FOLEY HOAG LLP

Product Liability **Update**

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January 2014

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

Massachusetts Federal Court Rejects Exception to "Learned Intermediary" Rule for Prescription Drug Advertised Directly to Consumers, and Excludes Expert Opinion of Inadequate Warnings as Unqualified and Unreliable Where Expert Was Not a Physician or Behavioral Specialist and Cited No Studies or FDA Regulations in Support of Opinion

In *Calisi v. Abbott Laboratories*, 2013 U.S. Dist. LEXIS 139257 (D. Mass. Sept. 27, 2013), plaintiff developed lymphoma after approximately four years of taking an arthritis drug manufactured by defendant. Plaintiff sued the manufacturer in the United States District Court for the District of Massachusetts for breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and negligence, asserting defendant failed adequately to warn about the alleged risk of lymphoma from the drug. Plaintiff offered expert testimony in support of her claims, including from one expert who would opine that the drug's labeling was inadequate to warn of its dangers. Defendant moved to exclude the expert testimony and for summary judgment, while plaintiff cross-moved for partial summary judgment seeking to preclude defendant from relying on the "learned intermediary" doctrine, under which a prescription drug manufacturer's duty to warn normally runs only to the physician, not the consumer.

Plaintiff's argument for inapplicability of the learned intermediary rule was that defendant voluntarily assumed a duty to warn her directly through use of TV ads, a website, a patient handout and a video designed to be given to patients by prescribing physicians. Rejecting this argument, the court first noted that no "direct-to-consumer" exception had been recognized in Massachusetts. In any event, the totality of defendant's advertising communications, and plaintiff's reasonable understanding of them, did not support a finding that defendant voluntarily assumed a duty it would not otherwise have. For example, plaintiff testified she paid no attention to defendant's ads and never used its website. The video was provided by her physician, not defendant, and included a number of general warnings and the direction to "please see full prescribing information."

As to plaintiff's "warnings expert," the court held he had neither the qualifications nor a reliable basis to opine about the adequacy of the drug's labeling for physicians or their likely perception of the labeling and marketing materials. Although he had a Ph.D. in pharmacology and many years of regulatory affairs experience in the pharmaceutical, biotechnology and medical device industries, the expert was not a medical doctor, psychologist or behavior specialist, had no clinical experience and cited no study data, literature or other methodology to substantiate his opinions. Although he sought to

opine that defendant's conduct fell below the standard of care for a reasonably prudent pharmaceutical company, he was unable to meaningfully explain how he determined that standard, such as by reference to United States Food and Drug Administration labeling regulations. Because proof of the inadequacy of defendant's warnings to physicians was a necessary element of plaintiff's claims, plaintiff's only expert on that issue had been excluded and an expert was required to help the jury understand and determine the issue, the court granted defendant's motion for summary judgment.

Massachusetts Federal Court Denies Summary Judgment for Obesity Drug Manufacturer, Finding Factual Dispute Regarding Whether Different Warnings to Plaintiff's Physician Would Have Changed His Prescribing Decision

In *Tersigni v. Wyeth-Ayerst Pharmaceuticals, Inc.*, 2013 U.S. Dist. LEXIS 174762 (D. Mass. Dec. 13, 2013), plaintiff was diagnosed with primary pulmonary hypertension ("PPH"), a progressive heart valve disease that ultimately leads to death in virtually all circumstances, which his treating physician attributed to his use of the combination anti-obesity medication popularly known as "Fen-Phen." Plaintiff began taking Fen-Phen in early 1997 based on a friend's endorsement and his doctor's recommendation, and signed a consent form that listed pulmonary hypertension (but not primary pulmonary hypertension) as a possible side effect. After plaintiff took the drug for about six months, his physician discontinued the prescription when reports of an elevated incidence of heart disease among the drug's users led the United States Food and Drug Administration to request its voluntary withdrawal from the market.

After his PPH diagnosis, plaintiff sued the drug's manufacturer in the United States District Court for the District of Massachusetts asserting claims for breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), negligence and fraud based on the manufacturer's failure adequately to warn his physician of the drug's risks, including PPH. Plaintiff alleged that although defendant knew of the risk of PPH as early as 1989, it did not update the product's labeling to include mention of the condition until 1996 and did not add a full warning of the risks until after the drug had been withdrawn from the market. The suit was initially transferred to a multidistrict litigation in the Eastern District of Pennsylvania, but after discovery it was remanded to Massachusetts. Defendant then moved for summary judgment, arguing plaintiff could not prove that different warnings would have changed the outcome because his physician was already aware of the association between Fen-Phen and PPH but chose to prescribe the drug anyway due to its therapeutic benefits.

