FOLEY HOAG LLP

Product Liability **Update**

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April 2019

Foley Hoag LLP publishes this quarterly Update primarily concerning developments in product liability and related law from federal and state courts applicable to Massachusetts, but also featuring selected developments for New York and New Jersey.

MASSACHUSETTS

First Circuit Holds Subsequent FDA Approval Of Drugs For Pediatric Use Not Conclusive Proof Of Effectiveness At Time Of Sale So As To Preclude Fraudulent Marketing Claims, And Individualized Proof Of Causation Of Prescriptions And Drugs' Ineffectiveness Not Required Where Claims Supported By Medical Literature And Expert Testimony

In *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Forest Pharms., Inc.*, 915 F.3d 1 (1st Cir. 2019), numerous individual purchasers and third-party payors sued multiple antidepressant manufacturers in the United States District Court for the District of Massachusetts in a putative class action, alleging they misrepresented the drugs' efficacy in marketing them for the non-FDA-approved or "off label" use of treating depression in multiple pediatric age groups, causing physicians to prescribe and plaintiffs to pay for ineffective drugs. Plaintiffs sought refund of the drugs' full price through claims under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962, for harm caused by "a pattern of racketeering activity" that included violation of the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 and 1343, the Minnesota Unfair Trade Practices Act, which prohibits deceptive commercial acts, and the similar Minnesota Consumer Fraud Act, which forbids misrepresentation to consumers. The district court granted summary judgment, holding the RICO claims lacked evidence of injury and the state law claims were derivative of the RICO claims.

On appeal by one consumer and health care fund each, the United States Court of Appeals for the First Circuit reversed. The court first rejected defendants' argument, which was not addressed by the trial court, that subsequent FDA approval of the off-label uses was dispositive proof the drugs were effective for those purposes and hence plaintiffs were not harmed regardless of any marketing inaccuracy. For one thing, while defendants relied on precedent that precluded recovery of the price paid for medical devices that were FDA-approved, even where plaintiffs alleged fraud on the FDA caused that approval, the devices at issue there were in fact approved at the time of plaintiffs' purchase, while the off-label uses at issue here were not. Further, even if subsequent approval were conclusive proof of effectiveness, the approvals here did not cover all the drugs or age groups at issue. The court did note that, although not dispositive, evidence of subsequent FDA approval was relevant and could be introduced at trial.

Regarding injury, the court rejected defendants' contention that plaintiffs had to prove individualized harm in the form of evidence that each specific patient whose drug costs were claimed had experienced no benefit from taking the drug. Instead, harm could be proved through scientific studies showing the drug would have been ineffective for the patient. As plaintiffs had produced studies showing no effect, or even detrimental effects, of the drugs compared to placebo, while defendants had produced studies to the contrary, including those ultimately relied on by FDA in granting approval, a fact dispute regarding plaintiffs' injury remained for trial.

Finally, the court rejected defendants' argument plaintiffs had not provided sufficient evidence that any allegedly fraudulent marketing caused the prescriptions in question. Rather, manufacturer marketing documents promoting the drugs' use in minors as well as expert testimony to the effect that sales correlated with marketing spending created a triable issue on causation.

First Circuit Holds Due Process Permits Personal Jurisdiction Over Foreign Manufacturer Selling In Massachusetts Through Out-of-State National Distributor, Concluding Acceptance Of Customers' Orders And Requirement That Distributor Provide Defendant's Direct Contact Information Supported Finding Defendant Purposefully Availed Itself Of Privilege Of Conducting Activities In State

In *Knox v. MetalForming, Inc.*, 914 F.3d 685 (1st Cir. 2019), a plaintiff injured in Massachusetts by a machine his employer purchased from a German manufacturer asserted various product liability claims against the manufacturer in the United States District Court for the District of Massachusetts. Defendant sold its products in the United States through an independent and exclusive Georgia distributor whom defendant provided with advertising materials; it also maintained a website accessible from the United States. The distributor solicited sales, sent purchase orders to defendant for acceptance and if it accepted defendant would then manufacture the machine in accordance with the order and sell it to the distributor, who would install it and provide training that included the manufacturer's contact information. On defendant's motion, the district court dismissed, holding due process forbade the exercise of personal jurisdiction because defendant had not "purposefully availed itself of the privilege of doing business in Massachusetts," as it had neither designated Massachusetts for special attention nor targeted buyers there.

