FOLEY HOAG LLP

Driving Business Advantage

Product Liability **Update**

In This Issue:

May 2009

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 Holds State Law Failure-to-Warn Claims Involving Prescription Drugs Not Preempted by FDA Approval of Warnings Absent Clear Evidence FDA Would Have Rejected Plaintiff's Proposed Warning

In *Wyeth v. Levine*, 555 U.S. --- (Mar. 4, 2009), plaintiff sued the manufacturer of a nausea drug in Vermont state court for negligent failure to warn and strict liability when an injection or "push" of the drug intended for her vein entered her artery, causing gangrene and leading to the amputation of her right forearm. Plaintiff argued that, although the drug's Food and Drug Administration ("FDA")-approved label specifically warned of the risk of gangrene and amputation from arterial penetration and expressed a preference that any intravenous administration of the drug be through an infusion or "drip," the absence of a stronger warning about the risks of administering the drug through injection rendered the drug defective. Following a jury verdict for plaintiff, the trial court denied defendant's motion for judgment as a matter of law based on an argument that plaintiff's claims were impliedly preempted as conflicting with the Food Drug and Cosmetic Act ("FDCA"), and rendered judgment in favor of plaintiff. The Vermont Supreme Court affirmed and the United State Supreme Court granted certiorari.

Defendant first argued that it would have been impossible to comply with both a duty to modify the drug's labeling under Vermont law and a duty to maintain the drug's approved labeling under the FDCA. The Court, however, identified an FDA regulation that permits a drug manufacturer to change a drug's label unilaterally, while simultaneously requesting FDA approval of the change, if the change adds or strengthens a contraindication, warning or precaution. Although defendant argued the regulation did not apply because a 2008 amendment required any such unilateral change to reflect "newly acquired information," the Court held that phrase included new analyses of old data as well as wholly new data, and emphasized that a drug's manufacturer, rather than the FDA, "bears primary responsibility for drug labeling." Thus the Court refused to find it impossible for defendant to have complied with both the FDCA and with state law by unilaterally adopting the warning required by the jury, absent "clear evidence" the FDA would have rejected the warning change, which defendant did not provide. Instead, the Court found the FDA had given only "passing attention" to the intravenous injection issue and had not specifically rejected the type of warning required by the jury. The Court also concluded that the defendant's making such a change to the drug's label would not have rendered the drug an unapproved "new drug" or "misbranded" under the FDCA.

Defendant next argued that requiring it to comply with a state law duty to change the labeling would obstruct the purpose and objective of the FDCA by interfering with Congress' purpose to entrust drug labeling decisions to the FDA. The Court, however, noted that Congress had never enacted an express preemption provision relating to drugs under the FDCA, which the Court contrasted with Congress' enactment of such a provision relating to medical devices and interpreted as "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." The Court also rejected defendant's reliance on the preamble to a 2006 FDA regulation stating that "FDA approval of labeling . . . preempts conflicting or contrary State law," noting that the preamble was issued without notice and opportunity for comment, reversed the FDA's prior position without any discussion, conflicted with the available evidence of Congress' purposes and contained a legal conclusion that was not entitled to deference.

First Circuit Holds Class Action Fairness Act Requires Removing Defendant To Demonstrate "Reasonable Probability" That Amount In Controversy Exceeds $5 Million

In *Amoche v. Guarantee Trust Life Insurance Company*, 556 F.3d 41 (1st Cir. Feb. 13, 2009), buyers of "single premium" credit insurance policies who paid off the underlying loan early sued the insurer alleging that it had failed to refund the unearned portion of the prepaid premium. Plaintiffs filed a putative class action in New Hampshire state court alleging breach of contract and breach of the implied covenant of good faith and fair dealing. After the state court granted plaintiffs' motions to certify a class of New Hampshire buyers and for summary judgment on the issue of liability, plaintiffs moved to amend the complaint to expand the class to include persons from states other than New Hampshire. The state court granted the motion, noting plaintiffs sought to include consumers from sixteen unidentified other states, a specification that did not appear in the third amended complaint. After defendant removed the action to the United States District Court for the District of New Hampshire, plaintiffs successfully moved to remand the action to the state court. The United States Court of Appeals for the First Circuit granted defendant leave to appeal from the remand order.

Defendant removed the action based on the Class Action Fairness Act, 28 U.S.C. §§ 1332(d) & 1453, which requires a removing defendant to, among other things, demonstrate that the amount in controversy exceeds $5 million. The court first held it is the removing defendant's burden to show that federal jurisdiction exists, including by showing a "reasonable probability" that the aggregate claims of the plaintiff class exceed $5 million. In reaching this conclusion, the court rejected defendant's argument that it need only show it is not a legal certainty that the amount in controversy is less than the jurisdictional minimum—the same burden as a plaintiff filing a diversity action in federal court—noting that "placing a removing defendant in the same posture as a plaintiff who originally files in federal court would conflict with the general rule of deference to the plaintiff's chosen forum."