Under the "learned intermediary" doctrine, a prescription drug manufacturer discharges its duty to warn the consumer by providing appropriate warnings to prescribers, but if the manufacturer does not provide adequate warnings it is liable for any resulting harm. At deposition, plaintiff's physician testified that as of early 1997 he did not believe the drug posed a fatal risk of PPH, as a study of the drug's effectiveness in treating chronic obesity (the "Weintraub study") reported no lasting or life-threatening side effects. Defendant offered evidence that as of that date it had revised the drug's labeling and corresponding Physician's Desk Reference ("PDR") entry and sent "Dear Doctor" letters to the physician reporting an elevated incidence of PPH, and argued that since the physician testified it was his practice to review such materials he was on notice of the drug's risks at the time he prescribed it.

The court held the physician's testimony suggested that, while it may have been his usual practice to review drug labeling and "Dear Doctor" letters, his reliance on the Weintraub study in prescribing Fen-Phen for plaintiff supported a reasonable inference either that he had not reviewed those materials in this case, or that the warnings therein were insufficient to disabuse him of his belief that the drug's benefits outweighed its risks. Moreover, evidence defendant had suppressed information about the full number and extent of adverse events when revising its communications also supported a conclusion that there was a triable issue regarding whether the physician would have prescribed the drug if given additional warnings. Accordingly, the court denied defendant's motion.

Massachusetts Appeals Court Reverses Dismissal of Plaintiff's Claims Against Pelvic Mesh Manufacturers, Holding Allegations that Defendants' Devices Included Mesh with Propensity to Erode and FDA Had Reported Over 1,000 Injuries Associated with Similar Devices Plausibly Suggested Entitlement to Relief

In *Allen v. Boston Scientific Corp.*, 84 Mass. App. Ct. 1114 (Oct. 9, 2013), plaintiff allegedly suffered serious injuries after being implanted with pelvic mesh devices to treat her stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"), conditions caused by weakening of or damage to the walls of the vagina. Plaintiff sued the devices' manufacturers in Massachusetts Superior Court for 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 the devices' allegedly defective design and the manufacturers' alleged failure to warn of their dangers.

Specifically, plaintiff alleged that the presence of a monofilament, polypropylene mesh in the devices rendered them biologically incompatible with their intended uses because the mesh had a propensity to erode and could cause chronic infections, vaginal scarring, severe pain and other complications. Plaintiff's complaint relied heavily on an October 2008 public health notification from the United States Food and Drug Administration ("FDA"), in which FDA described over 1,000 adverse events reported over a three-year period related to similar devices, including some manufactured by the defendants. Plaintiff then alleged that defendants never notified physicians or patients of the reported adverse events, the devices' biological incompatibility or the potential for serious harm.

Defendants moved to dismiss the complaint, arguing it alleged insufficient facts, as opposed to legal conclusions, to plausibly suggest an entitlement to relief. The trial court allowed the motion, ruling that plaintiff had indeed not pled sufficient facts with respect to defendants' particular devices to "nudge her claims across the line from conceivable to plausible." On appeal, however, the Massachusetts Court of Appeals reversed. The court observed that although the complaint contained a number of legal conclusions, it also alleged a number of facts supporting plaintiff's claims, including the presence of a monofilament, polypropylene mesh with a propensity to erode and defendants' failure to warn of that propensity. Such factual allegations were sufficient to raise plaintiff's right to relief above the speculative level.

First Circuit Holds Allegations in Complaint Supporting Inference of Omitted Essential Element Sufficient to Avoid Dismissal, Especially Where Relevant Facts are in Defendant's Control and "Modest" Discovery May Reveal Same

In *Garcia-Catalan v. United States*, 734 F.3d 100 (1st Cir. Nov. 4, 2013), plaintiff allegedly sustained injuries after slipping on liquid in the aisle of a military installation's commissary. She timely filed an administrative claim with the United States and, after the statutory period for disposition of her claim expired without a decision, sued the United States for negligence under the Federal Tort Claims Act in the United States District Court for the District of Puerto Rico. The district court granted defendant's motion to dismiss, holding plaintiff had failed to allege that some federal employee had actual or constructive knowledge of the liquid, a required element of the claim under Puerto Rico law, and therefore failed to plead sufficient facts to demonstrate a plausible entitlement to recovery as required by *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007).

