was safe or appropriate for such procedures.” Finding that no other facts alleged supported a non-preempted claim, the court granted the motion to dismiss.


In _Hatcher_, the plaintiff brought suit after he was injured by spinning blades while using an industrial woodworking machine, alleging breach of express and implied warranties, defective manufacture and design, and failure to warn. The court granted the manufacturer’s motion for summary judgment. The court found that the warranty claims were barred by the statute of limitations as the claims accrued when the plaintiff’s employer first purchased the machine. The court also found that the plaintiff failed to establish a defective manufacturing or design claim. Furthermore, the court ruled that the failure to warn claim failed as the danger of the spinning blade was obvious and regardless, the warnings in the accompanying manual were adequate to alert the user of any unobvious dangers from using the machine without a blade guard.

_In Re Zoloft (Sertralinehydrochloride) Products Liability Litigation_, 176 F. Supp. 3d 483 (E.D. Pa. 2016)

The court granted summary judgment finding the plaintiffs were unable to establish general causation. The court found that after multiple Daubert proceedings resulted in plaintiffs’ experts being unable to testify as to general causation, the plaintiff could not establish that Zoloft caused birth defects. The court rejected plaintiffs’ attempts to establish causation by using the differential diagnoses performed by a non-designated and non-treating physician to establish causation, or adverse reports that had been submitted to the FDA. Although the court noted that such adverse reports could form the basis of a study hypothesis, they were insufficient to support general causation. Accordingly, the court granted defendants’ motion for summary judgment.


Five plaintiffs brought separate suits against Bayer alleging injuries suffered as a result of using the female birth control device, Essure. The cases were consolidated and Bayer moved for judgment on the pleadings. The court dismissed the plaintiffs’ negligent training count, alleging that Bayer failed to properly train the implanting physicians, finding that although the claims were not preempted, plaintiffs could not sufficiently plead how the training departed from FDA guidelines or caused their injuries. The court also dismissed the plaintiff’s negligent entrustment count finding that the claim was preempted by the FDA’s safety requirements as to the qualifications of the implanting physicians. The court further dismissed plaintiff’s remaining claims except their claims of negligent misrepresentation and negligent failure to warn.

MIDDLE DISTRICT OF PENNSYLVANIA


In _Talarico_, the court reiterated that failure to recall or retrofit a product after its sale was not a basis for products liability under Pennsylvania law.
The case arose following the plaintiff’s decedent being fatally injured while using the defendant lessor’s scissor lift. The lessor moved to dismiss arguing that plaintiff’s negligence claim based on “failing to recall” the scissor lift was not a recognized cause of action. The court found that Pennsylvania had never recognized a post-sale duty to recall and/or retrofit products when the product was not defective at the time of sale. Accordingly, it found that no independent negligence cause of action exists in Pennsylvania for failure to recall and/or retrofit, and granted the motion to dismiss.

DISTRICT OF DELAWARE


Plaintiff alleges asbestos exposure that occurred while plaintiff worked as a mechanic over the course of six decades caused plaintiff’s mesothelioma and eventually death. The parties agreed to apply Mississippi law to this diversity case, given that a majority of the exposure took place in Mississippi. The Court granted defendants’ motions for summary judgment based on the Mississippi Products Liability Act (“MPLA”) which provides that to bring a claim for strict liability, a plaintiff must prove that at the time the product left the control of the manufacturer or seller the product contained a manufacturing or design defect, inadequate warnings, or breached an express warranty. Plaintiff could not prove he had sufficient exposure to some defendants’ products, and could not prove that certain defendants’ products actually contained asbestos. The Court also considered the “Bare Metal Defense” under which courts refuse to impose liability upon manufacturers for dangers associated with asbestos-containing products manufactured and distributed by other entities and ultimately granted Defendants’ motions for summary judgment.

NEW JERSEY STATE COURT


In a case of first impression certified to the Court by the Third Circuit, New Jersey’s highest court held that a landowner can have an extended duty with respect to toxins that are associated with so-called “take-home” liability toxic torts. The Court extended the rule, set out in Olivo v. Owens-Illinois, Inc., 186 N.J. 394 (2006) that held that a landlord can be held liable for injuries sustained by the spouse of a worker exposed to asbestos on the landowner’s property, to the extent the spouse’s exposure is the result of work performed there. In Schwartz, the Court refused to adopt a bright-line rule, but acknowledged and held that Olivo and the standard of care could be expanded to include non-spouse plaintiffs exposed through take-home toxic torts, given an assessment of factors including foreseeability, fairness, and predictability.


Appellate Court upheld trial court’s ruling that plaintiff could prevail on a products liability claim given the evidence adduced at trial, even in the absence of a products liability claim in the complaint itself in action associated with damage to home arising from power supplies associated with solar panels. Defendant moved at the conclusion of trial for an involuntary dismissal that the trial court denied, instead going on to rule that the court has the discretion to instruct the jury on claims not present in the pleading (which the court ultimately did).

DELAWARE STATE COURT


Court granted summary judgment to defendants on grounds that plaintiff must rely on expert testimony to establish both the existence of a defect and causation associated with that defect in product liability claim in which plaintiff alleged that a defect in a Toyota vehicle caused the vehicle to accelerate and thus
created an accident. The Court further held that proof of a defect was a requirement for plaintiff’s negligence claim because the negligence claim relied on the existence of a defect.

V. Fourth Circuit

Federal Officer Removal

Asbestos Litigation

_Hurley v. CBS Corp._, 648 F. App’x 299 (4th Cir. 2016)

In _Hurley_, multiple plaintiffs brought a wrongful death suit alleging injuries caused by exposure to asbestos-containing products sold and/or installed by the named defendants. General Electric Corporation (“GE”) removed the cases to federal court pursuant to federal officer jurisdiction. The district court ultimately granted summary judgment in favor of defendants. On appeal to the Fourth Circuit, plaintiffs challenged the removal in addition to their challenge to the district court’s grant of summary judgment.

The Fourth Circuit affirmed the removal pursuant to 28 U.S.C. §1442 (a)(1) and found that GE satisfied all three requirements for federal officer removal. First, GE was considered a “person acting under” a federal officer because it was acting under a valid governmental contract at all relevant times. The Fourth Circuit cited _Ruppel v. CBS Corp._, 701 F.3d 1176 (7th Cir. 2012) in support of this finding. Second, GE was found to have raised a colorable defense to plaintiffs’ claims, specifically, that GE was protected as a government contractor. Finally, the Fourth Circuit found plaintiffs’ allegations of negligence and failure to warn of asbestos-containing turbines and generators which GE installed and produced, where done pursuant to contracts with the Navy. Therefore, the Fourth Circuit held that the district court properly exercised jurisdiction over the cases.

Also, summary judgment as to all defendants was affirmed. The Fourth Circuit confirmed that the district court properly applied the “frequency, regularity, and proximity test” when determining whether injuries were proximately caused by asbestos-containing products, so as to establish liability for wrongful death under Maryland law.


Government contractors faced claims in Virginia state court for failing to warn of asbestos hazards and removed to the United States District Court for the Eastern District of Virginia pursuant to the federal officer removal statute. The district court remanded to state court citing longstanding precedent in the Eastern District of Virginia that denied the government contractor defense in failure to warn cases (i.e. holding that the second prong of 28 U.S.C. §1442 (a)(1) was not met sufficient for removal). The Fourth Circuit reversed, holding that the government contractor defense does apply in failure to warn cases. The Fourth Circuit remarked that no other jurisdiction that has considered this issue agrees with the Eastern District of Virginia.

The Fourth Circuit noted that proof of a “colorable” federal defense does not require that the defendant must win its case before having it removed, nor even establish that the defense is “clearly sustainable.” The case of reference concerning when the government contractor defense applies is _Boyle v. United Technologies Corp._, 487 U.S. 500, 108 S.Ct. 2510, 101 L.Ed.2d 442 (1988). The Fourth Circuit determined that the rationales identified in _Boyle_ remain applicable in failure to warn cases. The Fourth Circuit noted that just as decisions on military equipment design involve complex cost-benefit analyses in which the trier of fact is not well versed, “military procurement contracts and specifications involve manifold warning and labeling requirements inapplicable to nonmilitary equipment.” Further the separation of powers of the judiciary from military matters was a consideration. In sum, the Fourth Circuit “join[ed] the chorus” to hold that the government contractor defense is available in failure to warn cases. Having established this, the Fourth Circuit
remanded to the district court to decide whether there was sufficient proof to warrant removal pursuant to §1442.

Evidence

Transvaginal Surgical Mesh Litigation


A consumer of a transvaginal surgical mesh product brought an action against manufacturer, C.R. Bard, Inc. ("Bard") in the District Court for the Southern District of West Virginia. This is one of approximately 70,000 cases against the proprietors of transvaginal mesh medical devices used to treat pelvic issues. Several issues were raised on appeal by Bard, including, in pertinent part, evidentiary issues concerning Federal Rules of Evidence 403, 803 (17), 803 (18) and FRE 807.

Bard first argued that the district court abused its discretion in granting the consumer's motion in limine to exclude all evidence relating to Bard's compliance with the FDA's Section 510(k) product safety process. The Fourth Circuit affirmed the district court's ruling based on Rule 403, and opined that “the clear weight of persuasive and controlling authority favors a finding that the 510(k) procedures is of little or no evidentiary value." The district court excluded the evidence in part because allowing in such evidence would permit a “mini-trial” of sorts which presents a danger of misleading the jury and confusing the issues. The Fourth Circuit noted that while the 510(k) clearance might provide some evidence of the safety of the cleared product, it does not say very much “that is specific.” Thus, the Fourth Circuit affirmed the district court's finding in excluding the 510(k) evidence as its value would be more prejudicial than probative pursuant to Rule 403.

Second, Bard appealed the district court's denial of its motion in limine to exclude a material data safety sheet ("MSDS") on the basis that the MSDS was hearsay outside an exception. The district court allowed the MSDS to come into evidence for the limited purpose of showing that the statement was made and that Bard was aware of it. Also, the court sua sponte ruled that the MSDS was admissible for its truth under the hearsay exceptions of FRE 803 (17), 803 (18) and 807.

As to Rule 803 (17), the Fourth Circuit found that the district court erred in finding that the MSDS was admissible pursuant to this exception as it is not a market quotation, list, directory, or "other compilation" that is generally relied on by the public. The portion of report that consumer sought to rely on did not warrant presumption of reliability of numbers and data sets typically admitted under exception, since it was an opinion by the manufacturer of the material used in the product that the material was not fit for human implantation. As to Rule 803 (18), the Fourth Circuit also found that the MSDS was not admissible under this exception as it was not relied on by an expert. Because the MSDS was “nothing more than an assertion made by the self-interested manufacturer of polypropylene” it was also not admissible for its truth pursuant to Rule 807, the residual exception to Rules 803 and 804.

Despite the abuse of discretion noted (as to the Court's sua sponte ruling that the MSDS was admissible for its truth), the Fourth Circuit ultimately found that the MSDS warning was admitted only to show that Phillips made and Bard received the warning statement, despite Bard's argument on appeal that the MSDS was used for the truth of the matter. Accordingly, the judgment of the district court was affirmed.

Maryland Experts


The District Court of Maryland granted Defendant, Buyers Products Company's ("BPC") Motion in limine to exclude Plaintiff's expert, Michael Leshner ("Leshner") and BPC's motion for summary judgment. Plaintiff asserted claims against BPC for defects in both design and manufacturing of a swing-away trailer jack
for personal injury sustained when the jack collapsed, causing Plaintiff’s trailer to crush his hand. Leshner, a mechanical expert, was retained to opine as to the cause of accident and the defects of the BPC jack.

In sum, the district court found that Leshner’s testing methods lacked any objective and independent verification. For one, the district court found significant that Leshner did not examine the “burring or tapering” of Plaintiff’s actual BPC jack; rather, he examined irregularities in an “exemplar BPC jack.” Leshner compared the specifications of the exemplar BPC jack with a Fulton jack, to those of another company Waldes Truarc, using a chart he obtained from the Waldes Truarc catalog. Leshner cites the Waldes Truarc chart as proof of standardization in the industry and opines that Waldes Truarc is the “dominant manufacturer” without identifying why. This contradicted his deposition testimony that there are no published industry standards for swing-away jacks like those manufactured by BPC.

The district court noted that it is “insufficient to identify only one other competing product, note that the product is different, and conclude, without any scientific methodology or basis, that the second product is superior and the first product is therefore defective.” The district court found that because Leshner’s investigation lacked proper methodology and independent verification of his hypothesis, his opinions as to whether BPC’s jack was defective in either manufacturing or design were excluded. Without the expert testimony of Leshner, Plaintiff claims that the jack was defective failed, and summary judgment was entered in favor of BPC.

**North Carolina Preemption**


Plaintiff brought wrongful death claims against name brand manufacturers for fraudulent and negligent actions in promoting a drug under the name Cordarone®/amiodarone for off-label use for allegedly failing to adequately inform of dangers thereof and failing to provide a medication guide to distributors. Defendants’ Rule 12(b)(6) motions to dismiss were granted.

The failure to warn claim against the generic defendants, which is premised upon failure to provide adequate warnings accompanying the sale and distribution of amiodarone, is preempted by federal law as the Food Drug Cosmetic Act (FDCA) limits a generic manufacturer’s ability to attach additional warnings to their drug.

Plaintiff’s claims that off-label promotion of Cordarone®/amiodarone was in violation of the FDCA and related regulations were also preempted pursuant to *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 121 S.Ct.1012, 148 L.Ed.2d. 854 (2001) (holding in pertinent part that where the existence of federal enactments is a critical element in plaintiff’s case, and where a plaintiff’s claims exist solely by virtue of the FDCA requirements, state law claims are impliedly preempted by the FDCA). Plaintiff did not allege any conduct by the generic defendants that gave rise to recovery for off-label promotion under North Carolina law in absence of the FDCA. Plaintiff’s claims which were premised upon failure to provide a medication guide were also preempted under *Buckman*.

**South Carolina Removal**


Plaintiff alleged that a design defect in a two-row corn picker, designed and manufactured by defendants, resulted in Plaintiff’s left hand being severed from his arm. Plaintiff filed suit against Defendants, AVCO Corporation (“AVCO”), New Idea Corporation (“New Idea”) the alleged designers and manufacturers of the corn picker, and Godley Auction, an auctioneer (“Godley”) that sold the corn picker. AVCO filed a Notice of Removal pursuant to 28 U.S.C. §1441 (2012). AVCO stated that it is a Delaware Corporation with its principal place of business in Massachusetts and New Idea is “not an existing separate legal entity” and Godley is “not a legal person or entity.” AVCO argued that while Godley had its principal place of business in South Caro-
lina, Godley dissolved in 2013 and also that Godley was a "sham defendant" as there can be no right to relief against Godley.

First, the district court indicated that controlling South Carolina law clearly provides that dissolution of a corporation does not prevent commencement of a proceeding against it. Second, the district court did not find persuasive that AVCO met its burden under the fraudulent joinder doctrine. Moreover, it was considered to be a "novel issue" in South Carolina as to whether auctioneers can be held liable as sellers for product liability claims. The district court cited Hartley v. CSX Transp., Inc., 187 F.3d 422, 425 (4th Cir. 1999) which held in pertinent part that novel state legal issue cannot be the basis for finding fraudulent joinder. Based on the record before it, the district court found AVCO's fraudulent joinder claim to be unsuccessful and remanded the case.

**West Virginia Class Actions**


Plaintiffs purchased Electrolux washing machines and after years of use noticed a coat of bacteria and mold in the washer drum which caused a "noxious odor." Plaintiffs allege that Electrolux knew its washers allowed biofilm to develop but continued to market them with a "special 'Deep Clean Sanitize' cycle that it claimed would kill '99.9 percent' of bacteria." Plaintiff first filed the proposed class action in West Virginia state court and defendants removed the case to the Court under the Class Action Fairness Act 28 U.S.C. §§1453, 1711-1715. Electrolux filed a Rule 12 (b) (6) motion to dismiss for failure to state a claim and a motion to strike the class allegations. The Court granted in part and denied in part the Rule 12 (b) (6) motion pursuant to West Virginia law and granted Electrolux's motion to strike the class allegations.

Electrolux argued that plaintiffs’ class allegations should be stricken because each class member must prove individualized damages proximately caused by a defect in their individual machines. The district court found that it would not be able to apply a uniform formula for calculating damages and would require individualized evidence of damages. The district court indicated, “simply put, continuity of damages between class members cannot be guaranteed, making the only issue potentially amendable to class treatment the issue of whether Electrolux's washing machines were defective.” The court was concerned with the burden and complexity of parsing individual causality and damages claims, or “of bifurcating proceedings, will outweigh any benefits of class treatment on the defectiveness issue.” Accordingly, plaintiffs’ class allegations were stricken.

**VI. Fifth Circuit**

*Carlson v. Bioremedi Therapeutic Sys., Inc.*, 822 F.3d 194 (5th Cir. 2016)

In *Carlson*, the plaintiff experienced burns in both of his heels after being treated with an infrared therapy device, ProNeuroLight, for peripheral neuropathy, a condition commonly associated with diabetes. *Id.* at 197. The burns ultimately caused a bone infection, which led to the amputation of one leg below the knee and the heel of the opposite foot. *Id.* The plaintiff brought suit against the ProNeuroLight manufacturer and distributor, alleging design defect, manufacturing defect, and failure to warn claims. *Id.* at 197-98. The defendants' only witness was the plaintiff's chiropractor, Dr. Durrett, who recommended use of the ProNeuroLight. Dr. Durrett opined that the ProNeuroLight could not have caused the plaintiff’s injuries. *Id.* at 198. The district court permitted Dr. Durrett's opinion over objection without explanation, and instructed the jury to give his testimony the weight they thought it deserved. *Id.* at 201. The jury returned a unanimous verdict for the defendants. *Id.* at 198. On appeal, the Fifth Circuit expressed great doubt over whether Dr. Durrett was qualified to offer his medical opinions, *id.* at 199-200, but it did not decide that issue because it found the district court abused its discretion by not conducting a *Daubert* inquiry on the record. *Id.* at 201. Agreeing with the First, Seventh, and Tenth Circuits, the Fifth Circuit concluded that “[a]t a minimum, a district court must...
create a record of its *Daubert* inquiry and ‘articulate its basis for admitting expert testimony.’” *Id.* (citations omitted). The Fifth Circuit further found that the district court’s error was not harmless because it had denied defendants’ motion for judgment as a matter of law at the close of plaintiff’s case in chief, thereby implicitly finding sufficient evidence for a jury to rule for plaintiff. *Id.* at 202.

*Petrobras Am., Inc. v. Vicinay Cadenas, S.A.*, 815 F.3d 211 (5th Cir. 2016)

An oil company and its underwriters brought suit against the manufacturer of an underwater tether chain designed to secure the piping system between wellheads on the Outer Continental Shelf of the Gulf of Mexico to floating production storage and offloading facilities. *Id.* at 213. The tether chain broke shortly after installation, allegedly causing $400 million in damages. *Id.* The parties initially proceeded under the assumption that maritime law applied. *Id.* The district court granted the defendant’s motion for summary judgment under the maritime economic loss doctrine. *Id.* The plaintiffs later moved to amend their complaint, asserting for the first time that Louisiana law should apply under the Outer Continental Shelf Lands Act (“OCSLA”). *Id.* at 214. The magistrate judge recommended that the motion be denied as untimely, and the district court agreed. *Id.* On appeal, the Fifth Circuit concluded that OCSLA’s mandatory choice of law provision “cannot be waived by failure to raise the issue below.” *Id.* at 215. Next, the Fifth Circuit held that, under the OCSLA, the adjacent state law (Louisiana), rather than maritime law, should control. *Id.* at 216. On rehearing, the Fifth Circuit clarified that (1) its “holding does not address waiver of a choice of law argument outside of the OCSLA context and does not disturb authorities holding that, in other contexts, a choice of law argument may be waived,” and (2) it did “not opine on different scenarios, such as where a party raises a choice of law argument under OCSLA for the first time after trial and judgment.” 829 F.3d 770, 771 (5th Cir. 2016). A petition for writ of certiorari is currently pending before the United States Supreme Court. Petition for Writ of Certiorari, *Petrobras* (No. 16-544).

*Sims v. Kia Motors of Am., Inc.* -- F.3d --, 2016 WL 5831464 (5th Cir. Oct. 5, 2016)

The decedent’s children and grandchildren brought a products liability action against the manufacturers of a Kia Soul. *Id.* at *1. During a wreck, the decedent’s vehicle struck a yield sign, and the base of the yield sign (the flange) punctured a hole in the fuel tank, causing a fire that killed the plaintiffs’ grandfather. *Id.* The district court excluded plaintiffs’ two experts and then granted defendants’ motion for summary judgment. *Id.* at *2. The Fifth Circuit affirmed on appeal. Applying a “differential diagnosis approach,” plaintiffs’ engineer, Michael McCort, concluded that the fuel tank must have somehow dropped prior to the accident and then returned to its original position upon impact because, based upon his computer models, the car could not have lowered far enough to hit the 3.25 inch high flange. *Id.* at *4-5. The Fifth Circuit, however, explained that “merely ‘ruling out’ other possible explanations is not enough to establish reliability; experts must also have some scientific basis for ‘ruling in’ the phenomenon they allege.” *Id.* at *4. Because there were no reliable facts in the record “ruling in” McCort’s theory, the district court did not abuse its discretion in excluding his opinion. *Id.* at *6. Plaintiffs’ other expert, Jerry Wallingford, opined that defendants should have employed one of two safer alternative designs. *Id.* One proposed alternative design was fuel tank fastening straps that would have prevented the vehicle’s fuel tank from dropping prior to impact. *Id.* at *6-7. But, since McCort’s opinion that the fuel tank dropped was properly excluded, Wallingford’s opinion failed as well. *Id.* at *7-8. The second proposed alternative was a tank shield. But Wallingford did not perform any tests to establish the viability of the design, nor did he offer an opinion on the economic feasibility of the alternative design, as required by Texas law. *Id.* at *8-10. Thus, the district court did not abuse its discretion in excluding Wallingford’s opinion either. *Id.* at *10. With no experts, the district court correctly concluded “the plaintiffs cannot raise a genuine issue of material fact concerning key elements of their products liability claim.” *Id.* at *11.
VII. Sixth Circuit

Venue

Hefferan v. Ethicon Endo–Surgery Inc., 828 F.3d 488 (6th Cir. 2016)

In Hefferan, the Court considered a forum non conveniens motion brought by Defendants Ethicon. Plaintiffs Brandon and Sabine Hefferan lived as a married couple in Germany. In 2012, complications arose during a surgery that Brandon Hefferan underwent there. As a result, he allegedly endured twenty follow-up surgeries and sustained severe permanent injuries. The Hefferans blamed a surgical stapler used during his initial procedure, which they claimed malfunctioned. The stapler was manufactured in Mexico by Ethicon Endo–Surgery, which is incorporated and headquartered in Ohio.