The court then concluded defendant had failed to show that the amount in controversy exceeded $5 million. Defendant first argued the amount in controversy could be shown from the face of the Third Amended Complaint, which described a class of "a substantial percentage" of "hundreds of thousands" of credit insurance policies, with a "likely" unrefunded premium of "about $200" each. The court, however, declined to analyze this showing because it had been superseded by an amendment to the state court's order granting leave to file the Third Amended Complaint which changed the scope of the class from "sixteen" other states to "10 to 20," and an affidavit from plaintiffs' attorney specifying thirteen states that would comprise the class. Defendant next argued that, although its recordkeeping did not permit it to calculate a precise figure for the amount of unpaid refunds for policies related to those states, refund requests from New Hampshire plaintiffs alone were $452,472.29. The court, however, held defendant could not simply multiply this figure by thirteen, citing deficiencies in the way the figure was derived as well as "state-to-state differences in [defendant's] business practices." The court thus concluded that whether the amount in controversy supported federal jurisdiction under CAFA was "at best . . . a draw," and that defendant had failed to demonstrate a reasonable probability that the amount exceeded $5 million.

First Circuit Holds "Home State" Exception to Federal Jurisdiction Under Class Action Fairness Act Does Not Require Consideration of Citizenship of Class Members in Other Class Actions Arising Out of Same Factual Nucleus

In *In re Hannaford Bros. Co. Customer Data Security Breach Litigation*, --- F.3d ----, 2009 WL 1163855 (1st Cir. May 1, 2009), an individual who had used his debit card to make purchases at a grocery store sued the store's operator in Florida state court for failing to adopt adequate security measures after a computer hacker stole credit card information of the store's customers. Plaintiff sought to represent a class of approximately 1.6 million persons, but explicitly defined the class to exclude non-citizens of Florida. Defendant removed the case to a Florida federal court, from which the Judicial Panel on Multidistrict Litigation transferred the case to the United States District Court for the District of Maine, where it was consolidated with twenty-four other suits raising similar allegations. The district court then granted plaintiff's motion to remand the case to Florida state court based on the "home state" exception to the Class Action Fairness Act ("CAFA"), and defendant appealed to the United States Court of Appeals for the First Circuit.

The court first noted that the home state exception requires a federal district court to decline to exercise jurisdiction over a class action where "two-thirds or more of the members of all proposed plaintiff classes in the aggregate, and the primary defendants, are citizens of the State in which the action was originally filed." After determining that a plaintiff bears the burden of showing that the home state exception applies, the court turned to defendant's argument that the phrase "all proposed plaintiff classes in the aggregate" refers to the proposed plaintiff classes in all class actions arising from a single nucleus of fact. The court held that the most natural reading of the exception is with reference to the provision of Fed. R. Civ. P. 23 allowing a class to be divided into subclasses, and that the phrase "all proposed plaintiff classes in the aggregate" thus refers to all proposed subclasses in the class action at issue, rather than to all proposed classes in all class actions arising from the same nucleus of fact.

Defendant further argued that the court's interpretation would cause the exception to defeat Congress' intent to expand federal jurisdiction by allowing class action plaintiffs to tailor their complaints to avoid federal jurisdiction. The court, however, stated that its job was to interpret the plain language of the statute, "not to effectuate purported policy choices regardless of language." The court further expressed skepticism about the validity of defendant's policy argument, noting that the home state exception is narrow and that many of the policy concerns expressed by Congress in enacting CAFA—such as a state court's possible bias against foreign defendants or binding the rights of out-of-state parties to its view of the law—are not implicated by actions that qualify for the home state exception.

Finally, defendant argued that plaintiff's definition of the class to exclude non-Florida citizens was improper because citizenship is subjective and therefore impossible to ascertain. The court, however, rejected this argument, noting that the home state exception itself requires a court to assess the citizenship of class members, thus revealing that Congress did not consider such ascertainment impossible.

Massachusetts Supreme Judicial Court Holds "Light" Cigarettes Class Action Not Preempted by Cigarette Labeling and Advertising Act Based on United States Supreme Court Ruling, Not Subject to Chapter 93A Because FTC Consent Decree Did Not Affirmatively Permit Defendant's Statement

In *Aspinall v. Philip Morris, Inc.*, 453 Mass. 431 (Mar. 16, 2009), plaintiffs filed a class action in Massachusetts Superior Court alleging that defendant, a cigarette manufacturer, violated Mass. Gen. L. ch. 93A, the Massachusetts unfair and deceptive practices statute, by claiming that its "light" cigarettes delivered "lowered tar and nicotine." On cross-motions for partial summary judgment, the trial court granted the plaintiffs' motion, denied the defendant's motion and reported the decision to the Massachusetts Appeals Court. The Supreme Judicial Court granted plaintiffs' application for direct appellate review.

Defendant first argued that plaintiffs' claim was expressly preempted by the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333 et seq. (the "Act"). The court, however, rejected this argument, citing the United States Supreme Court's recent holding in *Altria Group, Inc. v. Good*, 128 S. Ct. 1119 (2008) (*see February 2009 Foley Hoag Product Liability Update*) that the Act's prohibition of state requirements "based on smoking and health" "does not encompass the more general duty not to make fraudulent statements."

