Product Liability: 2014 Year in Review

U.S. First Circuit/Massachusetts

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Massachusetts state and federal courts issued a number of interesting product liability decisions in 2014. The Product Liability and Toxic Tort Litigation Group at Nutter McClennen & Fish LLP recently reviewed these cases. Highlighted below are some of the key cases and issues decided in the past year.

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Genereux v. Raytheon Co., 754 F.3d 51 (1st Cir. 2014)

Significant Holding: The Supreme Judicial Court, not the First Circuit Court of Appeals, must determine whether a cause of action for medical monitoring can lie under Massachusetts law where plaintiffs merely faced an increased risk of harm. (Selya, J.)

Plaintiffs in this putative class action alleged they were negligently exposed to beryllium by Raytheon. No named plaintiff or class member had as yet developed Chronic Beryllium Disease ("CBD"), a very serious lung malady, but plaintiffs alleged that some might. Plaintiffs sought to compel Raytheon to establish a trust fund to finance appropriate medical monitoring.

Plaintiffs based their claim on Massachusetts tort law and, specifically, *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215, 914 N.E.2d 891 (2009). The class in *Donovan* shared a history of at least twenty pack-years of smoking, but none had as yet developed lung cancer. They sought to compel the defendant cigarette manufacturer to provide a court-supervised medical surveillance program for early cancer detection. In that case the Massachusetts Supreme Judicial Court ruled that the cost of medical monitoring may be recoverable in a tort suit under Massachusetts law under certain specific conditions, the most significant of which is that the traditional tort requirement of injury must be met. Plaintiffs in *Donovan* met this standard by alleging that each class member had some subcellular or physiological injury that put him or her at an increased risk of developing cancer. The SJC expressly did not decide and left "for another day" whether, if a manufacturer exposes a person to a dangerous carcinogen, a cause of action for medical monitoring would lie even though no subcellular or other physiological change had yet occurred.

Raytheon moved for summary judgment in the *Genereux* case, and the motion was allowed. The primary argument of the plaintiffs in *Genereux* in opposition to summary judgment and on appeal was that they fit within *Donovan*.

The pathogenesis of CBD begins with beryllium sensitization ("BeS"). Although BeS is regarded as an abnormal medical finding, it can be asymptomatic and is typically not treated. Nevertheless persons with BeS should receive periodic clinical screenings because they have a high risk of developing CBD. Plaintiffs' expert testified that BeS is the first manifestation of subcellular change resulting from beryllium exposure. He opined that if the entire membership of the plaintiff class were tested, somewhere between one and twenty percent would be found to have BeS. This one to twenty percent likelihood put the entire class at an appreciably higher risk of contracting CBD than a randomly selected baseline population.

The First Circuit noted a large hole in the expert's testimony which distinguished this case from *Donovan*. Plaintiffs' expert could not say that any of the named plaintiffs had actually developed BeS, nor could he indentify any member of the class as being known to have BeS. While the expert could opine that plaintiffs and the

class members were at an increased risk, he could not say any had as yet suffered any harm. Under the cause of action recognized in *Donovan*, increased epidemiological risk of illness caused by exposure unaccompanied by some subcellular or other physiological change is not enough to permit recovery in tort. Thus, plaintiffs' primary argument was unavailing.

Plaintiffs attempted to argue an alternative theory. They asked the First Circuit to rule on the issue the SJC had left "for another day," namely, whether an action for medical monitoring might lie without a showing of subcellular or other physiological change. The First Circuit refused to consider the issue. The Court catalogued the many instances in which plaintiffs had assured the district court that they were not pursuing this theory. Having not raised the issue below, they could not raise it for the first time on appeal.