In 2014, the Hefferans filed suit in the District of New Jersey against Ethicon and its sole shareholder Johnson & Johnson, which is incorporated and headquartered in New Jersey (collectively “Ethicon”). Ethicon moved to dismiss based on forum non conveniens. Instead of ruling on the motion, the New Jersey court transferred the case to the Southern District of Ohio. The Hefferans filed an amended complaint in the Ohio federal court stating claims for negligence, loss of consortium, and violations of Ohio product-liability law. Ethicon again moved to dismiss on forum non conveniens grounds in favor of proceeding in Germany. The district court granted the motion and the Hefferans appealed. The question before the Court was whether the Ohio forum was proper.

In Kryvicky v. Scandinavian Airlines Sys., 807 F.2d 514 (6th Cir. 1986), the Court held that “the country where the injury occurred had a greater interest in the ensuing products liability litigation than the country where the product was manufactured.” The Court applied that reasoning here and barred the Hefferan’s claims stating that, the stapler’s design and manufacture by an American company does not outweigh Germany’s interest in the controversy, to say nothing of the Hefferans’ German domicile. The court explained, the country where a product is sold, used, and regulated has a strong interest, often an insurmountably strong interest, in litigation involving that product.

The Court granted the Defendants’ forum non conveniens motion is dismissal without prejudice to filing in the alternative forum (Germany) citing Manez v. Bridgestone Firestone N. Am. Tire, LLC, 533 F.3d 578, 583 (7th Cir. 2008).


Workers who worked in a French factory requested class certification to bring a class action lawsuit on behalf of 700 similarly situated plaintiffs against Goodyear Dunlop Tires France (Goodyear France), the company they worked for, alleging that in the course of their employment, they were exposed to toxic substances. Plaintiffs allege that Goodyear U.S. manufactured toxic products in the United States and compelled Goodyear France to use those products in Amiens, but failed to warn Plaintiffs of risks the toxic products posed or to provide adequate safety equipment. The United States District Court for the District of Northern Ohio granted Goodyear U.S.’s motion to dismiss for forum non conveniens arguing that plaintiffs’ case belongs in a French court. Plaintiffs appealed the dismissal.

The Sixth Circuit affirmed the lower court’s decision stating that public interest factors weighed in favor of dismissing tort action by Plaintiffs even though they suffered injuries as a result of allegedly toxic products from Ohio-based manufacturer, under doctrine of forum non conveniens. In this case, although the manufacturer’s decision-making regarding the allegedly toxic products occurred in Ohio; the workers lived in France, worked for a French company in a French factory, and suffered injuries in France. The Court also held that the French courts’ lack of class actions, procedural mechanisms to discover prospective class members, and injunctive relief for medical monitoring did not preclude France from being an adequate alternative
forum for this claim. The Court further held, absence of class actions in France did not render an otherwise adequate forum inadequate, acknowledging France offered damages for anxiety, fear of future illness, and physical harm.

Causation

*Causation*

*Causation*


Plaintiff car purchasers commenced a class action lawsuit in the United States District Court for the Northern District of Ohio against Defendant Fiat Chrysler Automobiles (FCA) a successor company to Chrysler Group LLC alleging that the engine cradles and suspensions on their Chrysler Pacifica's eroded prematurely because of a manufacturer defect. FCA's motion for summary judgment was denied. FCA then filed a motion for judgment on the pleadings, arguing that FCA had no legal duty to warn the Plaintiffs of or to repair the alleged engine cradle defect. The District Court granted the motion. Plaintiffs appealed to the Sixth Circuit Court of Appeals arguing that they pleaded sufficient facts to establish that FCA owed them a duty to warn and a duty to address the defect.

The Court held that vehicle seller's successor company did not have an economic relationship with consumers creating a duty to warn. The Court explained, consumers of defects in vehicle engine cradles that caused premature rusting and corrosion, were not in an economic relationship when consumers failed to sufficiently allege that they had received an extended warranty for repairs. Further, the mere fact that they owned the vehicles sold by company's predecessor was insufficient to create an economic relationship. The Court also held that even if vehicle seller's successor company had knowledge of defects in vehicle engine cradles and warned consumers of such defects, company was not liable for consumers' injuries, where consumers' injury was economic, having to pay vehicle repair costs, which consumers would have needed to do irrespective of any warning. Thus, consumers' injuries were result of the defects, not company's failure to warn.

Kentucky Defects

*Smith v. Joy Techs., Inc.*, 828 F.3d 391 (6th Cir. 2016)

In *Smith*, the Court held that under Kentucky law, there is no duty on manufacturers to warn of known hazards in products-liability cases. The Court also held under Kentucky law, the presumption of a product's non-defectiveness can be overcome only if the plaintiffs show that the product was defective by a preponderance of the evidence.

In *Smith*, Plaintiff was working at a coal mine when conveyor car crashed on top of his leg. Plaintiff and his wife brought Kentucky state court action against manufacturer of high-wall mining (HWM) system and manufacturer of conveyor car, asserting claims for negligence and strict liability for defective design and failure to warn, as well as for loss of consortium. After removal, intervention of coal mine operator's insurer, dismissal of the conveyor-car manufacturer pursuant to settlement agreement, and a six-day jury trial, the United States District Court for the Eastern District of Kentucky entered judgment in favor of HWM system manufacturer. Worker and his wife appealed, and subsequently moved to certify to Kentucky Supreme Court questions of state law concerning certain jury instructions.

The Court held that under Kentucky law, an injured party whose knowledge of a product's danger prevents his recovery on a failure-to-warn claim is not completely devoid of a remedy. He still has the prospect of recovering on a design-defect claim. The Court affirmed the judgment of the District Court.

Kentucky Preemption

Patient brought pro se action against generic drug manufacturer, alleging the manufacturer was liable for the patient’s addition to drugs containing hydrocodone bitartrate and acetaminophen under Kentucky Products Liability Act (PLA). The patient alleged the manufacturer failed to warn about the potentially addictive nature of the drug. Manufacturer moved to dismiss, alleging the FDA had approved the labelling.

The Court held that it was impossible for manufacturer of generic drug containing active ingredients hydrocodone bitartrate and acetaminophen to comply with both state-law duty to change drug’s label to reflect potential dangers or side effects posed by the drug, and federal law, Federal Food, Drug, and Cosmetic Act §505, 21 U.S.C.A. §355(j)(2)(A)(v), prohibiting manufacturer from unilaterally altering labels of its generic drug. Therefore, federal law preempted state law on patient’s failure-to-warn claim under the Kentucky Products Liability Act (PLA).

**Kentucky**

**Experts-Daubert Issues**


Plaintiff brought action on behalf of decedent, alleging that during the course of his employment, decedent was exposed to toxic levels of a chemical used to preserve the wood in utility poles, and that defendant employer failed to warn decedent about the hazards of the material.

Defendants brought a Daubert motion and moved for summary judgment alleging that Plaintiff’s expert failed to establish which specific pole the decedent worked on that contained the chemical which could have caused the decedent’s death. The Court stated that per Kentucky law, the plaintiff must adequately identify the injury-causing product and its manufacturer to survive summary judgment. Because the plaintiff’s expert had failed to do so, the Court granted defendant’s summary judgment motion.

**Tennessee**

**Definition of Manufacturer and Seller**

*Upton v. BNFL, Inc.*, 646 F. App’x 421 (6th Cir. 2016)

Plaintiff independent subcontractors brought an action against BNFL, a company they contracted with to do demolition, salvage work, and decommissioning of a uranium plant, alleging that they were exposed to asbestos containing materials. Amongst various other claims, they alleged a products liability claim against BNFL. The United States District Court for the Eastern District of Tennessee granted BNFL’s motion for summary judgment. Plaintiffs appealed.

The Court held BNFL, the contractor hired to decommission uranium processing plant was not a “manufacturer” or a “seller” within meaning of Tennessee’s products liability law, which governs when a manufacturer or seller of a product can be liable for an injury caused by the product. The Court affirmed the District Court’s grant of BNFL’s motion for summary judgment.

**Michigan**

**Experts-Daubert Issues**


Consumer commenced product liability action in diversity alleging that Covidien Inc, the manufacturer of a hernia mesh product, defectively designed and inadequately tested the product. Further, the Plaintiff alleged the manufacturer failed to warn users of risks of off-label use of product after suffering health issues from use of the mesh. At trial, the manufacturer moved to limit testimony and opinion of treating physician expert’s testimony on patient’s future prognosis.
Ultimately, the Court held a treating physician could not offer testimony regarding a patient’s future prognosis without a written expert report, if the physician had not seen that patient in the five years following his surgery. The Court further held that an eminently well qualified clinician and surgeon in field of abdominal wall reconstruction was not qualified by training or education to offer expert opinion on crosslinked material, biomechanical science of crosslinking, or body’s immunological response to crosslinked materials. Thus the doctor’s opinion in this case was not admissible on the consumer’s product liability claim under Michigan law alleging that manufacturer defectively designed and inadequately tested hernia mesh product because the expert lacked scientific expertise in material science of crosslinking and body’s immunogenic response to product at issue.

VIII. Seventh Circuit

General Personal Jurisdiction: Illinois


Aspen American Insurance Company (“Aspen”) brought a lawsuit in Cook County, Illinois, against Interstate Warehousing, Inc. (“Interstate”) to recover money it had paid its insured for fish products that were damaged when a warehouse roof collapsed in Michigan. Interstate moved to dismiss for lack of general personal jurisdiction because it was incorporated in Indiana and had its principal place of business in Indiana. The trial court denied the motion and found that Aspen made a *prima facie* showing of personal jurisdiction because it was incorporated in Indiana and had its principal place of business in Indiana. The trial court further found that Interstate’s inability to quantify the percentage of its Illinois business as a percentage of its total business left Interstate unable to rebut Aspen’s *prima facie* showing of general personal jurisdiction.

Interstate appealed, and the appellate court affirmed with one dissent. The appellate court emphasized Interstate’s inability to quantify the percentage of its Illinois business as a percentage of its total business. The dissent argued that “[m]erely conducting business in Illinois from a home base in Indiana is hardly the sort of unusual fact that would render this an exceptional case amendable to the exercise of general jurisdiction in Illinois.”

Scooting Yourself Out of Court: Illinois


In *Caplan*, plaintiff brought a failure to warn claim against a government healthcare facility to recover for injuries that he sustained when the motorized Pride Victory 9 scooter (300 pound weight capacity) that he was operating tipped. The healthcare facility provided the Pride Victory 9 scooter for plaintiff to use while visiting the facility for an appointment. Plaintiff typically would use a Pride Victory Maxima scooter (400 pound weight capacity), but none were available. Plaintiff stands 6’5” tall and weighs 400 pounds. The United States moved for summary judgment and plaintiff filed a cross-motion for summary judgment.

In his briefing, plaintiff conceded that he was not maintaining a cause of action for failure to warn, so the district court granted the United States’ motion for summary judgment, but not before analyzing plaintiff’s cross motion for summary judgment. The trial court construed the cross motion as an attempt to plead a strict liability theory. The trial court rejected such a theory because strict liability applies to “the distributive chain of a product as it enters commerce, but outside the distributive chain, supplying equipment for convenience, even to encourage business, does not make the supplier strictly liable for harms caused by the equipment.” Accordingly, the district court also granted summary judgment in favor of the United States on plaintiff’s cross-motion for summary judgment.
Expert Qualifications: Illinois

*Hall v. Flannery*, No. 15-2602, 2016 WL 6543513, ___ F.3d. ____ (7th Cir. Nov. 4, 2016)

In *Hall*, the mother of 17-year-old Chelsea Weekly brought medical malpractice claims against a hospital and its surgeons to recover damages for the death of her daughter, which, she alleged, was the result of improper post-operative care. Plaintiff’s theory was that her daughter died from a seizure days after the surgery. The defendants’ theory was that plaintiff did not have a seizure and that she died of a heart condition. Prior to trial, plaintiff filed a motion in limine that sought to bar defense expert Dr. Miller from testifying that anything other than a seizure had caused Chelsea’s death. The trial court granted the motion to the extent that Dr. Miller had failed to disclose other opinions. Plaintiff also filed a motion in limine to bar defendants’ witnesses from denying that Chelsea’s death was caused by a seizure. The trial court denied that motion.

The case proceeded to trial. During the trial, defense expert Dr. John Ruge, opined, over plaintiff’s objection, that a seizure did not bring about Chelsea’s death, but rather “focal interstitial chronic inflammation” of Chelsea’s heart was the likely cause of death. Plaintiff specifically argued that there was no foundation for such an opinion and that Dr. Ruge was unqualified to render such an opinion. The trial judge allowed the opinion because it had been disclosed and because it did not violate any rulings on motions in limine. Plaintiff also objected to defense expert Dr. Miller’s opinion that it was overwhelmingly probable that Chelsea’s death was not caused by a seizure, but the trial judge allowed the opinion. The jury returned a verdict in favor of the defendants and plaintiff appealed. The Seventh Circuit reversed the trial court’s ruling to allow Dr. Ruge’s heart opinion and remanded the case for a new trial.

In reaching its decision to reverse, the Seventh Circuit first held that plaintiff forfeited any arguments with respect to the opinions of Dr. Miller and Dr. Rothman because plaintiff conceded at oral argument that she was not arguing that Dr. Miller’s and Dr. Rothman’s testimony violated Rule 702 and *Daubert*. The Seventh Circuit next analyzed whether to apply an abuse of discretion standard or a *de novo* standard of review to Dr. Ruge’s opinion testimony. The Seventh Circuit held that a *de novo* standard should apply because the trial court did not apply the Rule 702 / *Daubert* framework, and instead merely checked to make sure that Dr. Ruge’s opinions had been disclosed. Had the trial court applied the *Daubert* framework, the standard of review would have been an abuse of discretion.

The Seventh Circuit next analyzed Dr. Ruge’s seizure opinion. The Seventh Circuit concluded that Dr. Ruge had the requisite training and experience to render the opinion that Chelsea did not have a seizure. He had practiced for 25 years and was serving as the chief of pediatric neurosurgery for the Advocate Health Care System, which encompassed two children’s hospitals and approximately ten other hospitals. He was also certified by the American Board of Neurological Surgery. The Seventh Circuit also emphasized that Dr. Ruge “had operated on growing skulls fractures like [Chelsea’s], and had published articles on various pediatric neurosurgery topics including epilepsy, cranial cysts, and severe head injury. The Seventh Circuit also concluded that Dr. Ruge’s seizure opinion was based on a sufficiently reliable methodology because he relied on multiple medical records, depositions, and his own experience.

The Seventh Circuit next analyzed Dr. Ruge’s heart opinion, and held that he was not qualified to render such an opinion. The Seventh Circuit explained that “[n]either Dr. Ruge’s trial testimony nor his expert report and curriculum vitae indicate that he possesses any specialized education, knowledge, experience, or skill concerning focal interstitial chronic inflammation specifically, or more broadly cardiology.” Given that the existence of a seizure was a hotly contested issue, and given that Dr. Ruge’s heart opinion gave the jury another possible cause of death, the Seventh Circuit concluded that Dr. Ruge’s erroneously admitted opinion had substantial influence over the jury. Accordingly, the Seventh Circuit reversed the judgment in favor of the defendants and remanded for a new trial.
**Preemption: Illinois**


In *Houston*, plaintiff "brought tort claims in state court against the federally funded health clinic where he was treated for gout, the physician's assistant who prescribed allopurinol, and the drug manufacturer" to recover damages for a severe skin reaction that he developed after taking allopurinol. The United States removed the case to federal court and substituted itself for the federal healthcare providers. The United States moved to dismiss, and the trial court granted the United States' motion because the acts attributable to the healthcare providers occurred within the scope of federal employment, and plaintiff failed to exhaust administrative remedies. The trial court also granted the drug manufacturer's motion to dismiss because, the trial court reasoned, it would be impossible for the manufacturer to comply with a state-law duty to change the label or design of allopurinol while complying with its federal duty to keep the label and design the same. Plaintiff appealed, and the Seventh Circuit affirmed.

The Seventh Circuit first analyzed the trial court's decision to grant the United States' motion to dismiss. Under Illinois law, "'[a]n employee's action falls within the scope of employment if (a) it is of the kind he is employed to perform; (b) it occurs substantially within the authorized time and space limits; [and] (c) it is actuated, at least in part, by a purpose to serve the master.'" The Seventh Circuit concluded that plaintiff presented no evidence that the government physician and physician's assistant acted outside the scope of their employment. The Seventh Circuit also rejected plaintiff's argument that alleged negligent acts by the government physician and physician's assistant removed their actions from the scope of employment. Because the government physician and physician's assistant acted within the scope of employment, and because plaintiff conceded that he did not exhaust administrative remedies, the Seventh Circuit affirmed the trial court's ruling dismissing the United States.

The Seventh Circuit next rejected plaintiff's argument that the trial court should have remanded his claims against the manufacturer upon dismissal of the United States. The Seventh Circuit reasoned that plaintiff's claims against the manufacturer were part of the same case or controversy and thus fell within the trial court's supplemental jurisdiction. The Seventh Circuit next explained that Federal law imposes an "ongoing duty of sameness" on the drug manufacturer "to ensure that allopurinol's chemical design and labeling are the same as its brand-name counterpart . . . ." The Seventh Circuit further explained that that duty "preempts a state-law claim that would require the manufacturer to redesign its drug, change its labeling, or exit the market in order to avoid liability." The Seventh Circuit concluded that plaintiff's claims were preempted and affirmed the trial court's ruling dismissing plaintiff's claims against the manufacturer.

The Seventh Circuit also rejected plaintiff's attempt to distinguish the Supreme Court's decisions in *Mensing* and *Bartlett* on the basis that his claims arose after the passage of the Food and Drug Administration's Amendments Act of 2007. The Seventh Circuit explained that "the amendments still forbid a generic-drug maker from violating the duty of sameness without FDA permission."

**Personal Jurisdiction and Fraudulent Joinder: Illinois**

*In Re Testosterone Replacement Therapy Products Liability Litigation*, 164 F. Supp. 3d 1040 (N.D. Ill. 2016)

In this case, ten unrelated plaintiffs from nine different states, including Missouri and Illinois, jointly sued two pharmaceutical companies in Missouri state court to recover for injuries allegedly resulting from plaintiffs' use of defendants' testosterone replacement therapy drug AndroGel. The defendants were Delaware corporations with their principal places of business in Illinois. The defendants removed the case to federal court and filed motions to (1) stay proceedings pending transfer of the case to the Illinois multidistrict
At the outset of its decision, the trial court considered whether it should first analyze the subject matter jurisdiction issue or the personal jurisdiction issue. Plaintiffs urged the trial court to analyze the subject matter jurisdiction issue first because it was clear that there was a lack of complete diversity. Defendants countered by arguing that the Illinois plaintiff was fraudulently joined because a Missouri court could not exercise personal jurisdiction over the defendants for the Illinois plaintiff’s claims. In the alternative, defendants argued that the trial court should exercise its discretion and analyze the personal jurisdiction issue first. Plaintiffs’ argued, however, that the fraudulent joinder, which involves an assessment of the substantive merits of the claims involving the non-diverse parties, is not applicable because personal jurisdiction is a non-merits issue.

The trial court explained that there is no controlling Seventh Circuit precedent on whether the doctrine of fraudulent joinder applies “where the alleged deficiency in the joined claim involves a non-merits issue like personal jurisdiction, and whether the doctrine applies to the joinder of plaintiffs at all.” The trial court ultimately concluded that it had discretion to decide the personal jurisdiction issue first.

In analyzing whether a Missouri court would have personal jurisdiction over defendants for the Illinois plaintiff’s claims, the trial court first explained that plaintiffs were not arguing for the existence of general personal jurisdiction over the defendants. The trial court next explained that defendants did not dispute that their contacts with Missouri were substantial enough such that a Missouri court could exercise specific personal jurisdiction over defendants for a Missouri plaintiff’s claims. The trial court next framed the personal jurisdiction dispute as boiling down to “whether the existence of specific jurisdiction over a defendant for one plaintiff’s claims allows a court to exercise jurisdiction over that same defendant as to the other, unrelated plaintiffs’ claims.”

The trial court concluded that the existence of specific jurisdiction over a defendant for one plaintiff’s claims, did not automatically allow a court to exercise jurisdiction over that same defendant for an unrelated plaintiff’s claims. The trial court next concluded that since defendants’ contacts in Missouri were insufficient to confer jurisdiction over defendants for the Illinois plaintiff’s claims, the Illinois plaintiff’s claims must be dismissed. Because the Illinois plaintiff’s claims were dismissed, there was complete diversity, and the trial court denied plaintiffs’ motion to dismiss for lack of subject matter jurisdiction.

**Jury Size: Illinois**

*Kakos v. Butler*, 2016 IL 120377, ___ N.E.3d ____ (Ill. 2016)

In 2014, the Illinois legislature amended section 2-1105(b) of the Code of Civil Procedure to eliminate a party’s ability to request a jury of twelve (12) and to only permit a jury of six (6). In *Kakos*, defendant challenged the constitutionality of the amendment, and the Illinois Supreme Court held the amendment unconstitutional. The Illinois Supreme Court interpreted the Illinois Constitution enacted in 1970 as preserving the right to a jury of twelve (12).

**Class Settlement Affirmed: Illinois**

*Martin v. Reid*, 818 F.3d 302 (7th Cir. 2016)

In *Martin*, several class actions were “brought against Unilever to recover damages from a hair-smoothing product that allegedly destroyed users’ hair and burned their scalps.” The lead case, *Reid v. Martin*, was brought in the Northern District of Illinois, and related cases were transferred to Illinois and consolidated with *Reid*. Once the cases were consolidated, the parties pursued mediation and cases where otherwise stayed.
A year later, the parties reached a settlement on February 7, 2014, which the trial court approved on July 29, 2014. Objector Martin appealed the final approval of the settlement and raised multiple objections. The Seventh Circuit affirmed the settlement.

In analyzing Martin's objections, the Seventh Circuit explained that the following principles guide a court's evaluation of a class settlement agreement, "(1) the strengths of the class's case, (2) the complexity and expense of further litigation, (3) the amount of opposition, (4) the reaction of class members to the settlement, (5) the opinion of competent counsel, and (6) the state of the proceedings and the amount of discovery that was completed." The Seventh Circuit then analyzed Martin's objections related to the accuracy of the data on which the district court relied. Martin argued that if the class was larger than assumed, the dollar amounts for settlement would be inadequate. The Seventh Circuit rejected this objection and concluded that Martin's speculation regarding more claims was unsupported.

