

In This Issue:

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- Massachusetts Appeals Court Holds Birth Control Patch Manufacturer Had Duty to Warn Patient Directly But Packet Insert Adequately Warned of Greater Risk of Blood Clots As Compared to Birth Control Pill; Design Defect Claim Failed Because Pill Was Not Safer Alternative Design Due to Fundamentally Different Drug Delivery Method
- Massachusetts Federal Court Holds Mechanical Engineer's Design Defect and Causation Opinions Regarding Riding Mower Admissible Despite Failure to Use Accident Reconstruction and "Time-to-Blade-Access" Techniques, Biomechanical Engineer's Defect and Causation Opinions Also Admissible Because Human Factors Experience and Biomechanical Task Analysis Were Adequate Substitutes For Accident Reconstruction Training and Techniques
- Massachusetts Federal Court Grants Summary Judgment Against Punitive Damages On Plaintiff's Tort Claims Because No Statute Permitted Such Damages, But Allows Multiple Damages Claims Under Unfair and Deceptive Practices Statute
- Massachusetts Appeals Court Holds Jury Instruction on Substantial Contributing Factor Causation Appropriate in Cases Involving Multiple Tortfeasors or Other Potential Causes

Foley Hoag LLP publishes this quarterly Update concerning developments in product liability and related law of interest to product manufacturers and sellers.

Massachusetts Appeals Court Holds Birth Control Patch Manufacturer Had Duty to Warn Patient Directly But Packet Insert Adequately Warned of Greater Risk of Blood Clots As Compared to Birth Control Pill; Design Defect Claim Failed Because Pill Was Not Safer Alternative Design Due to Fundamentally Different Drug Delivery Method

In *Niedner v. Ortho-McNeil Pharmaceutical, Inc.*, 90 Mass. App. Ct. 306 (2016), plaintiff sued a birth control patch manufacturer in Massachusetts Superior Court for wrongful death and pre-death pain and suffering after her daughter suffered a massive pulmonary embolus and died three months after being prescribed defendant's patch. Plaintiff asserted claims for breach of express warranty, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), negligence and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute) based on theories of defective design, manufacturing defect and failure to warn of the greater risk of blood clots with a patch as compared to an oral contraceptive. The court granted defendant's motion for summary judgment on all claims, finding, among other things, that defendant's patient package insert warnings were adequate as a matter of law.

On plaintiff's appeal, the Massachusetts Appeals Court affirmed. The court first agreed with plaintiff that defendant fell under a narrow exception to the "learned intermediary" rule—under which a prescription pharmaceutical manufacturer's duty is only to adequately warn the prescribing physician, not the patient directly—established by the Massachusetts Supreme Judicial Court in *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131 (1985). Although *MacDonald* involved an oral contraceptive manufacturer, its rationale—which was based on the patient's heightened participation in decisions surrounding birth control—was equally applicable to defendant as manufacturer of a different type of hormonal contraceptive. The court held, however, that defendant had adequately discharged its duty as a matter of law, as the package insert included plain, numerous and comprehensive warnings detailing the comparatively greater risks of using the patch versus using the pill, including the risk of developing blood clots in the lung.

Regarding the alleged design defect, the court held there was no support for plaintiff's claim that the pill was a feasible safer alternative to the patch, as the differences in drug delivery methods made the products fundamentally different. Nor was there any evidence the specific patch used by plaintiff's daughter suffered from a manufacturing defect. Finally, as the risks associated with the patch were accurately explained in the insert and defendant had made no other representations to plaintiff's daughter, there was no evidence of any breach of express warranty or unfair or deceptive conduct in violation of ch. 93A.

Massachusetts Federal Court Holds Mechanical Engineer’s Design Defect and Causation Opinions Regarding Riding Mower Admissible Despite Failure to Use Accident Reconstruction and “Time-to-Blade-Access” Techniques, Biomechanical Engineer’s Defect and Causation Opinions Also Admissible Because Human Factors Experience and Biomechanical Task Analysis Were Adequate Substitutes For Accident Reconstruction Training and Techniques

In *Provanzano v. MTD Prods. Co.*, No. 15-11720, 2016 U.S. Dist. LEXIS 143402 (D. Mass. Oct. 17, 2016), plaintiff sued the manufacturer and retailer of a riding lawn mower in Massachusetts Superior Court after he was injured by reaching under the mower’s cutting deck. Plaintiff asserted claims for breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), breach of express warranty, negligence, and violation of Mass. Gen. L. ch. 93A (the state unfair and deceptive practices statute) based on theories of defective design and failure to warn.

Defendants removed the action to the United States District Court for the District of Massachusetts, where plaintiff sought to introduce a mechanical engineer’s testimony that the mower was defectively designed with respect to the mower’s blade’s stopping time, the layout of its controls, and the placement of warnings and that these defects caused plaintiff’s injuries. Defendants moved to exclude the expert’s causation opinion on the grounds that it was speculative and therefore unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), which require the proponent of expert testimony to show it is reliable in order to be admitted, and that plaintiff’s expert failed to perform an accident reconstruction or “time-to-blade-access” analysis. Defendants also argued plaintiff’s expert was unqualified to opine because he had neither been employed by an outdoor power equipment manufacturer nor designed riding mowers for consumers.

