Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

A PUBLICATION OF SHOOK, HARDY & BACON L.L.P. JANUARY 24, 2008

MDL COURT REJECTS CLASS CERTIFICATION FOR MEDICAL MONITORING CLAIMS IN DRUG CASE

A multidistrict litigation court in New York has denied motions for class certification filed on behalf of claimants from three states seeking to litigate medical monitoring claims on behalf of their respective state's residents, who used a drug to treat osteoporosis and were allegedly at risk of developing a rare jaw bone condition. *In re: Fosamax Prods. Liab. Litig.*, MDL No. 1789 (U.S. Dist. Ct., S.D.N.Y., decided January 3, 2008). Despite plaintiffs' attempt to certify single-state classes and thus limit the variations in law applicable to the claims, the court found that, because individual questions of fact predominated, the claims were not suited to class treatment.

The court reviewed the drug's history and the events that led to Food and Drug Administration (FDA) approval of a revised warning label for Fosamax® and reviewed cases from other federal districts involving putative class claims for personal injury allegedly caused by prescription drugs. According to the court, "[l]ower courts almost unanimously have rejected class certification in pharmaceutical products liability actions." Of particular significance to the court was that "The proposed class definitions do not set any dosage or duration of use limitations on class membership. Nor do they attempt to screen out persons with unique risk factors for ONJ [osteonecrosis of the jaw]." In light of the scientific uncertainties about the condition and its causes, the court did not believe the class representatives' claims were typical of other class members' claims.

The court was also concerned about intrusions into the FDA's regulatory mandate, stating, "Assuming that it would be appropriate for a court to determine whether someone who takes an FDA-approved drug is entitled to medical monitoring even before the FDA recommends such monitoring for any user of the drug, a more cautious, case-by-case approach on the particular factual circumstances of individual plaintiffs would be more prudent."

< Back to Top

CONTENTS

U.S. SUPREME COURT ACCEPTS APPEALS IN DRUG AND CIGARETTE PREEMPTION CASES

The U.S. Supreme Court has agreed to hear the appeals in two cases involving state-law claims that product manufacturers contend are preempted by federal law. In *Wyeth v. Levine*, No. 06-1249 (U.S., cert. granted January 18, 2008), the Court will consider "Whether the prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration pursuant to FDA's comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetics Act, preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." The issue arose in a case involving a woman who lost her arm when an anti-nausea drug was mistakenly injected into her artery. The Vermont Supreme Court affirmed her $6.8 million award, finding that FDA requirements impose a floor rather than a ceiling for state regulation.

In *Philip Morris v. Good*, No. 07-562 (U.S., cert. granted January 18, 2008), the Court will address a conflict between the First and Fifth Circuit Courts of Appeals over the preemptive effect of a federal law regulating the labeling and advertising of cigarettes. This case arose in Maine, where smokers seek to file claims under the state's deceptive commercial practices law challenging company advertisements for cigarette brands that are "light" or "low in tar and nicotine." Finding no preemption, the First Circuit allowed the claims to proceed, while the Fifth Circuit has ruled against the prosecution of similar claims filed in other states.

< Back to Top

FEDERAL COURT USES SETTLEMENT DEMAND TO DECIDE REMOVAL DISPUTE IN MOTORCYCLE LAWSUIT

A federal court in Alabama has ruled that it has jurisdiction over a case removed to it on the basis of diversity of citizenship because the plaintiff, allegedly injured when his motorcycle caught fire, made a settlement demand in excess of the jurisdictional "amount-in-controversy" requirement. *Bankhead v. Am. Suzuki Motor Corp.*, No. 3:07cv208 (U.S. Dist. Ct., M.D. Ala., Eastern Div., decided January 7, 2008). The plaintiff did not specifically allege an amount in controversy in his complaint, but the defendant argued that the $75,000 jurisdictional requirement was facially apparent given the claims made. The court disagreed with the defendant, but, looking to the plaintiff's initial settlement demand letter, which defendant had attached to its response in opposition to the remand motion, said it had met its burden of demonstrating that the jurisdictional minimum had been met.

The court acknowledged that the propriety of removal must be based on the removing documents. While plaintiff's $150,000 demand was not forwarded to the defendant until seven months after the case had been removed to federal court, the court determined that it "constitutes an effective amendment of American Suzuki's defective notice of removal." According to the court, "because there is nothing in the record to reflect, or even hint, that damages decreased between the time of removal and the tendering of the settlement letter, the letter provides post-removal clarification of the removal notice showing that the amount in controversy at the time of removal far exceeded the jurisdictional requirement."

The plaintiff defended his motion to remand by attaching a second settlement demand letter indicating that he sought only $70,000 to settle the case. The court decided to construe the second letter "as a post-removal waiver of a certain amount of damages in an effort to deprive this court of jurisdiction." Post-removal events do not oust the district court's jurisdiction; thus, the court denied plaintiff's motion to remand to state court.

