Shook, Hardy & Bacon L.L.P.

# Product Liability Litigation Report

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## STATE COURT SENDS BRITISH CLAIMANTS HOME TO TRY VIOXX CLAIMS

A New Jersey court has dismissed claims filed by U.K. residents against the manufacturer of Vioxx® on *forum non conveniens* grounds. *In re Vioxx® Litigation,* No. 619 (N.J. Superior Ct., decided October 5, 2006). In so ruling, the court rejected plaintiffs' claims that U.K. courts are unavailable or inadequate to remedy their purported injuries. They based this contention on the U.K.'s "loser pays" system, the lack of contingency fee arrangements and the inability to sue for loss of consortium or to recover punitive damages. The court order dismissing the claims includes the provisos agreed to by defendant Merck that the company would (i) not contest service if sued in the United Kingdom, (ii) satisfy any final judgment rendered by a U.K. court, (iii) not raise the statute of limitation as a defense to any claims not so barred and already pending in a U.S. court, and (iv) not prevent plaintiffs from returning to the N.J. courts if the U.K. court declines to accept jurisdiction. A law blogger has recalled that news sources reported at the end of 2005 that legal aid and private market insurers have refused to fund such litigation in the United Kingdom. *See PointofLaw.com archives,* December 13, 2005.

< Back to Top

## PLAINTIFFS UNABLE TO SHOW LINK BETWEEN LEUKEMIA AND CHICKEN LITTER DUST

An Arkansas jury has returned a defense verdict on behalf of clients represented by Shook, Hardy & Bacon lawyers in a case involving claims that exposure to arsenical gases in chicken litter caused children to develop leukemia. *Green v. Alpharma, Inc.* (Washington County Circuit Court, Arkansas, jury verdict rendered Sept. 26, 2006). The gases are apparently the by-product of a drug, made by defendants, used to control a parasite in broiler chickens. Plaintiffs claimed that the drug degraded into a harmful form of arsenic in chicken litter, which was spread as a fertilizer and also became airborne, carried into homes and schools as dust and gases. According to plaintiffs, children in the small town in which they lived developed leukemia at a higher than normally

*Contents*

expected rate. The defendants produced evidence that arsenic does not cause leukemia and that the levels of arsenic found in the house dust were no different than those in other homes that were not exposed to chicken litter. This case was the first of 158 that seek damages for cancer allegedly caused by exposure to the parasite drug. The next is set for trial in April 2007. Leading the successful defense effort were **Rob Adams**, **John Johnston** and **Steven Soden**.

< Back to Top

## SECOND CIRCUIT FINDS TRADITIONAL COMMON LAW CLAIMS NOT PREEMPTED BY FEDERAL DRUG LAW

"It has long fallen within the province of states to safeguard the health and safety of their citizens." So begins a Second Circuit Court of Appeals decision in a case involving injuries to Michigan residents allegedly caused by Rezulin.® ***Desiano v. Warner-Lambert & Co.*, Nos. 05-1705, 05-1743, 05-1745 (2d Cir., decided October 5, 2006)**. Ruling against the interests of the defendants, the court determined that the Michigan plaintiffs' claims could be distinguished from the "fraud-on-the-FDA" claims that the U.S. Supreme Court found to be impliedly preempted by federal law.

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The cases were initiated in Michigan and California state courts, removed to federal court and transferred by the Judicial Panel on Multidistrict Litigation to a federal judge in New York. Among the common law claims raised were breach of implied and express warranties, negligence, negligent misrepresentation, negligence *per se,* fraud, defective design, and defective manufacturing. Defendants sought judgment on the pleadings on the ground that liability was foreclosed under Michigan state law, which immunizes drugmakers in product liability suits where the Food and Drug Administration (FDA) has approved the drug in question. An exception to the rule, however, allows suit if the defendant intentionally withholds information from or otherwise makes misrepresentations to the FDA about the drug that would have altered the FDA's decision to approve the drug. Defendants claimed that the "fraud" exception in Michigan's law is impliedly preempted by the Food, Drug and Cosmetic Act and the Medical Device Act and should be severed from the rest of the state statute. Giving special deference to a Sixth Circuit decision that interpreted Michigan state law, the district court agreed with the defendants and dismissed the claims.

The court of appeals determined that such deference is required only where the sister circuit addresses an issue of state law; because this case involved "significant issues of federal law," the court did not feel constrained by the Sixth Circuit's decision except to the extent that it ruled the Michigan exception to immunity does not create a new cause of action for misleading the FDA. The court turned to *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001), which involved the federal preemption of "fraud-on-the-FDA" claims, and distinguished the Michigan exception from such claims on the grounds that (i) it cannot be characterized as a state's attempt to police fraud against the FDA, (ii) the plaintiffs are asserting claims that sound in traditional state tort law and are not pressing "fraud-on-the-FDA" claims, and (iii) proof of fraud against the FDA is not an element of the products liability claims alleged, but only arises should the defendants raise FDA compliance as an affirmative defense. According to the

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court, "Finding preemption of traditional common law claims where fraud is not even a required element – but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law – would result in preemption of a scope that would go far beyond anything that has been applied in the past." The court reversed the district court and remanded the case for further proceedings.

< Back to Top

## FDA PREEMPTION ISSUE CERTIFIED TO FEDERAL APPEALS COURT IN ANTI-DEPRESSANT SUIT

A federal district court in New Jersey has stayed proceedings in a products liability case alleging that the anti-depressant drug Zoloft® caused the suicide of plaintiff's decedent. *McNellis v. Prizer, Inc.,* No. 05-1286 (U.S. District Court, New Jersey, decided Sept. 29, 2006). The court had earlier denied Pfizer's motion for summary judgment, which sought dismissal of the claims on federal preemption grounds, finding that if the plaintiff could prove that Pfizer had "reasonable evidence of an association of a serious hazard with a drug" before decedent's death, then the enhanced warning she sought would not be preempted. Pfizer asked the court to vacate that order or certify the issue for interlocutory appeal, claiming that it had new evidence as to the meaning of applicable regulations in the form of a preamble to a Food and Drug Administration (FDA) final rule issued since the court had ruled on its preemption defense.