Kerrin v. Titeflex Corp., 770 F.3d 978 (1st Cir. 2014)

Significant Language: In contrast to *Genereux*, in the same year the court decided *Kerrin v. Titeflex Corp.*, where in conducting an injury-in-fact analysis for Article III standing purposes, the First Circuit recognized that exposure to an increased risk of future injury may constitute an injury in fact. However, the Court stated that those who assert such claims must allege sufficient facts to permit a court to evaluate the likelihood that the alleged defective product risk will occur. (Lynch, Chief J.)

Plaintiff brought product claims for "overpayment" for a defective product and the cost of remediation against the manufacturer of corrugated steel tubing used to provide natural gas to his outdoor firepit. Plaintiff alleged that direct and indirect lightning strikes can cause an electrical event that can puncture the steel tubing and ignite the natural gas within. The District Court for the District of Massachusetts granted defendant's motion to dismiss for lack of Article III standing, holding that plaintiff's injury was too speculative. The First Circuit agreed, stating, "in this case, [plaintiff] fails to allege either facts sufficient to assess the probability of future injury or instances of actual damage where the cause is clear, and concedes that [defendant] meets applicable regulatory standards specifically addressing the risk." *Id.* at 979.

Despite the First Circuit's affirmance, it did not adopt the District Court's reasoning that lightning strikes "present a textbook example of speculative risks and remote possibilities that are simply insufficient for injury in fact." *Id.* at 980. Rather the First Circuit, citing several cases with differing results on standing, stated that "the law of probabilistic standing is evolving." *Id.* Though the Court found that plaintiff failed to allege sufficient facts to calculate or estimate the risk of injury and cited numbers that the Court suggested revealed an exceedingly low probability of injury, the First Circuit stated that "it is conceivable that product vulnerability to lightning might, in some circumstances, constitute injury." *Id.* at 980, 983.

Plaintiff is a resident of Florida. The firepit and steel tubing at issue in this case are installed at his Florida residence. Defendant manufacturer apparently has its principal place of business in Massachusetts. Plaintiff asserted claims under Massachusetts law for negligence and strict liability. It does not appear that either the District Court or the First Circuit undertook a choice of law analysis, but both seem to have assumed that Massachusetts law applied. ("Although he argues that his injury is one recognized under Massachusetts law governing 'dangerously defective product[s],' he '*concedes* that the CSST [corrugated stainless steel tubing] in question does not violate any applicable regulatory standard,' *Kerrin*, 2014 WL 67239, at *1 (emphasis added), as is required to state a claim for a dangerously defective product in the absence of actual damage, *see Iannacchino* [*v. Ford Motor Company*, 451 Mass. 623, 631 (2008)].") There also was no analysis of the economic loss doctrine.

The case deserves careful reading with regard to what allegations of enhanced risk of future injury will satisfy the injury in fact component of standing under federal law. Yet recognition by the First Circuit that in certain circumstances a claim of enhanced risk of future injury will be considered sufficient is significant.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Zeman v. Williams, 2014 WL 3058298 (D. Mass. July 7, 2014)

Significant Holding: The Court refused to dismiss plaintiffs' claim for negligent drafting of a clinical trial's informed consent against the trial's sponsor stating that the FDA's regulations could be interpreted to imply a duty of the sponsor for warnings provided in the informed consent. (O'Toole, J.)

Plaintiff, who suffered from Young-Onset Parkinson's Disease, participated in a clinical trial of an innovative gene therapy. The study involved bilateral gene transfer, whereby healthy genes were to be injected into both sides of the brain using an experimental delivery system. The clinical trial was being conducted under the Investigational Device Exemption ("IDE") to the FDA's pre-market approval requirements. During plaintiff's treatment, the genes were accidentally injected into only one side of his brain. Thus, plaintiff received a "double dose" of the therapy in the left side of his brain, and nothing in the right side, allegedly causing serious harm. Plaintiff and his wife sued, *inter alia*, Medtronic, the manufacturer of the gene delivery system and Neurologix, the clinical trial sponsor, for negligently drafting and approving the clinical trial's informed consent form. Neurologix moved to dismiss, claiming that plaintiffs failed to establish that a trial sponsor owes a duty as to the content of the consent form.

