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Product Liability **Update**

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

Massachusetts Federal District Court Holds Hospital Not Fraudulently Joined in Medical Device Suit, as Warranty Claim Asserting Hospital Was Product Seller Rather than Service Provider Has Reasonable Basis; No Federal Question Presented as Food, Drug and Cosmetic Act Does Not Completely Preempt State Law so Claims Could Only Arise under Federal Law

Plaintiff in *Phillips v. Medtronic, Inc.*, 2010 WL 4939997 (D. Mass. Dec. 1, 2010), developed inflammatory masses causing pain and loss of certain functions after hospital treatment that included the implantation of two intrathecal pain pumps. The United States Food and Drug Administration ("FDA") had issued pre-market approvals for the devices prior to plaintiff's treatment, but several years after that treatment the manufacturer partially recalled the pumps after discovering an increase in reports of inflammatory masses.

Plaintiff sued both the device manufacturer and hospital in Massachusetts Superior Court, asserting claims of negligence, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute) based on the manufacturer's allegedly defective design of the devices and both defendants' failure to warn of the inflammatory mass risk. Plaintiff further contended that the devices' designs departed from specifications approved by the FDA. Defendants removed the case to the United States District Court for the District of Massachusetts, asserting jurisdiction based on diversity of citizenship because the in-state hospital allegedly had been fraudulently joined, and federal question jurisdiction because plaintiff's state law claims were allegedly preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). Plaintiff moved to remand the case to state court, arguing there was no basis for federal jurisdiction.

The court first noted that a party is not fraudulently joined if there is at least an "arguably reasonable basis" for predicting that state law would allow the claim against that party. Thus, in this case the question turned on whether, under Massachusetts law, the hospital could be deemed a seller or distributor of goods rather than provider of services in supplying the pumps as part of plaintiff's treatment, such that the hospital could be held liable on a breach of warranty theory. The court found no Massachusetts authority on point and a split of authority in other jurisdictions. Despite finding no clear answer, the court held plaintiff's warranty claims had a "reasonable basis" in the law, as it was plausible the Massachusetts Supreme Judicial Court would adopt a rule holding the hospital to be a seller or distributor under the circumstances.

Turning to federal question jurisdiction, the court observed that where a complaint on its face asserts only state-law claims, the defense of preemption does not make the claim arise under federal law unless that law effects "complete preemption" of all state law. Complete preemption requires both exclusive federal regulation of the subject matter of the claim and the existence of a federal cause of action addressing wrongs of the same type. The instant action did not satisfy these criteria because, although the MDA contains an express preemption clause, the FDCA does not provide a private right of action for statutory violations. Accordingly, finding it had neither diversity nor federal question jurisdiction, the court remanded the case to state court.

Massachusetts Federal District Court Holds Retailer Not Liable in Negligence as "Apparent Manufacturer" for Failure to Warn of Product Risks Where Retailer's Name Was Not on Product and There Was No Evidence Plaintiffs Believed Retailer Was the Manufacturer

In *Bernier v. One World Technologies, Inc.*, -- F. Supp. 2d ----, 2010 WL 3927765 (D. Mass. Sept. 29, 2010), plaintiffs were injured while using a table saw that "kicked back" causing their hands to make contact with the blade. The saw was not equipped with a new flesh-detection technology called "StopSaw" which automatically stops the blade when it first touches flesh. Neither did the saw incorporate an independent riving knife, which reduces "kickbacks." Plaintiffs sued the saw's manufacturers and retailer in the United States District Court for the District of Massachusetts, alleging negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) on the ground that the saw was defectively designed and defendants failed to warn of its dangers. The retailer moved for partial summary judgment with respect to the negligence claims, arguing it had no duty to warn potential users of any alleged defects in the saw.

In analyzing whether the retailer could be held liable in negligence, the court first turned to its own precedent in a similar case tried by different plaintiffs earlier in the year. In that case, the court held that a retailer that is not also the product's manufacturer cannot be held liable in negligence for latent defects in the product. However, a retailer that puts out a product as its own, even if not the manufacturer, may be held liable under the "apparent manufacturer" doctrine. The rationale for the doctrine is that when a seller causes the public to believe it is the manufacturer -- whether through labeling, advertising or otherwise -- the consumer will rely on the company's reputation and care in making products so the seller should be estopped to disclaim liability simply because it was not in fact the manufacturer. For the doctrine to apply, there must be evidence that the product's labeling or advertising is "likely to cause a consumer to rely on the retailer's reputation."

Here, the court found there was no such evidence. The retailer's name was not on the saw or its packaging, and plaintiffs put forth no evidence that they believed the retailer manufactured the product. Accordingly, the court allowed the retailer's motion for summary judgment.

First Circuit Reverses Trial Court Decision to Exclude Expert From Testifying Based on Pro-Plaintiff Bias, Holding Focus of Inquiry Should Be On Expert's Specialized Knowledge and Whether Testimony Will Assist Jury in Understanding Fact in Issue

In *Cruz-Vasquez v. Mennonite General Hospital, Inc.*, 613 F.3d 54 (1st Cir. 2010), plaintiffs sued a hospital and two physicians in the United States District Court for the District of Massachusetts, asserting medical malpractice and Emergency Medical Treatment and Active Labor Act claims after their daughter died two days after her premature birth.

At trial, plaintiffs proffered the expert testimony of a board-qualified—but not board-certified—physician in the fields of obstetrics and gynecology. Due to health issues, the physician had stopped seeing patients a number of years earlier. Since that time, he had served as an expert witness in approximately 150 medical malpractice cases, primarily for plaintiffs, and was collaborating with the plaintiffs' counsel to give lectures on issues of health law. After holding a hearing pursuant to *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), which requires that expert testimony be shown to be reliable in order to be admitted, in response to an oral motion by defendants, the court excluded the physician's testimony on the ground that he was biased in favor of plaintiffs in medical malpractice cases. The court also found the physician could

be excluded from testifying based on plaintiffs' failure to furnish defendants with his up-to-date curriculum vitae. The court then ruled that without the expert plaintiffs lacked evidence to support their claims and granted defendants' motion for judgment as a matter of law.