Plaintiff cross-moved to exclude the opinions of defendants’ biomechanics expert that the mower complied with the applicable standard for blade stopping time, the timing of the accident could not have occurred as described by plaintiff, human factors contributed to the accident and the mower was not defectively designed. Plaintiff argued the expert was not a qualified accident reconstructionist and that her methodology was unreliable because of flaws in her accident reconstruction.

Applying *Daubert* and Rule 702, the court first rejected defendants’ contention that plaintiff’s expert’s causation opinion was unreliable because it lacked evidentiary support, finding defendants merely disagreed with the conclusions the expert drew from the evidence. In addition, the expert’s failure to consider particular variables or use particular methods, such as accident reconstruction or “time-to-blade-access” analysis, might affect his testimony’s probative value but not its admissibility. Further, as a licensed mechanical engineer for 30 years with previous experience testifying in lawn mower litigation, the expert was qualified to opine about both design defect and causation.

Regarding defendants’ expert, who held a doctorate in mechanical science and bio-medical engineering, the court rejected plaintiff’s argument that the expert’s methodology—a bio-mechanical task analysis rather than accident reconstruction—was unreliable, holding that the differences in methodologies might affect the weight but not the admissibility of her opinions. Further, although the expert was not trained as an accident reconstructionist, she had performed human factors analyses as part of her extensive training in human biomechanics and such experience and techniques were sufficiently similar to accident reconstruction to support the admissibility of her opinions; once again, the court noted plaintiff could address any weaknesses in qualifications or methodology by cross-examination. Accordingly, based on its analyses of the dueling experts’ opinions, the court denied both parties’ motions to exclude them.

Massachusetts Federal Court Grants Summary Judgment Against Punitive Damages On Plaintiff’s Tort Claims Because No Statute Permitted Such Damages, But Allows Multiple Damages Claims Under Unfair and Deceptive Practices Statute

In *Elliston v. Wing Enters., Inc.*, No. 15-11739, 2016 U.S. Dist. LEXIS 166746 (D. Mass. Dec. 2, 2016), a pro se plaintiff sued a ladder manufacturer in the United States District Court for the District of Massachusetts, alleging he was injured when the ladder’s leg buckled and snapped off during use and seeking both compensatory and punitive damages. The manufacturer moved for summary judgment against plaintiff’s punitive damages claims.

The court first noted that under Massachusetts law, punitive damages are not available unless expressly authorized by statute. Here, there was no statute authorizing such damages for any of plaintiff's tort claims, which the court liberally interpreted to include claims for negligent failure to warn, negligent design and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), so the court granted summary judgment against punitive damages on those claims.

The court also interpreted plaintiff, however, to allege a violation of Mass. Gen. L. ch. 93A (the state's unfair and deceptive practices statute) premised on the alleged breach of warranty. The court noted that the statute's authorization of multiple—i.e., double or treble—damages for a defendant's "willful or knowing" violation of the statute made such damages essentially punitive in nature, as the amount of damages would be premised on the wrongfulness of defendant's conduct and not the amount of harm suffered by plaintiff. Accordingly, the court denied summary judgment to the extent plaintiff sought punitive damages in conjunction with his ch. 93A claim, noting that factual questions remained about whether defendant's conduct was indeed "willful or knowing."

Massachusetts Appeals Court Holds Jury Instruction on Substantial Contributing Factor Causation Appropriate in Cases Involving Multiple Tortfeasors or Other Potential Causes

In *Bonoldi v. DJP Hospitality*, 2016 Mass. App. Unpub. LEXIS 872 (Mass. App. Ct. Sep. 2, 2016), plaintiff, after slipping and falling in a bar parking lot, sued both the bar and lot owner for premises liability under a theory of negligence in Massachusetts Superior Court. At trial, the jury found for the bar and against the lot owner, but found the latter's negligence was not a "substantial factor" in causing plaintiff's harm. Plaintiff appealed the judgment in favor of both defendants and argued, without citation to legal authority, that the judge should not have given a "substantial contributing factor" instruction to the jury

but instead should simply have instructed that each defendant's conduct was "a legal cause" of plaintiff's harm.

The Massachusetts Appeals Court, in a decision published under a procedure usually invoked in cases controlled by well-established legal principles, affirmed the judgment. The court first noted that the "substantial contributing factor" test is useful in cases with multiple tortfeasors where there may be a question about whether any individual tortfeasor could have caused plaintiff's harm. Here, the jury was required to determine the causal link between the negligence of multiple alleged tortfeasors—the bar and lot owner—and plaintiff's harm. In addition, plaintiff's lifelong history of migraines also put into question the causal link between plaintiff's fall and her alleged injuries. For these reasons, the trial court properly instructed the jury on the substantial contributing factor standard.

This Update was prepared by Foley Hoag's Product Liability and Complex Tort Practice Group, which includes the following members:

David R. Geiger
Chair and Editor

Daniel J. Procaccini
Associate Co-Editor

Richard G. Baldwin

Shrutih V. Tewarie
Associate Co-Editor

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