< Back to Top

LEAD IN LIPSTICK ALLEGED IN CLASS ACTION LAWSUIT

According to a news source, L'Oreal SA and its U.S. subsidiary have been named as defendants in a putative class action alleging that they knowingly sold lipstick with hazardous levels of lead. *Frye v. L'Oreal SA, France*, 1:08cv00213 (U.S. Dist. Ct., N.D. Ill., filed January 9, 2008). The named plaintiff claims that she would not have purchased the product if she had known it contained hazardous amounts of lead. She apparently refers to testing undertaken in October 2007 by the Campaign for Safe Cosmetics showing that the company's lipstick had lead at levels of .65 and .58 parts per million (ppm). The U.S. Food and Drug Administration (FDA) has approved lead levels of .01 ppm for candy. The complaint alleges that lipstick is ingested by women when they lick their lips or eat and that lipstick is accessible to children, who sometimes apply their mothers' cosmetics. Plaintiff seeks a court order barring L'Oreal from selling the products, reimbursement for the products, and actual damages, statutory damages and punitive damages. The suit alleges violations of consumer protection laws, breach of implied warranty, negligence, and unjust enrichment. A company spokesperson was quoted as saying, "L'Oreal is in full compliance with FDA regulations as well as the EU Cosmetic Directive and the requirements for safety in the more than 130 countries in which our products are sold. We intend to vigorously defend our products in this lawsuit." *See Product Liability Law 360*, January 11, 2008.

< Back to Top

The complaint alleges that lipstick is ingested by women when they lick their lips or eat and that lipstick is accessible to children, who sometimes apply their mothers' cosmetics.

ANALYSTS LINK PUNITIVE DAMAGES RULING TO DECLINES IN AWARDS

According to some analysts and lawyers, the U.S. Supreme Court's decision in *Philip Morris USA v. Williams*, No. 05-1256 (2007), which held that juries may not punish defendants for conduct involving parties not before the court, has resulted in a reduction in punitive damages awards in the United States. From a high of $5 billion in 2005, the largest punitive damages verdicts have apparently fallen or been reduced on appeal to $1.6 billion in 2007. Plaintiff's attorneys are reportedly changing their trial approach in light of the Court's ruling and are even taking fewer cases. A lawyer with Lieff, Cabraser, Heimann & Bernstein in San Francisco was quoted as saying, "The major effect is on a case with small damages, but large potential punitives. You're much less likely to take it." *See Bloomberg.com*, January 15, 2008.

< Back to Top

Shook, Hardy & Bacon L.L.P.

SCIENTISTS CALL FOR COURTS TO ALLOW MORE EVIDENCE INTO TRIAL

According to a *Science News* article, scientists meeting recently under the auspices of Georgetown University's Project on Scientific Knowledge and Public Policy (SKAPP) considered how the courts have been dealing with expert evidence since the U.S. Supreme Court ruled in 1993 that courts must perform a gatekeeping role and keep "junk science" out of the courtroom. Apparently, a number of scientists are concerned that research prompted by litigation is almost automatically given short shrift by judges, while industry-sponsored research, which could be as affected by bias, is typically admitted with little question.

This article discusses the relative merits of independent research and research funded by industry or by tort plaintiffs. According to SKAPP scientists, pre-litigation, industry-funded science can "serve the same purpose and work in the same way" — supporting litigation — as "plaintiff-funded, tort-triggered research." They caution the courts not to use *a priori* rules to exclude certain types of evidence, urging them instead to allow juries to consider all pertinent and available evidence. As long as experts disclose their potential biases and conflicts of interest, scientists believe that cross-examination will adequately expose any weaknesses, flaws or nuances in the data and their interpretation. *See Science News*, January 19, 2008.

< Back to Top

As long as experts disclose their potential biases and conflicts of interest, scientists believe that cross-examination will adequately expose any weaknesses, flaws or nuances in the data and their interpretation.

VIOXX® SETTLEMENT TAKES ANOTHER STEP FORWARD

U.S. District Judge Eldon Fallon reportedly held a status conference January 19, 2008, to determine whether sufficient numbers of claimants had met a deadline and signaled their intent to settle their personal injury claims against Merck & Co., which made the anti-inflammatory drug Vioxx®. More than 95 percent have apparently agreed to register their cases, and plaintiffs' attorneys, who were concerned that the settlement would conflict with their professional obligations, have withdrawn their objections. An amendment to the settlement reportedly states, "Each Enrolling Counsel is expected to exercise his or her independent judgment in the best interest of each client individually before determining whether to recommend enrollment in the Program." Those claimants who have agreed to enroll must submit releases and medical records by February 29. If less than 85 percent complete the process, the deal will fail. *See The Wall Street Journal*, January 19, 2008.