The District Court denied the motion. The Court concluded that both a clinical trial's investigator and sponsor have "responsibilities under the regulations regarding obtaining a subject's informed consent. . . . A sponsor is 'responsible for selecting qualified investigators' and (among other things) 'providing them with the information they need to conduct an investigation properly.'" *Id.* at *3 (quoting C.F.R. § 312.50). The Court held that this provision of the FDA's regulations could be interpreted to establish a sponsor's role in obtaining "a properly *informed* consent." *Id.* (emphasis in original).

The Court acknowledged that neither the FDA's clinical trial regulations nor Massachusetts courts had authorized a cause of action by a patient against a sponsor for warnings provided in the informed consent. *Id.* at *3. Yet, the Court concluded plaintiffs adequately pled their claim against the sponsor because they alleged that Neurologix approved the informed consent form and "knew or should have known that the form did not adequately and reasonably present the alternatives to and risks and potential consequences of the trial." *Id.* at *4 (internal quotation omitted).

MASSACHUSETTS SUPREME JUDICIAL COURT

Ferreira v. Chrysler Group LLC, 468 Mass. 336, 13 N.E.3d 561 (2014)

Significant Language: A car manufacturer has a statutory duty to defend a dealer under M.G.L. c. 93B, § 8(a), even in the absence of a negligent design or manufacture claim, where the dealer promptly notifies the manufacturer in writing of the assertion of a claim alleging damages arising from a defective car or part caused solely by the fault or neglect of the manufacturer. (Gants, J.)

Car purchaser sued the car's manufacturer and dealer alleging breach of contract, breach of express and implied warranty, and unfair or deceptive acts or practices. The claim alleged that plaintiff's damages stemmed from the negligent acts or omissions of both the dealer and the manufacturer. The dealer filed a cross-claim against the manufacturer based on the manufacturer's failure to defend the dealer.

The Supreme Judicial Court, affirming the court below, held that where, as here, a claim alleges that both the dealer and the manufacturer or distributor are at fault, there is no duty under M.G.L. c. 93B, § 8(a) or (b) for one defendant to assume the defense of the other. *Id.* at 345. However, the Court, disagreeing with the lower court, stated that a manufacturer does have a statutory duty to defend under § 8(a), even in the absence of a negligent design or manufacture claim, where the dealer promptly notifies the manufacturer in writing of the assertion of a

claim alleging damages arising from a defective car or part caused solely by the fault or neglect of the manufacturer. The Court observed that, under § 8(a), a duty to defend arises from a claim "'*predicated upon* the negligent design or manufacture of a new motor vehicle' . . . not a claim for relief *alleging* negligent design or manufacture." *Id.* at 569 (emphasis in original).

MASSACHUSETTS SUPERIOR COURT

Albright v. Boston Scientific Corp., 2014 WL 3880506 (Mass. Super. July 29, 2014)

Significance: Jury delivers a defense verdict in the first trial of over 500 pelvic mesh cases relating to Boston Scientific's products pending in Massachusetts.

In the first trial of over 500 pelvic mesh cases pending in Massachusetts against Boston Scientific's products (and the first of over 12,000 cases against the company nation-wide), a state-court jury delivered a defense verdict. Plaintiff claimed that Boston Scientific's Pinnacle Mesh Kit caused severe pain and other physical side effects after she had the device implanted in 2010. Boston Scientific voluntarily removed the product from the market in May 2011. Plaintiff claimed that neither she, nor her doctors, were warned about the alleged defective design of the Pinnacle Mesh Kit. Jurors deliberated for more than six hours over two days before rejecting plaintiff's claims of breach of warranty and failure to warn.

Prior to the *Albright* verdict, juries in New Jersey and West Virginia had delivered plaintiffs' verdicts regarding Johnson & Johnson and C.R. Bard Inc.'s pelvic mesh products. By some estimates, there are over 60,000 lawsuits pending regarding various companies' pelvic mesh products.