The Seventh Circuit next analyzed Martin's objections regarding how the settlement treated the personal injury and tort claims. Martin's main argument was that the settlement value was too low because the settlement failed to account for different state laws. The Seventh Circuit rejected this argument because the settlement agreement had a choice of law provision specifying that Illinois law would apply.

Martin also objected because the settlement agreement did not contain injunctive relief preventing Unilever from marketing and making similar products. The Seventh Circuit explained that the trial court considered the need for injunctive relief and rejected it. The Seventh Circuit held that that decision was not an abuse of discretion.

Martin's next objection was that the settlement agreement should not have carved out people who had already signed releases. The Seventh Circuit explained, however, that it is up to the Special Master that the trial court appointed to determine the effect of any release. The Seventh Court had no problem with this approach.

Martin next argued that the documentation requirements for personal injury claimants was too onerous. The Seventh Circuit rejected this objection and explained that "[t]he fact that better documentation is needed for those with significant injuries is hardly a surprise."

Martin's final objections concerned class counsel’s fee. The Seventh Circuit rejected these objections and explained that "[n]othing in Rule 23 prohibits the deferral of the final fee award until after the agreement is approved, especially for an agreement structured as this one is, where the fees are kept entirely separate from the funds that will be available for compensation." The Seventh Circuit emphasized that such a provision "is to be encouraged, not criticized."

**Specific Personal Jurisdiction: Illinois**


Eight minor plaintiffs and their mothers filed a products liability lawsuit in Cook County, Illinois, to recover for birth defects allegedly resulting from ingestion of GlaxoSmithKline’s ("GSK") psychiatric drug, Paxil. The plaintiffs were from six different states, including Illinois. GSK moved to dismiss the out-of-state plaintiffs' claims for lack of specific and general personal jurisdiction. The trial court denied the motion and GSK sought leave to file an interlocutory appeal. The appellate court granted GSK leave to file an appeal, and the appellate court affirmed the trial court's ruling.

In reaching its decision to affirm, the appellate court solely analyzed whether Illinois could exercise specific personal jurisdiction over GSK. Plaintiffs did not argue for the exercise of general personal jurisdiction over GSK. This is not surprising because GSK’s sole member is a Delaware corporation with its principal place of business in Delaware. Further, GSK’s corporate and administrative headquarters are in Pennsylvania.
and North Carolina. The appellate court focused on the following facts in affirming the trial court’s order: (1) GSK’s counsel conceded that GSK had purposeful contacts with Illinois; (2) GSK contracted with 17 Illinois physicians to conduct clinical Paxil trials on a continuous basis from 1985 to 2003; and (3) GSK collaborated on another Paxil clinical trial that occurred exclusively in Illinois between 2001 and 2003.

The appellate court held that plaintiffs made a prima facie showing of specific personal jurisdiction by showing (1) that GSK engaged in purposeful activities in Illinois and (2) that plaintiffs’ claims directly arose from or related to GSK’s purposeful activities in Illinois. The appellate court explained that aside from GSK’s counsel conceding purposeful activity in Illinois, GSK contracted with 17 physicians to conduct Paxil trials and employed 217 employees that lived in Illinois. GSK also maintained a registered agent in Illinois.

As for the “directly arising from” prong of the specific jurisdiction analysis, the appellate court explained that plaintiffs allege that their injuries arise out of deficiencies in the clinical trials, some of which occurred in Illinois. The appellate court further explained that the allegedly inadequate Paxil labels were informed, at least in part, by the Illinois trials. Accordingly, the appellate court concluded that plaintiffs’ claims directly arose from GSK’s activities in Illinois.

The appellate court next analyzed whether it was reasonable for GSK to litigate the out-of-state plaintiffs’ claims in Illinois. The appellate court held that it was reasonable to require GSK to litigate the claims in Illinois because Illinois has an interest in resolving claims stemming from clinical trials in Illinois and because piecemeal litigation would raise costs.

Stretching for Personal Jurisdiction: Illinois

Noboa v. Barceló Corporación Empresarial, 812 F. 3d 571 (7th Cir. 2016)

In Noboa, Vanessa Noboa, while living in Illinois booked a trip to stay at a hotel in Mexico. When she arrived at the hotel, she signed up for a tour operated by a tour company. While on the tour, Noboa’s ATV overturned and she died from her injuries. Her estate sued the hotel and tour company. The district court dismissed for lack of personal jurisdiction, and the Seventh Circuit affirmed.

In reaching its decision to affirm, the Seventh Circuit explained that there was no question that Illinois did not have general persona jurisdiction over the defendants. The Seventh Circuit further explained that a plaintiff’s conduct cannot create specific personal jurisdiction over a defendant. “Only intentional contacts by the defendant with the forum jurisdiction can support specific jurisdiction.” Because no such intentional contacts by defendants existed, the Seventh Circuit affirmed the trial court’s decision dismissing the case for lack of personal jurisdiction.

Partially Qualified Product Expert: Illinois


In Ostrinsky, the estate of Michael Ostrinsky brought wrongful death negligence and survival negligence claims against Black & Decker to recover damages for Ostrinsky’s death, which allegedly resulted from a defective toaster. Plaintiff alleged that the toaster failed to pop up a bagel, which resulted in a fire and Ostrinsky’s death from smoke inhalation and carbon monoxide poisoning. Black & Decker filed a motion to bar certain testimony of plaintiff’s expert, Darl Ebersole.

The trial court first analyzed if Ebersole was qualified to opine as to the cause of the fire. The trial court held that he was qualified. Although Ebersole lacked training on toaster design and the toaster industry, he had a degree in electrical engineering. The court further emphasized that Ebersole had more than generalized education and concluded that “Ebersole’s training in electrical engineering and electrical safety, and his experience with fire investigations are sufficient to qualify him to opine whether a negligent design in the toaster caused the fire.” Similarly, the trial court concluded that Ebersole’s qualifications were sufficient for
him to opine that it was unreasonable for Black & Decker to design a toaster that would indefinitely heat food products to the point of combustion.

The trial court next emphasized that Ebersole’s alternative design opinion differed from his causation opinions because it was connected to a proposed alternative design as opposed to analyzing the safety of the existing design. Accordingly, the trial court found Ebersole unqualified to render an alternative design opinion. The trial court also found Ebersole unqualified to render an alternative warning opinion. The trial court reasoned that “Ebersole has not pointed to sufficient prior training or education that would qualify him to render an opinion as to what language would have been necessary in order to effectively communicate to consumers risks associated with the toaster in 1994.”

The trial court next analyzed the reliability of Ebersole’s causation, alternative design, and alternative warning opinions. The trial court concluded that Ebersole had conducted adequate testing albeit with a wheat bagel and not an onion bagel that was believed to have been involved in the fire. Any perceived deficiencies in his testing could be addressed on cross examination. The trial court barred Ebersole’s alternative design and warning opinions because not only was he unqualified to render such opinions, but he also provided no evidence of testing any proposed alternatives. With respect to his failure to develop, let alone test a proposed warning, the trial court explained that “Ebersole cannot simply speculate in the abstract that an alternative warning should have been included in the owner’s manual of the toaster.”

**Spoliation: Illinois**

*Schaefer v. Universal Scaffolding*, 839 F.3d 599 (7th Cir. 2016)

In *Schaefer*, plaintiff, a construction worker, brought products liability claims against a scaffolding manufacturer, Universal Scaffolding, for injuries that plaintiff sustained as a result of a piece of allegedly defective scaffolding falling on his head. Plaintiff also brought negligence claims against Dynegy, the company that hired plaintiff’s employer (Brand Energy Services) to erect the scaffolding. Once it was clear that the piece of scaffolding at issue had been lost, plaintiff added spoliation claims against Dynegy and Brand Energy Services. Plaintiff’s wife also brought spoliation claims against Dynegy and Brand, and a loss of consortium claim against all parties. Universal moved for summary judgment on all claims against it, and the trial court granted the motion. Dynegy moved for summary judgment on the negligence claims against it, and the trial court granted the motion. Dynegy and Brand also moved for summary judgment on plaintiff’s spoliation claims, and the trial court denied the motions. As a trial approached, Dynegy and Brand filed a motion in limine to bar evidence of defective scaffolding. The trial court granted the motion, and then granted summary judgment in favor of Dynegy and Brand on plaintiffs’ spoliation and loss of consortium claims. Plaintiffs appealed, and the Seventh Circuit reversed the trial court’s order granting summary judgment in favor of Dynegy and Brand on plaintiffs’ spoliation claims. The Seventh Circuit affirmed all of the trial court’s other rulings.

The Seventh Circuit first analyzed plaintiffs’ claims against Universal Scaffolding. The Seventh Circuit explained that, “[u]nder Illinois law, plaintiffs in product liability actions must identify the manufacturer of the product and demonstrate a causal relationship between the injury and the manufacturer’s product.” The Seventh Circuit further explained that plaintiff must establish that a defect existed in the subject scaffolding bar. The Seventh Circuit held that plaintiff’s product liability claims against Universal, and his wife’s loss of consortium claim, must fail because without the subject scaffolding bar, plaintiff could not present evidence that the bar caused his injuries.

The Seventh Circuit next analyzed plaintiff’s negligence claim against Dynegy. The Seventh Circuit concluded that while Dynegy had an onsite safety person, Dynegy did not retain control over the scaffolding
erection project. The Seventh Circuit also rejected plaintiff’s attempt to hold Dynegy liable under a premises liability theory because he cited no authority holding that ill-fitting scaffolding components constitute a condition of the land. The Seventh Circuit also rejected plaintiff’s negligent failure to warn theory against Dynegy because he, as one of the people installing the scaffolding, had an equal, if not greater, level of knowledge as Dynegy. The Seventh Circuit explained that a plaintiff must produce evidence of unequal knowledge in order to prevail on a negligent failure to warn claim.

As for the spoliation claims, the Seventh Circuit explained, that under Illinois law, spoliation is merely a variety of negligence. To prevail, a plaintiff must show a duty to preserve and a breach of that duty causing damages. There are “relationship” and “foreseeability” elements to whether a duty exists. With respect to the relationship element, a duty must “arise[] by agreement, contract, statute, special circumstance, or voluntary undertaking.” With respect to the foreseeability element, it is necessary that “a reasonable person should have foreseen that the evidence was material to a potential civil action.” In this case, the foreseeability element was clearly established because Brand collected the scaffolding bar after the accident and gave it to Dynegy’s safety person for safe keeping. With respect to the relationship element, the Seventh Circuit explained that for a duty to arise by special relationship, something more than possession and control are required. For example, “a request by a plaintiff to preserve the evidence, or a defendant’s segregation of evidence for the plaintiff, are recognized as special circumstances.”

The Seventh Circuit held that a special circumstance existed between plaintiff and Brand because within a year of the accident, plaintiff served discovery requests on Brand, and although they did not specifically request the scaffolding bar, Brand knew that plaintiff was looking to Brand for information about the allegedly defective bar. Further, Brand had collected the bar and delivered it to Dynegy. As to Dynegy, the Seventh Circuit held that the relationship element of the duty analysis was satisfied because Dynegy made a voluntary undertaking to preserve the scaffolding bar.

The Seventh Circuit next explained that plaintiffs must show that (1) the loss of the scaffolding piece would cause them to lose their underlying lawsuit; and (2) they would have a “reasonable probability” of winning with the scaffolding piece. The Seventh Circuit concluded that the trial court incorrectly required plaintiffs to show that they would have won their underlying case. The Seventh Circuit held that plaintiffs presented sufficient evidence to create a question of fact as to the causation element of their spoliation claim. Such evidence included a pervasive problem with the scaffolding at the Dynegy facility. In light of its holding on plaintiffs’ spoliation claims, the Seventh Circuit also reversed the trial court’s motion in limine ruling to exclude all evidence of defective scaffolding.

Asbestos Directed Verdict: Illinois


Plaintiff and his spouse brought a products liability action against the manufacturer of an asbestos containing tape to recover damages for his development of pleural plaques and interstitial fibrosis. At trial, defendant moved for a directed verdict, but the trial court denied the motion. The jury returned a verdict in favor of plaintiff and awarded damages. Defendant appealed and argued that plaintiff had suffered no physical harm. The appellate court reversed.

In reaching its decision, the appellate court explained that physical harm is an essential element of any action for products liability. The appellate court reasoned that physical harm requires more than alteration to the structure of one’s body. Physical harm requires that any physical changes or alterations to one’s body have some detrimental effect on the person. In this case, the majority of the appellate court concluded there was no evidence of any detrimental effect on plaintiff. Although he had pleural plaques and interstitial
fibrosis, they were asymptomatic, and, despite being a smoker, a pulmonary function test revealed “excellent diffusion capacity” according to plaintiff’s treating physician of 20 years.

**Proximate Cause and Res Ipsa Loquitur: Indiana**

*Blasius v. Angel Automotive, Inc.*, 839 F.3d 639 (7th Cir. 2016)

In *Blasius*, plaintiff brought suit after he entrusted his vehicle to an automobile repair shop to upgrade the vehicle, and the next day the vehicle caught fire and was destroyed. The district court granted summary judgment in favor of defendants, stating that plaintiff did not show proximate cause, despite the fact that plaintiff’s expert’s report concluded the repairs were most likely related to the cause of the fire.

On appeal, the appellate court held that summary judgment was inappropriate because the expert does not serve as the fact finder, but rather, helps plaintiff get to the fact finder. Plaintiff provided a consistent theory, supported by expert testimony and other evidence, regarding the cause of the fire, and thus, summary judgment was not appropriate on the issue of proximate cause.

The appellate court also held that plaintiff was entitled to rely on the doctrine of *res ipsa loquitur*, which requires: (1) the instrumentality was in the exclusive control of defendant, and (2) the accident is of the type that does not ordinarily happen if those who have the control exercise proper care. The Court reasoned that to apply *res ipsa loquitur*, defendant does not need to be physically in control of the instrument causing injury at the moment of the injury, but rather, plaintiff needs to show that defendant was the last person in control of the instrument.

**Negligence—Proximate Cause: Indiana**

*Carson v. ALL Erection & Crane Rental Corp.*, 811 F.3d 993 (7th Cir. 2016)

Indiana law imposes a duty on suppliers to conduct a proper inspection of the product to disclose any defects, but that does not require finding defects that occur rarely and are difficult to replicate. In *Carson*, plaintiff brought suit against a crane supplier for injuries he sustained when he fell underneath the tread of a crane that his employer leased from defendant. Plaintiff was working in front of the crane while the crane was not in “travel detent,” meaning that the crane should not have moved on its own. Plaintiff fell into the path of the crane, and the crane’s treads crushed his right foot, which had to be amputated. Plaintiff alleged that defendant breached its duty to conduct a reasonable inspection of the crane, specifically, the travel detent, upon delivering to plaintiff’s employer, and that the breach was the proximate cause of his injury.

Defendant moved for summary judgment on the grounds that there was no evidence in the record that defendant’s alleged breach was the proximate cause of plaintiff’s injuries. The district court granted summary judgment.

Indiana law imposes a duty on the supplier of a chattel to conduct a proper inspection which would disclose the existence of a defect. To determine whether a supplier breached the duty of reasonable care, it may be proper to inquire into the reasonable discoverability of a defect. The district court found that since the problem was intermittent and difficult to replicate, a jury could not reasonably find that defendant breached the duty by failing to inspect in the intensive manner necessary to replicate the failure.

The district court found that plaintiff did not put forth any evidence permitting a reasonable inference of proximate cause, since the accident happened three months after plaintiff’s employer had begun using it and there was no information about how often the travel detent was used before the day of the accident.

**Strict Liability—Manufacturing Defect: Indiana**

Plaintiff brought this action against the manufacturer of an air condensing unit when a fire destroyed the home of its insured, which plaintiff claims was caused by the defective air condensing unit. Plaintiff alleged negligence, strict liability, and breach of warranty. Plaintiff moved for summary judgment on all claims. The district court granted defendant’s motion for summary judgment for plaintiff’s claims of design defect and failure to adequately warn but, in reliance upon *Ford Motor Co. v. Reed*, 689 N.E.2d 751 (Ind. Ct. App. 1997), denied defendant’s motion on the strict liability claim.

Indiana law states that a plaintiff may prove a product defect by using any of four methods: (1) producing an expert to officer direct evidence of a specific manufacturing defect; (2) using an expert to circumstantially prove that a specific defect caused the product failure; (3) introducing direct evidence from an eyewitness of the malfunction, supported by expert testimony explaining the possible causes of the defective condition; or (4) introducing inferential evidence by negating other possible causes. The district court clarified that the factors set forth in *Reed* are “helpful tools,” but in some instances, “circumstantial evidence can produce reasonable inferences from which a jury can reasonably find that the defendant manufactured a product containing a defect.” Although plaintiff’s expert testified during his deposition that he would not be offering any opinion that the product at issue possessed a manufacturing defect, the district court held that plaintiff had sufficiently eliminated other reasonably possible causes of the fire and denied Lennox’s motion for summary judgment as to the manufacturing defect.

**Pleadings and IPLA: Indiana**


Plaintiff brought suit alleging common law negligence and breach of warranty after a cardiac defibrillator, manufactured by Medtronic, allegedly caused her to sustain severe injuries. Medtronic filed a motion to dismiss for failure to state a claim, asserting that plaintiff’s complaint failed to plead any valid breach of warranty claim under the Indiana Product Liability Act (IPLA), and that plaintiff’s tort claims were preempted under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. §360k. The district court agreed that plaintiff’s complaint was insufficient under Rule 12(b)(6), and ordered plaintiff to file an amended complaint that only included claims for manufacturing defect, design defect, or failure to warn, in compliance with the IPLA, and plead facts that support her claims. The district court dismissed plaintiff’s common law negligence claim, since Indiana law states that when a consumer states identical facts to support both strict liability and negligence claims, even though they have alleged underlying theories of design defects, manufacturing defects, and negligence, the IPLA governs, and the negligence claim duplicates the strict liability claim. The district court did not resolve whether plaintiff’s claim was preempted by Medical Device Amendments, since plaintiff’s complaint was so lacking, the court could not determine what plaintiff was alleging.

**Strict Liability—Seller Treated as Manufacturer: Indiana**


Plaintiff brought suit when a metal cutoff disc he bought from Home Depot failed during use and injured him. Plaintiff’s liability expert determined the disc failed as a result of cracks in the disc that occurred during the manufacturing process. Defendants in this action were the distributor, Freud America, Inc., which does not manufacture the discs, but designed the label affixed to the disc and organized the layout of the label, and the retail store, Home Depot, who sold the disc. Defendants moved for summary judgment.

Under Indiana law, a “manufacturer” includes a seller who has “actual knowledge of a defect in a product.” Ind. Code §34-6-2-77(a)(1). When Home Depot sold the disc to plaintiff, Home Depot had notice
that the discs cracked through its customer reports. Therefore, the district court denied Home Depot's motion for summary judgment.

Sellers may be deemed a manufacturer and held strictly liable under the Indiana Products Liability Act (IPLA) in narrow circumstances. When the court does not have jurisdiction over a manufacturer of a defective product, the manufacturer's principal distributor or seller will be considered the manufacturer of the product. The district court held that a reasonable jury could conclude that Freud America is a “manufacturer” of the disc because the original manufacturer was a foreign corporation, and the facts did not indicate that the original manufacturer could be haled into court in Indiana. Accordingly, the district court denied Freud's motion for summary judgment.

**Preemption and the Food, Drug, and Cosmetics Act: Indiana**


In *McAfee*, plaintiff brought suit against a medical device manufacturer for failure to warn under Indiana’s Product Liability Act (IPLA) and common law claims for failure to warn. Medtronic asked the court to dismiss the state law claims alleging failure to warn. The primary issue raised in defendant's motion to dismiss was whether plaintiff’s amended complaint sufficiently alleged causation for its failure to warn claim, and whether the claim was preempted by federal law. To avoid preemption on a parallel failure to warn claim, plaintiff must allege that: 1) defendant violated a federal requirement applicable to the product; 2) that state law imposes a “genuinely equivalent” requirement; and 3) the federal violation caused plaintiff’s injuries. The district court concluded that to the extent plaintiff alleged that he was injured because defendant did not warn physicians and their patients of adverse events, 21 U.S.C. §360k(a) preempted his claim.

**Preemption and the Food, Drug, and Cosmetics Act: Wisconsin**

*Wagner v. Teva Pharmaceuticals USA, Inc.*, 840 F.3d 355 (7th Cir. 2016)

Appellant/Plaintiff took both brand-name and generic hormone therapy drugs as prescribed by her gynecologist to treat her post-menopausal endometrial hyperplasia. After taking the drugs, appellant developed breast cancer. Appellant sued multiple pharmaceutical companies that designed, manufactured, promoted and distributed the drugs she took. Appellees/Defendants were the only pharmaceutical companies that manufactured the generic form of the hormone therapy drugs.

Appellees moved for Rule 12(c) judgment on the pleadings, arguing that federal law preempted appellants claims. In response, appellant asserted, for the first time, that appellees delayed updating their generic brand labels to match the updated, stricter labels on the brand-name drug.

The district court granted appellees' motion for judgment on the pleadings, finding that the Food, Drug, and Cosmetics Act (“FDCA”), 21 U.S.C. §301 et seq., preempted appellant's state law claims. It also rejected appellee's failure to update claim on the basis that it was (1) untimely and (2) legally and factually futile. An appeal ensued.

Upon review, the appellate court began its analysis by noting that *PLIVA, Inc. v. Mensing*, 564 U.S. 604, (2011) and *Mutual Pharmaceutical Co. Inc. v. Bartlett*, ___ U.S. ___, 133 S.Ct. 2466, (2013) impose a “duty of sameness” on generic drug manufacturers that requires “generic drug labels be the same at all times as the corresponding brand-name labels.” Flowing from that duty, federal law preempts state tort laws when the generic drug manufacturer could not have abided by this duty without: (1) changing the drug’s formula; (2) changing the drug’s label; or (3) withdrawing the generic drug from the market altogether.

While the appellate court acknowledged that the Food and Drug Administration Amendments Act of 2007 (“FDAAA”) imposed certain obligations on generic drug manufacturers when they propose labeling changes, it ultimately concluded that the FDAAA did not remove the prohibition against making changes uni-
laterally and it still forbids a generic-drug maker from violating the duty of sameness without FDA permission.

The appellate court also agreed that appellant’s failure-to-update claim was legally and factually futile. The appellate court recognized a split in authority as to whether federal law preempts state law failure-to-update claims and noted that the question remains open in the Seventh Circuit. However, it ultimately found that factual deficiencies in appellant’s complaint alone precluded reversal of the district court.