Defendant also argued that plaintiffs' claim was exempted pursuant to Mass. Gen. L. ch. 93A, § 3, which provides: "Nothing in this chapter shall apply to transactions or actions otherwise permitted . . . by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States." The court noted that a defendant's burden to prove an exemption under ch. 93A, § 3 is satisfied only where a regulatory scheme affirmatively permits the practice that is challenged as unfair or deceptive. Defendant argued that a 1971 consent decree between the Federal Trade Commission ("FTC") and another cigarette manufacturer permitting that manufacturer to use the "lowered tar and nicotine" claim, if accompanied by a specific statement of tar and nicotine yields calculated by the "FTC method" test, permitted defendant to do likewise. Again citing *Good*, the court held that the consent decree only enjoined conduct proscribed by the decree, rather than affirmatively permitting conduct not proscribed by the decree, and moreover bound only the parties to the decree. Although defendant argued that *Good* concerned preemption and not the issue of a state law exemption under ch. 93A, § 3, the court nonetheless held that defendant's failure to identify anything showing the FTC affirmatively permitted defendant's use of the "lowered tar and nicotine" claim was insufficient to satisfy defendant's burden under the statute.

Massachusetts Federal District Court Dismisses Putative Class Action Against Manufacturer of Recalled Heartworm Medication Based on Economic Loss Rule and Plaintiff's Inability to Show Compensable Loss Where She Received Product's Expected Benefit

In *Rule v. Fort Dodge Animal Health, Inc.,* 604 F. Supp. 2d 288 (D. Mass. Mar. 11, 2009), plaintiff twice had her dog injected with a heartworm medication that later was recalled due to reported adverse reactions among injected dogs, including death. Although plaintiff's dog suffered no adverse consequences and did not develop heartworm, and plaintiff was unaware of any increased risk to the dog at the time of the injections, plaintiff filed a putative class action against the manufacturer of the medication in the United States District Court for the District of Massachusetts, alleging claims of negligence, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), breach of the implied warranty of fitness for a particular purpose, breach of contract and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute), and seeking damages measured by the difference between the actual value of the medication and what its value would have been had it not been defective. Defendant moved to dismiss all claims.

The court first dismissed plaintiff's negligence claim based on the rule that purely economic losses—which plaintiff acknowledged were her only damages—are not compensable in a tort action absent personal injury or property damage. The court rejected plaintiff's argument that the economic loss rule applies only to cases where the defendant interferes with a contract or economic opportunity.

The court then dismissed plaintiff's implied warranty of merchantability claim for failure to allege a cognizable injury. Plaintiff cited a case in which the Massachusetts Superior Court allowed a plaintiff to recover for breach of the implied warranty of merchantability where the alleged defect in the product at issue—a car jack—never manifested itself. The court, however, distinguished that case on the ground that the car jack allegedly had not fulfilled its anticipated useful life, whereas the heartworm medication—which was designed to have a preventive effect lasting six months—had. In short, plaintiff had received the full benefit of the bargain she anticipated by receiving six months of heartworm protection with no adverse effects. The court dismissed plaintiff's claim of breach of the implied warranty of fitness for the same reason, and also because plaintiff had failed to allege any unique "particular" purpose for the medication apart from the ordinary one for which it was sold and used.

The court dismissed plaintiff's breach of contract claim, finding that, although defendant had guaranteed it would pay certain veterinary expenses for dogs using the medication who developed heartworm, plaintiff's dog had not developed heartworm. The court also noted plaintiff would not be an adequate class representative for this reason.

Finally, the court dismissed plaintiff's ch. 93A claim. After reviewing the "somewhat less-than-tidy jurisprudence of the Chapter 93A 'injury' requirement under Massachusetts law," the court held that plaintiff had failed to allege a compensable loss because she had received the benefit of the bargain she anticipated. The court acknowledged that one state supreme court precedent could be read to hold that an increased

exposure to health risks, without actual physical harm, constitutes an "injury" under ch. 93A, but the court refused to extend this principle to damage to property such as a dog. The court emphasized that, as a federal court applying Massachusetts law under diversity-of-citizenship jurisdiction, it should not be expected to "embark on bold new holdings in applying state law." The court also raised the possibility that, if Massachusetts case law was read to eliminate any requirement of an actual injury from ch. 93A claims, a federal court might be without jurisdiction to entertain certain ch. 93A claims due to the constitutional "case or controversy" requirement of some injury-in-fact.

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

David R. Geiger
Chair

Matthew C. Baltay
Update Editor

James J. Dillon

Jonathan M. Ettinger

Jeffrey S. Follett

Barbara S. Hamelburg

Vickie L. Henry

Michael B. Keating

Carter D. Morse

Colin J. Zick

Eric Haskell
Associate Editor

Rachel M. Brown

Lisa M. Burnett

Dakis Dalmanieras

Kirk Hanson

Gabriel M. Helmer

Brian L. Henninger

Eric J. Huang

Matthew E. Miller

Raghavan Nagarajan

Bianca L. Peskin

Creighton K. Page

Katherine B. Schmeckpeper

Claudia Trevor-Wright