On appeal, the United States Court of Appeals for the First Circuit reversed. The court interpreted the *Twombly-Iqbal* pleading standard as requiring a two-part analysis: (1) distinguishing the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited); and (2) determining whether the factual allegations are sufficient to support a reasonable inference that defendant is liable. The court asserted that the *Twombly-Iqbal* standard "does not demand a high degree of factual specificity" and that circumstantial allegations can suffice.

Applying these principles, the court observed that plaintiff had pled the existence of a dangerous condition, open to view, in a public area controlled by defendant. These circumstances, the court concluded, were sufficient to support a plausible inference that some federal employee had actual or constructive knowledge of the condition. The court also noted that, because defendant controlled access to information about how long the liquid was on the floor and who

(if anybody) was aware of it, the circumstances described in the complaint supported an expectation that "modest discovery may provide the missing link" of evidence of tortious conduct. Finally, the court observed that the complaint had been modeled on a form appended to the Federal Rules of Civil Procedure. Such a form, the court held, remained viable after *Twombly-Iqbal* as long as the complaint pled sufficient facts to make the claim plausible.

Massachusetts Federal Court Holds Lack of Expert Testimony Regarding Existence of Defect Warrants Summary Judgment Against Plaintiff's Claim Based on Allegedly Faulty Operation of Airbag System

In *Adelman v. American Honda Motor Co.*, Inc., 2013 U.S. Dist. LEXIS 159585 (D. Mass. Nov. 7, 2013), plaintiff was driving a car manufactured by defendant approximately 5-10 miles per hour in a grocery store parking lot when the car hit a small bump and the passenger side airbag deployed. Plaintiff was sufficiently frightened that she lost control of the vehicle and hit a lamppost, injuring her ribs, nose and face and totaling the car. Plaintiff sued in the United States District Court for the District of Massachusetts asserting claims for 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 the allegedly defective design of the airbag system. When plaintiff failed to timely designate an expert to testify regarding any alleged defect in the system (or any other component of the car), defendant moved for summary judgment. In opposing the motion, plaintiff argued there was no need for expert testimony because the airbag system as a whole clearly failed, and "operated in a defective manner."

The court first noted that, except in rare cases, a plaintiff asserting claims for negligence and/or breach of warranty for a design defect must present competent expert testimony that a defect in the product, present at the time it was sold, caused his or her injuries. Expert testimony is unnecessary only when "a jury can find of their own lay knowledge that there exists a design defect which exposes users of a product to unreasonable risks of injury." Because the airbag system in the plaintiff's car was complex and involved the interaction of a number of component parts, the court held expert testimony was required, following a similar holding approximately 20 years earlier by the Massachusetts Supreme Judicial Court. Moreover, defendant's expert testified that deployment of the passenger side airbag without a seated passenger would not by itself indicate a defect. Accordingly, the court granted defendant's motion.

Massachusetts Federal Court Holds Plaintiff's Expert Testimony Regarding Cause of Water Filtration System Failure Admissible and Sufficient to Avoid Summary Judgment Where Expert Performed Two Rounds of Testing, Considered and Purported to Exclude Defendant's Causation Theory and Identified Feasible Alternative Design

In *Federal Insurance Co. v. Pentair Residential Filtration, LLC*, 2013 WL 6145531 (D. Mass. Nov. 21, 2013), a condominium building's water filtration system ruptured causing flooding and over $1 million in damages. Insurers for the building owner and tenant sued the system manufacturer's successor in the United States District Court for the District of Massachusetts for negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), alleging defective design. Plaintiffs' expert opined that the inside corner radius of the filter cap was insufficiently thick to withstand normal water pressure and that this defect, over time, caused the cap to rupture, while defendant contended the rupture was caused by a modification to the original design, namely the addition of a plastic tube or "stand pipe" between the filter canister and cap. Defendant moved for summary judgment, arguing plaintiffs' expert's testimony was scientifically unreliable and hence inadmissible under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and that the expert had not identified a feasible alternative cap design, a necessary element of a design defect claim.