**Daubert, Class Certification: Wisconsin**


When an expert’s report or testimony is critical to class certification, a court must conclusively rule on *Daubert* challenges prior to ruling on a class certification motion. In this class action lawsuit, the district court denied plaintiffs’ motion for class certification because both of plaintiffs’ experts were excluded as unreliable and unhelpful to the trier of fact, and therefore, plaintiffs did not meet their burden of demonstrating that common questions of fact predominate or that they had a viable method of showing class-wide injury with common proof.

**Breach of express and implied warranty: Wisconsin**


Defendant manufactured and sold industrial packaging machinery and equipment to plaintiff. The contract contained a warranty that products sold were free from defects in materials and workmanship, and further stated: “[t]he Warranties set forth herein are in lieu of all other warranties, whether expressed, implied or statutory, including but not limited to implied warranties of merchantability and fitness for a particular purpose.” The defendant made written and oral representations and warranties, claiming that the machine was capable of processing 720 plastic bags and 60 cartons per minute, and buyer relied on these representations when purchasing the machine.

The machine was not able to produce as many bags and cartons as quickly as it claimed, and had other failures. Plaintiff brought suit for breach of express and implied warranties.

Since the contract disclaimed any implied warranties, the district court dismissed plaintiff’s claim of breach of implied warranty. However, the district court determined that defendant’s representation as to the amount of product the machine would be able to produce and the speed it could operate was an express warranty that plaintiff relied on in making its purchase. Even if the disclaimer was proper, it would be inconsistent with the express warranty made by defendant, and result in “unbargained for language and the buyer’s surprise.” Accordingly, the district court denied defendant’s motion to dismiss for the breach of express warranty claim.

**Malfunction as Evidence of Defect: Wisconsin**


Romo Incorporated (“Romo”) purchased five barrel heaters from Briskheat Corporation (“Briskheat”). One of the five barrel heaters, which had been running continuously for a couple of months, malfunctioned, causing the contents of the barrel to vaporize and resulting in large clean-up costs for Romo. The parties’ experts agreed that the malfunction occurred because of a cracked solder joint between the barrel heater’s capillary tube and bellows. They disagreed, however, on the cause of the crack.
Romo argued that the crack resulted from Briskheat’s negligent repair of the barrel heater, which had twice been returned to Briskheat for service because it failed to maintain a stable temperature, or, in the alternative, a manufacturing defect. Briskheat, in contrast, contended that Romo’s employees had negligently serviced the unit before the incident. While both parties denied that their respective employees had performed any repairs in the area where the crack was found, a screw was missing from the housing under which the crack was located and tool marks were found in the surrounding area.

Ultimately, Briskheat moved for summary judgment on Romo’s claim that the unit had been defectively manufactured. In response, Romo argued that if the jury credits the testimony offered by both parties, namely that none of their respective employees performed any repairs in the area where the crack was found, it would be reasonable to conclude that the barrel heater had a manufacturing defect that caused it to fail and, therefore, summary judgment was inappropriate. To support its argument, Romo cited to Greco v. Buccioni Engineering Co., 283 F. Spp. 978, 984 (W.D. Pa. 1967), for the proposition that “[a] malfunction evidences a defect.”

The district court agreed with Romo and denied summary judgment. In reaching its holding, the district court noted that Briskheat could not point to a single provision of Wisconsin’s product liability statute that “would lead the court to conclude that the fact a properly designed product fails prematurely from normal and expected use would not constitute evidence of a defect in its manufacture.” The court further noted that “[w]hile it is true that the metallurgical analysis needed to identify a manufacturing defect, if one existed, was apparently not performed by Plaintiff’s expert, this does not eliminate the inference that in the absence of mishandling or a negligent repair effort, a manufacturing defect is the most likely explanation for the failure.”

**Implied Preemption and Negligence Per Se: Wisconsin**


Plaintiffs brought state law claims of negligence and wrongful death against Zydus Pharmaceuticals (USA) Inc. (“Zydus”), among others, for injuries sustained by Shirley Johns (“Johns”), who died as a result of taking a drug commonly known as Amiodarone. Plaintiffs alleged that Zydus failed to provide certain medication guides required by the Food, Drug, and Cosmetic Act (“Act”), 21 U.S.C. §337, to any of the pharmacies from which Johns obtained Zdyus’s drugs.

The Act does not allow private litigants to enforce its provisions. Accordingly, Plaintiffs argued that that they were merely relying on the Act’s medication guide requirements to establish the standard of care for their claim that Zydus was negligent per se in failing to warn Johns about the side effects of Amiodarone. In other words, Plaintiffs asserted that Zydus was negligent because it violated a federal statute related to public health and safety.

Zydus moved to dismiss the complaint on the grounds that plaintiffs’ negligence per se claim was impliedly preempted by the Act. The district court denied Zydus’s motion to dismiss. The district court determined that (1) Plaintiffs’ claim was not subject to implied preemption under the doctrine announced in Buckman Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341 (2001), and (2) plaintiffs may bring a negligence per se claim under Wisconsin law based on alleged violation of the medication guide regulations.

In reaching its holding on the implied preemption issue, the district court noted that Buckman distinguished claims based on traditional state law tort principles that had predated the federal statute (and are not subject to implied preemption) from claims for fraud-on-the-agency (claims in which the existence of federal requirements was a critical element and are therefore subject to implied preemption). The district court concluded that because plaintiffs had alleged a well-recognized state law duty to warn that is independent
of federal requirements, their claim was a tort law claim based on Zydus’s alleged failure to warn rather than fraud on a federal agency. Accordingly, the district court determined that plaintiffs’ claims were not subject to implied preemption under *Buckman*.

The district court then held that a plaintiff may bring a negligence *per se* claim under Wisconsin law based on an alleged violation of the medication guide regulations. The district court reasoned that while “it is not clear how the Wisconsin Supreme Court would weigh the enforcement limitation in the [Act] when analyzing the legislative intent to impose civil liability under state law, the state court of appeals concluded in *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 867 (Wis. Ct. App. 2004)] that a drug manufacturer’s violation could constitute negligence *per se*."

**Statute of Repose in Asbestos Cases: Wisconsin**


Decedent worked as a union steamfitter from 1955 to 1992. For four months in 1968 or 1969, Decedent worked an “overhaul” of a fossil fuel turbine at the Oak Creek Power Plant (“Oak Creek”). The “overhaul” required removal and reinstallation of insulation including asbestos blankets, asbestos sheets, and asbestos pipe covering. Decedent’s duties at Oak Creek included covering pipes on the turbine floor.

Subsequently, between 1964 and 1965, decedent worked at Port Washington Power House (“Port Washington”) on another turbine outage. During this time, decedent covered pipes with insulation, cut pipes, and worked on the turbine floor.

Plaintiff asserted that defendant sold, installed, and removed asbestos products at Oak Creek and Port Washington and manufactured asbestos-containing products that were used at both locations. Plaintiff further asserted that decedent was exposed to and inhaled airborne asbestos fibers released while using or working in proximity to others using or removing such products at Oak Creek and Port Washington. Accordingly, plaintiff filed negligence and strict product liability claims against defendant on the basis that decedent’s exposure to said asbestos fibers by defendant had caused decedent’s asbestosis and malignant mesothelioma.

Defendant moved for summary judgment under Wisconsin’s statute of repose, Wisconsin Statute §893.89, which precludes claims for injury brought more than ten (10) years after the date of substantial completion of an improvement to property. Defendant argued that the overhaul of the Oak Creek and Port Washington turbines constituted an improvement and, as a result, plaintiff’s claims were barred. In response, Plaintiff argued that overhaul was maintenance or repair work as improved to an improvement to real property.

The district court held that the statute of repose was inapplicable to plaintiff’s claims. The district court began its analysis by that noting an improvement to real property is “[a] permanent addition to or betterment of real property that enhances the capital value, involves the expenditure of labor and money, and is designed to make the property more useful and valuable.” Utilizing the aforementioned test, the district court concluded that the evidence, when taken in the light most favorable to the nonmoving party, revealed that (1) defendant’s work involved tearing down and rebuilding rather than removing or installing a new system and (2) defendant’s workers were on site five days a week for repair and recovering of the pipes—work done to keep the pipes in proper condition. Consequently, the district court could not definitively say that defendant’s work constituted an improvement rather than repair or maintenance.

**Economic Loss Doctrine: Wisconsin**


Defendants designed and manufactured highway safety equipment, including a guardrail end terminal system known as the ET Plus. In 2000, the Federal Highway Administration (“FHWA”) approved the
ET Plus, but, in the years that followed, defendants changed the design of the ET Plus without informing the FHWA. The changes made the system less safe, and, when they finally came to light, defendants found themselves as defendants in a *qui tam* lawsuit. A jury ultimately returned a substantial verdict against them in the *qui tam* lawsuit, but that award compensated the United States government and not other entities that had purchased ET Plus units.

Plaintiff filed a class action lawsuit on behalf of state and local highway departments that purchased ET Plus end terminals. Plaintiff asserted, among other things, a claim for a design defect against defendants and sought to recover for damages for “the decreased value of the guard rails” that it ordered, “[t]he safety and feasibility [of which] must now be studied, inspected, tested, and potentially each unit must be replaced.”

Defendants moved for summary judgment on the design defect claim on the basis that the economic loss doctrine bars plaintiff from recovering these damages in tort. The district court agreed and granted defendants’ motion to dismiss plaintiff’s design defect claim.

In reaching its holding, the district court noted that the economic loss doctrine precludes recovery for “the diminution in the value of the product because it is inferior in quality and does not work for the general purposes for which it was manufactured and sold.” The district court reasoned that this diminution in value is what plaintiffs were alleging in this case, *i.e.* that they purchased ET Plus units expecting that they would function as promised, but the products failed to meet those expectations. The district court also determined that none of the three exceptions to the economic loss doctrine (the fraudulent inducement exception, the services exception, or the noneconomic loss/other property exception) applied.

**IX. Eighth Circuit**

*General Verdict Form – Effect on New Trial Motion*

*Coterel, et al. v. Dorel Juvenile Group, Inc.*, 827 F.3d 804 (8th Cir. 2016)

Plaintiffs, the parents of a deceased minor, brought a negligence and products-liability action against Dorel Juvenile Group, Inc. (“Dorel”) alleging that a doorknob cover designed and manufactured by Dorel was defectively designed and unreasonably dangerous. *Id.* at 805. The suit arose from an incident in which the Plaintiffs’ minor child allegedly defeated the doorknob cover, left the Plaintiffs’ home, and drowned in a nearby pond. *Id.* at 806. Dorel answered the suit denying liability and asserting the affirmative defenses of comparative fault and sole cause. *Id.*

Before trial, Plaintiffs sought to exclude evidence that they had failed to secure a chain lock on the door in question and their knowledge that the child was able to defeat the doorknob arguing that their actions at most were a contributing cause – not a sole cause. *Id.* Dorel argued that the evidence was relevant to its sole-cause defense and central to its ability to defend the product-liability and negligence claims. *Id.* The district court denied the motion and admitted the evidence. *Id.* At trial, a jury unanimously found that Dorel was not liable for the child’s death. *Id.* at 807.

On appeal, Plaintiffs argued that the district court erred in admitting the evidence. *Id.* In reviewing the district court’s evidentiary rulings, the Eighth Circuit Court of Appeals stated that the “the key question [is] whether a new trial is necessary to prevent a miscarriage of justice.” *Id.* citing *Hallmark Cards, Inc. v. Murley*, 703 F.3d 456, 462 (8th Cir. 2013). Further, the Court found that a jury’s verdict should not be disturbed unless the “district court clearly abused its discretion by admitting the evidence” and “the error[s] prejudicially influenced the outcome of the trial.” *Id.* citing *Regions Bank v. BMW N. AM., Inc.*, 406 F.3d 978, 980 (8th Cir. 2005).

To determine whether the evidentiary errors discussed above prejudicially influenced the outcome of the case, the Court looked to the jury’s verdict. *Id.* at 808 citing *Qualley v. Clo-Tex Int’l, Inc.*, 212 F.3d 1123,
In this case, the verdict form submitted simply asked the jury to determine whether it found in favor of Plaintiffs or Dorel. *Id.* Because of the use of this general verdict form, the Court found that Plaintiffs could only speculate as to whether any alleged evidentiary error actually prejudiced them. *Id.* Because speculation is not a sufficient basis for determining if a parties' substantial rights were affected, the Court affirmed the district court's admission of the evidence. *Id.*

**Manufacturer’s Duty – Optional Equipment Doctrine**

Susan R. Parks, Wife and Next of Kin of Timothy Glen Parks, deceased, and Executor of the Estate of Timothy Glen Parks, deceased v. Ariens Company, Case No. 15-2664 (8th Cir. 2016)

Plaintiff, the wife and executor of the estate of the deceased, brought a negligence and products-liability action against Ariens Company (“Ariens”), alleging that the lawnmower manufactured by Ariens was defective because it was sold without a rollover protection system (“ROPS”). *Id.* The suit arose from an incident in which the Plaintiff’s decedent was operating the lawnmower on his property and fell off the edge of an embankment and rolled over on top of him. *Id.* Plaintiff’s decedent died from asphyxiation. *Id.*

At the time the lawnmower was sold, the ROPS was an optional safety feature that consisted of a roll bar and seat belt. Evidence was presented establishing that Plaintiff’s decedent had been informed of the option to purchase the ROPS feature and declined to do so. Ariens moved for summary judgment on the claims arguing that it satisfied any duty owed by offering the ROPS as an optional feature. *Id.* The district court agreed and granted the motion. *Id.*

Plaintiff appealed arguing that Ariens was negligent for not including the ROPS with every similar model lawnmower it sold. *Id.*

The Eighth Circuit Court of Appeals found that the doctrine that a manufacturer is, under certain circumstances, not negligent if a purchaser fails to buy optional safety equipment that would have prevented the accident originated in *Biss v. Tenneco, Inc.*, 409 N.Y.S.2d 874 (N.Y. App. Div. 1978). *Id.* That court, faced with a similar claim regarding a product sold without a ROPS, held that the manufacturer had not breached any duty because it had made the ROPS available as an optional feature and the purchaser of the product was “the party in the best position to exercise an intelligent judgment to make the trade-off between cost and function.” *Id.* citing *Biss* 409 N.Y.S.2d at 877.

The Court found the requirements for the optional equipment doctrine are as follows:

The product is not defective where the evidence and reasonable inferences therefrom show that:

1. the buyer is thoroughly knowledgeable regarding the product and its use and is actually aware that the safety feature is available;
2. there exist normal circumstances of use in which the product is not unreasonably dangerous without the optional equipment; and
3. the buyer is in a position, given the range of uses of the product, to balance the benefits and the risks of not having the safety device in the specifically contemplated circumstances of the buyer’s use of the product. In such a case, the buyer, not the manufacturer, is in the superior position to make the risk-utility assessment, and a well-considered decision by the buyer to dispense with the optional safety equipment will excuse the manufacturer from liability. *Id.*

Because Iowa law governed the case and because the Iowa Supreme Court had not considered the optional equipment doctrine, the Court was faced with the question of whether the Iowa Supreme Court would adopt the doctrine. *Id.* Based on the Eight Circuit’s previous finding that the reasoning in *Biss* is sound and because of the popularity of the doctrine, the Court found that the Iowa Supreme Court would adopt it.
Based upon the application of the optional equipment doctrine, the Court found that Ariens fulfilled any duty it had to Plaintiffs’ deceased when it provided the ROPS as an optional feature for the lawnmower and ensured that he had the information to make an informed choice. *Id.*

**Curative Instructions**


Plaintiffs, husband and wife, brought a negligence, strict liability, and breach of warranty action against numerous manufacturers and distributors of microwave popcorn and butter flavoring alleging that a chemical named diacetyl, once used in the butter flavoring of microwave popcorn, caused the husband to develop bronchiolitis obliterans. *Id.* at 412.

At trial, a number of experts agreed the husband has bronchiolitis obliterans. *Id.* at 413. Opinions differed as to whether the condition was caused by diacetyl exposure or an unrelated autoimmune disease. *Id.* Defendants presented evidence from Dr. Richard Meehan, a rheumatologist who testified that the husband’s bronchiolitis obliterans was caused by an autoimmune disease. *Id.* During his testimony, Dr. Meehan admitted that he had not considered whether diacetyl had caused the husband’s bronchiolitis obliterans. *Id.* Following this concession that he had not performed a proper differential diagnosis, the district court struck Dr. Meehan’s testimony. *Id.* The jury was instructed: “I have just stricken all of Dr. Meehan’s testimony. *Id.* You’re not to speculate as to the reason or reasons why. *Id.* But you are instructed that you have to disregard all of his testimony.” *Id.*

In addition, Defendants presented the testimony of Dr. Coreen Robbins, an industrial hygienist who testified “consumer exposure to diacetyl from popping microwave popcorn is insignificant.” *Id.* at 414. Dr. Robbins testified about an “experiment” in which she popped popcorn to see when she could put her nose in the bag, which she determined to be approximately one minute. *Id.* She also measured the temperature of the air coming out of the bag and determined “[y]our really can’t stick your nose right in it” because it is too hot. *Id.* The district court struck the experiment portion of the Dr. Robbins testimony and instructed the jury:

> [T]here are just too many dissimilarities between what she did and what The husband was doing. We don't have the same popcorn bags. We don't have the same strength [microwave]. We don't know how long it was cooked for. There's just a whole lot of variables that aren't the same or similar enough to make it admissible evidence.

*Id.*

Following a jury verdict in Defendants’ favor, Plaintiffs appealed arguing that they were entitled to a new trial because the jury was improperly influenced by the testimony of Dr. Meehan and Dr. Robbins despite the limiting instructions. *Id.* The Court reviews a district court’s “denial of a new trial for a 'clear abuse of discretion,' reversing only ‘to prevent a miscarriage of justice.” *Id.* citing *Behlmann v. Century Sur. Co.*, 794 F.3d 960, 963 (8th Cir. 2015).

The Eighth Circuit Court of Appeals, in affirming the denial of Plaintiffs’ new trial motion, found that because Plaintiffs failed to contemporaneously object to the district court’s curative instructions they waived any error “absent a showing of plain error.” *Id.* at 415 citing *Horstmyer v. Black & Decker, (U.S.), Inc.*, 151 F.3d 765, 771 (8th Cir. 1998). The Court noted that generally it is presumed that a jury will follow an instruction to disregard inadmissible evidence inadvertently presented to it, unless there is an overwhelming probability that the jury will be unable to follow the court’s instructions. *Id.* citing *Greer v. Miller*, 483 U.S. 756, 766 n. 8, 107 S.Ct. 3102, 97 L.E.2d 618 (1987). Because other witnesses provided similar testimony at the trial, the Court was not convinced there was an overwhelming probability the jury could not follow the curative instructions and affirmed the district court’s denial of the motion for new trial.
X. Ninth Circuit

Sealing Confidential Documents

_Ctr. For Auto Safety v. Chrysler Group, LLC_, 809 F.3d 1092 (9th Cir. 2016)

Plaintiffs filed a class action against Chrysler alleging dangerous defects in a part found in certain Chrysler vehicles. The parties entered a stipulated protective order for confidential documents, and Chrysler produced 86,000 documents in discovery, including confidential and trade secret documents. Plaintiffs then moved for a preliminary injunction to require Chrysler to notify its customers of the alleged defect. Both parties attached “confidential” discovery documents, which were filed under seal, to their memoranda supporting and opposing the motion. Shortly before the court denied the preliminary injunction, the Center for Auto Safety (“CAS”) filed motions to intervene and unseal the “confidential” documents.

Prior Ninth Circuit opinions had adopted a “dispositive/nondispositive” test for keeping documents under seal: where the motion at issue is “dispositive” (i.e., brings about a “final determination”), a party seeking to keep documents under seal must show “compelling reasons,” but if the motion is nondispositive, the party need only show “good cause.” The rationale being that the public has less of a need for records attached to nondispositive motions, and therefore the right of access does not apply equally. Relying on this approach, the district court denied CAS’ motion to unseal the documents, finding that the motion was “nondispositive” and that “good cause” existed to keep the documents under seal.

The Ninth Circuit rejected the use of the “binary” “dispositive/nondispositive” approach. The single-judge majority opinion held that the words “dispositive” and “nondispositive” in prior Ninth Circuit cases were merely intended as “descriptive terms [which] are indicative of when a certain test should apply.” After examining precedent from the Ninth Circuit, as well as the standards adopted by the First, Second, Third and Eleventh Circuits, the majority opinion held that “[t]he focus in all of our cases is on whether the motion at issue is more than tangentially related to the underlying cause of action.” The Court stated:

Consistent with our precedent, we make clear that public access to filed motions and their attachments does not merely depend on whether the motion is technically “dispositive.” Rather, public access will turn on whether the motion is more than tangentially related to the merits of a case. While many technically nondispositive motions will fail this test, some will pass.

The majority opinion found that Plaintiffs’ preliminary injunction motion was “more than tangentially related to the merits” of the case. Therefore, on remand, Chrysler is required to demonstrate compelling reasons to keep the documents under seal.

The concurring opinion would have held that reversal was warranted even under the binary “dispositive/nondispositive” test, since the preliminary injunction motion at issue was literally “dispositive” of Plaintiffs’ request that Chrysler issue notice to its customers.

The dissent vigorously opposed the majority opinion, stating that the majority invents a new rule which is inconsistent with existing precedent and vitiates Rule 26(c). In particular, “the majority’s test effectively holds that all sealed documents attached to any filing that has any relation to the merits of the case are subject to the public’s presumed right of access, and therefore deprives protective orders issued under Rule 26(c) of any force or effect.” (emphasis in original). The dissent also notes that the “more than tangentially related” test “has no discernible meaning[,]” and expresses concern that future litigants can no longer rely on protective orders, and will have to “chart [their] course through discovery cautiously and belligerently, to the detriment of the legal system.”

On October 3, 2016, the U.S. Supreme Court denied Chrysler’s Petition for Writ of Certiorari.
Consumer Expectation vs. Risk-Benefit Test / Circumstantial Evidence

Michery v. Ford Motor Co., 650 F. App’x 338, 339 (9th Cir. 2016)

Plaintiff was injured in a vehicle accident when he swerved his 1999 Ford Expedition into a roadway median and sideswiped a palm tree. The vehicle sustained “major damage” in the accident; the top was smashed, the door was torn off, the windshield was shattered, both airbags deployed, and there was damage to the left light assembly, front fender, hood, and driver side floorboard. Plaintiff brought a strict products liability action against Ford under a design defect theory, alleging that the vehicle’s “structural components” and “interior configuration and components” entrapped his left lower extremity and failed to provide adequate crash protection. The subject vehicle, however, was destroyed before it could be inspected.