On plaintiffs' appeal, the United States Court of Appeals for the First Circuit first observed that the "overarching subject" of a trial court's inquiry when assessing proposed expert testimony is the scientific validity of the testimony. By focusing its inquiry on the expert's potential bias, as distinguished from his specialized training or knowledge, the district court's reasoning had nothing to do with the scientific validity of the expert's opinion. Considerations such as the expert's financial interest in the outcome of a case, his bias towards plaintiffs or whether he was currently seeing patients went to his testimony's probative weight, not admissibility. The court also noted that specific credentials, such as a current board certification, were not required for an expert to be qualified to testify, and that defendants were not prejudiced by plaintiffs' production of the physician's outdated curriculum vitae.

The court then explained that the physician's specialized knowledge – namely his medical training and experience in the field of obstetrics and gynecology and whether it would assist the factfinder better to understand a fact in issue – was the appropriate field of inquiry for the district court's expert gatekeeping function under *Daubert*. By deviating from that field and excluding the expert based on potential bias, the court had invaded the province of the jury and abused its discretion. The appellate court therefore vacated the judgment for defendants and remanded for further proceedings.

Massachusetts Appeals Court Affirms Defense Verdict Despite Plaintiffs' Claim Judge Erroneously Failed to Instruct Jury that "Substantial Contributing Factor" to Plaintiffs' Injuries Need Not Be "But For" Cause of Same, as Plaintiffs Failed to Request Instruction

The Massachusetts Appeals Court's decision in *Hobbs v. TLT Construction Corp.*, 78 Mass. App. Ct. 178 (2010), serves as a reminder to counsel that any objection to jury instructions, and the grounds therefor, must be stated at the time the instruction is given in order to preserve the right to appeal. In Hobbs, several plaintiffs alleged injury as a result of exposure to three toxic substances during a high school flooring renovation project. Among other things, they alleged that isocyanates in the flooring emitted noxious fumes that caused skin irritation, allergies and respiratory problems. Plaintiffs sued the flooring manufacturer/installer, the architect who designed the renovation project and the general contractor in Massachusetts Superior Court asserting claims of negligence and breach of warranties. After the architect settled before trial, the jury found the contractor liable for negligently creating excessive construction dust which caused some of plaintiffs' injuries. As to the flooring manufacturer/installer, however, the jury found there was no breach of warranty and, although the manufacturer was negligent in handling the isocyanates, such negligence was not a "substantial contributing factor" in causing the plaintiffs' injuries.

On appeal, plaintiffs argued that the trial judge erroneously instructed the jury as to causation and damages with respect to joint tortfeasors' liability by failing to instruct that a substantial contributing factor to plaintiffs' injuries need not be a necessary or "but for" cause of such injuries. On examination of the trial record, however, the appellate court found that plaintiffs had never requested the "but for" language either before or after the jury instructions were given. Accordingly, the issue was resolved by Mass. R. Civ. P. 51(b), which provides that no party may assign error to a jury instruction unless he objects before the jury retires, stating distinctly the subject of and grounds for the objection. The court thus affirmed the trial court judgment.

Massachusetts Federal District Court Holds Plaintiff Could Not Prove Causation in Manufacturing Defect Suit Due to Lack of Proof Alleged Defect Was Caused by Manufacturer Rather than Plaintiff's Employer

In *Brown v. Husky Injection Molding Systems, Inc.*, 2010 WL 4638761 (D. Mass. Nov. 17, 2010), a worker injured his hand when he reached into an injection molding machine that was not equipped with the standard "front pulley guard" on its frame. He sued the machine manufacturer in the United States District Court for the District of Massachusetts, asserting failure to warn and negligent and/or defective manufacturing claims. Defendant argued there was no

evidence the machine was missing its front pulley guard when delivered to plaintiff's employer and indeed there was evidence the employer had rebuilt the machine in 2000, some twenty-five years after it was manufactured and delivered by defendant. After the parties stipulated to dismissal of the failure-to-warn claims, defendant moved for summary judgment on the manufacturing defect claims arguing plaintiff could not prove the defect was caused by the manufacturer rather than an intermediate handler such as plaintiff's employer.

The court first observed that a manufacturing defect claim is different from a design defect claim in that a design defect plaintiff need only show the defect existed at the time the product left the manufacturer. In contrast, a manufacturing defect plaintiff must also put forth evidence the defect was not caused by an intermediary party. Here, plaintiff offered two forms of evidence: (i) testimony of a fellow employee that no safety guards were removed from any of the machines during his years as an employee; and (ii) photographs appearing to show the machine lacked the capability for installation of a front pulley guard. Defendant offered testimony from an investigator that a pulley guard could have been attached, and noted that the employee whose testimony was relied on by plaintiff had not been hired until the year after the machine was delivered by defendant.

Plaintiff argued that he was not required to eliminate all possibility that defendant's conduct was not a cause, but rather only to introduce evidence from which a reasonable juror could conclude it was more probable than not that plaintiff's injuries were caused by defendant's conduct. While the court agreed this was the correct legal standard, here plaintiff had offered no evidence at all to account for the machine's condition between the time it was delivered and the time the testifying employee was hired. Even more critically, there was no evidence as to the presence or absence of a front pulley guard before and after the employer's rebuilding of the machine in 2000. Accordingly, the court granted summary judgment based on plaintiff's inability to prove the alleged defect was caused by defendant.

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

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