

UNITED STATES SUPREME COURT

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MASSACHUSETTS

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- Massachusetts Federal Court Holds Failure-To-Warn And Unfair And Deceptive Practices Claims Against Medical Device Manufacturer Based On Alleged Inadequate Adverse Event Reporting To FDA Preempted, As Federal Food, Drug, And Cosmetic Act Forbids Imposing State Law Obligations Except Those That "Parallel" Federal Requirements, And Massachusetts Law Does Not Require Manufacturers To Report Adverse Events To FDA
- Massachusetts Federal Court Holds Triable Issues Exist In Maritime Claims Against Navy Vessel Turbine Manufacturer For Failure To Warn Of Risks Of Third-Party Asbestos Insulation Based On Testimony That (1) Turbine Rooms Would Be Unbearably Hot Without Insulation, As Plaintiff Need Not Prove Turbines "Useless" Without It, (2) Defendant Was Aware Of Risks, And (3) Navy Had Not Warned Plaintiff Of Them, Even Though Defendant Might Have Expected That
- First Circuit Affirms Exclusion Of Physician Expert's Testimony Regarding Pharmacy's Filling Of Prescription And Allegedly Resulting Dermatologic Condition As Expert Admitted He Did Not Know Pharmacist Standard Of Care And Had Limited Understanding Of Dermatologic Condition; Pharmacy Negligence Claim Failed Without Expert Testimony And Implied Warranty Claim Failed Because Pharmacists Primarily Provide Services Rather Than Goods

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- New Jersey Appellate Division Holds Trial Judges Improperly Excluded All Evidence Pelvic Mesh Medical Devices Received Section 510(k) Marketing Clearance From FDA, And Of Related Regulatory Communications, But Courts May Limit Such Evidence To Avoid Regulatory Mini-Trials Or Jury Confusion; 510(k) Clearance Is Not FDA Approval, Licensure Or Finding Of Generally Accepted Safety And Efficacy So As To Preclude Punitive Damages Under New Jersey Product Liability Act
- New York Federal Court Holds Expert Testimony Needed To Support Strict Liability and Negligence Design Defect Claims Against Crossbow Manufacturer, As Feasibility Of Alternative Finger-Guard Designs Required Engineering Knowledge Beyond Lay Jury, And Implied Warranty Of Merchantability Claim Failed As Plaintiff Could Not Articulate Purpose For Which Crossbow Was Unfit Other Than That Underlying Strict Liability Claim

Foley Hoag LLP publishes this quarterly Update primarily concerning developments in product liability and related law from federal and state courts applicable to Massachusetts, but also featuring selected developments for New York and New Jersey.

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In *Ford Motor Company v. Montana Eighth Judicial District Court*, 141 S. Ct. 1017 (2021), two plaintiffs, one a Minnesota resident and the other the estate representative of a Montana resident, brought product liability suits in their home states' courts against an out-of-state motor vehicle manufacturer for injury or death suffered in vehicle accidents in the forum. Defendant moved to dismiss each suit for lack of personal jurisdiction, arguing that because defendant did not design, manufacture or sell plaintiffs' individual vehicles in-state, due process forbade the exercise of jurisdiction over defendant with respect to the specific claims at issue. Both states' trial courts denied defendant's motion, and the Montana and Minnesota Supreme Courts affirmed, each relying in large part on the fact that defendant advertised, sold and maintained dealerships that serviced the vehicle models at issue in the forum. The United States Supreme Court then granted review to address the specific jurisdiction issue.

Under various of the Supreme Court's specific personal jurisdiction decisions, due process permits the exercise of specific jurisdiction only when plaintiffs' claims "arise out of or relate to" defendant's contacts in the forum, and defendant argued this required its forum contacts to have caused plaintiffs' injuries, a circumstance not present here. The Court, however, rejected such a "causation-only approach," asserting that prior precedent generally required only "a 'connection' between a plaintiff's suit and a defendant's activities," and inclusion of the words "relate to" in the "arise out of or relate to" phrase implied that "some relationships will support jurisdiction without a causal showing." In addition, the Court had previously, albeit only in dicta, cited the example of a vehicle manufacturer that regularly marketed its products in the forum as a paradigm case that would support the exercise of jurisdiction over suits involving such vehicles.

