FOLEY HOAG LLP

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.

United States Supreme Court Reverses First Circuit and Holds Federal Food Drug & Cosmetic Act Preempts Design Defect Claims against Generic Pharmaceutical Manufacturers

In *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (June 24, 2013), plaintiff suffered a severe dermatologic reaction after taking sulindac, a generic version of the non-steroidal anti-inflammatory drug Clinoril®. Plaintiff sued the drug's manufacturer in New Hampshire state court alleging, among other things, that the drug was defectively designed. After defendant removed the case to the United States District Court for the District of New Hampshire, the jury returned a $21 million verdict for plaintiff.

The United States Court of Appeals for the First Circuit affirmed, holding that the Federal Food Drug & Cosmetic Act ("FDCA") did not preempt design defect claims against generic pharmaceutical manufacturers (*see* **July 2012 Foley Hoag Product Liability Update**). The circuit court acknowledged that under the FDCA the generic manufacturer could not change the drug's design to vary from that of the branded manufacturer, but reasoned that because the manufacturer could lawfully decide not to sell the drug at all, there was no actual conflict between defendant's state and federal law obligations.

After granting certiorari, the United States Supreme Court first noted that under the Hatch-Waxman Amendments to the FDCA, a generic manufacturer's drug was required to have the same active ingredients, route of administration, dosage form, strength and labeling as the brand-name drug on which it was based. Under New Hampshire design defect law, however, the manufacturer had a duty to ensure that its product's design was not unreasonably dangerous, and the warnings accompanying the product were a factor to be weighed in assessing the adequacy of the design. Accordingly, defendant could only have satisfied its state law duties either by changing the drug's design or its labeling (or both), either of which would have been a violation of defendant's duties under the FDCA (the Court also noted that a design change would not be possible as a matter of basic chemistry, as sulindac is a single-molecule drug). Because it was impossible for defendant to comply with both its state- and federal-law duties, plaintiff's design defect claim was preempted.

The Court then explicitly rejected the First Circuit's rationale that defendant could escape the impossibility of complying with both federal and state law by stopping the sale of sulindac in New Hampshire. The Court noted that this rationale was incompatible with all or virtually all of the Court's previous conflict preemption decisions, which presumed that a defendant seeking to satisfy both its federal and state law obligations was not required to cease acting altogether in order to avoid liability. Indeed, "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'"

United States Supreme Court Holds Agreement Mandating Individualized Rather than Classwide Arbitration Enforceable Even Where Expense of Arbitrating Exceeds Any Potential Individual Recovery

In *American Express Co. v. Italian Colors Restaurant*, 133 S. Ct. 2304 (June 20, 2013), plaintiffs filed a putative class action in the United States District Court for the Southern District of New York, claiming defendant had violated antitrust law by using its monopoly power in the market for non-credit charge cards to force merchants accepting the defendant's credit cards to pay inflated fees. Defendant obtained an order compelling arbitration of the named plaintiff's claim pursuant to a provision of the parties' agreement that mandated arbitration of all claims on an individual basis. The United States Court of Appeals for the Second Circuit then reversed, concluding the agreement was unenforceable because plaintiff had demonstrated that pursuing an individual claim was impractical, as the expert analysis needed to prosecute the claim would cost at least several hundred thousand dollars, far more than the maximum recovery of approximately $40,000.

The United States Supreme Court granted certiorari and remanded the case for reconsideration in light of *Stolt-Neilsen v. AnimalFeeds Int'l Corp.*, 559 U.S. 662 (2010), which held that a party may not be compelled to class arbitration absent an agreement to do so. The Second Circuit then reaffirmed its holding, and did so again on *sua sponte* review prompted by the Supreme Court's subsequent decision in *Concepcion v. AT&T Mobility LLC*, 131 S. Ct. 1744 (2011), which held the Federal Arbitration Act ("FAA") preempted a state law barring enforcement of a class arbitration waiver (*see* **July 2011 Foley Hoag Product Liability Update**).

After granting certiorari for a second time, the Supreme Court first noted that the FAA mandates the enforcement of an agreement to arbitrate according to its terms, absent a contrary congressional command. The Court held that neither the antitrust laws on which plaintiffs' claims were based, nor Federal Rule of Civil Procedure 23 providing for class actions generally, evinced a congressional intent to guarantee the availability of class proceedings to resolve antitrust claims.

