

- **United States Supreme Court Holds Food, Drug and Cosmetic Act Preempts State Law Claims Against Medical Device that Received Premarket Approval from Food and Drug Administration**
- **Massachusetts Appeals Court Decertifies Class of Mouthwash Purchasers Due to Differences Among Purchasers' Exposure to, and Reliance on, Allegedly Deceptive Advertisements**
- **Massachusetts Superior Court Refuses to Certify Class of Buyers/Lessees of Vehicles that Included Twenty-Three Distinct Jacks, Finding Lack of Common Factual Issues, Predominance of Common Over Individual Issues and Superiority of Class Action Method of Adjudication Over Individual Claims**
- **Massachusetts Appeals Court Holds Alleged Failure to Warn Was Not Proximate Cause of Injury Because Plaintiff Did Not Read and Heed the Warnings that Were Provided**
- **Massachusetts Appeals Court Holds Failure to Move for Dismissal Within Reasonable Time Waives Pleaded Defense of Insufficient Service of Process**

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 Food, Drug and Cosmetic Act Preempts State Law Claims Against Medical Device that Received Premarket Approval from Food and Drug Administration

In *Riegel v. Medtronic, Inc.*, --- U.S. ---, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008), a balloon catheter ruptured in plaintiff's coronary artery while he was undergoing a coronary angioplasty, requiring him to undergo emergency bypass surgery and be placed on life support. Plaintiff, his wife and - after his death - his wife as administrator of his estate sued the catheter's manufacturer in United States District Court for the Northern District of New York, asserting various claims under New York common law including: strict liability; breach of implied warranty; negligence in the design, testing, inspection, distribution, labeling, marketing, sale, and manufacturing of the catheter; and loss of consortium. The district court dismissed these claims as preempted by the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a). The United States Court of Appeals for the Second Circuit affirmed and the United States Supreme Court granted certiorari.

The Court noted that the FDCA expressly preempts any state "requirement" purporting to apply to a medical device if the requirement is "different from, or in addition to, any requirement applicable . . . to the device" under the FDCA and "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the FDCA. The Court first determined that federal law imposed "requirements" on the catheter because the premarket approval process through which the catheter was approved focuses on safety, requires a reasonable assurance of the device's safety and effectiveness, is specific to the individual device and permits no deviations from the specifications contained in its application for approval. The Court contrasted the premarket approval process with the process under 21 U.S.C. § 510(k) by which many medical devices are cleared for marketing, which focuses on whether the device is "substantially equivalent" to an already marketed device.

The Court then determined that the catheter's safety and effectiveness were the very subjects of plaintiff's common law claims and that state common law duties, such as those invoked by plaintiff's claims, are "requirements." The Court observed that a jury applying state tort law pursuant to a negligence or strict liability standard sees only the costs of a challenged device's design, not the benefits, and therefore could readily disrupt the federal regulatory scheme by effectively requiring a device to be safer but less effective than FDA

approval requires. The court noted that preemption applies only to state law requirements that are “different from, or in addition to,” requirements imposed by the FDCA - and not to “parallel” state law requirements - but refused to address plaintiff’s argument that his lawsuit raised parallel state claims, as plaintiff had not made such an argument to the court of appeals.

The Court rejected plaintiff’s argument, based on a reading of a certain FDA regulation, 21 C.F.R. § 808.1.d(1), that state common law requirements cannot be preempted because they are not device-specific, noting that the plain language of the FDCA does not require a state law requirement to be device-specific to be preempted.

Massachusetts Appeals Court Decertifies Class of Mouthwash Purchasers Due to Differences Among Purchasers’ Exposure to, and Reliance on, Allegedly Deceptive Advertisements

In *Kwaak v. Pfizer, Inc.*, 71 Mass. App. Ct. 293 (2008), plaintiffs sued a mouthwash manufacturer in Massachusetts Superior Court for fraud, unjust enrichment and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive trade practices statute) in connection with defendant’s allegedly deceptive advertising campaign. The campaign included four different television advertisements, print advertising, and labels and tags attached to some bottles of the mouthwash. Early versions of the television and print advertisements claimed the mouthwash was “as effective as floss,” while later versions stated consumers should “floss daily” and “there’s no replacement for floss.” Similarly, the “as effective as floss” claim appeared on some, but not all, bottle labels and tags.

