Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

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COURT RULES STATE CONSUMER FRAUD CLAIMS PREEMPTED BY FEDERAL DRUG LAWS

In a split decision, the Third Circuit Court of Appeals has dismissed putative class claims alleging that a drug manufacturer violated state consumer protection laws, finding them preempted by federal law. ***Pa. Employees Benefit Trust Fund v. Zeneca, Inc.*, No. 05-00075 (3d Cir., decided August 17, 2007)**. The drug at issue, a proton-pump inhibitor intended to treat acid reflux disease and heartburn, was advertised as superior to another of the defendant's proton-pump inhibitors whose patent was due to expire in 2001 when it would become available for sale as a generic. In 2001, defendant obtained approval from the Food and Drug Administration (FDA) for labeling the new drug and launched a large-scale promotional campaign, including physician-directed marketing and direct-to-consumer advertising.

Plaintiffs contended that the new drug was not superior to the older one and alleged unlawful advertising under a state consumer fraud act; violations of the consumer protection statutes of 50 states for false, misleading and deceptive advertising; unjust enrichment; and negligent misrepresentation. The district court dismissed the complaint with prejudice, and the plaintiffs appealed. The appeals court first determined that the district court erred by reading the state statute too broadly. According to the court, the plain language of the statute, which contains an exemption for advertising complying with Federal Trade Commission rules and regulations, does not apply to marketing based on labeling the FDA approves. The court, nevertheless, upheld the lower court's dismissal, ruling that state consumer fraud claims were preempted under the implied conflict preemption doctrine. In this regard, the court stated, "[T]he purpose of protecting prescription drug users in the [Food, Drug, and Cosmetic Act] would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA." The dissenting judge would have found no conflict with federal law and thus no preemption.

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THIRD CIRCUIT IMPOSES ADDITIONAL REDUCTIONS ON PUNITIVE DAMAGES AWARD

The Third Circuit Court of Appeals, in a 2-1 decision, has reduced a $30 million punitive damages verdict to $750,000. ***CGB Occupational Therapy, Inc. v. RHA Health Servs, Inc., Nos. 05-3409 & 3586 (3d Cir., decided August 23, 2007)***. The case involved allegations of tortious interference with contractual relationships, and the jury returned compensatory damages verdicts of $109,000 and $576,000 on two claims of interference. The jury also awarded $1.3 million in punitive damages to the plaintiff without allocating it between the two interference claims. On appeal, the Third Circuit affirmed the $109,000 verdict but reversed the other and remanded the case for a new trial on the question of punitive damages because it was "impossible" for it to determine how the punitive damages award should be allocated. On remand, the jury awarded the plaintiff $30 million in punitive damages, which the trial court found excessive and reduced to $2 million.

The appeals court focused on the degree of defendant's reprehensibility and the disparity between the harm and the award. As to reprehensibility, the court found that three of the five reprehensibility factors established by the U.S. Supreme Court in cases such as *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), were present. Because the harm suffered was economic and not physical, however, and because the tortious conduct did not demonstrate an indifference to or a reckless disregard for the health or safety of others, the court found that the conduct was not sufficiently egregious to warrant a remitted punitive damages award of $2 million. The court also examined the ratio of punitive damages to harm and concluded that a double-digit ratio of 18 to 1 called for special justification. Finding none, the court determined that the award was constitutionally excessive and reduced it to $750,000, or a punitive damages to harm ratio of less than 7 to 1.

The dissenting judge did not believe that the punitive damages issue should have been retried on remand, stating "A litigant appealed to our Court and won a partial reversal, and yet the judicial system left that litigant worse off on remand than it had been before it appealed." This judge would have capped the punitive damages at $1.3 million, the amount of the original award, and remanded for the lower court to determine what part of the punitive damages award should have been allocated to the compensatory award that survived the first appeal.

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STATE COURT ALLOWS INDIRECT PURCHASERS TO BRING UNFAIR COMPETITION CLAIMS IN SMOKELESS TOBACCO CASE

Deciding a matter of first impression, the New Hampshire Supreme Court has determined that consumers who purchased smokeless tobacco from state retailers may bring claims against the manufacturers under New Hampshire's Consumer Protection Act (CPA). ***LaChance v. U.S. Smokeless Tobacco Co., No. 2006-564 (N.H., decided August 24, 2007)***. The plaintiffs

alleged that the defendants removed competitors' racks from retail stores and entered agreements with store retailers to restrict the sale, advertising and display of competing brands. As a result, defendants were alleged to have increased the price and limited and reduced the supply of moist snuff tobacco products, acts purportedly constituting unfair and deceptive competition under the CPA. The plaintiffs claimed they sustained actual damages and non-economic harm because their "product choice had been limited and each plaintiff had been wrongfully denied the free choice to purchase a lower-priced consumer product." The trial court dismissed the claims and denied the class certification motion, ruling that plaintiffs were "indirect purchasers" who could not bring such claims.