In this case, "the business that the company regularly conducts" in the forum state involves advertising and selling defendant's vehicles there, including the two specific models at issue, and maintaining numerous dealerships there both to sell such

vehicles—new and used—to the public, and maintain and repair them. Accordingly, because “resident-plaintiffs allege that they suffered in-state injury because of defective products that [defendant] extensively promoted, sold, and serviced in [the state,] . . . the connection between the plaintiffs’ claims and [defendant]s activities in [the state] . . . is close enough to support specific jurisdiction.”

The Court’s resolution of the “arise out of or relate to” issue based solely on the case’s specific facts will no doubt prompt a vast amount of future litigation. As just a few examples, whether only in-state marketing of the specific product model at issue will count as a “related” contact, whether the Court’s relaxed standard would apply equally if only plaintiff’s residence or place of accident, but not both, were in-state, and whether the Court really meant to base specific jurisdiction over claims involving defendant’s past conduct on the extent of its current forum contacts, all seem questions ripe for further disputes.

Foley Hoag LLP’s **Foley Hoag’s Product Liability and Complex Tort Practice Group** chair **David R. Geiger** recently authored a commentary on this case in a Legal Backgrounder published by the Washington Legal Foundation, available at <https://www.wlf.org/2021/04/22/publishing/the-u-s-supreme-courts-ford-motor-company-decision-jurisdictional-sympathy-prevails-over-logic/>.

MASSACHUSETTS

Massachusetts Supreme Judicial Court Holds That In Most Negligence Cases, Including Those With Multiple Potential Causes, “But-For,” Not “Substantial Contributing Factor,” Is Correct Factual Causation Standard, But In “Rare” Cases Involving Two Independently Sufficient Causes Neither Is Exculpated And Each Is Factual Cause; “Substantial Factor” Language In Asbestos And Toxic Tort Cases Left Undisturbed But May Be Reexamined In Future

In *Doull v. Foster*, 487 Mass. 1 (2021), plaintiffs brought suit in Massachusetts Superior Court against a nurse practitioner and her supervising physician after they prescribed decedent a topical cream to treat perimenopausal symptoms. They alleged the cream caused a pulmonary embolism that led to chronic thromboembolic pulmonary hypertension

that ultimately resulted in decedent’s death, and asserted negligence claims for failure to obtain informed consent and failure to timely diagnose the pulmonary embolism. At trial, defendant’s expert testified there was no evidence the cream could cause clotting, and decedent’s pulmonary hypertension due to other causes was already longstanding at the time of the alleged failure to diagnose, so any such failure did not affect her outcome.

The jury returned a verdict for defendants, finding no failure to obtain informed consent and that, even though the nurse practitioner was negligent in failing to diagnose plaintiff’s embolism, and the physician was negligent in his supervision, neither failure caused plaintiff’s subsequent harms or death. Plaintiffs moved for a new trial, arguing the trial court incorrectly instructed the jury on a “but-for” factual causation standard, when a “substantial contributing factor” instruction should have been given because there were multiple possible causes of decedent’s injuries. The trial court denied the motion, plaintiff appealed to the Massachusetts Appeals Court, and the Massachusetts Supreme Judicial Court transferred the case for direct appellate review on its own motion.

The court started by noting that under Massachusetts law, a defendant is usually considered the factual cause of plaintiff’s harm—a determination separate from “legal” or “proximate” causation, which provides additional limitations—if the harm would not have occurred “but for” defendant’s negligence. On the other hand, some of the court’s opinions had also used the “substantial factor” or “substantial contributing factor” concept, which largely originated in the 1934 Restatement of Torts and was maintained in the 1965 Restatement (Second) of Torts, without making clear that standard’s relationship, if any, to the but-for standard. In the first two Restatements, the concept was expressly defined as but-for causation, subject to an exception when there are two *independently sufficient* causes of the harm such that applying the but-for test would unjustly exculpate both actors, as in the classic case where two negligently set fires combine to destroy plaintiff’s property and either would have done so on its own. The court noted that at least some courts have also used the “substantial factor” standard in asbestos or other toxic tort cases, and the court’s own such cases had used that language, in part due to the perceived difficulty in that context of establishing what contributing factors were but-for causes.