As to plaintiffs' argument that the disparity between arbitration costs and the maximum potential individual recovery prevented them from effectively vindicating their antitrust rights through individual claim arbitrations, the Court acknowledged the existence of an "effective vindication" exception to the enforceability of arbitration agreements. But the Court held this exception applied only where an arbitration agreement prospectively waived the assertion of a statutory right, and "perhaps" also where the arbitration fees were so high as to render the arbitral forum itself impracticable. Here, however, there was no advance waiver of antitrust claims but merely impracticality in proving them. Finally, the Court noted that *Concepcion* all but resolved the present case, as it held state law could not condition the enforceability of an arbitration agreement on the availability of class arbitration even if this might mean that some claims would thereby "slip through the legal system."

Massachusetts Supreme Judicial Court Holds Agreement for Individualized Arbitration Unenforceable Where It Confers on Retailer "De Facto" Immunity from Unfair and Deceptive Practices Liability

In *Feeney v. Dell, Inc.*, 465 Mass. 470 (Jun. 12, 2013) ("*Feeney II*"), plaintiffs filed a putative class action claiming the defendant computer retailer had violated Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute) by collecting sales tax on class members' purchases of service contracts when no such tax was legally due. Defendant, represented by **Foley Hoag LLP**, obtained an order compelling arbitration of the named plaintiff's individual claims pursuant to sale terms that mandated arbitration of all claims on an individual basis. After the arbitrator ruled for defendant on the merits and the trial court dismissed the lawsuit, the Massachusetts Supreme Judicial Court ("SJC") in *Feeney v. Dell, Inc.*, 454 Mass. 192 (2009) ("*Feeney I*") (*see* **August 2009 Foley Hoag Product Liability Update**), held the arbitration agreement violated Massachusetts public policy favoring classwide resolution of small-value consumer claims and therefore was unenforceable. The Court rejected the contention that such a rule was preempted by the Federal Arbitration Act ("FAA"), noting its section 2 savings clause provided an exception to the enforceability of arbitration agreements on "such grounds that exist at law or in equity for the revocation of any contract," and holding that a public policy defense is such a ground.

Several years later, on remand to the trial court, defendant moved to reinstate the judgment of dismissal, arguing *Feeney I* had been overruled by the United States Supreme Court's decision in *Concepcion v. AT&T Mobility LLC*, 131 S. Ct. 1744 (2011) (*see* **July 2011 Foley Hoag Product Liability Update**), which held the FAA preempts even generally applicable state-law rules that are an obstacle to accomplishing the FAA's objectives. The Court ruled that invalidating a class action waiver in an arbitration agreement frustrated the statute's objectives of enforcing such agreements as written and permitting inexpensive and informal procedures to which class actions stood in contrast. After the trial court denied defendant's motion, the Massachusetts Appeals Court granted interlocutory review and the SJC then granted direct appellate review.

The Court held the FAA does not preempt an arbitration agreement that effectively precludes a consumer from obtaining a remedy to which he is entitled, reasoning Congress had not intended to require enforcement of an agreement under such circumstances and therefore a state law rule rendering such an agreement unenforceable would not frustrate the statute's objectives. The Court then ruled that the arbitration agreement at issue conferred on defendant "de facto immunity" from ch. 93A liability. The Court noted that the agreement lacked the consumer-friendly incentives that the agreement in *Concepcion* contained, which made arbitration a more attractive option than class litigation in that case. The Court also cited the complexity of plaintiffs' sales tax claims, the small value of individual damages, the voluminous size of the record and the absence of mandatory fee-shifting (notwithstanding that ch. 93A *does* require fee-shifting in the event of a successful claim) as evidence that the plaintiffs could not practically vindicate their claims through individual arbitrations.

Shortly following the decision, defendant petitioned the SJC for rehearing in light of the United States Supreme Court's opinion in *American Express Co. v. Italian Colors Restaurant*, 133 S. Ct. 2304 (Jun. 20, 2013), summarized above. The petition is currently pending.