DiPasquale v. Suburban Propane Limited Partnership, 11-CV-1539-F, 2014 WL 7343976 (Mass. Super. Dec. 22, 2014)

Significant Holding: Companies that include warnings regarding another's product in their instructions for use voluntarily assume a duty to warn. (Curran, Assoc. J.)

Decedent died as a result of a propane fire in her basement. Plaintiff, decedent's executrix, claimed the fire was caused, in part, by the negligence of both Whirlpool Corp. ("Whirlpool") and Sears, Roebuck and Co. ("Sears"), manufacturer and distributor, respectively, of a propane dryer owned by the decedent and serviced by Suburban Propane Limited Partnership ("Suburban Propane").

After having the dryer serviced by Suburban Propane, decedent placed a load of laundry into the machine. Realizing that the dryer had been running for an extended period of time, decedent removed the load of laundry and began another load. Upon beginning the second load, a fire knocked her back and she was badly burned. Decedent died of injuries sustained in the fire a few days later. It was later discovered that the copper tubing connecting the dryer to the propane source had been detached. Whirlpool and Sears moved for summary judgment on the claims alleging wrongful death, punitive damages, conscious pain and suffering, and negligent infliction of emotional distress.

The court allowed in part and denied in part Whirlpool and Sears' motion. The court held that while a manufacturer is not required to warn about those risks that are solely attributable to the use or misuse of another's product, Whirlpool and Sears voluntarily assumed a duty to warn the plaintiff about the dangers of using propane when they included some information about the risks of propane in the dryer's instruction manual. *Id.* at *3. The Court held that because Whirlpool and Sears had voluntarily included warnings in the dryer's instruction manual and on the dryer itself which attempted to warn the consumer about the risks of fire due to propane gas and instructions as to what

the consumer should do if she smelled gas, the companies could be held liable for negligently performing a duty they had voluntarily assumed. As such, the Court refused to dismiss plaintiff's wrongful death and conscious pain and suffering claims. *Id.* at *3-4.

Nutter's Product Liability: 2014 Year in Review is a publication of the Product Liability and Toxic Tort Litigation Group of Nutter McClennen & Fish LLP in Boston. The bulletin was prepared by Shagha Tousi, Rebecca H. Gallup, and Alison T. Holdway, with editorial assistance from Andrew J. McElaney, Jr. For further information or if we can be of assistance, please contact your Nutter products liability lawyer or the chairperson of the Product Liability and Toxic Tort Litigation Group:

David L. Ferrera
Chair, Product Liability and Toxic Tort Litigation Group
617.439.2247
dferrera@nutter.com

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PRODUCT LIABILITY AND TOXIC TORT LITIGATION GROUP

Partners

Nelson G. Apjohn	617.439.2246	napjohn@nutter.com
Stephen J. Brake	617.439.2223	sbrake@nutter.com
Dawn M. Curry	617.439.2286	dcurry@nutter.com
David L. Ferrera	617.439.2247	dferrera@nutter.com
Sarah P. Kelly	617.439.2461	skelly@nutter.com
Robyn S. Maguire	617.439.2493	rmaguire@nutter.com
Andrew J. McElaney, Jr.	617.439.2251	amcelaney@nutter.com
Alexa H. O'Keefe	617.439.2274	aokeefe@nutter.com
Shagha Tousi	617.439.2872	stousi@nutter.com

Associates

Rebecca H. Gallup	617.439.2418	rgallup@nutter.com
Alison T. Holdway	617.439.2141	aholdway@nutter.com
Jean L. Kampas	617.439.2680	jkampas@nutter.com
Brian K. Lee	617.439.2490	blee@nutter.com
Andrew R. McArdell	617.439.2339	amcardell@nutter.com
Katy O. Meszaros	617.439.2892	kmeszaros@nutter.com
Matthew P. Ritchie	617.439.2711	mritchie@nutter.com