Although the first two Restatements used the substantial

contributing factor terminology, the 2010 Restatement (Third) of Torts discontinued it, asserting it was not widely adopted and noting it posed a significant risk of confusing the jury, including by inducing it to skip the but-for inquiry altogether even though that inquiry was necessary except in the rare independently sufficient cause situation. The court agreed with these concerns, and added that most negligence cases involve multiple alleged causes of the harm, typically nothing prevents the jury from determining “which of the causes alleged by the plaintiff were actually necessary to bring about the harm” and the jury had been readily able to do that in this case. Indeed, multi-cause cases “may be where the but-for test is most important and useful, as it serves to separate the necessary causes from conduct that may have been negligent but may have had nothing to do with the harm caused.”

Accordingly, the court held that “in the majority of negligence cases” the jury should be instructed on causation under the but-for standard, and in the “exceedingly rare” situation that involves multiple independently sufficient causes the jury should additionally be instructed that such causes are also factual causes of the harm. With respect to asbestos and toxic tort cases, since that issue was not before the court and would benefit from full briefing and argument, the court expressly did not disturb its precedent applying substantial factor causation in such cases, but noted that in an appropriate case it would consider doing so.

Massachusetts Federal Court Holds Failure-To-Warn And Unfair And Deceptive Practices Claims Against Medical Device Manufacturer Based On Alleged Inadequate Adverse Event Reporting To FDA Preempted, As Federal Food, Drug, And Cosmetic Act Forbids Imposing State Law Obligations Except Those That “Parallel” Federal Requirements, And Massachusetts Law Does Not Require Manufacturers To Report Adverse Events To FDA

In *Plourde v. Sorin Grp. United States*, No. 17-cv-10507-ADB, 2021 U.S. Dist. LEXIS 38736 (D. Mass. Feb. 5, 2021), plaintiffs’ daughter was born with health complications that required catheterizations of her aortic valve, and at age ten required a valve replacement. Her surgeon, in consultation

with plaintiffs, decided to implant a bioprosthetic valve manufactured and sold by defendants and made of bovine pericardium sewn onto a polyester stent. Plaintiffs’ daughter experienced significant complications from the surgery, and following a procedure to replace defendant’s valve with a mechanical one never regained consciousness and ultimately died. Plaintiffs sued in Massachusetts Superior Court for breach of express warranty, negligent failure to warn and violation of Mass. Gen. L. ch. 93A (the state unfair and deceptive business practices statute). Defendants removed the case to the United States District Court for the District of Massachusetts and moved for summary judgment.

Plaintiffs’ failure-to-warn claim was predicated on defendants’ alleged failure to adequately report adverse events associated with use of their valve in patients under thirty to the United States Food and Drug Administration (“FDA”), including omitting certain incidents or the patient’s age at implantation. Defendants argued the claim was preempted by the Medical Device Amendments (“MDA”) to the Federal Food, Drug, and Cosmetic Act (“FDCA”). The MDA expressly preempts state law requirements that are “different from, or in addition to” federal law, but not those that merely parallel federal requirements, and defendants argued there was no duty under Massachusetts law to report to FDA that paralleled reporting requirements under the FDCA. The court agreed, finding that Massachusetts cases cited by plaintiffs merely mentioned such a duty *might* exist, but did not determine the issue. Further, plaintiffs could not identify any basis for extending the “learned intermediary” doctrine, which requires prescription product manufacturers to provide adequate warnings to medical practitioners, to require such manufacturers to further report dangers to FDA, as numerous courts in other jurisdictions had refused to do so.