After the trial court certified, under both Mass. R. Civ. P. 23 and Mass. Gen. L. ch. 93A, § 9(2), a class of all Massachusetts consumers who purchased the mouthwash during the advertising campaign, defendant’s petition for review by a panel of the Massachusetts Appeals Court was granted by a single justice of that court.

The appellate court first analyzed ch. 93A’s class certification requirements because they are less stringent than those of Rule 23. Under ch. 93A, a class may be certified if the allegedly deceptive act or practice has caused similar injury to numerous

similarly situated persons and the plaintiff adequately and fairly represents such other persons. Under Rule 23, a court must find that, in addition to satisfying the requirements of numerosity, commonality, typicality, and adequacy reflected in ch. 93A, “the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy.” Under both standards, plaintiff bears the burden of providing information sufficient to enable the judge to form a reasonable judgment that the purported class meets the applicable requirements.

Plaintiffs argued they satisfied the requirement of showing similar injury to numerous similarly situated persons by showing the advertising campaign was deceptive and had caused economic injury to the class equaling the difference between the deceptively advertised and actual values of the mouthwash. The court, however, held there was insufficient information in the record to demonstrate similarity of exposure, deception and causation among class members. Specifically, plaintiffs sought to certify a class of everyone who purchased the mouthwash during the advertising campaign, regardless of whether they actually were exposed to the advertisements. Moreover, the court observed that some putative class members who were exposed may have been exposed to unfair or deceptive acts but others exposed only to permissible “puffery” because the campaign had become less aggressive over time. Further, there was no showing that all putative class members had purchased the mouthwash as a result of the advertising.

The court rejected plaintiffs’ argument that they could bridge such differences among putative class members by reasoning that the deceptive aspects of the marketing campaign raised the value of the product for all purchasers. The court held that, in contrast to cases involving publicly traded securities, there is no presumption of “a nearly perfect market in information” in consumer fraud cases, so that plaintiffs must provide sufficient information that all class members were exposed to the alleged deception.

Massachusetts Superior Court Refuses to Certify Class of Buyers/Lesseees of Vehicles that Included Twenty-Three Distinct Jacks, Finding Lack of Common Factual Issues, Predominance of Common Over Individual Issues and Superiority of Class Action Method of Adjudication Over Individual Claims

In *Holzman v. General Motors Corp.*, 2007 WL 4098913 (Mass. Super. Ct. Nov. 6, 2007), plaintiff sued the manufacturer of his automobile for breach of express warranty, 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 and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive trade practices statute) in connection with an allegedly defective jack that came with his car. Plaintiff then sought to certify a class of Massachusetts owners and lessees of automobiles manufactured by defendant that came equipped with any of twenty-three different models of jacks.

Applying the requirements of Mass. R. Civ. P. 23, the court first found the proposed class to lack questions of law or fact common to the proposed class because it encompassed twenty-three distinct jack models that were placed in numerous vehicle models over numerous model-years - all characteristics that affect jack performance. The court next found any common questions did not predominate over questions affecting only individual members of the proposed class because of the reasonable likelihood of different findings regarding the merchantability of different jacks or jack-vehicle combinations. The court also noted that some members of the proposed class may have made a previous claim under an express warranty applicable to their vehicle and that the assertion of a claim for breach of the implied warranty of fitness for a particular purpose would require individualized fact-finding concerning the dealer's knowledge of the vehicle's intended use and the buyer or lessor's reliance on the dealer's skill and judgment. The court also found class treatment to be an inferior method of adjudication due to the lack of commonality among claims and plaintiffs.

Finally, the court found that the proposed class was not certifiable even under Mass. Gen. L. ch. 93A, § 9(2), observing that even the "more generous standards" that ch. 93A establishes for class certification by not requiring predominance or superiority do not compel "a complete disregard of the practicalities," and reiterating that the existence of some degree of commonality among plaintiffs and claims would not prevent the proceeding from disintegrating into a myriad series of mini-trials.

Massachusetts Appeals Court Holds Alleged Failure to Warn Was Not Proximate Cause of Injury Because Plaintiff Did Not Read and Heed the Warnings that Were Provided

In *Rozenvayn v. BMW of North America, LLC*, 70 Mass. App. Ct. 1107, 2007 WL 3132936 (Oct. 26, 2007), plaintiff was injured when his car fell from its tire jack while he was working underneath it. Plaintiff sued the car's manufacturer and retailer in Massachusetts Superior Court alleging negligence and failure to warn of the risks associated with using the jack to elevate the car.