Massachusetts Supreme Judicial Court Holds (i) Proof of Safer Alternative Design that Would Not Unduly Interfere with Product's Cost or Performance Is Prerequisite to Design Defect Liability, (ii) Product May Be Unreasonably Dangerous Even if Dangers Do Not Exceed Ordinary Consumer's Expectations and (iii) Plaintiff Need Not Prove Decedent Would Have Used Alternatively Designed Product to Prove Causation

In *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411 (June 11, 2013), the plaintiff executor of his mother's estate sued the defendant manufacturer of Newport cigarettes when his mother died of lung cancer after smoking Newports for approximately 40 years. Plaintiff asserted claims for negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), among others, alleging Newports were defectively designed because they contained significant amounts of tar and nicotine while technology existed to create a product with zero or near-zero levels of these ingredients. Plaintiff's experts identified three such products that had been on the market at various times, but conceded smokers would not likely purchase such alternative "cigarettes" except perhaps to a limited extent and only if all "ordinary cigarettes" were banned from the market.

At trial, the judge initially instructed the jury in connection with both the negligence and warranty counts that proof of a reasonable safer alternative design was required to prove a design defect, but in later instructions on the negligence count alone instructed that "you *may* but you are *not required to* consider whether there was a safer alternative design available." The jury also was instructed that it "*may* also consider whether the Newport cigarettes met the consumer's reasonable expectations as to its safety." The jury found Newport's design defective under both negligence and warranty theories and awarded $50 million for decedent's pain and suffering, $21 million for decedent's wrongful death and $81 million in punitive damages; the judge later reduced the compensatory award to $25 million for pain and suffering and $10 million for wrongful death.

Defendant appealed to the Massachusetts Appeals Court, and the Massachusetts Supreme Judicial Court ("SJC") granted direct appellate review. The Court first held that, under Massachusetts law, to establish design defect

liability in negligence or for breach of the implied warranty of merchantability, "the plaintiffs must show 'an available design modification which would reduce the risk without undue cost or interference with the performance of the [product].'" In so holding, the Court quoted with approval § 2(b) of the Restatement (Third) of Torts: Product Liability and its comment f to this effect. Because the trial judge had erroneously instructed the jury that it "may," but was not required to, consider the existence of a safer alternative design in deciding whether defendant was negligent, the Court vacated the jury's finding of negligence liability.

On the warranty count, however, the trial judge did not commit the same error. Moreover, while the Court agreed in principle with defendant's argument that it would be improper to impose categorical liability on all cigarettes by allowing plaintiff to propose a safer alternative design that is "not truly a cigarette," it held the evidence at trial was more than sufficient to permit a reasonable jury to conclude that the ultra low-tar, low-nicotine cigarettes plaintiff proposed were a reasonable alternative even if they did not have the characteristics, *i.e.*, significant levels of tar and nicotine, that are desired by consumers who are already addicted. The Court reasoned that the only subclass of consumers that must be considered when evaluating the reasonableness of the alternative design were those who were not yet addicted and thus retained the ability to make rational informed decisions about whether to smoke and what kinds of cigarettes to smoke; otherwise, the Court observed, "addictive chemicals would be the only substance whose presence in a product could not, as a matter of law, be found to constitute a defect in the product's design, because there could be no reasonable alternative design that did not include them." Interestingly, the Court did not cite any record evidence that even this subclass of consumers would find the virtually tar- and nicotine-free cigarettes proposed by plaintiff acceptable.

The Court then rejected defendant's contention that as a matter of law a product cannot be unreasonably dangerous if the danger is not beyond that contemplated by the ordinary consumer. Instead, the Court held that, under the risk-utility balancing test embodied in § 2 of the Restatement (Third), the jury may consider consumer expectations as merely one factor, albeit an important one, in determining whether a product is unreasonably dangerous, so that the jury was instructed properly as to this issue.

The Court also rejected defendant's argument that, in light of evidence decedent had not liked low-tar and -nicotine cigarettes when she tried them, plaintiff had not proved Newport's design defect was a cause of her cancer. The Court stated that plaintiff was not required to prove decedent would have used the product if designed according to plaintiff's alternative, but rather merely that the product's defect, *i.e.*, significant tar and nicotine, caused her harm. The Court did not address the likelihood that even if Newports had been designed differently plaintiff would still have suffered her disease as she would have chosen to smoke other regular cigarettes rather than the alternatively designed Newports.

The Court also discussed numerous other issues that are not addressed here for reasons of length, including: (1) whether for purposes of failure to warn claims, the risks of cigarette smoking became "obvious" after Congress mandated warning labels on all cigarette packages; (2) whether cigarette manufacturers who were part of issuing the 1954 "Frank Statement to Cigarette Smokers" voluntarily assumed a duty to research the health hazards of smoking and accurately disclose them to the public; (3) when a smoker's design defect cause of action accrues for statute of limitations purposes; (4) excessiveness of the compensatory and punitive damages awards; (5) application of collateral estoppel based on the findings of the United States District Court for the District of Columbia in *United States v. Philip Morris USA, Inc.*, 449 F. Supp.2d 1 (D.D.C. 2006); and (6) a variety of alleged trial errors relating to evidentiary matters and alleged bias.