On plaintiff's appeal, the United States Court of Appeals for the First Circuit reversed. For personal jurisdiction to satisfy due process, defendant must have certain minimum contacts with the forum state such that maintenance of the suit does not offend traditional notions of fair play and substantial justice. While this standard has three components—the claim's relatedness to defendant's forum activities, defendant's purposeful availment of the privilege of conducting activities in the forum and the reasonableness of exercising jurisdiction—defendant only contested purposeful availment. To satisfy that requirement, plaintiff had to demonstrate defendant "purposefully availed itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws."

Although each side argued the Supreme Court's decision in *J. McIntyre Machinery, Limited v. Nicastro*, 564 U.S. 873 (2011) (*see* Foley Hoag July 2011 Product Liability Update), meant it should prevail, the court agreed with plaintiff. While the district court focused on specific targeting of the forum, the circuit court held purposeful availment rests on the totality of defendant's voluntary activities that connect it to the forum, and under *Asahi Metal Indus. Co., Ltd. v. Superior Court of Cal.*, 480 U.S. 102, 111-12 (1987), these can include "designing the product for market in the forum State, advertising in the forum State, establishing channels for providing regular advice to customers in the forum State, or marketing the product through a distributor who has agreed to serve as the sales agent in the forum State." Here, defendant, through its distributor, had over sixteen years sold forty-five machines in Massachusetts, each individually approved and manufactured to the customer specifications, and sold 234 parts there. Moreover, while the mere shipment of products to Massachusetts would not suffice, the manufacturer's providing its contact information allowed a plausible inference that in-state purchasers used that information to communicate with defendant, thus creating a direct link to those customers.

In its opinion, the court did not focus on the Supreme Court's specific language in *Nicastro* requiring defendant's claim-related activities to have been "conduct[ed] . . . within the forum State." Nor did it address the Court's more recent opinion in *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773 (2017) (*see* Foley Hoag August 2017 Product Liability Update), which, among other things, rejected an argument for jurisdiction over an out-of-state defendant based on the in-state presence of its national distributor, absent any allegation that defendant had "engaged in relevant acts together with [the distributor] in [the forum]."

Massachusetts Federal Court Holds (1) Related Corporations' Use of Common Website And Conclusory Deposition Testimony That Entities Were Not Separate Did Not Demonstrate Pervasive Control Needed To Pierce Corporate Veil, (2) Expert Testimony Regarding Design Defect Created Triable Issue On Implied Warranty Of Merchantability, And (3) Whether Literature Representations Were "Puffery" Or Were Relied Upon Created Triable Issues On Misrepresentation

In *Evans v. Daikin N. Am., LLC*, 2019 U.S. Dist. LEXIS 17477 (D. Mass. Feb. 4, 2019), homeowners who alleged economic damages from premature coil corrosion in an HVAC system requiring repairs and ultimately replacement sued the current North American sales and manufacturing/service affiliates of the system's Japanese manufacturer, as well as a Delaware statutory trust established to hold the assets of the manufacturer's former North American sales affiliate, in the United States District Court for the District of Massachusetts. Plaintiffs did not sue the distributor from whom they had purchased the system, but alleged that sales literature of the former sales affiliate, which was also part of the chain of sale, included statements that the system could "be installed practically anywhere" and would "perform flawlessly in any climate." Plaintiffs asserted claims against all defendants for breach of express warranty and the implied warranties of merchantability and fitness for a particular purpose, as well as negligent and intentional misrepresentation.

Defendants moved for summary judgment on all counts. In response to the non-trust defendants' argument that they had no role in the HVAC system's sale, plaintiffs argued the service/manufacturing defendant had "directed" the non-party distributor to sell the system to plaintiffs and they were entitled to pierce the corporate veil among the three affiliated defendants, hence rendering all defendants liable for any obligations traceable either to the distributor or the former sales affiliate. The court rejected the first theory, holding that any relationship the service/manufacturing defendant might normally have had with the distributor did not apply to the system in question, which the distributor had actually purchased from yet another distributor.

As for veil-piercing, plaintiffs argued the current and former affiliates had shared a single website, and a manager for the current sales affiliate testified his employer was not a separate corporation from the trust and the current service/manufacturing affiliate was a "representative" of his employer. The court first noted the basic tenet of Massachusetts law that "corporations are separate and distinct entities, whatever the relationships that may exist between or among them," and that Massachusetts is "especially strict in respecting the corporate form." Accordingly, ignoring the separateness of two corporations is permitted only if one exercises "some form of pervasive control" over the other's activities and "there is some fraudulent or injurious consequence of the intercorporate relationship." Here, the common website and conclusory employee testimony relied on by plaintiffs were insufficient to establish pervasive control, and the court granted summary judgment to the current affiliates on all counts.