While the state supreme court acknowledged the appeal of defendants' argument, i.e., that antitrust claims should be brought and decided under antitrust statutes and principles, the court refused to read into the CPA a requirement that only those who have *directly* purchased the product from the manufacturer may bring an unfair business practices claim. "Either the statute requires privity, or it does not. We have held that it does not." The court further stated, "To adopt the defendants' position and hold that indirect consumers are prohibited from bringing CPA claims would be to prevent the real victims – those who purchase goods at higher prices – from recovering damages for the injuries caused by an alleged violation of [the law]. Such a result would seriously undermine or erode the expansive remedial goals of the CPA." The court also ruled that the trial court erred in denying class certification, finding that claims of unfair methods of competition come within the definition of those unlawful acts that may be pursued as a class action under the CPA.

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PLAINTIFFS AWAIT DAMAGES IN VIOXX® CASES

"In fact, none of the 45,000 people who have sued Merck, contending that they or their loved ones suffered heart attacks or strokes after taking Vioxx, have received payments from the company," reports Alex Berenson in a recent *New York Times* article about ongoing lawsuits involving Merck & Co.'s pain-killer Vioxx®. Merck has successfully defended itself against most suits claiming that prolonged use of its drug caused heart attacks, but plaintiffs' lawyers have criticized the company for failing to settle with plaintiffs. "Merck's goal is to manipulate the legal system to deprive justice to tens of thousands of people whose cases can never be heard," opined plaintiffs' lawyer W. Mark Lanier, who won his client a $253.5 million verdict now under appeal. "Justice delayed is justice denied."

Berenson notes, however, that judges have refused the efforts of plaintiffs' lawyers to combine potential suits into a single class action, mainly because the variations in individual cases require each suit to be tried separately. "We're continuing our strategy of looking at each case on the individual facts," stated an attorney representing Merck. "Did they really have a heart attack? Did they really take the medicine? Did they take the medicine in proximity to the heart attack?" Legal scholars such as Fordham University law professor Benjamin Zipursky have also argued that Merck "may have felt

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it had little choice" but to contest some lawsuits; otherwise the company would have faced an "essentially unlimited pool of plaintiffs" given the frequency of heart attacks in the United States and the popularity of Vioxx. *See The New York Times* and *The WSJ Law Blog,* August 21, 2007.

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LAWSUITS FILED AGAINST MATTEL OVER LEAD-TAINTED TOYS

Philadelphia-based law firm Woloshin & Killino, P.C. has reportedly filed a class-action lawsuit in Los Angeles County Superior Court seeking to compel Mattel, Inc. to fund medical monitoring for children exposed to lead found in the toy manufacturers' products. Mattel earlier this month recalled more than 1 million lead-tainted toys after an investigation revealed that the Chinese-made products contained leaded pigment. The complaint in *Powell v. Mattel,* which follows a similar suit filed in Pennsylvania federal court, alleges strict product liability, negligence and violations of the business professions code of California. "The only reasonable way to determine whether plaintiffs and the class members have suffered lead poisoning is to have them undergo preventative medical screening and monitoring, including but not limited to blood tests," according to the complaint. If enough children show evidence of lead poisoning, plaintiffs' lawyer Jeffery Killino also said he will consider a "mass tort action." *See CNNMoney.com,* August 20, 2007; *The Legal Intelligencer,* August 21, 2007; and *Knowledge@Wharton,* August 22, 2007.

Meanwhile, legal experts have focused on the Mattel case as one that is likely to drive the "'medical monitoring' debate," according to a recent article in *The Wall Street Journal.* Shook, Hardy & Bacon Public Policy Partner **Victor Schwartz** said that medical-monitoring suits are "among the greatest divisions in all of tort law among judges" because they violate the legal precept that a person must prove injury before recovering money. He also explained that these types of class actions would quickly exhaust resources otherwise destined for injured plaintiffs, an argument the Supreme Court reiterated in 1997 when it ruled that medical monitoring would hurt plaintiffs "who depend on a tort system than can distinguish between reliable and serious claims on the one hand, and unreliable and relatively trivial claims on the other." "Once you go down that path, you're greatly augmenting [the meaning] of liability," Schwartz was quoted as saying. *See The Wall Street Journal,* August 20, 2007.