< Back to Top

ALL THINGS LEGISLATIVE AND REGULATORY

Senators Propose Banning Education "Junkets" for Judges

U.S. Senators Jon Kyl (R-Ariz.) and Russ Feingold (D-Wis.) have reportedly circulated a draft amendment to a bill on judicial salaries that would prohibit judges from attending any educational program hosted by organizations other than the federal government or judicial and bar association groups.

Shook, Hardy & Bacon L.L.P.

The compensation bill, titled the "Federal Judicial Salary Restoration Act," which could raise judicial salaries by more than $50,000, is currently pending before the Senate Judiciary Committee. The proposed amendment would also apparently place limits on gifts, defined to include travel expenses and accommodations, exceeding $1,500 for a single trip or $5,000 annually. While the U.S. Judicial Conference apparently supports judges attending educational seminars regardless of sponsoring organization as long as disclosure requirements are met, public interest groups have long been critical of such practices. The latter believe that a bill giving judges substantial raises provides "a perfect opportunity to do something about this." *See Daily Journal*, January 16, 2008.

While the U.S. Judicial Conference apparently supports judges attending educational seminars regardless of sponsoring organization as long as disclosure requirements are met, public interest groups have long been critical of such practices.

Cosmeceutical Makers Walk Fine Regulatory Line

Cosmetics manufacturers looking to cash in on baby boomers' quest for the fountain of youth are reportedly exercising care not to cross the line into making product claims that will subject them to Food and Drug Administration (FDA) regulations applicable to drugs. Thus, they advertise skin formulations as effective in reducing "the appearance" of wrinkles rather than claiming their products will reduce wrinkles. Drugs are subject to more stringent regulatory controls and take longer to get to market. A cosmetic product marketed as a drug will prompt an FDA warning letter or even confiscation, if the product actually contains a drug. Regulatory enforcement actions often lead to product liability litigation, according to those who focus their law practices on products liability. Such lawsuits are expected to increase as the "cosmeceutical" industry continues to grow. *See Portfolio Media*, January 14, 2008.

< Back to Top

LEGAL LITERATURE REVIEW

Catherine Sharkey, "Products Liability Preemption: An Institutional Approach," *George Washington Law Review* (forthcoming 2008)

New York University School of Law Professor Catherine Sharkey analyzes product liability cases from the past 15 years and concludes that the courts tend to adopt agency positions on the preemptive effect of federal laws and regulations in cases involving state-law claims. Sharkey suggests that this deference should be openly acknowledged and urges the courts to adopt an agency reference model as part of its preemption jurisprudence. While the model is a clear departure from the traditional "presumption against preemption" approach used in the absence of express congressional direction, Sharkey contends that it would provide coherence and predictability to the law and guide both federal and state courts to optimal results in preemption cases. Her argument is premised on the belief that federal agencies are the players best able to assess whether public interests as to a specific product are better protected under a national regulatory scheme.

New York University School of Law Professor Catherine Sharkey analyzes product liability cases from the past 15 years and concludes that the courts tend to adopt agency positions on the preemptive effect of federal laws and regulations in cases involving state-law claims.

Shook, Hardy & Bacon L.L.P.

Howard Erichson, "CAFA's Impact on Class Action Lawyers," *University of Pennsylvania Law Review* (forthcoming 2008)

This article, which is part of a symposium, explores how the Class Action Fairness Act of 2005 (CAFA) affected the plaintiff's bar, the types of class actions that are filed and the courts that have become centers of class-litigation activity. According to Seton Hall School of Law Professor Howard Erichson, the law, which targeted plaintiff's lawyers, had the unintended effect of strengthening leading members of the plaintiff's bar and concentrating new forms of class litigation in federal courts most receptive to them. Erichson concludes, "If CAFA's proponents expected it to squelch class actions, the statute appears unlikely to achieve that goal. Similarly, if CAFA's proponents expected the statute to disempower the class action bar or its most powerful members, they are in for disappointment. But if the point was to deprive class action plaintiffs of their favorite state court forums and to reduce the franchise of class action lawyers with forum-dependent practices, then the statute appears to be succeeding."

According to Seton Hall School of Law Professor Howard Erichson, the law, which targeted plaintiff's lawyers, had the unintended effect of strengthening leading members of the plaintiff's bar and concentrating new forms of class litigation in federal courts most receptive to them.