Regarding the trust defendant, the court granted summary judgment against plaintiffs' express warranty and implied warranty of fitness claims, holding the one-year express warranty period had long expired and the HVAC system was not used for any sort of peculiar purpose that could give rise to a warranty of fitness for that purpose. But the court denied summary judgment on plaintiffs' implied warranty of merchantability claim, as their proffered expert testimony created a question of fact regarding whether the system was defectively designed. The court also denied summary judgment on the misrepresentation claims, as whether the literature statements cited by plaintiffs were "mere puffery" and whether plaintiffs had actually relied on the statements in purchasing the system were also disputed issues of fact.

Massachusetts Supreme Judicial Court Holds Statute Of Repose For Tort Claims Arising Out Of Deficiencies Or Neglect In Improvements To Real Property Applies Even If Claim Involves Disease with Extended Latency Period

In *Stearns v. Metropolitan Life Insurance Company*, 481 Mass. 529 (Mar. 1, 2019), a pipe inspector's estate sued a steam turbine manufacturer in the United States District Court for the District of Massachusetts, alleging his mesothelioma was caused by asbestos exposure during installation of defendant's generators. Defendant moved for summary judgment under Mass. Gen. L. ch. 260, § 2B, a statute of repose which sets a six-year time limit for tort actions "arising out of any deficiency or neglect in the design . . . [or] construction . . . of an improvement to real property," generally running from the earlier of the dates of "(1) the opening of the improvement to use; or (2) substantial completion of the improvement and the taking of possession for occupancy by the owner." Plaintiffs argued the statute should not apply to cases involving diseases with an extended latency period, as it would extinguish meritorious claims before they even came into existence. The district court denied defendant's motion but, after defendant moved for reconsideration or to certify an interlocutory appeal, instead certified to the Massachusetts Supreme Judicial Court ("SJC") the question whether § 2B "can be applied to bar personal injury claims arising from diseases with extended latency periods, such as those associated with asbestos exposure, where defendants had knowing control of the instrumentality of injury at the time of exposure."

The SJC concluded the statute applies to such claims. While noting that it interprets a statute according the legislature's intent, § 2B was clear and unambiguous, and thus "conclusive as to the Legislature's intent." Moreover, the legislature had expressly provided for exceptions to the statute, such as for medical malpractice cases involving foreign objects left in the body. *See* G.L. ch. 260 § 4. In addition, statutes of repose are meant to eliminate a cause of action by a time certain, regardless of whether injury or harm has occurred, and their effect is to abolish the remedy, not merely bar the action. Accordingly, unlike statutes of limitation, statutes of repose may not be tolled for any reason.

Lastly, prior precedent had noted that § 2B was intended to limit the liability of persons involved with the design or construction of improvements to real property such that liability would not follow them throughout their professional lives or even into retirement. Thus the statute serves a legitimate public purpose, and in establishing a six-year limit the legislature struck a balance between the public's right to a remedy and the need to set an outer limit on tort liability. Despite its conclusion, the Court in a footnote encouraged the legislature to consider exempting asbestos-related illnesses from the statute of repose, which plaintiffs suggested other states have effectively done.

Massachusetts Federal Court Holds Pharmaceutical Failure-To-Warn Claims Not Preempted, As Manufacturer's Literature And Adverse Events Disclosures To FDA Could Be Found Inadequate, Permitting Manufacturer Unilaterally To Add Pregnancy Warning And Rendering FDA Rejection Of Warning Not Conclusive Proof Agency Would Have Rejected Warning With Full Disclosure

In *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 2019 U.S. Dist. LEXIS 18327 (D. Mass. Feb. 5, 2019), a multi-district litigation centralized in the United States District Court for the District of Massachusetts, numerous parents, individually and on behalf of their minor children, brought state law claims against a pharmaceutical manufacturer alleging its drug caused birth defects when used during pregnancy and defendant failed to warn of that risk. The drug was approved by the United States Food and Drug Administration ("FDA") for the prevention of nausea and vomiting caused by chemotherapy, radiation and post-operative care, but it was also widely prescribed off-label for pregnant women. Defendant moved for summary judgment, arguing the claims were preempted by the Food, Drug and Cosmetic Act because the FDA had approved defendant's drug labeling and rejected subsequent attempts to add plaintiffs' proposed warning.