Massachusetts Federal Court Holds Medical Monitoring Claim Based on Exposure to Dangerous Substance Requires Proof of Subcellular Change, and Expert Testimony that Exposure Merely Increased Risk of Such Change or of Actual Disease Is Insufficient

In *Genereux v. Hardric Laboratories, Inc.*, 2013 WL 3157520 (D. Mass. June 23, 2013), current and former employees of defendant aerospace and defense manufacturer, and members of their families, sued in the United States District Court for the District of Massachusetts alleging defendant's negligent handling of beryllium at its plant exposed them to elevated levels of the substance and thereby increased their risk of various diseases, particularly chronic beryllium

disease ("CBD"). None of the plaintiffs exhibited any CBD symptoms, so they sought a program of medical monitoring for CBD rather than damages. The court initially dismissed the claim for failure to allege actual injury, but reinstated it after the Massachusetts Supreme Judicial Court ("SJC") decided *Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891 (Mass. 2009) ("*Donovan I*") (*see* **April 2010 Foley Hoag Product Liability Update**), holding that a suit "for medical monitoring, based on . . . subclinical effects . . . state[s] a cognizable claim and/or permit[s] a remedy under Massachusetts state law." The SJC held that the elements of this claim included, among other things, proof that "the plaintiff [was] exposed to a hazardous substance that produced, at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury."

Shortly after plaintiffs' claims were reinstated, defendant moved for summary judgment on the basis that plaintiffs could not prove they had suffered subcellular changes from beryllium exposure. Plaintiffs' expert had opined only that plaintiffs were at a significantly increased risk of developing beryllium-related diseases, including associated subcellular changes, and admitted he could not state with any degree of medical certainty that any plaintiff had in fact already suffered such changes. Plaintiffs contended their evidence nevertheless was sufficient because *Donovan I*'s rationale was that persons exposed to dangerous substances and placed at an increased risk of harm should be entitled to medical monitoring, thus these were the only two essential elements of their claim.

At the outset, the court noted that it had not been requested to, nor would it, decide the issue the SJC in *Donovan I* said it would "leave for another day" – namely, "consideration of cases that involve exposure to levels of chemicals or radiation known to cause cancer, for which immediate medical monitoring may be medically necessary although no symptoms or subclinical changes have occurred," – as plaintiffs' complaint specifically alleged subcellular change. Although plaintiffs' expert opined plaintiffs had an increased risk of developing beryllium-related diseases, he could not opine that any plaintiff actually had suffered subcellular changes, or that beryllium exposure necessarily causes such changes in all cases (although he did try to amend his testimony to add this opinion - which the court did not allow because the amendment would have clearly conflicted with his prior sworn testimony – when it became clear such an opinion might help plaintiffs avoid summary judgment). Moreover, there was no evidence any plaintiff had tested positively for beryllium sensitization, the first detectable sign of subcellular change.

Accordingly, the court allowed defendant's motion, holding "increased risk" of subcellular change insufficient to support medical monitoring because it does not satisfy *Donovan I*'s requirement of a physiological "impact" that fits the medical-monitoring doctrine into traditional tort law rubrics and tempers the prospect of purely risk-based recovery. The court also noted that its decision was not inconsistent with the court's class certification decision in *Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. 1 (D. Mass. 2010) ("*Donovan II*") (*see* **July 2010 Foley Hoag Product Liability Update**), not only because that case concerned class certification rather than summary judgment but, more significantly, because plaintiffs' experts there had opined that "twenty pack-years of smoking *necessarily* causes subcellular harm" and that "*everyone* with a twenty pack-year smoking history has suffered subcellular harm." (emphasis added).