Stephen Burbank, "The Class Action Fairness Act of 2005 in Historical Context: A Preliminary View," *University of Pennsylvania Law Review* (forthcoming 2008)

Law Professor Stephen Burbank places the Class Action Fairness Act within the context of federal diversity litigation and suggests that Congress enact amendments to the law to preserve the right of states to address purely local disputes. According to Burbank, the law represents an affront to federalism in two respects: first, by depriving states of the ability to regulate matters of intense local interest "on the basis of a definition of national interest that rests on legal fictions," and second, by doing so with "exceptions so complicated that even some academics have been unable to penetrate them." Burbank claims that "Congress has created incentives for litigants and courts to create ever bigger 'litigations.' Whether in the form of multistate class actions or through non-class aggregations, such litigation packages may replicate in federal court some of the supposed abuses in state court class actions to which CAFA supposedly responded, including the subordination of factual and legal differences of intense interest to individual states."

< Back to Top

LAW BLOG ROUNDUP

MLK and the Fairness of Preemption?

"If you're looking for the most strained use of Martin Luther King, Jr., as a metaphor, look no further than a non sequitur at Bizarro-Overlawyered, where Kia Franklin calls on King's memory as an argument against preemption." Ted Frank, attorney and director, American Enterprise Institute Liability Project, commenting on statements in the TortDeform blog about how Dr. King's vision is reflected in the work of those fighting for civil justice and against corporate privilege.

Overlawyered.com, January 21, 2008.

FDA Proposes Preemption Friendly Regulatory Initiative

"Since plaintiffs argue that CBE [Changes Being Effected regulations for drugs] lets manufacturers make any changes they want [to product labeling], the regulatory amendment will restrict this argument (the most potent plaintiffs have) to new or significantly increased risks supported by adequate scientific evidence – eliminating it from cases where FDA's already reviewed essentially the same evidence." Attorneys James Beck and Mark Herrmann, blogging about a Food and Drug Administration (FDA) proposal that will restrict the ability of manufacturers to make label changes without FDA approval. FDA states that the proposal simply codifies longstanding agency policy and has a preemptive effect on state law. 73 Fed. Reg. 2848 (January 16, 2008).

Drug and Device Law Blog, January 15, 2008.

< Back to Top

THE FINAL WORD

David Vladeck, "The Emerging Threat of Regulatory Preemption," *American Constitution Society White Paper*, **January 2008**

Georgetown University Law Center Professor of Law David Vladeck argues that the Bush Administration's practice of placing preemption statements into "lengthy and obscure preambles in *Federal Register* notices" related to agency regulatory initiatives "is neither transparent nor democratic" and insulates "big business from tort litigation … as a matter of federal policy." Vladeck further contends that these practices raise questions about separation of powers. The white paper discusses specific regulatory initiatives undertaken by the Food and Drug Administration, the National Highway Traffic Safety Administration, the Consumer Product Safety Administration, and the Federal Railroad Administration that purport to preempt the remedies provided under state tort law. According to Vladeck, (i) "none of the statutes the agencies administer explicitly bars tort claims," (ii) "in arguing in favor of obstacle preemption, agencies disregard the benefits that flow from traditional tort litigation," and (iii) "agency decisions to extinguish common law remedies are not made in a transparent way." Claiming that "[p]reemption decisions are simply too important to entrust to unelected and largely unaccountable senior political appointees, many of whom will simply return via the revolving door to the industry that they have overseen during their brief tenure in government," Vladeck concludes "The loser will be the tens of thousands of Americans injured through no fault of their own but who will no longer have any means of redress."

< Back to Top

"The loser will be the tens of thousands of Americans injured through no fault of their own but who will no longer have any means of redress."

UPCOMING CONFERENCES AND SEMINARS

GMA, The Association of Food, Beverage and Consumer Products Companies, New Orleans, Louisiana – February 19-21, 2008 – "2008 Food Claims & Litigation Conference: Emerging Issues in Food-Related Litigation." Shook, Hardy & Bacon Product Liability Litigation Partner **Laura Clark Fey** and

Shook, Hardy & Bacon L.L.P.

Pharmaceutical & Medical Device Litigation Partner **Paul La Scala** will discuss "Product Liability When There Is No Injury: The Deceptive Trade Practices Class Action. Shook, Hardy & Bacon is co-sponsoring this event.

DRI, New Orleans, Louisiana – May 1-2, 2008 – "Drug and Medical Device Seminar," Shook, Hardy & Bacon Pharmaceutical & Medical Device Partner **Scott Sayler** will chair the program, and Pharmaceutical & Medical Device Litigation Partner **Marie Woodbury** will present a session titled "Crossing Borders and Seas – International Regulatory Events and Their Impact on United States-Based Litigations and Trials."

< Back to Top

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).

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000

Houston, Texas
+1-713-227-8008

Irvine, California
+1-949-475-1500

Kansas City, Missouri
+1-816-474-6550

London, England
+44-207-332-4500

Miami, Florida
+1-305-358-5171

San Francisco, California
+1-415-544-1900

Tampa, Florida
+1-813-202-7100

Washington, D.C.
+1-202-783-8400