The jack itself bore the warning: "CAUTION Before use consult Owner's Manual." The instructions in the owner's manual warned: "The jack is designed for changing tires only Never lie beneath the vehicle when it is supported by the jack - risk of fatal injury!" Plaintiff admitted in a deposition that he had seen in the owner's manual instructions relating to use of the jack to change a tire, but did not read those instructions, instead looking at certain pictures associated with the instructions. Plaintiff further admitted that he recognized the international warning symbol that appeared in the owner's manual alongside the tire-changing instructions, but testified he did not see the symbol when he looked at the pictures. The trial court granted defendants' motion for summary judgment, holding the dangers associated with the plaintiff's use of the jack were open and obvious.

On plaintiff's appeal, the Massachusetts Appeals Court affirmed the judgment on different grounds. The court held that an alleged failure to warn cannot be considered the proximate cause of an injury if plaintiff cannot prove that he would have read and heeded a better warning. In this case, plaintiff

acknowledged that he only looked at the pictures included with the tire-changing instructions and did not read the associated warnings. The court thus affirmed summary judgment because plaintiff's indifference to the warnings provided, rather than any deficiency in the warnings themselves, proximately caused his injury.

Massachusetts Appeals Court Holds Failure to Move for Dismissal Within Reasonable Time Waives Pleaded Defense of Insufficient Service of Process

In *Raposo v. Evans*, 71 Mass. App. Ct. 379 (2008), plaintiffs sued defendant in Massachusetts Superior Court in connection with an automobile accident. Service on defendant was effected by a deputy sheriff's leaving at defendant's purported last and usual place of abode, and also mailing to him, a copy of the summons and complaint. The Massachusetts Insurers Insolvency Fund ("Fund") undertook to represent defendant, whose insurer was insolvent, after he initially defaulted. In its answer, the Fund pleaded insufficient service as a defense.

Following a twenty-month stay while plaintiffs exhausted all other insurance benefits, the Fund moved to dismiss based on insufficient service, which the court denied for lack of evidence rebutting the sheriff's affidavit and return of service. The Fund then participated in the litigation - including agreeing to a joint discovery schedule, opposing plaintiffs' motion for default judgment and filing a joint pretrial memorandum - until defendant was defaulted on the issue of liability for failure to respond to discovery. The Fund then filed a second motion to dismiss for insufficient service, in support of which it presented evidence that service had been made to a commercial property that could not have been defendant's place of abode. The trial court denied the motion, concluding defendant had waived the defense of insufficient service, assessed damages against defendant, and entered final judgment, from which defendant appealed.

Relying on federal court precedent, the Massachusetts Appeals Court held that a defendant who challenges service of process in his answer must move to dismiss within a reasonable time,

prior to substantially participating in discovery and litigating the merits of the case. Here, the court faulted defendant's first motion as "bare bones" and found defendant waived the defense of insufficient service by agreeing to a discovery schedule and participating in motion practice as well as the final pretrial conference before filing a motion to dismiss for insufficient service supported by evidence nearly five years after his answer. The court did not address the significance of Mass. R. Civ. P. 12(d), which provides that any Rule 12(b) defense - including insufficiency of service of process - whether made in a pleading or by motion, shall be heard and determined before trial on application of any party, unless the court orders the hearing deferred until the trial.

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 Zick

Eric Haskell
Associate Editor

Dakis Dalmanieras

Lauren E. Dwyer

Walead Esmail

Katherine J. Fick

Gregory T. Gentry

Howard P. Goldberg

Kirk Hanson

Gabriel M. Helmer

Brian L. Henninger

Matthew E. Miller

Bianca L. Peskin

Jonathan B. Rabin

Katherine Schmeckpeper

Ericka Harper Snyder

Claudia Trevor-Wright

Lynn M. Zuchowski



BOSTON | WASHINGTON | EMERGING ENTERPRISE CENTER | FOLEYHOAG.COM

This Update is for information purposes only and should not be construed as legal advice or legal opinion on any specific facts or circumstances. You are urged to consult your own lawyer concerning your own situation and any specific legal questions you may have. United States Treasury Regulations require us to disclose the following: Any tax advice included in this Update and its attachments is not intended or written to be used, and it cannot be used by the taxpayer, for the purpose of avoiding penalties that may be imposed on the taxpayer.

Copyright © 2008 Foley Hoag LLP.

Attorney Advertising. Prior results do not guarantee a similar outcome.