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ALL THINGS LEGISLATIVE AND REGULATORY

Food and Drug Administration Seeks Comment on Risk Communication Study

The Food and Drug Administration (FDA) has issued a **notice** seeking comments on its plan to study the impact of distraction on consumer understanding of risk and benefit information in direct-to-consumer (DTC) prescription drug broadcast advertisements. According to the FDA, compelling visuals are

characteristic of DTC television ads for prescription drugs. "Many assert that the visuals present during the product risk presentation are virtually always positive in tone and often depict product benefits. A consistently raised question is whether advertising visuals of benefits interferes [sic] with consumers' understanding and processing of the risk information in the ad's audio or text." Participants will be over age 40 and will represent a range of education levels, although all will be literate and English-speaking. The study will be limited to high blood pressure medication. Public comments on the study must be submitted by October 22, 2007. *See Federal Register*, August 22, 2007.

Nanotech Office Posts Prioritization Document for Comment

The National Nanotechnology Coordination Office has **announced** a public comment period for a document that identifies and prioritizes environmental, health and safety research and information needs relating to the understanding and management of potential nanomaterial risks. The document, created by the government nanotechnology working group, reflects input from industry liaison groups and a public meeting held in January 2007. The additional feedback requested concerns "whether parties agree with the identified priorities of the Government or would suggest different or additional priorities. Support for the submitted perspectives is requested." Comments are due by September 17. *See Federal Register*, August 16, 2007.

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NIH Reviews Environmental Sciences Division

The National Institutes of Health (NIH) has reportedly announced plans to review two member agencies, the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP), in response to questions about alleged conflicts of interest. The review will focus on grant management, human resources and ethics programs criticized by the U.S. House of Representatives in a recent appropriations measure, which called for an investigation into "numerous incidents at [NIEHS]" concerning "areas as diverse as management of scientific journals, employee complaints about performance appraisal systems, alleged conflict of interest by outside contractors hired to operate peer review systems, and improper use of federal funds in office renovation and support staff assignments." NIEHS carries out research on chemicals that pose a threat to human health.

Critics have specifically pointed to a recent controversy involving Sciences International, Inc., an outside contractor NIEHS hired to draft a report on bisphenol-A despite its ties to Dow Chemical Co., a bisphenol-A manufacturer. In addition, Senator Charles Grassley (R-Iowa) has questioned whether a form that NIEHS used to track employee contacts with Congress is an attempt to "flush out whistleblowers." "Congress and others have raised important questions and concerns over the past few months, and we will be fully responsive," NIH Director Elias Zerhouni was quoted as saying. "It is critical that this review be done in a fair, comprehensive and independent manner." *See Greenwire,* August 22, 2007.

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LEGAL LITERATURE REVIEW

Michael Scott, "Tort Liability for Vendors of Insecure Software: Has the Time Finally Come?," 62 *Maryland Law Review* (forthcoming 2008)

Southwestern Law School Professor Michael Scott discusses whether software vendors should be responsible for security vulnerabilities that allow hackers and cyberterrorists to access sensitive electronic information. Noting that, to date, the courts have allowed vendors to shift the risk of insecure software to the licensee, the article discusses the relative merits of holding vendors liable under several legal theories including product liability. The author suggests that if software can meet the definition of a product and if security vulnerability can be viewed as a design or manufacturing defect, then vendors could be held strictly liable when the programs they market to protect computer security fail. The article explores the difficulties in applying product liability law in this arena, but concludes that something needs to be done to improve the performance of security software. "It is also clear that most vendors will not take the initiative in this area, unless forced to do so by an external force – such as a threat of [Federal Trade Commission] fines or the specter of large damage awards."

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Stephen Choi, G. Mity Gulati & Eric Posner, "Professionals or Politicians: The Uncertain Empirical Case for an Elected Rather than Appointed Judiciary," Olin Working Paper (August 2007)

Examining state high court opinions for effort, skill and independence, professors from New York University Law School, Duke Law School and the University of Chicago Law School tested the conventional wisdom that appointed judges are better than elected judges. They report that elected judges, who write more opinions than their appointed counterparts, behave like politicians and focus on providing service to those who elect them. On the other hand, appointed judges write higher quality opinions and behave like professionals by focusing on their long-term legacy as creators of precedent. Despite these differences, the authors found that elected judges do not appear less independent than appointed judges. They also found that the higher productivity of elected judges results in the same number of case citations over time for both elected and appointed judges.