The Ninth Circuit affirmed the district court’s finding that the consumer expectations test did not apply to Plaintiff’s claim. Quoting Soule v. Gen. Motors Corp., 882 P.2d 298 (Cal. 1994), the Court noted that “[t]he consumer expectations test is reserved for cases in which the everyday experience of the products’ users permits a conclusion that the product’s design violated minimum safety assumptions, and is defective regardless of expert opinion about the merits of the design.” Because Plaintiff’s claim involved the “precise behavior of several obscure components of her car under the complex circumstances of a particular accident[,]” the Ninth Circuit concluded that “[l]ike Soule, ordinary experience and understanding would not inform a consumer how safely an automobile design should perform under these circumstances . . . .”

The Ninth Circuit reversed the district court’s finding that Plaintiff failed to raise a genuine issue of material fact under the risk/benefit test. The Court held that Plaintiff made a prima facie showing that his injuries were caused by the defective design of the vehicle, based on the opinions of his expert, crash tests conducted on the same model and similar vehicles, and the police report, photographs, medical records, and witness statements. Accordingly, under California law, the burden should have shifted to Ford to establish that, in light of the relevant factors, the benefits of the design outweigh the risk of danger inherent in such design.

The Ninth Circuit also held that the district court erred in discarding the declaration of Plaintiff’s expert based on Triton Energy Corp. v. Square D Co., 68 F.3d 1216 (9th Cir. 1996). Triton involved an allegedly defective circuit breaker that had been destroyed due to a miscommunication before it could be examined by experts from either side. As a result, the sole evidence that was available at trial “essentially consisted of opposing expert opinion.” Applying Nevada law, the Ninth Circuit in Triton affirmed the dismissal of the product liability claim, holding that “[a] jury should not be asked to evaluate the credibility of experts concerning the defectiveness of a [product] when it left the hands of [the manufacturer], which the experts have neither seen nor can see, and which was manufactured more than two decades ago.”

In the instant case however, the Ninth Circuit noted that California law permits a plaintiff to prove a design defect through circumstantial evidence, “even when the accident itself precludes identification of the specific defect at fault.” Further, unlike in Triton, Plaintiff alleged a defect in the design of all 1999 Ford Expeditions, and accordingly, the evidence did not consist solely of speculative expert opinion. Therefore, the declaration of Plaintiff’s expert should not have been discarded.

District Court Cases – Arizona

Specific Personal Jurisdiction


This case ("NMTC") arose from a building fire in Arizona which was alleged to have originated from a defective lithium-ion battery that was manufactured and/or supplied by Techway, a Taiwan corporation. Plaintiff argued that the Court had specific personal jurisdiction over Techway under a “stream of commerce” theory.
The Supreme Court first addressed the stream of commerce theory in products liability cases in *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286 (1980). In that case, the Court held that a “forum State does not exceed its powers under the Due Process Clause if it asserts personal jurisdiction over a corporation that delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State.” As the Supreme Court explained, “the foreseeability that is critical to due process analysis is not the mere likelihood that a product will find its way into the forum State. Rather it is that the defendant’s conduct and connection with the forum State are such that he should reasonably anticipate being haled into court there.” Thus, “if the sale of a product … is not simply an isolated occurrence, but arises from the efforts of the manufacturer or distributor to serve, directly or indirectly, the market for its product in other States, it is not unreasonable to subject it to suit in one of those States ….” As noted by the NMTC Court, however, since the opinion in *World-Wide Volkswagen*, “a majority of the Supreme Court has not agreed on a stream of commerce rationale for specific jurisdiction.”

In *Asahi Metal Industry Co. v. Superior Court of California*, 480 U.S. 102 (1987), Justice O’Connor’s plurality opinion, joined by three justices, adopted a narrower “stream of commerce plus” test, under which “[t]he placement of a product into the stream of commerce, without more, is not an act of the defendant purposefully directed toward the forum State.” According to Justice O’Connor, there must be “additional conduct” of the defendant indicating “an intent or purpose to serve the market in the forum State[.]” Thus, “a defendant’s awareness that the stream of commerce may or will sweep the product into the forum State does not convert the mere act of placing the product into the stream into an act purposefully directed toward the forum State.” Justice Brennan's concurring opinion, which was also joined by three justices, rejected the more stringent “stream of commerce plus” test. Justice Brennan's concurrence held that a showing of “additional conduct” is not required under the Due Process Clause. According to Justice Brennan, “[t]he stream of commerce refers not to unpredictable currents or eddies, but to the regular and anticipated flow of products from manufacturer to distribution to retail sale. As long as a participant in this process is aware that the final product is being marketed in the forum State, the possibility of a lawsuit there cannot come as a surprise.”

In *J. McIntyre Machinery, Ltd. v. Nicastro*, 564 U.S. 873 (2011), another plurality opinion, the United States Supreme Court issued its most recent decision on the stream of commerce theory in products liability cases. Justice Kennedy, joined by three justices, rejected Justice Brennan’s concurrence in *Asahi*. Justice Kennedy’s plurality opinion held that “[t]he principal inquiry in cases of this sort is whether the defendant's activities[, as opposed to expectations,] manifest an intention to submit to the power of a sovereign.” Thus, “[t]he defendant's transmission of goods permits the exercise of jurisdiction only where the defendant can be said to have targeted the forum; as a general rule, it is not enough that the defendant might have predicted that its goods will reach the forum State.” Justice Breyer’s concurring opinion, joined by one other justice, disagreed with the plurality’s “strict” rule that a defendant who does not “intend[d] to submit to the power of a sovereign” cannot “be said to have targeted the forum.” Rather, Justice Breyer focused his analysis on the original stream of commerce approach in *World-Wide Volkswagen* and the separate opinions of the Court in *Asahi*. Justice Breyer noted that under existing precedent, “a single sale of a product in a State does not constitute an adequate basis for asserting jurisdiction over an out-of-state defendant, even if that defendant places his goods in the stream of commerce, fully aware (and hoping) that such a sale will take place.” Simply placing a product into the stream of commerce, without something more than awareness that the stream “may or will sweep the product into the forum State[,]” does not establish jurisdiction. On the other hand “jurisdiction should lie where a sale in a State is part of ‘the regular and anticipated flow’ of commerce into the State, but not where that sale is only an ‘edd[y];’ i.e., an isolated occurrence[.]”
In NMTC, the Court noted that “[w]hen a fragmented [Supreme] Court decides a case and no single rationale explaining the results enjoys the assent of five Justices, the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds[].” See Marks v. United States, 430 U.S. 188 (1977). Accordingly, the Court viewed “the holding of the fragmented J. McIntyre decision to be that of the narrow ground set forth in Justice Breyer’s concurrence in the judgment.” Thus, “a stream of commerce approach that dispenses with an examination and weighing of the nonresident defendant’s contacts with the forum and that imposes personal jurisdiction on no more than the defendant’s use of a national distributor which directs product of any quantity to the forum must be rejected.” The Court also concluded that this approach is consistent with the Ninth Circuit’s approach in Holland America Line Inc. v. Wärtsilä North America, Inc., 485 F.3d 450 (9th Cir.2007), which expressly adopted Justice O’Connor’s “stream of commerce plus” test.

**The Discovery Rule / Identity of Proper Defendant**


Plaintiff alleged that he was injured by a certain pain pump used by his doctor during a surgery in 2006. Plaintiff realized he was injured in 2008. Before filing suit, Plaintiff’s attorney found conflicting evidence as to whether the pump was manufactured by I-Flow or Breg. The operative report pointed to Breg, but the billing letter from Plaintiff’s doctor pointed to I-Flow. During informal conversations, Plaintiff’s doctor told Plaintiff’s attorney that “it had to have been an I-Flow pump” and that he “had stopped using Breg pumps by the date of that surgery.”

Plaintiff filed two separate suits against I-Flow, in August of 2008 and February of 2010. Neither suit named Breg as a defendant. During discovery in the second suit, Plaintiff’s law firm was provided access to an electronic database of Plaintiff’s medical records, which were available to download. As of July 2011, the database included the product identification sticker for the pump, which identified Breg as the manufacturer. Plaintiff’s law firm downloaded several records, but not the records containing the product identification sticker. In April of 2012, counsel for I-Flow informed Plaintiff’s attorney that the database included the product identification sticker. Plaintiff filed his first lawsuit against Breg in December of 2012, in California state court. That lawsuit was voluntarily dismissed.

Plaintiff then filed the current lawsuit against Breg in March of 2014. Breg moved to dismiss under the statute of limitations. Plaintiff argued that under the discovery rule, his claim did not accrue until April of 2012, when Plaintiff’s attorney first viewed the product identification sticker. The Court framed the issue as “when a reasonable plaintiff should have discovered that Breg was the proper Defendant.” The Court held that, given the “contradictory inferences” which could be drawn from the information known and/or available to Plaintiff, there was a genuine issue of material fact as to whether Plaintiff “knew or with the exercise of reasonable diligence could have known” the identity of the correct defendant. In particular, the Court noted, “the evidence would allow a reasonable jury to determine that it was reasonable for Plaintiffs not to have discovered the proper Defendant until either the product identification sticker was available to them, in 2011, or they actually uncovered it, in 2012.”

**Federal Civil Rule 26(b)(1)**


The plaintiffs in this MDL action allege that Bard’s IVC filters suffer from a dangerous design defect. Plaintiffs sought discovery of electronically stored communications regarding the IVC filters between Bard’s foreign subsidiaries/divisions and foreign regulatory bodies. The Court took this opportunity to address the
scope of discovery under the “new” Federal Civil Rule 26(b)(1), which was amended December 1, 2015. The new rule states:

Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Thus, like the old rule, parties may obtain discovery of information that is “relevant to any party’s claim or defense.” Significantly, however, the new rule no longer provides that inadmissible evidence is discoverable if it “appears reasonably calculated to lead to the discovery of admissible evidence.” As noted by the Court, citing the Advisory Committee on the Federal Rules of Civil Procedure, the “reasonably calculated” phrase has been used to “incorrectly” define the scope of discovery. Thus, the new rule eliminates the phrase “reasonably calculated.” Pursuant to the Rules Enabling Act, 28 U.S.C. §2072, “the 2015 amendment effectively abrogated cases applying a prior version of Rule 26(b)(1). The test going forward is whether evidence is ‘relevant to any party’s claim or defense,’ not whether it is ‘reasonably calculated to lead to admissible evidence.’” As noted by the Court, however, “many courts continue to use the phrase. Old habits die hard.”

“The 2015 amendments also added proportionality as a requirement for permissible discovery. Relevancy alone is no longer sufficient — discovery must also be proportional to the needs of the case.” However, the burden of proving proportionality is not on the party seeking discovery. “Rather, “[t]he parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes.”

Under the new rule, the Court held that the burden and expense of producing the communications sought by Plaintiffs outweighed its likely benefit, since (1) there are no Plaintiffs from foreign countries, and (2) Plaintiffs only sought the communications “to determine if any of those communications have been inconsistent with Defendants’ communications with American regulators.”

**District Court Cases – California**

**Strict Liability / Product vs. Service Transaction**


Defendant hotel operator developed the “Get Fit Kit” (the “Kit”)—a duffel bag with small exercise equipment—which it makes available to its hotel guests. The Kit included an elastic resistance band, called the Xering, which was manufactured by a non-party. However, the Kit did not include any instructions for using the various items in the bag. Defendant offers the Kit to all guests, but does not sell the kits. Plaintiff was a guest at one of Defendant’s hotels. When she was in her room, she attempted to use the Xering as she had used other resistance bands. Sitting on the floor with her legs extended, Plaintiff placed the Xering around her feet and pulled the band toward her body. “[T]he band rolled over the top of her shoes, which caused her left fist to recoil backwards into her left eye.” Plaintiff’s eye ultimately had to be removed as a result of the injury. Plaintiff brought a negligence and strict products liability claim against Defendant.

Plaintiff alleged that Defendant was negligent by (1) failing to perform a risk assessment in accordance with hotel industry standard, and (2) failing to ensure that the Kit included instructions. The Court held that there were genuine issues of material fact on the negligence theory. However, the Court dismissed Plaintiff’s strict products liability claim. In California, as long as the purchase of a product is the primary objective of the transaction, strict liability can apply even to “mere conduits” in distributing the product. However, strict
liability does not apply “where the transaction's service aspect predominates and any product sale is merely incidental to the provision of the service.” The Court concluded that the primary purpose of the transaction between Defendant and Plaintiff was service-related. “While hotels that sell workout kits, shower heads, or beds to their guests are more like retailers and distributors and may be strictly liable for the products they provide guests and offer to sell, [Defendant] is not such a hotel.”

**Expert Witness Deadlines**


In November of 2013, Roger Rodas and “The Fast and the Furious” actor Paul Walker were both killed in vehicle accident. Rodas was driving a 2005 Porsche Carrera GT (“Carrera GT”), and Walker was his passenger. Plaintiff, Rodas’ wife, brought product liability claims against Porsche based on four alleged defects with the Carrera GT: (1) absence of a crash cage; (2) substandard side impact protection; (3) lack of a fuel cell; and (4) failure of the suspension component (or “toe rod”). Defendant moved for summary judgment on all four alleged defects based on lack of causation evidence. Because Plaintiff essentially conceded that there was no evidence that the first three alleged defects played any role in Rodas’ death, the question before the Court was whether Plaintiff had shown a genuine issue of material fact as to whether the accident was caused by the failure of the suspension component.

As noted by the Court, the question of “whether a defectively designed or manufactured suspension component was the cause of the accident (as opposed to, for example, driver error) is outside the purview of a layperson.” Accordingly, Plaintiff was required to submit expert evidence to establish causation. Before the expert disclosure pretrial deadline, however, the only expert causation evidence that Plaintiff had produced was the preliminary investigative report of Plaintiff’s expert, David Renfroe. The Court held that Renfroe’s report was inadmissible “because it fail[ed] to apply reliable principles to the actual facts of this case.” In particular, “[t]he only fact which supports Renfroe’s theories is that the right tire mark was significantly shorter than the left tire mark in January, 2014, but Plaintiff admits that fact is not an accurate representation of the tire marks on the night of the accident.”

In opposing Defendant’s motion for summary judgment, Plaintiff submitted an additional declaration from Renfroe. The new declaration contained new opinions which directly contradicted his preliminary investigative report. The Court refused to consider the new declaration. “Even if the Renfroe declaration had been submitted in time for the rebuttal deadline, it is not a proper one. A rebuttal report should directly respond to or address ‘new unforeseen facts’ brought out in the other side’s report on the same subject matter, and is not the ‘proper place for presenting new arguments.’” Accordingly, the Court granted Defendant’s motion for summary judgment in its entirety.

**Forum Non-Conveniens**


Defendant is a California company that designs, manufactures and sells medical devices that are implanted in patients with degenerative spinal diseases. One of the devices, the M6-C, was implanted in Plaintiffs. Plaintiffs are both residents of Germany. Plaintiff’s implant operations were performed in Germany. Defendant’s wholly-owned German subsidiary sold the devices that were implanted in Plaintiffs. Plaintiffs brought a purported class action against Defendant in California, alleging product liability and negligence claims. Significantly, “California law provides for punitive damages in products liability cases, while German law does not.”

Defendant moved to dismiss on the grounds of forum non-conveniens, arguing that Germany was the preferred forum. Accordingly, Defendant had the burden of showing “that there is an adequate alternative
forum, and that the balance of private and public interest factors favors dismissal.” First, the Court found that Germany is an adequate alternative forum because Defendant is “amenable to service process” in Germany, and German law provides “at least some remedy for the harm suffered by Plaintiffs.” Second, the Court found that the “private interest factors” weigh in favor of dismissal. While some witnesses in California have knowledge of the product’s design, the majority of critical witnesses, “including Plaintiffs themselves, their family members, co-workers, the implanting surgeons, and the treating physicians,” are located in Germany and are beyond the Court’s subpoena power. In addition, although some documentary evidence exists in California, Defendant agreed to produce the documents in a German proceeding. Finally, the Court found that the “public interest factors” were all neutral except for one factor: the Court’s familiarity with governing law. Because the Court would likely have to apply or interpret German law, “the balance of public interest factors weigh slightly in favor of dismissal.” Accordingly, the Court determined that Germany was the most appropriate forum for litigating the case, and granted Defendant’s motion to dismiss.

**General and Specific Personal Jurisdiction**


Plaintiff was driving a Ford truck equipped with a Theiman lift gate. As Plaintiff was standing on the lift gate, the metal plates of the lift gate opened, causing his legs to drop down. The lift gate then closed, trapping and injuring Plaintiff’s legs. Plaintiff sued Ford and Theiman.

Relying on *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), the Court concluded that it did not have general personal jurisdiction over Ford. Despite Ford’s contacts in California (business offices, a Research and Innovation Center, active marketing in California, over 200,000 vehicles sold in California in 2015, and more), the Court held that this was not the type of “exceptional case” in which the “corporation’s affiliations with the State are so continuous and systematic as to render it essentially at home in the forum State.”

As to the issue of specific personal jurisdiction, the Ninth Circuit has established a three-part test. Under the second prong of the test, the “relatedness” prong, the plaintiff must show that the claim “arises out of or relates to the defendant’s forum-related activities[.]” The Ninth Circuit applies a “but for” test to this prong. Plaintiff urged the Court to adopt the California Supreme Court’s recent holding in *Bristol-Myers Squibb Co. v. Superior Court*, 377 P.3d 874 (Cal. 2016), which held that “the defendant's activities in the forum state need not be either the proximate cause or the ‘but for’ cause of the plaintiff’s injuries.” Rather, under *Bristol*, the relatedness prong “is satisfied if there is a substantial nexus or connection between the defendant’s forum activities and the plaintiff’s claim.” However, because “federal law is controlling on the issue of due process under the United States Constitution[,]” the Court in *Sullivan* refused to adopt the holding in *Bristol*. The Court noted that the truck was not designed or manufactured in California, the truck was sold to a dealership in Minnesota, and the lift gate was not installed by Ford. “Because [Plaintiff could not] show that but for Ford’s California contacts he would not have been injured by the Ford truck and attached lift gate, the Court decline[d] to exercise specific jurisdiction over Ford.”

**District Court Cases – Hawaii**

*Restatement (Second) of Torts §402A, comment k*


Plaintiffs alleged that Thomas Segovia died as a result of taking Eliquis, an anti-coagulant/blood thinner developed by Defendants. Defendants’ filed a motion to dismiss Plaintiffs’ strict liability design defect claim, asking the Court to adopt a blanket immunity to all prescription drug manufacturers from composition-based design defect claims, under the Restatement (Second) of Torts §402A, comment k. Comment k
provides that certain “unavoidably unsafe” products are not defective as long as the products are properly manufactured and proper warnings are given.

Although the Hawaii courts have acknowledged that comment k might be applicable to some products, the cases do not create a blanket rule of design defect immunity, but rather employ a case-specific analysis. Furthermore, the Court noted, “the clear language of the comment indicates it is to apply to only some products[.]” (emphasis added). Accordingly, the Court declined to extend comment k “to an entire field of products[.]” The better reasoned view, the Court explained, “is that courts should determine on a case-by-case basis whether a product is within the scope of comment k — that is, examining cost, risk, safety and policy considerations, among others, to determine whether it is an ‘unavoidably unsafe’ product.”

**District Court Cases – Idaho**

**Fraudulent Joinder / Hospital Liability for Defective Medical Devices**


Plaintiff alleged that her doctor used defective DePuy surgical screws during an operation she received at a hospital in Idaho. Plaintiff sued DePuy and the hospital in state court, asserting claims for strict liability, negligence, and products liability under the Idaho Products Liability Reform Act (IPLRA). Although Plaintiff and the hospital are both Idaho residents, DePuy removed the case to federal court on the grounds that the hospital was fraudulently joined. DePuy argued that Plaintiff had no plausible cause of action against the hospital, because the Hospital Defendants are not “product sellers” under Idaho law and therefore cannot be sued under the IPLRA.

Under the IPLRA, the term “product seller” includes manufacturers, wholesalers, distributors, or retailers, but it expressly exempts “provider[s] of professional services who utilize[] or sell[] products within the legally authorized scope of its professional practice.” The Court noted that “the issue of whether a hospital may be held liable for defects in devices used in medical procedures” has not been addressed by any Idaho court. *DePuy* and the hospital argued that Idaho courts would take the “majority approach” and hold that hospitals are not “product sellers” but rather “professional service providers” for purposes of product liability. The Court found this interpretation “eminently reasonable.” Nevertheless, because there are no “settled rules of the state” on this issue, and because “uncertainties as to controlling law must be resolved in the Plaintiffs’ favor[,]” the Court remanded the case back to state court.

**District Court Cases – Nevada**

**Fraudulent Joinder / Liability of Sale Representatives**


James Emerson was injured in an ATV accident. At the time he purchased the ATV, a sales associate, Hall, and the sales/financing manager, Pastor, told him the ATV was “safe, ‘fit for use as an off-highway vehicle,’ and ‘perfect for what Mr. Emerson was looking for.’” After the accident, Emerson and his wife brought suit against Arctic Cat Sport, Inc., Hall, Pastor and others. Although Plaintiffs, Hall and Pastor are all residents of Nevada, Defendants removed the case based on diversity jurisdiction. In opposing Plaintiffs’ motion to remand, Defendants argued that Hall and Pastor were fraudulently joined because, under Nevada law, they cannot be held liable for strict product liability.

Under Nevada law, a seller is defined as “a person who sells or contracts to sell goods.” NRS §104.2103(1)(c). The Court held that neither of the cases relied upon by Defendant “stand for the proposition that all sales representatives are categorically excluded from the definition of sellers in NRS §104.2103(1)(c).” In particular, in *Kite v. Zimmer US, Inc.*, 2006 U.S. Dist. LEXIS 85420, 2006 WL 3386765 (D. Nev. Nov. 22, 2006), the fraudulently joined defendant delivered medical devices to a Nevada hospital, and “served only as a
conduit’ through which a hospital could request medical devices ….” In *Thompson v. Medtronic, Inc.*, 2006 U.S. Dist. LEXIS 91846, 2006 WL 3544937 (D. Nev. Dec. 8, 2006), “the fraudulently joined defendant … only set up a ‘course of sales’ by providing the manufacture’s phone number to the plaintiffs, which the court deemed an insufficient ‘causal nexus’ to establish the defendant as a seller.”

The Court held that “*Kite* and *Thompson* were based on specific facts about the defendants in the respective cases.” Further, unlike in *Kite* and *Thompson*, Plaintiffs in the instant case alleged that “Hall and Pastor directly interacted with Plaintiffs and made affirmative representations regarding the ATV.” Given the “dearth of case law in Nevada state courts defining what a ‘seller’ is for purposes of strict products liability[,]” and given that similar claims have been recognized by other jurisdictions, the Court held that “Defendants have failed to meet the heavy burden required to show that Hall and Pastor were fraudulently joined and that diversity jurisdiction exists.”