The court also found plaintiffs’ ch. 93A claim, which alleged defendants’ failure to provide accurate information to FDA was unfair and deceptive, was derivative of their failure-to-warn claim and failed for the same reasons. Lastly, the court granted summary judgment on plaintiffs’ breach of warranty claim. Although plaintiffs argued defendants offered “exaggerated and misleading” safety expectations, they could not identify any specific statements creating those expectations, especially given that the valve included an explicit warning regarding use in younger individuals.

Massachusetts Federal Court Holds Triable Issues Exist In Maritime Claims Against Navy Vessel Turbine Manufacturer For Failure To Warn Of Risks Of Third-Party Asbestos Insulation Based On Testimony That (1) Turbine Rooms Would Be Unbearably Hot Without Insulation, As Plaintiff Need Not Prove Turbines “Useless” Without It, (2) Defendant Was Aware Of Risks, And (3) Navy Had Not Warned Plaintiff Of Them, Even Though Defendant Might Have Expected That

In *Sebright v. G.E.*, No. 19-10593-WGY, 2021 U.S. Dist. LEXIS 46660 (D. Mass. March 21, 2021), plaintiff alleged his mesothelioma was caused by exposure to numerous defendants’ asbestos-containing products while working as a machinist mate on various United States Navy vessels, and brought claims including negligent failure to warn in the United States District Court for the District of Massachusetts.

One defendant, a manufacturer of turbines allegedly covered by a third party’s asbestos insulation, moved for summary judgment, arguing it had no duty to warn of the risks of the third party’s product under the United States Supreme Court’s decision in *Air and Liquid Systems Corp. v. DeVries*, 139 S. Ct. 986 (2019). Under *DeVries*, maritime law requires a manufacturer to warn if “(i) its product requires incorporation of a part, (ii) the manufacturer knows or has reason to know that the integrated product is likely to be dangerous for its intended uses, and (iii) the manufacturer has no reason to believe that the product’s users will realize that danger.”

Applying *DeVries*, the court first held there was a genuine issue of fact as to whether insulation was “required” for the turbine to operate, as plaintiff and multiple shipmates testified that without insulation the rooms housing the turbines would be unbearably hot, and contrary to defendant’s argument plaintiff did not need to prove the turbines would be entirely “useless” without insulation. There was also a genuine factual dispute regarding *DeVries*’ second prong, as one of plaintiff’s experts testified that both the Navy and defendant were aware asbestos dust was dangerous decades before plaintiff’s exposure.

As for the third prong, the court noted *DeVries*’ wording was “somewhat confusing,” as its use of the present tense makes it difficult to determine whose knowledge at what point in time is material. Further, as defendant argued, the language implies a plaintiff cannot prevail if defendant had *any* reason to believe

product users would be aware of the presence and dangers of asbestos, and here defendant argued it had a reasonable expectation the Navy would inform its sailors of such dangers. Ultimately, however, the court pointed to other language in *DeVries* suggesting a “balancing of risks and burdens,” as well as maritime law’s “overarching mandate to protect the interests of seamen in the absence of applicable statutory law,” to hold that where the manufacturer’s burden of warning a product user is slight, the user should be presumed to be ignorant of the risk regardless of whether the product’s purchaser could also be expected to warn of it. Here, because plaintiff testified the Navy never warned him of any asbestos risk, there was a genuine issue of fact as to the third *DeVries* prong.

Lastly, the court rejected defendant’s argument that plaintiff lacked any evidence that asbestos exposure associated with its turbines was a substantial factor in causing his mesothelioma. Plaintiff testified he had inhaled dust from the turbines’ insulation “at least about four times per year” for at least two years, which alone raised “an inference of more than minimal exposure.” In addition, although plaintiff’s experts had not provided any quantitative assessment of his exposure or product-specific allocation of risk, their opinions that his exposure while in the Navy would have been “thousands to millions of times higher than the background concentration,” and was “sufficiently substantial and significant to cause his malignant mesothelioma,” were enough to create a genuine issues of fact on causation.

For all these reasons, the court denied the turbine manufacturer’s motion. The court did grant summary judgment to a valve manufacturer defendant, as there was no evidence any of its valves on plaintiff’s vessels included asbestos components or were insulated.