Massachusetts Appeals Court Affirms Dismissal of Design Defect and Failure-to-Warn Claims Involving Industrial Fan Because Dangers Were Open and Obvious and Plaintiff Did Not Offer Expert to Testify Proposed Safer Alternative Design Would Not Unduly Interfere with Product's Cost or Performance

In *Christensen v. Thornton*, 988 N.E.2d 471 (Mass. App. Ct. June 3, 2013), plaintiff suffered injuries when he caught his hand in an industrial exhaust fan while installing drywall in a customer's home. The operating instructions supplied with the fan warned that if it was installed at a height of less than seven feet, it must be used with a guard in order to meet federal Occupational Safety and Health Administration safety standards, and a warning label to the same effect was affixed to all such fans. The fan's manufacturer made a guard that could be purchased as a separate component, and guards made by other manufacturers also could be used, but the fan could not be purchased with a guard preinstalled. After acquiring the fan secondhand, the homeowner, a licensed electrician, temporarily mounted it to the frame of a door that opened at the top of a three-step stairway. The bottom of the fan was flush with the edge of the top step and the fan was parallel to the path of the stairs with its blades exposed. The

homeowner did not obtain the operating instructions when he purchased the fan, and did not remember a warning label on it. However, he testified at deposition that even if he had seen such a warning, this would not have deterred him from installing the fan in the manner in which he did.

Plaintiff sued the homeowner and the fan's manufacturer and distributor in Massachusetts Superior Court, alleging the fan was defectively designed and unreasonably dangerous because it did not have a pre-installed guard or safety clutch and defendants had failed to adequately warn of its dangers. Following plaintiff's opening statement, but before any evidence was taken, the trial court dismissed plaintiff's claims against the manufacturer and distributor as a matter of law. After the jury returned a verdict for plaintiff in the case against the homeowner, plaintiff appealed.

Affirming the trial court's dismissal of plaintiff's claims, the Massachusetts Appeals Court held the failure-to-warn claim could not succeed because the undisputed facts revealed that the dangers of operating the unguarded fan at ground level and immediately adjacent to the path of transit where plaintiff was working were objectively obvious, and thus plaintiff should have appreciated the danger substantially to the same extent as if a warning had been provided. Indeed, plaintiff testified at his deposition that he did not want to go anywhere near the unguarded fan because he was aware it posed serious dangers. The court also affirmed dismissal of the design defect claim because plaintiff had not offered an expert to substantiate that claim. While the court acknowledged no expert was needed for the jury to understand that a fan not equipped with a guard or safety clutch could cause serious injury, an expert was needed to assess whether adding such safety features would unduly interfere with the fan's cost or performance, especially since it was made for commercial and industrial uses. Indeed, there was evidence that use of a guard does diminish the fan's effectiveness.

Massachusetts Federal Court Grants Summary Judgment for Power Tool Manufacturer on Design Defect Claim Because Plaintiff Offered No Expert Evidence Regarding Existence of a Defect, Safer Alternative Design or Causation

In *Torres v. Skil Corporation*, 2013 WL 3105815 (D. Mass. June 17, 2013), plaintiff was injured while using a circular saw when the saw's blade guard did not automatically snap into place after he finished his cuts. Aware of the danger of putting the saw down without the blade guard in place, plaintiff tried to "flick" it down with his right hand. Plaintiff's hand missed the blade guard, however, causing his ring finger to be partially and permanently severed and the tip of his middle finger to be amputated almost fully.

Acting *pro se*, plaintiff sued the saw manufacturer 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) asserting, among other claims, the saw was defectively designed. Plaintiff contended the saw should have incorporated a "kill switch" that would have stopped the rotating saw blade instantaneously upon activating the switch. Neither plaintiff nor anyone else on his behalf had inspected or tested the mechanical components of the saw for evidence of a defect; rather, plaintiff testified it was his opinion the blade guard's failure to deploy must have been the result of a defect. The manufacturer moved for summary judgment on the ground that plaintiff had not proffered any expert testimony that the saw was defective, there was a feasible alternative design or the alleged defect caused his injury.

In granting the motion, the court explained that, except in rare circumstances where the dangers of a product are within the common knowledge of a layperson, a design defect plaintiff must present competent expert testimony that a defect in the product, present at the time it was sold, caused his injuries. This includes evidence of a safer, feasible alternative design that could have been incorporated without undue cost or interference with the product's performance. Here, plaintiff's reliance on his own assertions regarding the need for a kill switch to stop the spinning saw blade was insufficient to survive summary judgment because the mechanical components of the saw's blade guard were beyond a layperson's common knowledge. Moreover, there was evidence the saw had been designed and manufactured consistent with industry standards. While not dispositive as to the absence of a defect, this evidence was sufficient to permit a jury to find for defendant in the absence of any evidence the industry could and should have done more to ensure a safer blade design.

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