**District Court Cases – Oregon**

**Daubert / Relevance & Reliability of Expert Opinion**


Plaintiff was injured when she purportedly fell from an inversion table (the “InvertAlign”) while it was fully inverted. Plaintiff claims that she was wearing lace up tennis shoes, stepped on the InvertAlign, and secured the “ankle locking mechanism” as close as possible to her ankles. While she was fully inverted, she blacked out. When she regained consciousness, she was on the ground, unable to move her legs. She is now a permanent paraplegic. Plaintiff had used the InvertAlign with no problems for six months before the incident. Plaintiff alleges strict product liability based on the defective design of the “ankle lock” feature of the inversion table. Plaintiff moved to strike the expert reports and opinions of Defendants expert neurosurgeon, Dr. Johnson.

Dr. Johnson opined that before the incident, Plaintiff had an undetected and nearly undetectable degenerative condition of her cervical spine, referred to as “OPLL.” He opined that if Plaintiff did not have OPLL, she would only have suffered a minor injury, and that it is possible Plaintiff would have become paralyzed at some point in the future due to some other “minor” head or neck injury. The Court struck these opinions as “legally irrelevant” based on the “eggshell plaintiff” doctrine. In particular, “Defendants may not escape liability or seek reduced damages by arguing that Plaintiff would not have suffered catastrophic injuries but for her unknown, preexisting OPLL or that because of her condition she possibly would have become paralyzed anyway.” In addition, the Court noted, the opinion that Plaintiff might possibly become paralyzed at some point in the future is speculative and insufficiently reliable.

Dr. Johnson also opined that Plaintiff may have become spontaneously paralyzed in the moments just before falling from her InvertAlign. The Court struck this opinion as speculative and unreliable. The Court noted that Dr. Johnson developed this opinion “expressly for the purposes of testifying[,]” and did not identify any “objective, verifiable evidence” regarding instantaneous spontaneous paralysis caused by OPLL in the absence of any trauma. Thus, “Dr. Johnson’s opinion that it is ‘possible’ Plaintiff could have become paralyzed and then fell from her InvertAlign does not rest on sufficient facts or data, is unreasonably speculative, and is not helpful to a jury, at least without more.”

**District Court Cases – Washington**

**Constitutionality of RCW 4.20.020**

(Beneficiaries in Wrongful Death & Survival Actions)

Ha Ram Kim—a 20-year old from South Korea who had recently arrived in the United States—died from injuries she sustained in a collision between a motorcoach, in which she was a passenger, and an amphibious tourist vehicle that was being operated by defendant Ride the Ducks/Seattle, and which had been modified by defendant RTDI. Ms. Kim’s father and mother reside in South Korea. Ms. Kim’s father, as the personal representative of her estate, brought claims against Defendants for, inter alia, negligent maintenance or repair, negligent operation, and product liability.

In Washington, tort claims arising from a death caused by the negligence of another are “strictly a matter of legislative grace and are not recognized in the common law.” Washington statutes define two ways in which such tort claims may be pursued. First, such claims may be pursued as a wrongful-death claim for the benefit of the persons identified in RCW 4.20.020. Under this statute, if the decedent does not have a spouse, state registered domestic partner, or children, the only beneficiaries entitled to recover are the parents or siblings of the decedent who (i) “may be dependent upon the deceased person for support,” and (ii) “are resident within the United States at the time of his or her death.” Second, such claims may be pursued under the survival of actions statute, except that “damages for pain and suffering, anxiety, emotional distress, or humiliation personal to and suffered by” the decedent are recoverable only on behalf of “those beneficiaries enumerated in RCW 4.20.020[.]”

Ms. Kim did not have a spouse, state registered domestic partner, or children. Further, her parents and siblings were neither dependent on her nor resident within the United States at the time of her death. Without any such beneficiaries, the Court dismissed the wrongful-death claim and the prayer for non-pecuniary damages in the “survival” action.

The Court rejected Plaintiffs’ argument that the dependency and residency requirements were impliedly repealed by the Washington Law Against Discrimination (“WLAD”). The Court also rejected Plaintiffs’ argument that the dependency and residency requirements ran afoul of the Equal Protection Clause of the Fourteenth Amendment and the Privileges and Immunities Clause of the Washington constitution. As to the dependency requirement, the Court noted that the argument has been repeatedly rejected. As to the residency requirement, the Court noted that this issue has received little judicial attention. Nevertheless, the Court held that the wrongful-death and “survival” of actions statutes are “textually neutral,” and do not distinguish between citizens and non-citizens or any impermissible immutable characteristic. “A resident alien, who is a financially dependent parent or sibling of a decedent, may recover under RCW 4.20.020 to the same extent as a similarly situated American citizen residing in the United States.” Thus, Washington has not denied “to any person within its jurisdiction the equal protection of the laws.”

**Removal / Amount in Controversy**


Plaintiff brought strict product liability, negligence, and breach of implied warranty claims against Monster Beverage Corporation and Monster Energy Company based on a hemorrhagic stroke he allegedly sustained after consuming four, sixteen-ounce Monster energy drinks in one day. Monster removed the suit to the district court on the basis of diversity jurisdiction. Plaintiff’s complaint did not specify the amount of damages sought, and Plaintiff sought to remand the case, arguing that Monster failed to establish it is “more likely than not” that the amount in controversy exceeds $75,000. Citing to *Mireles v. Wells Fargo Bank, N.A.*, 845 F. Supp. 2d 1034, 1055 (C.D. Cal. 2012), the Court allowed Monster to rely on settlements and jury verdicts in analogous cases as evidence of the amount in controversy. Although the cases relied upon by Monster were not identical to the instant case, all three cases involve plaintiffs who suffered similar injuries, and established that the amount in controversy most likely exceeds the jurisdictional minimum.
**Standing to Bring Product Liability Claims**


The City of Spokane filed strict products liability and other claims against Monsanto, seeking to hold Monsanto liable for the costs of cleaning up PCB contamination in the Spokane River and reducing PCB discharge from Spokane's wastewater and stormwater systems. PCBs were used in many industrial and commercial applications before they were mostly banned in 1979. Most of the PCBs in the United States were produced, marketed, and distributed by Monsanto. The production, use, and disposal of PCBs has resulted in widespread environmental contamination, including contamination of the Spokane River. PCBs are harmful to fish, birds, and other animals, and exposure to humans is associated with cancer and a number of other serious health conditions.

Monsanto argued that Spokane's common-law claims were preempted by the Washington Product Liability Act (WPLA). The Court rejected this argument because the WPLA “does not preempt common-law claims where substantially all of the injury-producing events occurred prior to the WPLA’s effective date, June 26, 1981, even if the injury occurs later.”

Monsanto also argued that Spokane lacked standing to bring a products liability claim because it was not a “consumer or user” of the products at issue. However, to the extent Spokane's claims arise from conduct occurring after July 26, 1981, the Court held that Spokane had standing under the WPLA, because the act expressly defines a claimant to include “any person or entity that suffers harm” and provides that “[a] claim may be asserted . . . even though the claimant did not buy the product from, or enter into any contractual relationship with, the product seller.” Nevertheless, the Court held that Spokane did not have standing to bring a common-law strict products liability claim, because Washington law only extends such claims to users or consumers of a product, and in some cases, certain bystanders and/or household members whom the manufacturer should reasonably expect to use or be exposed to its product. Spokane was not a bystander in close proximity to and directly injured by another's use of a defective product. The Court did not decide “the precise contours of the line between” those who have standing and those who do not “because, wherever that line is located, Spokane is well beyond it.” “Spokane is not the type of plaintiff the common-law product defect cause of action is intended to encompass, and it therefore lacks standing to bring a common-law strict-liability claim.”

**Failure to Warn / Preemption**


Paraplegic drivers commonly use one of two techniques to move between a wheelchair and a vehicle: transfer boards and the “popover” method. Since 1983, Plaintiff, a paraplegic physician, has used a less common transfer method that involves placing his right foot in the wheel well, grabbing the overhead handle on the ceiling with his right hand, pushing up with his left hand, and then moving laterally into the driver's seat. As Plaintiff entered his leased Mercedes vehicle one day, the handle detached from its anchor points, causing him to fall between the vehicle and his wheelchair and injure his rotator cuff. Plaintiff sued Mercedes under the Washington Product Liability Act, asserting both manufacturing defect and failure to warn claims. Mercedes moved for partial summary judgment on the failure to warn claim.

The Court rejected Mercedes' argument that Plaintiff’s use of the handle was unforeseeable and therefore it had no duty to warn. The Court noted that “[u]nlike in a negligence claim, a tortfeasor's inability to foresee harm does not negate a duty to warn.” In particular, “[f]or a failure to warn claim, the test . . . is one of strict liability, not ordinary negligence, and so foreseeability is not an element.”

The Court also held that genuine issues of material fact existed as to each essential element of Plaintiff's failure to warn claims. Since Mercedes described Plaintiff’s method of entering vehicles as “repeatedly
swinging back and forth from the handle with his bottom swaying mid-air,” the manner in which Plaintiff used the overhead handle was a genuine issue of material fact. In addition, a genuine issue of material fact existed as to “whether in the absence of a warning, an ordinary consumer would expect the handle to be safe for daily use to assist entry and exit.” Finally, since the Court must accept as true Plaintiff’s allegation that he would have heeded a warning, there was a genuine issue of material fact as to whether any failure to warn was a cause-in-fact of Plaintiff’s injuries.

The Court rejected Mercedes’ argument that Plaintiff failed to adequately specify the substance of the missing warning. Although it was Plaintiff’s burden to “specify the substance of the missing warning or instruction that would have prevented his or her harm[,]” this burden “does not require a plaintiff to specify exact words.” Plaintiff satisfied his burden by alleging that Mercedes should have warned users: “Do Not Use Grab Handle To Assist Entry or Exit from Vehicle.” Indeed, the Court noted, “[e]ven an allegation that Mer-cedes should have warned users against using the handle for ingress and egress would have been sufficient.”

Finally, the Court rejected Mercedes’ argument that federal law preempts Plaintiff’s claim that Mer-cedes should have included a warning on the sun visor. Mercedes’ argument was premised on the fact that FMVSS 208 mandates the specific language and placement of sun-visor warning labels concerning air bags. The Court acknowledged that FMVSS 208 occupies the field of visor-mounted airbag warnings, and thus preempts claims where the alleged missing warning pertains to airbags. However, because FMVSS 208 only addresses airbag warnings, and because the savings clause at 49 U.S.C. §30103(e) “requires a narrow approach to implied conflict preemption between state tort claims and federal motor vehicle safety standards,” the Court found no conflict between FMVSS 208 and Plaintiff’s claim that Mercedes should have warned against using the overhead handle for entry and exit.

XI. Tenth Circuit

Pre-emption - Clear Evidence


Parents and child commenced products liability action alleging that drug manufacturer failed to warn of risk that infertility treatment drug would cause birth defects. Manufacturer moved for summary judgment. The Motion was granted. The court held that the Food and Drug Administration’s (FDA) denial of prior citizen petitions arguing for infertility treatment drug label alterations, standing alone, was clear evidence that FDA would not have permitted drug manufacturer to strengthen label of that drug to include warnings of risks of birth defects if taken prior to pregnancy, and thus denial of prior petitions conflict-pre-empted state-law failure-to-warn claims; petitions’ request to alter drug’s label was exact theory and substance on which claimants’ case relied, and FDA’s rejection of claimants’ theories occurred many years after claimant took drug to induce ovulation. U.S.C.A. Const. Art. 6, cl. 2; 21 C.F.R. §§10.30, 314.70.

Court also held that the FDA’s inaction with respect to Clomid’s labeling is highly persuasive evidence that the FDA would not have approved strengthening Clomid’s label prior to 1992. Since 1967, Clomid’s label has consistently warned about the risk to a fetus if Clomid is ingested during pregnancy. In the nearly five decades Clomid has been used to induce ovulation, the FDA has never required Clomid to carry warnings suggesting birth defects associated with Clomid use prior to pregnancy. Furthermore, since 1994, the FDA has approved Clomid labeling that acknowledges that Clomid exposure prior to pregnancy does not cause birth defects at a rate greater than that observed in the general population.

Husband of patient who allegedly died as a result of taking prescription drug for multiple sclerosis brought products liability action against manufacturers, alleging negligence, negligent failure to warn and negligent misrepresentation. Court held that husband’s failure to provide expert testimony regarding adequacy of drug’s warning label prevented him from establishing causation. Specifically, Utah products liability law requires expert medical testimony to establish causation where the nature of the injury involves obscure medical factors which are beyond an ordinary lay person’s knowledge. The court further held that the drug’s label adequately warned of increased risks of developing fatal brain infection. Moreover the state law claims were preempted because there was clear evidence that the FDA would not have approved a change to the label prior to 2012. There was evidence that Biogen met with regulators at the FDA on two separate occasions and on both occasions the FDA rejected the proposed labeling changes concerning antibody testing and the use of the assay with Tysabri, concluding there was insufficient data at the time.

**Limitation of Actions**

*Birch v. Polaris Industries, Inc.*, 812 F.3d 1238 (10th Cir. 2015)

Plaintiff purchased an off road vehicle. After riding it, crashing it, and damaging its rollover protections system, they took it in to get a new ROPS for the vehicle. They went to a dealer who purchased one on Craigslist and modified it making several design changes. Plaintiff later crashed his vehicle again and died when the ROPS buckled on impact.

The district court held that plaintiffs could not survive summary judgment because they could not prove that “there was a defect in the product at the time and point of sale.” The plaintiffs requested to amend their complaint to add new legal theories such as failure to warn and request additional discovery. The trial judge denied their request and dismissed their case on summary judgment. The Tenth Circuit Court of Appeals affirmed the trial judge’s decision to dismiss the wrongful death/product liability lawsuit against it for plaintiffs’ failure to amend the complaint prior to the deadline.

*Ziots v. Stryker Corporation*, 2016 WL 3865829 (10th Cir. July 12, 2016)

Patient who was treated with allegedly defective pain pump following shoulder surgery brought products liability claim against manufacturer of pain pump. Plaintiff relied on an operative report that identified the pain pump as a “PainBuster catheter” and assumed because PainBuster is a brand of pump trademarked and exclusively distributed by I-Flow that the catheter used was manufactured by I-Flow. I-Flow’s response in 2011 making Plaintiff aware that they were unable to confirm whether it manufactured the pain pump should have placed her on notice to make further inquiry into the actual manufacturer. Plaintiff did not seek additional information from the Hospital until March of 2013, and at that point she was provided information about the true manufacturer in less than a week. Court held that it was not reasonable for patient to rely on operative report to identify manufacturer of pain pump, and that diligent inquiry should have led patient to have identified the manufacturer of her pain pump before she filed product liability suit against incorrect manufacturer over two years after she discovered her injury. Therefore, the district court’s order granting summary judgment was affirmed.

**Presumption of Defect - Useful Life**

*Helmer v. Goodyear Tire & Rubber Co.*, 828 F.3d 1195 (10th Cir. 2016)

Homeowners brought class action products liability suit against manufacturer of radiant-heating hose, claiming the hose suffered design defects leading to cracks and leaks. After jury returned verdict in favor of manufacturer, the United States District Court for the District of Colorado denied homeowners’ renewed motion for judgment as a matter of law and their motion for new trial. Homeowners appealed.
Plaintiffs suggested Goodyear presented insufficient evidence to support the instruction on Heatway’s nonparty liability. Under Colorado law, a defendant may designate a nonparty at fault as a defense to liability. §13–21–111.5(3)(b). Because Goodyear designated Heatway as a nonparty at fault, the jury instructions and the verdict form directed the jury to apportion liability if it decided that Entran 3 was defectively designed. Because the jury found Entran 3 was not defectively designed, it did not proceed to the subsequent questions on the verdict form concerning nonparty fault.

The Court held that even if Plaintiffs were correct that insufficient evidence supported Heatway’s nonparty liability, the instruction did not affect the jury’s verdict. A jury’s negative answer to a threshold question of liability may render a verdict form’s subsequent erroneous questions harmless. Because the jury concluded Entran 3 was not defectively designed, it did not reach any question as to nonparty liability. Thus, even assuming insufficient evidence of nonparty fault, any error was harmless.

Plaintiffs also argued that the district court erred in denying their Rule 50 motions as to presumptions arising in product liability cases. In particular, they argued the court must consider a product’s useful life in determining whether Colorado’s presumption applies. In Colorado, “[t]en years after a product is first sold for use or consumption, it shall be rebuttably presumed that the product was not defective.” Plaintiffs argue that the phrase “necessary facts giving rising to the presumption” is ambiguous, and the presumption should only be triggered if the product has been used beyond its useful safe life. The Court disagreed and held that under §13–21–403(3), a plaintiff advancing a strict liability claim against a product whose useful safe life has not expired may present evidence to rebut the presumption. The Court declined to infer a useful safe life requirement as a “necessary fact” giving rise to a jury instruction as to the presumption holding instead that “had the General Assembly intended otherwise, it could have used language to that effect.”

**Proof of Defect**

_Tolman v. Stryker Corp._, 640 Fed.Appx. 818 (10th Cir. 2016)

Consumer of nail surgically implanted into bone brought action against manufacturer of nail after nail broke, causing consumer’s bone to break and consumer to suffer permanent injury, asserting claims of negligence, strict products liability, and loss of consortium. Summary judgment was granted to the manufacturer and the consumer appealed. The Court of Appeals affirmed and held that consumer failed to demonstrate that he was entitled to an inference of defectiveness of nail, and thus manufacturer was not liable.

Under Wyoming law, both negligence and strict product liability require them to prove the nail was defective. Although the plaintiffs had no evidence of any specific defect, the court acknowledged they could still make a prima facie case by relying on an inference of defect. To do so, however, “[i]t is not enough to show that an injury occurred during use of the product,” _Rohde v. Smiths Med._, 165 P.3d 433, 437 (Wyo.2007), or even that “the product failed ‘to perform in the manner reasonably to be expected in light of [its] nature and intended function,’ ” _id._ at 438 (quoting _Sims_, 751 P.2d at 361). They must also present “proof” that the product’s failure occurred “in the absence of ... reasonable secondary causes.” _Id._ (quoting _Sims_, 751 P.2d at 361).

In this case the manufacturer identified a reasonable secondary cause: “bone nonunion,” the failure of Mr. Tolman’s fractures to heal adequately. To show this secondary cause was reasonable, the manufacturer pointed to the warning it distributed with the nail cited to Mr. Tolman’s medical records.

**XII. Eleventh Circuit**

_Roper v. Kawasaki Heavy Indus., Ltd._, 646 F. App’x 706 (11th Cir. 2016)

Plaintiff appealed the district court’s exclusion of his expert witness and grant of summary judgment for defendant. Plaintiff alleged the voltage regulator in his motorcycle failed, which drained the battery and
caused his motorcycle to crash. The district court excluded plaintiff’s expert witness on the basis that his testimony was unreliable. The expert failed to exclude other causes that may have contributed to the crash during his scientific analysis. Further, the expert failed to account for data that did not conform with his hypothesis. Because the plaintiff’s expert was excluded, the evidence was insufficient to create a genuine issue of material fact that there was any defect in the motorcycle or that there was any failure to warn. Therefore, the district court’s decision to award summary judgment was affirmed.

*Seamon v. Remington Arms Co., LLC*, 813 F.3d 983 (11th Cir. 2016)

Plaintiff brought an action against Remington Arms Co., a gun manufacturer, alleging that a defect in the design of a rifle’s trigger system caused her husband’s death. The district court granted Remington’s motion for summary judgment and motion to exclude Plaintiff’s liability expert. The district court excluded Plaintiff’s expert’s opinion on the basis that it was unreliable due to the expert’s failure to account for possible alternative causes of the shooting and because he had formed his opinions based on facts not in the record. The Eleventh Circuit Court of Appeals found that the district court abused its discretion in concluding that the opinion of the Plaintiff’s expert was unreliable and, thus, summary judgment for Remington was reversed. The Court found that it was evident from the record that the expert did provide a reasonable explanation for why Remington’s proposed alternative cause was not in fact the cause of Plaintiff’s husband’s death. Additionally, the district court conflated reasonable inference with improper speculation when considering the circumstances of the shooting. The Court held that “[o]nce an expert opinion has satisfied Daubert, a court may not exclude the opinion simply because it believes that the opinion is not – in its view – particularly strong or persuasive. The weight to be given to admissible expert testimony is a matter for the jury.”

*Thurmon v. Georgia Pacific, LLC*, 650 Fed. App’x 752 (11th Cir. 2016)

Plaintiffs, the estate and surviving children of William Thurmon, appealed an award of summary judgment to Crane Co., who Plaintiffs alleged manufactured products that lead to the decedent’s asbestos related death. The District Court for the Northern District of Georgia granted summary judgment on the grounds that Georgia law recognizes the “bare metal defense.” The bare metal defense stands for the proposition that a valve manufacturer is not liable for asbestos related injuries created by components incorporated into the final product or used as replacement parts that were not manufactured or distributed by the defendant-manufacturer. The Eleventh Circuit Court of Appeals upheld the entry of summary judgment because Plaintiffs could not prove the decedent’s injuries were caused by any product Crane Co. manufactured. Further, Plaintiffs’ negligent design and failure to warn claims also failed because they could not prove Crane Co’s was the proximate cause of decedent’s injuries.

*Witt v. Stryker Corp. of Michigan*, 648 Fed. Appx. 867 (11th Cir. 2016)

The Eleventh Circuit Court of Appeals held that the district court’s finding that Plaintiff’s expert’s opinion was unreliable *ipse dixit* under Federal Rule of Evidence 702 was not an abuse of discretion. Plaintiff asserted claims alleging defective design against the manufacturer of a prosthetic knee implant. After the implant was placed, Plaintiff continued to experience pain and, upon removal of the implant, her surgeon noted that a component of the implant appeared loose. Plaintiff’s expert provided only a two paragraph report containing his opinions and concluding that the looseness of the component was indicative of a mechanical failure in the device. The district court determined that the opinion lacked “any explanation, foundation, or support, and therefore had to be excluded because of its unreliability.” The Court found that the exclusion was not an abuse of the district court’s discretion, because the expert’s sparse report neither provided any explanation for how the looseness of the component related to the mechanical operation failure, nor did the expert consider or evaluate any alternative explanations.
Alabama


Plaintiff purchased ramps used to load lawnmowers into the back of a pickup truck, but did not receive the proper packaging or safety instructions because he purchased them off a display. Subsequently, Plaintiff was injured when fell while loading a lawnmower as a result of the ramps having been improperly connected to the back of the truck. Plaintiff alleged the ramps were defectively designed, that Defendant failed to warn about the dangers of incorrectly connecting the ramp to the back of a truck, and breached express and implied warranties. Defendant moved to dismiss Plaintiff’s complaint. The court agreed and held that Plaintiff’s design defect claim failed because he did not produce evidence of a safer, practical, alternative design. Plaintiff’s failure to warn claim was also dismissed because he failed to show he would have heeded a more precise warning if one had been provided to him. Additionally, the court dismissed Plaintiff’s breach of warranty claim because there was no privity. Further, the court held that, because the product was fit for its ordinary purpose, Plaintiff had no viable claim for breach of the implied warranty of merchantability.