First Circuit Affirms Exclusion Of Physician Expert's Testimony Regarding Pharmacy's Filling Of Prescription And Allegedly Resulting Dermatologic Condition As Expert Admitted He Did Not Know Pharmacist Standard of Care And Had Limited Understanding Of Dermatologic Condition; Pharmacy Negligence Claim Failed Without Expert Testimony And Implied Warranty Claim Failed Because Pharmacists Primarily Provide Services Rather Than Goods

In *Carrozza v. CVS Pharm., Inc.*, No. 19-1776, 2021 U.S. App. LEXIS (1st Cir., Mar. 31, 2021), plaintiff sued a pharmacy in the United States District Court for the District of Massachusetts after it filled his prescription for a quinolone-class antibiotic he alleged caused a severe dermatologic condition known as Stevens-Johnson Syndrome ("SJS"). Plaintiff alleged the pharmacy's computer system contained a "hardstop" warning that he was allergic to quinolones and brought claims for negligence, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and violation of Mass. Gen. L. ch. 93A (the state unfair and deceptive business practices statute).

In support of his claims, plaintiff proffered an expert allergist-immunologist who opined that filling the prescription violated the pharmacy's duty of care, and that the antibiotic likely caused plaintiff's SJS. Defendant argued its pharmacist filled the prescription based on notes that plaintiff had filled three prior quinolone prescriptions without adverse effects, and moved to exclude plaintiff's expert's testimony as lacking a reliable basis. The district court allowed the motion, noting the expert admitted he did not know the standard of care applicable to a pharmacist under the circumstances and finding that he "had a limited understanding of the facts of the case and SJS generally," and granted summary judgment for defendant. [\[see Foley Hoag LLP November 2019 Product Liability Update\]](#)

On plaintiff's appeal, the United States Court of Appeals for the First Circuit affirmed. Plaintiff first argued the district court had abused its discretion in excluding his expert's testimony because his experience as a practicing physician, and particularly his professional interactions with pharmacists, qualified him to testify to custom and usage in that field and allergists and pharmacists are "sufficient[ly] close in their careers to both know when the other should not give a

medication to a patient"; further, the expert's admission that he did not know the standard of care for pharmacists was merely the result of not being prepared for deposition and being "tripped up" by the standard of care questions.

In rejecting plaintiff's arguments, the appellate court noted that the district court had identified the proper factors under Fed. R. Evid. 702 governing the admissibility of the expert's testimony, namely "(1) whether the proposed expert is qualified by 'knowledge, skill, experience, training, or education'; (2) whether the subject matter of the proposed testimony properly concerns 'scientific, technical, or other specialized knowledge'; and (3) 'whether the testimony [will be] helpful to the trier of fact, i.e., whether it rests on a reliable foundation and is relevant to the facts of the case.'" Given the expert's admissions that he could not testify to the relevant standard of care, or the nature or causes of SJS, the trial court did not abuse its discretion in excluding the testimony.

Further, summary judgment was appropriate on all claims. Expert testimony was required to support plaintiff's professional negligence claim. Plaintiff failed to allege any "common-law, statutory, or other established concept of unfairness" that was violated by the pharmacy's conduct, which would be necessary to support a claim under ch. 93A. And under Massachusetts law, a claim for breach of the implied warranty of merchantability can only arise from a sale of goods, while a pharmacist's dispensing of a prescribed medication is considered to constitute predominantly the provision of services.

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New Jersey Appellate Division Holds Trial Judges Improperly Excluded All Evidence Pelvic Mesh Medical Devices Received Section 510(k) Marketing Clearance From FDA, And Of Related Regulatory Communications, But Courts May Limit Such Evidence To Avoid Regulatory Mini-Trials Or Jury Confusion; 510(k) Clearance Is Not FDA Approval, Licensure Or Finding Of Generally Accepted Safety And Efficacy So As To Preclude Punitive Damages Under New Jersey Product Liability Act

In *Hrymoc v. Ethicon, Inc., and McGinnis v. C.R. Bard, Inc.*, Docket Nos. A-5151-17 & A-1083-18, 2021 N.J. Super LEXIS 24 (N.J. Super. Ct. App. Div. Mar. 2, 2021), two women alleged that pelvic mesh devices implanted to correct pelvic organ prolapse and stress urinary incontinence caused injuries, including severe chronic vaginal pain and pain during intercourse, that persisted even after the mesh was removed. Both brought design defect and failure-to-warn lawsuits against the respective mesh manufacturers in New Jersey Superior Court. The suits were managed along with a large number of similar suits as part of a multicounty litigation (“MCL”), and assigned to different judges for trial.