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LAW BLOG ROUNDUP

Court Upholds Mandatory Binding Arbitration Clause

"(You can just hear the collective mwoohahaha of homebuilders everywhere)," progressive think tank fellow and lawyer Kia Franklin, highlighting the dissenting opinion to a Florida appeals court ruling that compelled the arbitration of a personal injury claim against a home builder. The dissenter argued

that the majority "places an imprimatur of judicial approval on a scheme whose ambitious end is the elimination of personal injury claims in any case where the victim has a contractual relationship with the tortfeasor."

tortdeform.com, August 23, 2007.

Drug Maker's Strategy Goes Head-to-Head with Docket-Clearing Devices

"By avoiding class actions or joint trials, by declining to settle early, and by litigating each individual case to the hilt, Merck has improved its bargaining position." Seton Hall Law Professor Howard Erichson, blogging about Vioxx® litigation in New Jersey, where the trial court, with nearly 14,000 cases on its docket, has proposed a plan to move the cases more quickly by means of simultaneous trials with four judges and multiple plaintiffs.

lawprofessors.typepad.com/mass_tort_litigation, August 23, 2007.

No Injury?, No Lawsuit

"Unfortunately, the pulmonologist who re-read your chest x-rays determined them to be negative." Reporter Paul Davies, quoting the "good news/bad news" letter written to 50 of 125 silicosis plaintiffs who were dropped as clients. According to Davies, "no disease means no lawsuit and no potential payout." The plaintiff's lawyers apparently sought second opinions in light of a federal court's 2005 ruling that found thousands of lung-damage claims from silica dust exposure "were manufactured for money."

"Unfortunately, the pulmonologist who re-read your chest x-rays determined them to be negative."

blogs.wsj.com/law, August 21, 2007.

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THE FINAL WORD

High-Profile Plaintiff's Lawyer Charged with Criminal Contempt

According to news sources, Dickie Scruggs and his Mississippi law firm were charged with criminal contempt for violating a preliminary injunction and refusing to deliver to a federal judge documents related to a Hurricane Katrina insurance dispute. The U.S. Justice Department apparently declined to prosecute Scruggs, so Judge William Acker brought the charges and named special prosecutors to prosecute the case under Rule 42(a) of the Federal Rules of Criminal Procedure, which provides the judiciary with the means to vindicate its authority without depending on another branch of government. Scruggs has represented plaintiffs in asbestos, tobacco and medical device litigation. *See Associated Press* and *The Wall Street Journal Law Blog*, August 22, 2007.

Upcoming Conferences and Seminars

Charleston School of Law, Charleston, South Carolina – September 7, 2007 – "Punitive Damages, Due Process, and Deterrence: The Debate After Williams." Speakers include Shook, Hardy & Bacon Public Policy Partner **Victor Schwartz** who will address the topic "Looking Forward: Punitive Damages in the Next Two Decades – Guideposts From Precedent, History & Sound Public Policy."

Center for Business Intelligence, Washington, D.C. – September 24-25, 2007, "Global Data Security and Privacy Summit." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Madeleine McDonough** will discuss "Critical Privacy Issues in Electronic Document Discovery."

American Conference Institute, New York City, New York – December 12-14, 2007 – "12th Annual Drug and Medical Device Litigation" conference. Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Harvey Kaplan** will serve on a panel that will discuss "Jury Communication: Changing Perceptions of the Industry/FDA and Putting Adverse Events and the Approval Process in Context."

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ABOUT SHB

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys have unparalleled experience in organizing defense strategies, developing defense themes and trying high-profile cases. The firm is enormously proud of its track record for achieving favorable results for clients under the most contentious circumstances in both federal and state courts.

The firm's clients include many large multinational companies in the tobacco, pharmaceutical, medical device, automotive, chemical, food and beverage, oil and gas, telecommunications, agricultural, and retail industries.

With 93 percent of its nearly 500 lawyers focused on litigation, Shook has the highest concentration of litigation attorneys among those firms listed on the AmLaw 100, *The American Lawyer's* list of the largest firms in the United States (by revenue).

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GLOBAL PRODUCT LIABILITY LAW FIRM OF THE YEAR 2005|2006|2007 WHO'S WHO LEGAL

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