In this case, the court had to determine whether, in an admiralty claim for strict product liability, it would apply the Restatement (Second) of Torts or the Restatement (Third) of Torts. The court noted that, in recent years, courts sitting in admiralty have begun to apply the Third Restatement to product liability claims more frequently. However, the Eleventh Circuit had previously adopted the Second Restatement as the principles of law applied in deciding product liability claims. Therefore, the court found that §402A of the Restatement (Second) of Torts would apply to the product liability claim at issue.


This case is the product of the decertification of a statewide class of smokers in Engle v. Ligget Group, Inc., 945 So. 2d 1248 (Fla. 2006). Plaintiff asserted Phillip Morris was liable to her under theories of negligence, strict liability, fraudulent concealment, and conspiracy to conceal. After a jury trial, Plaintiff was awarded $6.25 million in compensatory damages, with 40 percent comparative fault, and over $20 million in punitive damages based on the fraud claims. However, the court subsequently reduced the award pursuant to a motion for a judgment as a matter of law, finding Plaintiff had not sufficiently proven she relied on Defendant’s concealments and misrepresentations about the hazards of cigarette smoking. Defendant then filed a renewed motion for judgment as a matter of law. The court focused on whether Plaintiff’s state law negligence and strict liability claims were preempted by the federal Cigarette Labeling and Advertising Act. The court found the state law claims were not preempted through “obstacle preclusion” and, therefore, the renewed motion as a matter of law was denied.

Florida


Plaintiff brought an action against the manufacturers of the brand name and generic forms of a hormone replacement drug. The district court found that because the Plaintiff was provided only with the generic version of the drug, and the Defendant generic manufacturer’s drug was the chemical equivalent and bioequivalent of its brand name counterpart, Plaintiff’s design defect claim was preempted by the Supreme Court’s decision in Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S. Ct. 2466 (2013). The Court in Bartlett held that Federal law preempts a cause of action against a generic drug manufacturer for defective design when the defective design claim would require that the generic manufacturer either redesign the drug or change the drug’s warnings. Plaintiff’s negligence claim was also preempted because the claim was premised on the manufacturer’s failure to warn of the risks associated with its drug and the drug’s defective design.
Accordingly, there was no action that the manufacturer could have taken to discharge its duty under state negligence law without violating federal law.


The district court granted a medical device manufacturer’s motion to dismiss finding that certain claims brought by the patient-Plaintiff were preempted by federal law while other of the claims were not viable under state law. Plaintiff alleged that after implantation of a metal hip resurfacing system, he began experiencing elevated chromium and cobalt levels in his blood. He claimed that the system was defective because it failed to comport with FDA requirements and failed to follow the FDA’s Current Good Manufacturing Practice provision. Plaintiff brought an action against the manufacturer asserting state law claims for negligence, strict products liability, breach of contract, and misrepresentation. The district court held that since the system was a Class III medical device, which underwent pre-market approval, state-law claims related to safety or effectiveness different from, or in addition to, any applicable Federal requirements were preempted. In order to properly allege parallel state-law claims that would not be preempted, a plaintiff is required to set forth facts pointing to specific premarket approval requirements that were violated. However, the court found that Plaintiff’s claims would still fail under Florida law, because he was essentially seeking to enforce the FDA premarket approval requirements against the manufacturer and Florida law does not recognize claims premised on violations of FDA regulations. Moreover, a plaintiff may not attempt to recast a claim for a violation of the FDCA as a state-law claim simply by pleading it as such. The mere fact that Plaintiff prefaced all such allegations with the disclaimer that they were brought “only to the extent that they are parallel to and not different from or in addition to the requirements of federal law,” did not negate the fact that the allegations were a plain attempt at circumventing 21 U.S.C. §337(a), which impliedly preempts suits by private litigants for noncompliance with the medical device provision.


Plaintiffs, the estate and widow of a deceased Navy mechanic, alleged claims of negligence, strict liability, fraudulent concealment, and loss of consortium. The decedent worked in the Navy in various capacities, and came into contact with asbestos in many aspects of his job. Plaintiffs alleged the dust mask designed and sold by 3M was defective. 3M sought to exclude the plaintiffs’ expert who stated the mask was defectively designed. The court permitted the expert to testify as to whether the mask the decedent wore was the 3M mask, but did not allow the expert to testify as to the design of the mask. The court found that the expert’s opinion was not supported by sufficient studies to be considered reliable. Further, the court granted summary judgment as to the design defect and fraudulent concealment claims because there was no indication the mask was supposed to be used for toxic substances. However, as to the failure to warn claim, the court found an issue of fact existed as to whether the defendant properly warned that the mask would not protect against asbestos.

_Diaz-Grandados v. Wright Medical Technology, Inc._, No. 6:14-cv-1953, 2016 WL 1337264 (M.D. Fla. April 1, 2016)

The district court denied Defendant-manufacturer’s motion for summary judgment in a product liability action. Plaintiff alleged that his hip implant failed as a result of a design defect. In addition to the design defect claim, Plaintiff alleged that the Defendant-manufacturer was aware, prior to implantation of the device, of the availability of a superior design, but did not employ that design until five years later. Plaintiff also claimed the Defendant failed to adequately warn orthopedic surgeons of the significant risks involved when the device was used in overweight and active patients, such as Plaintiff, and marketed the device for use in patients with active lifestyles. The Defendant argued that under the learned intermediary doctrine, the undisputed evidence demonstrated that the warnings accompanying the device were adequate as a matter
of law. Specifically, the Defendant pointed out that it had warned against the precise failure that occurred in Plaintiff. However, the court found that genuine issues of material fact existed as to whether the Defendant-manufacturer's warning was adequate and whether the device was cleared by the FDA for sale at the time it was implanted in Plaintiff.


The District Court granted Defendant-denture cream manufacturer's motion for summary judgment, in part, in a product liability action. The MDL Plaintiffs alleged that levels of zinc contained in certain brands of denture cream caused copper deficiency and neurological injuries. The present cases were consolidated and transferred and at the time of the action only six Plaintiffs remained. During expert discovery, the Original Plaintiffs disclosed ten expert witnesses to establish general causation. The Remaining Plaintiffs in the instant action did not disclose any general causation expert witnesses. The Defendant-manufacturer moved to exclude the Original Plaintiffs' ten experts' testimony under 702 and Daubert. The court granted the motion and excluded all of the Original Plaintiffs' general causation experts' opinions. After the Daubert Order, the majority of the MDL Plaintiffs stipulated to dismissal for the purpose of appeal; the Remaining Plaintiffs did not so stipulate and contended that they were not subject to the Daubert Order. After the Eleventh Circuit Court of Appeals affirmed the Daubert Order, the Defendant moved for summary judgment against the Remaining Plaintiffs based on the lack of legally admissible expert testimony on general causation. Remaining Plaintiffs argued that Daubert was inapplicable because their cases were filed or transferred to the court after the Original Plaintiffs became subject to the Daubert Order. However, the MDL proceeding clearly fell within the category of Eleventh Circuit's toxic tort cases in which the medical community does not recognize the allegedly toxic substance as both toxic and causing the Plaintiff's alleged injury. Because the claims fall within the above mentioned category, the court held that it must undertake a Daubert inquiry before admitting opinions regarding both general causation and specific causation. Because the Remaining Plaintiffs must prove both forms of causation, the court granted summary judgment and concluded they had failed to prove either form of causation. Since the court found the general causation expert reports submitted by the first batch of MDL Plaintiffs inadequate in its Daubert Order, which the Eleventh Circuit affirmed, the Remaining Plaintiffs failed to prove general causation – an essential element of their case.


The District Court denied an auto manufacturer's motion for summary judgment, among others, in a product liability action. An automotive mechanic brought action against an automobile manufacturer that used asbestos-containing brake and clutch parts and chemical producer (later dismissed) seeking to recover for injuries sustained from exposure to asbestos dust from products that were mined, processed, supplied, manufactured, and distributed by them. The manufacturer argued that it was precluded from liability due to the bare metal defense. Specifically, the manufacturer argued that it cannot be held liable because the Plaintiff could only identify a total of eight repair jobs where he encountered equipment containing asbestos. Moreover, the manufacturer relied on the fact that Plaintiff performed other repair jobs on its vehicles that involved the use of other manufacturer's parts – claiming that it cannot be held liable based on exposure to products that it did not place in the stream of commerce. While the court agreed with the Defendant-manufacturer's recitation of the bare metals defense, nevertheless, it found a hole in the argument because Plaintiff still performed at least eight repair jobs with the original manufacturer's equipment. The court found that this fact, alone, meaningfully distinguished the case from those cited by the manufacturer that applied the bare metal defense. Furthermore, the court found that these eight repair jobs by the Plaintiff precluded the application of the defense as a wholesale bar to liability because the manufacturer was not only a bare metal supplier, but also a manufacturer. Thus, any argument that the asbestos exposures from the eight repairs involving the
Defendant-manufacturer’s equipment were not a substantial factor in bringing about Plaintiff’s disease presents a fact-intensive question that is better resolved by a jury.

**Georgia**


The district court granted Defendant-manufacturer’s motion for summary judgment in an action brought by Plaintiffs seeking to recover damages for injuries allegedly caused by the Defendant’s failure to adequately warn users of their spray paint about the dangers of overexposure. Plaintiff was injured while spray painting a forklift in the course of his job as a maintenance mechanic. The spray paint cans contained a warning label, stating that the user should avoid inhalation, that overexposure could cause a list of issues, and that the product should be used with adequate ventilation or a properly fitted respirator. Plaintiff’s employer instructed him to use the spray paint without a respirator because the area was well ventilated. Plaintiff eventually developed leukemia, allegedly as a result of the exposure to the paint. The Defendant argued that Plaintiff’s claims were preempted by the Federal Hazardous Substances Act (FHSA). However, the court rejected this defense because the spray paint was labeled and marketed solely for industrial use, and there was no evidence that under any reasonably foreseeable condition it might be found in or around a dwelling, so that the paint was not covered by the FHSA. Secondly, the Defendant argued that Plaintiff failed to introduce any admissible evidence that the paint could cause leukemia or that exposure to the paint actually had caused Plaintiff’s leukemia. Because the court found that Plaintiff’s experts’ testimony was unreliable and thus inadmissible, Plaintiff had no admissible evidence showing either that the spray paint could cause leukemia or that, even if it could, it actually had caused done so. Accordingly, Plaintiff could not establish that any alleged defect in the warnings accompanying the spray paint was the cause of Plaintiff’s illness, and the Defendant-manufacturer was thus entitled to summary judgment on plaintiffs’ failure-to-warn claims.


Plaintiff alleged product liability claims against defendant, the manufacturer of a component of the plaintiff’s hip replacement system (the PROFEMUR® neck). Plaintiff received the hip replacement in 2005. In 2012, plaintiff was diagnosed with a fracture in the PROFEMUR® neck, which caused permanent injury. Defendants sought to exclude plaintiff’s experts. Expert 1 was an orthopedic surgeon, who would testify that the component caused the damage rather than the actual implantation of the device and generally that the device was overall defective. The court excluded three of the Expert 1’s opinions because it found that he was not properly qualified. Specifically, the Expert 1 admitted he would defer to a biomedical engineer or a metallurgical expert on topics regarding the design of the product. Thus, the court excluded Expert 1’s opinions related to the product’s design. Expert 2 was an engineer who would testify to the design defects and inadequate warnings. The defendant challenged the sufficiency of Expert 2’s methodology in testing the data. The court found that plaintiffs did not sufficiently demonstrate the reliability of Expert 2’s opinion and proposed testimony that the product’s failure rate was unacceptable in the industry, and therefore excluded such. Expert 3 was an engineer who would testify as to the cause of failure. The defendant argued Expert 3’s conclusions were based on speculation and were, therefore, unreliable, and would not assist the trier of fact. As to Expert 3, the court excluded his conclusion to the extent it relied on an “osteolysis” theory of causation because the testing had not been subject to peer review or gained general acceptance in the community.


This case was the leading case from a multidistrict litigation involving defective hip replacement devices. Plaintiff asserted causes of action in strict product liability (design defect), negligence (design defect),
fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation and sought compensatory and punitive damages. At the end of the trial, the jury returned the verdict form with inconsistencies. While it answered first that the device was not defectively designed, the jury also continued to fill out the form and award damages to Plaintiff. The court found the jurors were confused either about their findings or how the form should be completed, or both and gave the jury a supplemental verdict form. During further deliberation, one juror had to be excused for juror misconduct. Then, the jury returned a verdict for Plaintiff in the amount of $1 million in compensatory damages and $10 million in punitive damages. The Defendant appealed, arguing it was entitled to a judgment as a matter of law because the jury had originally answered “no” to whether the Defendant was liable for a defectively designed product. The Defendant also requested a new trial based on juror confusion and dismissal of the juror during deliberations. The court granted a remittitur of punitive damages to $1,100,000 because it found that the Defendant's conduct was not extremely malicious or carried out with actual intent to harm. However, the court refused to reduce the compensatory damages award because it was not so excessive that it appeared to result from misunderstanding or prejudice.


Plaintiff suffered from diabetes, and after taking the drug manufactured by the Defendants, she was diagnosed with diabetic ketoacidosis. Plaintiff brought a product defect claim under Georgia law against the drug manufacturers, alleging design defect and failure to properly market, manufacture, distribute, supply, and sell the drug. Plaintiff’s claims included claims for failure to warn and placing adequate warning and instructions on the drug. The Defendants moved to dismiss. As to the design defect claims, Defendants argued those claims were preempted because federal law precluded the manufacturers from redesigning a prescription drug without FDA approval. The district court agreed and found that any claim by Plaintiff that the Defendants should change the formulation of the drug was preempted by FDA regulations. However, the district court also found that Plaintiff’s design defect claim was not preempted because some of the strengthened warnings proposed by the Plaintiff could have been applied without prior FDA approval. Additionally, the court found that when a company does not have the New Drug Application, it has “no more power to change the label” of a drug than a generic manufacturer. Therefore, any failure to warn claims against Defendants that were not the holder of the NDA were preempted by federal law.


Plaintiff motor vehicle driver sued the manufacturer of her car and the manufacturer of the car’s turbocharger, alleging strict products liability on the basis of design defect. As plaintiff was accelerating on the highway, her car continued to accelerate even when plaintiff removed her foot from the pedal. The continued acceleration caused an accident in which plaintiff sustained serious injuries. The jury awarded plaintiff $7 million and $1 million to plaintiff’s husband for loss of consortium. The jury found the plaintiff was 40 percent at fault, so the court reduced the damages accordingly. Defendants sought a judgment as a matter of law, which was denied. The court found the plaintiff’s experts were qualified under Daubert and the verdict was not against the great weight of the evidence. Plaintiff also sought alteration of the judgment, alleging it was improperly reduced. The court cited a recent Supreme Court of Georgia decision stating that the comparative fault statute in Georgia applies to products liability cases. Therefore, the motions to alter the verdict were denied.

XIII. D.C. Circuit

Daubert

D.C. Court of Appeals

After decades of reliance on the Dyas/Frye standard for determining the admissibility of expert testimony, the District of Columbia Court of Appeals finally adopted the Daubert/Rule 702 standard.

Plaintiffs brought suit against a collection of cell phone manufacturers, service providers, and trade associations, alleging that long-term exposure to cell phone radiation caused brain tumors. Defendants sought interlocutory appeal after the trial court judge determined that some of plaintiff’s experts’ causation testimony would be admissible under Dyas/Frye, but acknowledged that most, if not all of it, would be excluded under Daubert.

In considering the question of whether to adopt Daubert, the court, en banc, reviewed and weighed the history and principles of both the Dyas/Frye standard and Rule 702 as interpreted by Daubert. The court concluded that “Rule 702, with its expanded focus on whether reliable principles and methods have been reliably applied, states a rule that is preferable to the Dyas/Frye test. The ability to focus on the reliability of the principles and methods, and their application, is a decided advantage that will lead to better decision-making by juries and trial judges alike.” Accordingly, the court adopted Rule 702 and Daubert as applicable to any civil or criminal case in which trial begins after the date of the opinion.

District Court

In re Rail Freight Fuel Surcharge Antitrust Litig., 2016 WL 2962186 (D.D.C. May 20, 2016)

In this multidistrict litigation against several rail freight carriers, the plaintiffs sought to have the court perform a Daubert determination as to the admissibility of defendants’ experts’ testimony prior to the class-certification hearing.

The court found that no pre-certification-hearing determination was required. The court recognized that a Daubert analysis would likely be necessary, as testimony that cannot withstand such a challenge cannot prove that Rule 23(a) prerequisites have been met or establish that Rule 23(b) is satisfied. However, because the court would be essentially serving as gatekeeper for itself, as there would be no jury at the hearing, a pre-hearing determination was unnecessary. Furthermore, many of the arguments in plaintiffs’ brief did not challenge the principles or methodologies of defendants’ expert, but rather were attacks on his opinions and his responses to plaintiffs’ experts’ opinions. Accordingly, the court found that the Daubert determination could be performed at the class-certification hearing.

Amendment of Complaint

District Court


United States brought suit against Honeywell for unjust enrichment and under the False Claims Act. The United States alleged Honeywell knew that its component, the Z Shield, used in bullet proof vests was defective and degraded more quickly than it represented. Prior to the completion of discovery, the United States sought to amend its complaint to add three additional “factual allegations” against Honeywell: (1) that the water-based coating process used by Honeywell exacerbated the degradation problem; (2) that the shield used in Z Shield was too fragile; and (3) that Honeywell’s publicly disclosed warehouse testing data had been manipulated to make “Z Shield’s retention of its ballistic performance over time appear much better than in actuality.”

Honeywell opposed the motion for leave to amend, arguing that the original complaint had focused only on the “Zylon fiber used in Z Shield” and no other aspect of the Z Shield. Honeywell argued that it was prejudiced by the new allegations because approximately 50 depositions had already occurred and Honeywell
would have to incur additional expense to depose overseas witnesses or be denied the opportunity to present facts and evidence to defend against the new allegations. Honeywell also argued that the United States had been dilatory in the moving to amend the complaint as it knew about the problems with the “water-based coating process” five years prior to the filing of its motion to amend.

The court granted the motion to amend, finding that allowing the amendment would not cause Honeywell to suffer undue prejudice. The court found that the “water-based coating” allegation served only to clarify the United States’ legal theory as to the defective condition alleged, and that although Honeywell would have to reopen fact discovery and potentially take depositions in Netherland and Israel and supplement its expert discovery, this did not qualify as undue prejudice. The court applied this same analysis to the two other additional allegations, finding that the original complaint provided adequate notice of these potential theories of liability and that Honeywell would not be unduly prejudiced by any additional discovery required to defend the allegations.

**Attorney Work Product / Attorney-Client Privilege**

**District Court**


Federal Trade Commission (FTC) petitioned for enforcement of administrative subpoena that had been issued during its investigation into alleged unfair trade practices by Boehringer Ingelheim Pharmaceuticals, Inc., and its competitor, Barr Laboratories, in entering into a patent settlement agreement. Boehringer asserted claims of work-product doctrine and attorney-client privilege in refusing to produce documents. Following appeal to the Court of Appeals, the case was remanded to the District Camera, which performed *in camera* review of post-settlement documents including emails between executives of the company and charts, graphs, and spreadsheets that had been attached to the emails, to determine if either the work-product or attorney-client privilege would apply.

After thorough analysis of the parameters of the attorney-work product doctrine, the court found that many of the documents were not covered by the attorney work-product doctrine as they did not reveal any impressions of counsel or were only fact work product. However, some of the emails, those which included both corporate/executive staff’s and the attorneys’ analysis of the financial analyses attached to the emails was protected as attorney work product.

Although not protected as attorney work product, the court found that emails from one business executive to another executive providing information from the financial analyses attached to the email was protected by the attorney-client privilege because to reveal the information in the email would reveal the facts that were ultimately transmitted to the attorneys for the purpose of having the attorneys provide legal counsel. The court additionally found that emails from in-house counsel to directors of the company providing analysis and advice based on financial analyses attached to the emails were covered by attorney-client privilege.

The court further found that the attorney client privilege applied to the attachments to the emails, including power point presentations, graphs, charts, and spreadsheets, that summarized facts regarding the litigation with Barr, and described how different settlement and litigation outcomes would affect Boehringer financially. The court noted that the attachments must independently satisfy the attorney-client privilege in order to be protected, regardless of whether the underlying email was protected. The court found that these documents, although only fact work product, were protected as they were created during the litigation and Boehringer’s attorneys had requested the analyses to assist in the ongoing litigation.

The court reasoned that documents could “bear on both business and legal matters simultaneously” and still be protected by the privilege, despite the FTC’s arguments to the contrary, as the privilege protects
“even purely factual communications between attorney and client when those facts are gathered at the request of in-house counsel for the purpose – or at least with a significant purposes – of providing legal advice to the corporation.”

**Standing**

**District Court**


Non-profit organizations and individuals brought suit against the Food and Drug Administration (FDA) asking that the court to compel the FDA to take a stronger regulatory position regarding mercury used in dental amalgam. The FDA moved to dismiss on the grounds that each of the plaintiff’s lacked standing to sue.

The court first considered whether the non-profit organization the International Academy of Oral Medicine & Toxicology (IAOMT) had organizational standing to sue. The court found that IAOMT did not suffer sufficient injury to establish standing as IAMOT could not show that any projects or funds were diverted other than its “issue advocacy,” which did not on its own qualify as an injury sufficient to support standing. The court further found that IAMOT having to spend funds to challenge the FDA’s final rule and to educate its members about the regulations did not give rise to standing. Similarly, the court found that the Coalition for Mercury-free Drugs (CoMeD) lacked standing as its only alleged injury also related to the funding of issue advocacy.

The court also found that IAOMT and another non-profit, Dental Amalgam Mercury Solutions (DAMS), lacked representational standing. Representational standing requires that an organization have “(1) at least one of their members has standing to sue in her or his own right, (2) the interests the association seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of an individual member in the lawsuit.” The court found IAOMT failed to meet these requirements as it did not identify a single dentist or dental student that would suffer injury from future exposure to dental amalgam and mercury by being unable to run a mercury-free practice without failing financially, or suffer disciplinary charges as a result of the FDA’s rule. DAMS also lacked representational standing as the single individual it cited as its basis also lacked standing because he could not sufficiently allege an injury from the FDA’s rule.