In each case, the trial judge granted plaintiff’s motion to exclude all evidence that defendant had marketed the device only after receiving a § 510(k) clearance (based on the applicable section of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act) from the United States Food and Drug Administration (“FDA”), and all evidence of communications with the agency during the clearance process. Under § 510(k), a new medical device can be marketed if its manufacturer demonstrates it is substantially equivalent to a device already on the market. Otherwise, any new device that poses a significant degree of risk (a “Class III” device), including most implants, can only be marketed if FDA grants the manufacturer’s application for premarket approval (“PMA”), a more rigorous process that requires showing that based on all available evidence, including any clinical studies, there is reasonable assurance of the device’s safety and effectiveness.

Each trial judge ruled that, unlike PMA, a 510(k) clearance does not evaluate the device’s safety and therefore is

irrelevant in a product liability claim. One judge held alternatively that the evidence was inadmissible under N. J. R. Evid. 403, as any relevance was substantially outweighed by the possible prejudice and jury confusion arising from a mini-trial and battle of experts over the significance of 510(k) clearance. That judge also rejected defendant’s argument that a 510(k) clearance precluded punitive damages under New Jersey’s Product Liability Act, N.J.S.A. 2A:58C-1 to -11 (“PLA”), which forbids such damages for a drug, device, food or food additive that is “subject to [FDA] premarket approval or licensure” and “was approved or licensed[,] or is generally recognized as safe and effective,” concluding that a 510(k)-cleared product did not fall within those terms.

Following trial, one jury awarded \$5 million in compensatory and \$10 million in punitive damages, and the other \$33 million and \$35 million respectively. Both manufacturers appealed, and the Superior Court’s Appellate Division consolidated the appeals solely to issue an opinion addressing the common 510(k) issues.

The court first held the categorical exclusion of all 510(k) evidence was improper and required a new trial. Although the majority of decisions addressing this issue—most of which stem from rulings of a judge in the federal transvaginal mesh multidistrict litigation—have excluded such evidence, there is no consensus. While a 510(k) clearance is not a plenary determination of safety and effectiveness, the FDA’s review of a 510(k) submission can address safety issues, including whether any differences from the predicate device affect the new device’s safety or efficacy, and may involve detailed clinical and scientific data concerning adverse effects. At a minimum, the clearance shows the manufacturer obtained regulatory authorization to market its device, which is relevant to the reasonableness of its design. Moreover, excluding all regulatory evidence was particularly unjust because plaintiffs’ counsel repeatedly told jurors the manufacturers performed no clinical studies before plaintiffs’ devices were implanted, and the manufacturers were unable to respond by showing FDA expressly stated it did not require clinical studies to support at least one of the 510(k) submissions. Worse still, jurors may have based their punitive damages decisions on the incorrect belief the manufacturers marketed their devices without any regulatory oversight.

While excluding all 510(k) evidence is improper, trial courts

should limit the volume of such evidence to avoid a mini-trial on FDA regulations or confusing the jury about them. Accordingly, judges should hold a pre-trial hearing under N.J. R. Evid. 104 to determine how much regulatory information should be presented, whether it should be in the form of a stipulation or actual evidence and what instructions might be necessary for the jury to understand the information.

Regarding punitive damages, the appellate court agreed that a 510(k) clearance does not preclude such damages under the PLA. Section 510(k) clearance is not a “premarket approval” or “licensure,” since FDA regulations specifically prohibit manufacturers from promoting a cleared device as “approved.” Nor does clearance signify general recognition that the device is safe and effective, as the FDA has only determined it is substantially equivalent to a previously marketed device.