Citing the United States Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009) (*see* May 2009 Foley Hoag Product Liability Update), the court noted that because under FDA's "changes being effected" ("CBE") regulations drug manufacturers can add safety information to labels

based on newly-acquired information without prior agency approval, manufacturers arguing preemption must show FDA would subsequently have rejected the proposed warning. Here, although FDA had rejected both a citizen petition and defendant's own proposal to add a warning that use during pregnancy could cause fetal harm, plaintiffs argued FDA only rejected the proposals because defendant failed to completely disclose the available evidence regarding the drug's risk. Specifically, plaintiffs argued defendant inadequately disclosed three animal studies and a human study, miscoded adverse event data, and failed to disclose an accurate description of the drug's biological mechanism of action, which plaintiffs alleged disrupts cardiac rhythm and thus can cause fetal heart defects.

The court denied summary judgment, concluding that defendant, which bore the burden of proving the affirmative defense of preemption, had not shown either that "the CBE process was unavailable to it to make more substantial warnings" about pregnancy use, or that there was "'clear evidence' that the FDA would not have approved a label including such warnings." While defendant had referred to the three animal studies in an annual report to the agency, there remained a material dispute as to whether that disclosure, without more, was sufficient and whether the studies were material such that they constituted newly-acquired information allowing a CBE labeling change. Similarly, there were material disputes as to whether defendant had properly disclosed the human study and mechanism of action information, and whether the alleged adverse event miscoding was material.

NEW YORK/NEW JERSEY SUPPLEMENT

Second Circuit Holds Pharmaceutical Failure-to-Warn Claims Preempted Where Plaintiffs Did Not Sufficiently Allege Newly Acquired Information Permitting Manufacturers To Change Warnings Without FDA Approval, And Joinder Of In-State Defendant Did Not Prevent Removal To Federal Court Where Defendant Had Not Been Served As Of Time Of Removal

In *Gibbons v. Bristol-Myers Squibb Co.*, 2019 U.S. App. LEXIS 9010, (2d Cir. Mar. 26, 2019), dozens of plaintiffs brought claims against manufacturers of a blood thinning drug alleging failure to warn it could cause excessive bleeding. The United States District Court for the Southern District of New York, presiding over a multi-district litigation ("MDL") consolidating cases involving the drug, dismissed the claims as preempted by the Federal Food, Drug, and Cosmetic Act, and also denied certain plaintiffs' motions to remand their actions to state court.

On plaintiffs' appeal, the United States Court of Appeals for the Second Circuit affirmed. Under United States Supreme Court precedent, because the United States Food and Drug Administration ("FDA")'s premarket approval of a drug includes its label and warnings, plaintiffs' state law failure-to-warn claims were preempted unless they could plead a labeling deficiency that defendants could have corrected without prior FDA approval under the agency's "changes being effected" or "CBE" regulations, which allow a manufacturer to unilaterally change a label in order to "reflect newly acquired information" if the changes "add or strengthen a contraindication, warning, precaution, or adverse reaction" or "add or strengthen an instruction about dosing and administration that is intended to increase the safe usage of the drug product." 21 C.F.R. § 314.70(c)(6)(iii). Here, the circuit court agreed with the district court that plaintiffs' complaints contained only "conclusory and vague" allegations that did not plausibly allege the existence of such newly acquired information. While plaintiffs identified reports and studies that allegedly confirmed problematic bleeding events associated with the drug, they provided no basis upon which the court could determine that these risks were different or more frequent from those already discussed with FDA during the drug's initial approval.

The Second Circuit also rejected plaintiffs' argument that certain suits originally brought in Delaware state court should not have been removed to federal district court, and hence subsequently transferred to the MDL, because some defendants' home state was Delaware and 28 U.S.C. § 1441(b)(2) provides that a suit solely removable because of diversity of citizenship of the parties "may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought." The district court had ruled that by its terms the statute did not bar removal because the Delaware corporations had not been served as of the time defendants removed the actions to federal court. Plaintiffs argued this plain-meaning interpretation created an absurd result and would lead to non-uniform application of the removal statute depending on variations in state law service requirements, such that whether a defendant could remove would depend on whether its home-state requires a delay between filing and service. The Second Circuit rejected both arguments, noting first that Congress could have adopted the "properly joined and served" requirement "to both limit gamesmanship and provide a bright-line rule keyed on service" or the lack thereof. Moreover, state-by-state variation was not uncommon in federal litigation—for example, the deadline for removal depends on state or local rules governing when and how defendants receive complaints—and thus did not justify looking beyond the plain meaning of the statutory text.

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