The court last considered whether IAOMT had environmental standing based on IAOMT claiming it and its members suffered an “informational injury” as a result of the FDA’s failure to prepare an Environmental Impact Study (EIS) or an Environmental Assessment (EA). However, the court found that “informational injury” alone was insufficient to support standing. Accordingly, all of the plaintiffs’ challenges to the FDA’s rule were dismissed for lack of standing.

**XIV. Federal Circuit**

**Constitutionality of the “Vaccine Act”**

*Milik v. Secretary of Health and Human Services, 822 F.3d 1367 (Fed. Cir. 2016)*

This case originated in the U.S. Court of Federal Claim, Office of the Special Master, which administers a no-fault compensation program under the National Childhood Vaccine Injury Act (“Vaccine Act”). The petitioners filed a claim for compensation on behalf of their child, whom they alleged suffered injuries including spastic diplegia, severe gross and fine motor difficulties, and delayed learning skills as a result of being administered the measles, mumps, and rubella (“MMR”) vaccine. Upon holding evidentiary hearings, the spe-
cial master issued a detailed decision denying the petitioners’ claim for compensation upon a finding that the MMR vaccine did not cause their son’s neurological condition. The petitioners appealed. The Court of Federal Claims affirmed, finding that the ruling was not arbitrary or capricious.

On appeal to the Federal Circuit, petitioners argued in part that the Vaccine Act and its arbitrary and capricious standard of review is unconstitutional because it denies petitioners their right to de novo review in an Article III court. The Federal Circuit rejected this claim, tracing the legislative history of the Vaccine Act, and the 1987 amendment that created that arbitrary and capricious standard of review. The Federal Circuit also recognized Congress’ authority to preempt state law causes of action that conflict with federal standards and policies set forth in federal statute. Citing Bruesewitz v. Wyeth, LLC, 562 U.S. 223 (2011), the Federal Circuit noted that this is precisely what Congress did when it passed the Vaccine Act.

The Federal Circuit also pointed out that petitioners could revisit the issues decided by the special master (which are only causation and injury) in an Article III court in the context of claims alleging manufacturing defects, breach of express or implied warranty, or breach of contract. The Federal Circuit also rejected petitioners’ argument that the special master’s finding was unsupported in the record, finding that the special master thoroughly reviewed the evidence and therefore, his decision was not arbitrary or capricious.

Reversal for Failing to Consider Entire Record of Evidence

Moriarty ex rel. Moriarty v. Secretary of Health and Human Services, 643 F. App’x 997 (Fed. Cir. 2016)

Petitioners filed claims under the Vaccine Act in 2003, alleging first that their daughter suffered from autism as a result of her MMR vaccinations, but later amending their claims to allege that she suffered from a seizure disorder as a result of the vaccines. After evidentiary hearings, including expert testimony on both sides, the special master denied their petition based upon a determination that petitioners had failed to prove either the first or second prongs of the three part test outlined in Athen v. Sec. of Health and Human Services, 418 F.3d 1274, 1276-78 (Fed. Cir. 2005). Prong one is that a petitioner must show a medical theory causally connecting the vaccination at issue to the injury; prong two is that petitioners must show a logical sequence of cause and effect showing that the vaccination at issue was the reason for the injury. The Federal Circuit vacated and remanded the special master’s finding, holding that the special master erred in refusing to consider the second expert report by the petitioners’ expert, including the materials cited in that report, based upon his erroneous conclusion that he only had to review record evidence that was the subject of testimony at the hearing.

The Court expounded that the Vaccine Act requires the special master to consider any medical records or reports contained in the record regarding the nature, causation, or aggravation of the petitioner’s injury, as well as, other relevant medical and scientific evidence contained in the record. The report disregarded by the special master and the articles cited were relevant medical and scientific evidence, indeed one of the articles squarely addressed seizure disorders caused by administration of a measles vaccine. The Court went on to suggest that the evidence supported a finding of causation, but it was hesitant to determine that in the first instance, instead remanding the case.

XV. Canada

Class Action Certification – Commonality of Product Defect Across Proposed Class – Leave to Appeal Certification Order

Dine v. Biomet, 2016 ONSC 4039

This was a motion for leave to appeal an order granting certification of a class proceeding relating to allegedly defective hip implants. Both possible avenues under 62.02(4) of Ontario’s Rules of Civil Procedure...
for allowing leave to appeal were raised by the defendants. Both were denied by the court and the defendants’ motion for leave to appeal was dismissed.

First, the defendants asserted that leave to appeal was judicially desirable since a review of analogous cases demonstrated a stark divide between two eminent Ontario judges regarding the correct method for assessing commonality evidence in certification hearings. Specifically, the defendants submitted:

> [t]he difference in approaches taken by Justices Belobaba and Perell effectively means that the outcome of a certification motion may depend entirely on which of the two judges is assigned to the matter. On the one hand, Justice Perell compels disclosure of plaintiff medical records with a low threshold and considers defence evidence pertaining to different characteristics of devices in assessing commonality; on the other hand, Justice Belobaba refuses to grant disclosure of the plaintiffs’ medical records and refuses to consider defense evidence on commonality.

By extension, certification may thereby come down to the idiosyncrasies of the presiding judge. It was therefore desirable for the Divisional Court to remedy this outstanding ambiguity. The plaintiff submitted that no such difference in approach existed.

The Divisional Court disagreed with the submissions of the defendants and found that a consistent judicial methodology for reviewing commonality evidence in a certification hearing existed. Using the same methodology, the certification judge was entitled to conclude that the plaintiff established a sufficient basis of fact for commonality. Accordingly, the defendant failed to satisfy the first test for leave to appeal.

The defendants further argued that there was reason to doubt the correctness of the certification judge’s order, and that the matter had importance for the wider public and development of the law. The defendants alleged that the certification judge made several errors, including acceptance of unsupported assertions by the plaintiff and an incorrect determination of preferability. The Court found that there was “no doubt” enough evidence to satisfy a “some-basis-in-fact” commonality threshold. Moreover, there was no credible basis provided by the defendant to doubt the correctness of the certification judge’s finding of preferability.

**Class Action Certification – Analysis of Merits – Appeal of Certification Order**


The appellant was denied a certification order by the Alberta Court of Queen’s Bench in a proposed class proceeding relating to hip implants. In a stiffly worded majority decision, the Alberta Court of Appeal overturned the lower court’s decision. The Court of Appeal focused on the appropriate weight to be given to a merits analysis at the certification stage of a class proceeding.

The appellant had a “Birmingham System” implanted in her hip. Following the implant, toxic levels of cobalt were found in her blood. The Birmingham System was removed and the appellant had an additional surgery for a hip replacement and bone graft. The certification judge found that several of the necessary pre-conditions for certifying a class proceeding in Ontario were not satisfied. The appellant failed to identify a class of two or more persons, raise a common issue, demonstrate the preferability of class proceedings, and to show that she was an appropriate representative plaintiff.

On appeal, the appellant argued that the certification judge did not use the correct threshold (*i.e.* “some basis in fact”) for each of the above requirements. The appellant further argued that key facts remained unconsidered, evidence was misapprehended and that irrelevant considerations were used by the certification judge.

A majority of the Alberta Court of Appeal held that a “liberal approach” is necessary to achieve the statutory objectives of class proceedings: judicial economy, access to justice and behaviour modification. Accordingly, a “robust analysis of the merits at the certification stage” is to be avoided.
The Court found it unnecessary to provide evidence of the specific identity of prospective class members at the time of certification. Further, when assessing commonality requirements, common issues do not need to “predominate” over non-common issues. Individualized claims outside of common issues will, generally, not be enough to detract from commonality amongst class members. The Court also held that “…it is not open to the certification judge to weigh conflicting evidence to opine on the relative merits of the parties’ positions at the certification motion”. Accordingly, the merits-focused analysis of the certification judge was found to be “impermissible”. Finally, the Court held that the certification judge’s preference for using a joinder of claims for litigation to proceed was “not a sufficient reason to find that a class action is not preferable”.

Writing in partial dissent, Justice Slatter held that a class proceeding was not the preferable method to litigate all of the appellant’s claims. He also noted that earlier certification cases have “under-emphasized” a review of the merits. In Justice Slatter’s view, it was problematic that the representative plaintiff had not provided any demonstrable method for showing that the metal ions released by the device caused serious, long-term health effects. A civil trial was determined to be unsuitable to resolve what was effectively a “mystery” among the scientific community. However, Justice Slatter did concur with the majority that a class proceeding was the preferable procedure for a smaller sub-class of individuals experiencing more general complications relating to the device.

Product Liability Class Action – Waiver of Tort as a Common Issue – Conflicting Case Law

Sweetland v. GlaxoSmithKline LLC, 2016 NSSC 18

The Plaintiff brought a proposed class action against the defendants in relation to the Avandia medication developed and marketed for the treatment of Type 2 diabetes. The class alleged that the medication caused heart diseases and cardiac events and was therefore negligently designed, manufactured and marketed.

Amongst the proposed common issues was that of the controversial claim of “waiver of tort”, an ill-defined procedure allowing a plaintiff to retrieve profits earned by a defendant as a result of a wrong, regardless of whether the plaintiff suffered a prejudice or whether the profits were derived from the plaintiff’s property.

In Canada, courts have often certified but declined to rule on the merits of “waiver of tort” claims. In Sweetland, the Supreme Court of Nova Scotia held that the availability and the liability arising from waiver of tort claims should be determined at the common issues trial and that the quantification issue was to occur even later, despite a recent line of cases having determined that waiver of tort causes of action should no longer be routinely certified and, as the case may be, could be assessed before the trial and before discoveries have occurred. The Plaintiff’s class action was thus certified and will proceed towards a common issues trial.

Sweetland offers a clearer procedure in relation to waiver of tort claims, despite conflicting with other recent decisions, especially decisions in the Province of Ontario. More developments are to be expected in Canada about waiver of tort claims, and the time may have come for an appellate court to tackle that issue.

Recovery of Settlement Amount from Third Parties – Causation and Individual Issue – Summary Judgment

IPEX Inc. v. AT Plastics and Lubrizol, 2016 ONSC 1859

The Plaintiff IPEX Inc. manufactured Kitec – a composite pipe composed of various plastics and adhesives – widely used in plumbing and heating in North America. At some point, end-users experienced widespread failures of Kitec and IPEX Inc. faced dozens of class action proceedings in the US and Canada. In 2012, IPEX Inc. entered into a universal settlement of all the claims it was facing for $125M.

After the settlement, IPEX Inc. instituted proceedings against some of the suppliers of Kitec’s components, alleging that their products led to Kitec’s failure, and sought contribution against them for the
amount of the settlement. The defendants brought a motion for summary judgment on the basis that it could not be proven that they caused any part of the loss underlying the settlement and that no connection could be made between the defendants’ components and the alleged failures.

In Canada, it is accepted law that a party that has settled may seek contribution against a non-settling party as long as the settlement is determined by the court as being within a range of reasonableness, and that the liability can be apportioned between the parties.

As for the summary judgment application itself, the court found that IPEX Inc. could plausibly establish causation at the trial by showing that the defendants’ components were minimally a cause of the failure, which issue is not incumbent on individual evidence of causation, but rather expert evidence about the root cause of the failure. The court thus ruled that IPEX Inc.’s claim was raising a genuine issue for trial incumbent on a full evidentiary basis.

**Class Certification – Allowing Unharmed Intermediary Supplier to Sue Manufacturer**

1688782 Ontario Inc. v. Maple Leaf Foods Inc., 2016 ONSC 4233

This was a proposed class action brought on behalf of a class of Mr. Sub franchisees. As part of a franchise agreement with Mr. Sub, the plaintiff, a Mr. Sub franchisee, was required to sell “ready to eat meats” (RTE Meats). In 2008, the defendants announced a recall of RTE meats after certain quantities were contaminated with listeria. As a result of the infection, 22 people died and 57 people became ill. The proposed class alleged (i) economic damages from lost business, (ii) that the manufacturer breached its duty to manufacture a product fit for human consumption, and (iii) that the manufacturer breached its duty to provide an appropriate warning to the franchisees.

The defendants argued that the plaintiff could only sue in tort if its customers were actually harmed as a result of contaminated RTE meats. The Ontario Superior Court disagreed. “Risk of danger”, it found, particularly in regards to illness or death, is a sufficient basis for tort liability. In such contexts, the manufacturer has a duty to the intermediary (in this case, franchisees) to take reasonable care not to distribute a product that is dangerous to the consumer. Even if the ultimate customer is never harmed, it is still possible for the original manufacturer to be liable to an intermediary supplier.

The Court also found that a manufacturer owes a duty of care to distributors to warn them about defective products they make. The duty to warn is elevated when an otherwise safe product becomes dangerous. Moreover, the economic loss of the plaintiffs, the Court held, was both a proximate and foreseeable outcome of the defendant's actions. The plaintiff being an intermediary between the defendants and the consumer of RTE Meats did not make them too remote to be liable.

Finally, the Court disagreed with the defendants that concerns of indeterminate liability were engaged. Contrary to the arguments of the defendants, the defendants’ scope of liability was easily determinable. The defendants knew the identity of all Mr. Sub franchisees and had them in consideration when the events surrounding the RTE Meats arose. The Court thereby issued a certification order for the plaintiff.

**Proposed Product Liability Class Action – Defective Airbags – Admissibility of Apologies in Pleadings**

Coles v. Takata Corp., 2016 ONSC 4885

The plaintiff, TK Holdings, Inc. (TKH), was an airbag manufacturer and co-defendant in five separate class proceedings. In their statements of claim, the plaintiffs relied on four public statements made by executives of one of TKH’s subsidiaries expressing regret for the company's product failure and apologizing for the resultant injuries and fatalities.
TKH brought a motion to strike certain sections of the pleadings for contravention of Ontario’s Apology Act. The Apology Act provides that, subject to certain exceptions, an apology made “by or on behalf of a person in connection with any matter” will not: (i) constitute an admission of fault or liability or (ii) be taken into account for determining fault or liability.

The defendants argued that the Apology Act was inapplicable, since any statements that could be construed as apologies were not spoken in Ontario. Rather, the statements were made in either Japan or the U.S. Neither jurisdiction precludes apologies from being admissible in Ontario as evidence. Finally, as a matter of procedure, the representative plaintiffs also argued that the conflict of laws and admissibility questions at bar were neither plain nor obvious. Consequently, they should not be decided on the basis of a motion to strike.

The Court noted that the Apology Act has received comparatively sparse judicial treatment. It was also acknowledged that courts may consider statements where apologetic admissions, subject to the Apology Act, and non-apologetic admissions, which are not, become entwined. In such scenarios, courts will undertake a contextual analysis to see whether admissible facts can be disentangled from the whole and allowed as evidence. The Court held that the plaintiff’s apologies were evidence. It thereby ordered that they be struck from the pleadings, since evidence cannot be plead under Rule 25.06(1) of Ontario’s Rules of Civil Procedure.

The Court also held that the law of evidence, to which the Apology Act relates, is procedural in nature. The procedural law of the court with jurisdiction to hear a dispute will be applied for procedural matters relating to that dispute. Therefore, the Ontario Superior Court was entitled to order that sections of the pleadings be struck out under the Ontario procedural legislation.

Duplicative Class Actions

Abuse of Process Doctrine Stay of Proceedings

Hafichuk-Walkin v. BCE Inc. et al., 2016 MBCA 32

In 2004, Class Counsel firm Merchant Law Group (MLG) filed, for all practical purposes, identical class action proceedings in all Canadian provinces but Prince Edward Island, and sometimes multiple claims per province, all seeking to certify an identical national class action against telecommunications corporations in relation to a fee charged for cellular phone services.

MLG elected to pursue the proceedings in its home province of Saskatchewan, leaving all other claims dormant, and eventually was partially successful in having that claim certified, successive attempts to broaden its scope thereafter having failed.

In that context, with a certified class action in one province, the defendants moved to have the proceedings in the other provinces stayed on the basis that they serve no useful propose other than to potentially re-litigate the matter later, which would amount to an abuse of process.

The Court of Appeal of Manitoba indicated that although parallel class actions may be permissible in a federal system, it specified that “multi-jurisdictional class actions are abusive when they are duplicative and no legitimate purpose would be served by allowing more than one class action to proceed on behalf of overlapping class members from one or more provinces”.

The Court concluded that the proposed class action filed in Manitoba was an abuse of process due to the “extreme delay” in prosecution and having been introduced with no bona fide intent to pursue it, but “as nothing more than a form of insurance for the possibility of an unsuccessful result”. The Court further concluded that “carbon copy” class actions involving the same plaintiffs, defendants, lawyers and allegations being allowed to proceed in two different jurisdictions once a final certification of a class action has occurred in one jurisdiction … offends the principle of comity and exposes the parties and courts to incurring the evils that a multiplicity of proceedings can give rise to".
The proposed class action was thus stayed as a result. Of note is that courts in other jurisdictions where MLG had filed the other impugned claim came to the same conclusion. Applications for leave to appeal to the Supreme Court of Canada have been filed in relation to these rulings, and further developments may ensure.

**Class Action – Common Issue Trial Before a Jury – Jury Assessing Expert Evidence**

*Bartram v. GlaxoSmithKline Inc., 2016 BCSC 1409*

In 2012, a class action was certified against the defendant in relation to newborn infants having suffered cardiovascular birth defects as a result of their mothers using the anti-depressant drug Paxil during pregnancy. In anticipation of the common issues trial scheduled to last 40 days and set to address 10 common issues varying from the adequacy of the medication to causation, the plaintiff served a notice requiring a trial by jury.

The defendant sought an order striking the jury notice and requiring that the trial of common issues be heard by a judge alone, notably on the basis of the complexity of the scientific issues to be addressed and the extent of evidence to be considered.

At the outset, commenting on jury trials in class actions, the Court indicated that nothing in the British Columbia *Class Proceedings Act* precludes a common issues trial by jury despite the additional considerations associated with this procedural vehicle, and that trying the common issues before a jury does not preclude contrary findings in subsequent trials of individual claims, notably in relation to causation.

As for the substance of the defendant's position, the Court indicated that a judge sitting alone is no more likely than a jury to read all of that material and come to a conclusion unaided. Also, as experts are expected to vulgarize the basis for their conclusions, a layperson – whether a judge or a juror – shall be capable of understanding and analyzing them and coming to the decision. Also, this motion having been heard before all expert reports have been filed, speculating about the complexity of the scientific analysis is hypothetical. Furthermore, the process of hearing and analyzing expert evidence will not necessarily be different from what juries do in a variety of other cases involving complex personal injuries.

The Court thus refused to strike out the jury notice, while indicating that the issue could be revised during the course of trial if it appears that the matter is too intricate or complicated to be conveniently tried with a jury.

**Defective Product – Consumer Protection Legislation**

**Legal Warranty**

*Fortin v. Mazda Canada Inc., 2016 QCCA 31*

Mazda 3 vehicles (model years 2004-2007) marketed and sold in Canada and elsewhere were allegedly affected by a design defect allowing the locking mechanism on the driver's door to unlock upon a strategically delivered impact near the handle.

A class action was authorized by the Superior Court of the Province of Quebec and moved to a common issues trial. At the trial level, the Court found that the Mazda 3 vehicles were not defective as the locking mechanism was performing its intended purpose in normal circumstances and creating a sufficient obstacle reducing the possibility of theft. The Court also found that the criminal activity by which an ill-intended person would break into the vehicle or steal it was breaking causation between the alleged defect and the damages that would have been sustained by class members. The class action was thus dismissed on its merits.

The Court of Appeal of Quebec disagreed and granted the class action. Quebec's *Consumer Protection Act* provides that a good must be fit for its intended purpose for a reasonable period of time. If a good cannot be used for its reasonably expected purpose or perishes prematurely as a result of a consideration of its own
(i.e. not as a result of its abusive usage or an external element), it is presumed to have been defective at the time of its sale.

The evidence at trial showed that Mazda 3 vehicles' locking mechanism would unlock very easily if a soft impact was directed at a specific location on the door. For the Court of Appeal, it cannot be said that the locking mechanism worked very well and was creating a reasonable obstacle against malicious intrusions, which is the basic purpose of a lock. The Court further agreed with the plaintiff’s argument that consumers would not have purchased Mazda 3 vehicles, or would not have paid the same price, had they known about this deficiency. Furthermore, any criminal activity was made possible as a result of the deficient design of the vehicle, which it sought to prevent. There is no break in causation.

The Court of Appeal thus concluded that the vehicles were presumed to have been defective at the time of their sale, allowing for compensatory measures. The class members whose vehicles were damaged or stolen are entitled to compensation for the loss they have suffered. However, those class members, who did not suffer an actual prejudice but solely experienced the “inconvenience” of returning to their dealerships in the context of Mazda’s campaign to palliate to the defect, have legally suffered no harm and were not entitled to any compensation.

**Failure to Inform Consumer**

**Non-Industry Standard Product Requirements**

*Swern v. Amazon Hardwood*, 2015 ONSC 7590

This case was an appeal from the Small Claims Court to the Divisional Court. The appellant sold hardwood floors to the respondents that had special, non-industry standard humidity requirements. The recommended humidity level for the purchased flooring was 40 percent to 55 percent. The normal industry standard range was acknowledged to be between 30 percent to 50 percent. The respondents were unaware of these unusual requirements, which were necessary for proper maintenance of the flooring. Correspondingly, the floors “cupped and cracked” following installation, due to being kept in sub-optimal humidity conditions.

The Deputy Judge found for the respondents. The appellant had failed to advise the respondents of the recommended humidity range to maintain the flooring. The appellant also failed to inform the respondents of the consequences of such a failure. These constituted omissions of material facts in circumstances where the respondents were relying on the appellant and, therefore, negligent misrepresentations.

The appellant argued six grounds of appeal. The Divisional Court considered these and went on to uphold the Deputy Judge's decision.

The first two grounds concerned whether the respondent had actual knowledge of the higher humidity requirements. This was based on the warranty, installation and maintenance guides provided to the appellant, the purchase invoice, and communications with a sales agent. The Court, however, was not persuaded these documents and interactions meant the respondents had the required knowledge. On the third and fourth grounds of the appeal, the appellants contended that the Deputy Judge failed to address conflicting assertions in the expert reports. The Court found that the reports did not conflict regarding the cause of the floors cupping and cracking. Fifth, the appellants sought to enforce an exclusionary clause in the contract, releasing the appellant from liability in the event that flooring was damaged “due to improper humidity conditions during storage or at the installation site.” The Court ruled that *contra proferentum* was applicable and that the clause only pertained to the flooring at the time of installation. As such, the exclusionary clause was inapplicable for any damage occurring afterward. Finally, the Court also ruled that fulfilling certain duties under the *Sale of Goods Act*, did not invariably preclude the respondents from tort liability for negligent misrepresentation.