Plaintiffs' expert based his opinions on two rounds of testing. First, he examined the filter system and concluded that the cap's corner radius was thinner than permitted by good design practices, and that the rupture was caused when this thinness allowed a tiny pre-existing crack in the radius to grow by fatigue or corrosion over time until the remaining cross-section could not resist the system water pressure. Later, after being advised of defendant's contention that the filter had been modified from its original design, the expert performed an additional round of testing, after which he adhered to his initial

conclusion and offered the further opinions that the stand pipe appeared to have been part of the original design, and in any event did not contribute to the filter cap failure.

Defendant argued that the expert's opinion that the purported design defect, rather than the insertion of the stand pipe, had caused the cap to fail was scientifically unreliable because it was based on a number of speculative assumptions. For example, the expert assumed system water pressure typically measured 100 psi even though he conceded he could not definitively determine the actual water pressure anywhere in the building at the time of the rupture. Thus, defendant argued, the expert could opine only that a design defect *could* have caused the rupture, not that it *did*. In denying summary judgment, however, the court held that *Daubert* does not require a party offering expert testimony to prove that the expert's conclusion is correct; it requires only that the expert's opinion has been arrived at in a scientifically sound and methodologically reliable fashion. Here, defendant's attacks on the expert's opinion went to its weight, not its admissibility.

Finally, the court rejected defendant's argument that plaintiffs' expert had not identified a feasible safer alternative design, noting that his opinion specifically identified insufficient inside corner radius thickness as the defect and opined that a thicker wall would have prevented any rupture-causing crack from forming.

Massachusetts Appeals Court Holds Statute of Limitations Bars Negligent Design Claim Against Pipe Liner Engineer Because Plaintiff Was on Notice of Possible Design Defect More than Three Years Before Suit, Even Though Expert Did Not Deliver Supporting Report Until Later

In *Insituform Technologies, Inc. v. Jacobs Civil, Inc.*, 84 Mass. App. Ct. 1115 (Oct. 16, 2013), defendant was hired to provide engineering services to rehabilitate an East Boston branch sewer, including by designing a cured-in-place pipe liner. Plaintiff, a nationally-regarded expert in sewer relining, was sub-contracted to perform the lining work. During the parties' initial discussions, plaintiff's project manager questioned defendant's proposed liner design, but thereafter plaintiff proceeded to install the liner in six sections in August and September 2003. One month later, plaintiff had discovered over 200 leaks in five of the six sections. In early 2004, plaintiff replaced those sections but the replacements failed as well, and shortly thereafter plaintiff sued its insurer to recover the cost of replacing the liners. Plaintiff also hired an expert to conduct an inspection, which ended in early 2005, by which time plaintiff discovered that the only liner section that had not been replaced previously had also failed.

Over two years later, in May 2007, plaintiff sued in Massachusetts Superior Court for negligent design of the pipe lining. Defendant moved for summary judgment, arguing that all claims were barred by the three-year statute of limitations, and the negligence claim was barred by the economic loss rule. The lower court allowed the motion on both grounds and plaintiff appealed.

Addressing only the statute of limitations, the Massachusetts Appeals Court affirmed. The heart of plaintiff's claim was that it did not know, nor should it have known, that defendant's design caused the pipe failure until plaintiff's investigation was complete and its expert issued his report in 2006. The court held, however, that plaintiff had sufficient information to stimulate further inquiry concerning the adequacy of defendant's design as early as plaintiff's initial project discussions in 2003, when it expressed reservations about the design. In any event, a few months thereafter plaintiff became aware of hundreds of leaks, and when it brought suit against its excess insurer in 2004 it presumably considered an array of options as to why the liners had failed. Thus the lower court properly determined that a reasonable plaintiff would have been aware of at least the possibility of a design defect more than three years before suit.

The court also rejected plaintiff's contention that the failure of the one liner section that failed significantly later than the others constituted a separate injury triggering a separate limitations period. The lower court had found that failure was part of the overall sequence of injuries stemming from defendant's design. The appellate court agreed, noting that subsequent damages stemming from the same conduct do not extend the limitations period and that if knowledge of the full extent of injury was required before a cause of action accrued, the fixed time period of statutes of limitations would effectively be destroyed.

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