After addressing the common 510(k) issues, the court rejected the manufacturers’ various individual appellate grounds. For example, one trial judge properly refused a “state of the art” jury instruction that no design defect exists if there was no practical and technically feasible alternative design that would have prevented plaintiff’s harm, as there was no evidence any of the alternative designs suggested by plaintiff were not feasible. And in the other trial, plaintiff had adequate evidence her device would not have been implanted had defendant provided adequate warnings despite her physician’s comment that he did not “think” he would have prescribed the device with the warnings plaintiff sought, as the bulk of his testimony made clear he was unaware of some of the risks and would have discussed them with plaintiff had he been aware, while she testified she would not have agreed to the implantation after such a discussion.

New York Federal Court Holds Expert Testimony Needed To Support Strict Liability and Negligence Design Defect Claims Against Crossbow Manufacturer, As Feasibility Of Alternative Finger-Guard Designs Required Engineering Knowledge Beyond Lay Jury, And Implied Warranty Of Merchantability Claim Failed As Plaintiff Could Not Articulate Purpose For Which Crossbow Was Unfit Other Than That Underlying Strict Liability Claim

In *Nemes v. Dick’s Sporting Goods, Inc.*, No. 17-cv-1688, 2021 U.S. Dist. LEXIS 34362, (S.D.N.Y. Feb. 23, 2021), plaintiff sued the manufacturer and seller of a crossbow in the United States District Court for the Southern District of New York, asserting claims for strict liability, negligence and breach of the implied warranties of merchantability and fitness for a particular purpose after the bow’s string severely lacerated her thumb, requiring its partial amputation. Plaintiff’s claims were based on allegations the bow contained a design defect because its finger reminder or guard, a barrier between the bow’s stock and the path of its string, did not prevent her thumb from slipping into the string’s path when she fired it.

The court, in an earlier decision, had granted defendant’s request to preclude plaintiff’s expert from testifying about a feasible alternative design, holding his opinion on the subject was speculative because he did not provide any useful details on alternative safety devices that had been successfully implemented in similar products. Defendant then moved for summary judgment, arguing that without expert testimony, plaintiff could not prove the existence of a technologically and economically feasible safer alternative design, a necessary element of a design defect claim.

Plaintiff argued she had sufficient non-expert evidence, including testimony from her husband about a guard he had designed, evidence regarding comparable crossbows on the market with wider guards, testimony from defendants’ employees about the ability to design a wider finger barrier, and a United States Consumer Product Safety Commission report, to establish that a safer alternative design was feasible. The court agreed that expert testimony is not always necessary to prove a design defect, as in some cases lay factfinders could find feasible alternative designs obvious or readily understandable. Here, however, evaluating

the feasibility of more complex alternative designs such as crossbow safety features required expert engineering knowledge beyond that of a layperson, as had been held in prior cases involving the feasibility of guardrails on concrete mixing trucks and safety guards on saws. Accordingly, plaintiff's strict liability and negligence claims both failed, as despite any uncertainty as to whether they were functionally equivalent under New York law, it was clear both required proof of a feasible alternative design.

Regarding plaintiff's warranty claims, the court first noted that an implied warranty of fitness for a particular purpose only arises on proof of a specific purpose known to the seller other than the product's ordinary purpose, but here plaintiff had only addressed the crossbow's ordinary purpose.

As for breach of the implied warranty of merchantability, plaintiff had to prove the product was not fit for its ordinary purpose. In order for that claim to succeed where her strict liability claim had already failed, however, plaintiff had to allege the product was unfit for a different purpose than that involved in the strict liability risk-utility analysis. Here, plaintiff had not argued for the crossbow's unfitness for any purpose other than target shooting, the same use involved in her strict liability claim. In response to her novel argument that, regardless of the purpose of the bow as a whole, the finger guards themselves were not fit for their ordinary purpose because they failed adequately to protect the user, the court held the warranty of merchantability looks to the purpose of the product as a whole, and not any constituent part. The court thus granted summary judgment on plaintiff's implied warranty claims as well.

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