According to the court, despite the fact that the preamble simply repeats what the agency had argued to the court in *amicus* briefing, it is new evidence and constitutes "an official agency statement purporting to establish preemption of conflicting state law claims." Nevertheless, the court refused to reverse its earlier ruling, stating it would give less deference to the agency's interpretation because "the FDA's position regarding the preemptive force of its regulations has not been consistent." In this regard, the court observed, "the 2006 Preamble was a novation, not subjected to prior public notice or comment while inverting the agency philosophy standing behind the regulations when proposed in 2000.…the abrupt rejection of the agency's own prior interpretation (while the regulations themselves are unchanged) suggests a degree of informality yielding an interpretation unhinged from the text and original intent of the regulations themselves."

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The court noted that the statute does not contain express preemptive language and that requiring a drug manufacturer to strengthen its warnings does not conflict with federal law. The court also found that the "Preamble's words are in irreconcilable tension with the Final Rule itself" and cannot be enforced to nullify the regulations that the preamble purports to interpret. Yet, the court decided to certify the question for consideration by the Third Circuit Court of Appeals because it presented a "controlling question of law" as to which there were "substantial grounds for a difference of opinion" and "resolution of the issue to be appealed will materially advance the termination of the litigation." Because further discovery was required for the plaintiff to advance her cause, the court determined that it would better serve the interests of justice to have the issue decided now.

< Back to Top

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## THIRD CIRCUIT JOINS OTHERS TO REWRITE CAFA

The Third Circuit Court of Appeals has decided that requiring an appeal to be filed "not less than 7 days after entry of the order" is a typographical error and that what Congress meant to say was "not *more* than 7 days after entry of the order." ***Morgan v. Gay*, No. 06-8045 (3d Cir., decided October 16, 2006)**. The requirement, which appears in the Class Action Fairness Act (CAFA), allows a party to seek review of a district court's decision granting or denying a motion to remand a class action to the state court from which it was removed. Characterizing instances where clear legislative intent is at odds with the literal terms of a statute as "rare," the court joined the Ninth, Tenth and Eleventh Circuits in rejecting an interpretation of the statute that would "impose a seven-day waiting period followed by a limitless window for appeal." The issue arose in a case filed by skin cream purchasers in New Jersey who allege false advertising and other claims.

< Back to Top

## TORT REFORMS TURN TIDE AGAINST QUESTIONABLE CLASS ACTIONS

Class action litigators and bar researchers are reportedly finding that a coordinated tort reform campaign that has produced caps on damages, changes to certification and jurisdiction requirements and judicial suspicions about the quality of expert opinions has had its intended effect, i.e., fewer class action cases filed and more claims dismissed. According to Shook, Hardy & Bacon Public Policy Group Partner **Mark Behrens**, "Plaintiffs will continue to bring good cases, but defendants have learned the lesson that if you make the plaintiffs' lawyers work hard and put up barriers, a lot less junk cases are going to get filed." The article in which Behrens is quoted discusses the effects of tort reform nationwide, particularly in the asbestos and silica exposure arenas, and notes that while individual reforms are modest, the rhetoric may have had more of an impact. One commentator contends that rhetoric alone is "shriveling the tort system." *See National Law Journal Online,* October 9, 2006.

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< Back to Top

## *DAUBERT* STANDARDS COMMITTEE ISSUES REPORT

The Committee on *Daubert* Standards, under the auspices of the National Research Council of the National Academies, has issued a **report** summarizing the issues raised during meetings held in 2005 to consider the impact of *Daubert* and its progeny on court decisions and identify questions for future study. The report provides an overview of the U.S. Supreme Court's decisions on the admissibility of expert testimony, observing that the decisions "have led to increasing attention on the part of judges to scientific and technical issues." According to the committee, judges are tending to admit expert testimony less often as they exercise their "gatekeeping" function, and many believe that this has improved the quality of scientific evidence being presented in the courtroom.

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Among the questions raised by the committee are "whether there is sufficient recognition of minority views in science," and "whether judges, by excluding too much evidence, are intruding on the constitutional role of the jury to resolve disputed facts." The committee also suggests that further study be made of the differences between scientific and legal approaches to issues and whether more can be done to enhance scientific understanding among legal professionals. Those serving on the committee include Margaret Berger, who has contributed chapters to the Federal Judicial Center's Reference on Scientific Evidence, Wisconsin Supreme Court Chief Justice Shirley Abramson, law professors, practitioners, and scientists. Among those asked to review the report before its recent release was Shook, Hardy & Bacon's **Mark Behrens**.

< Back to Top

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## LEGAL LITERATURE REVIEW

**Suzanna Sherry, "Logic Without Experience: The Problem of Federal Appellate Courts," 82 *Notre Dame L. Rev.* (2006)**

Vanderbilt University Law Professor Suzanna Sherry suggests that populating the federal appellate bench with individuals who lack district court experience has resulted in a court system that is broadening federal jurisdiction while at the same time giving trial judges less discretion. The dual trends are producing a serious misallocation of judicial resources, according to Sherry. She contends that the jurisdictional expansion trend "is worrisome because the Court has not acknowledged – much less explained – its change of direction. As a result, the new rules are often unclear and inconsistent with existing precedent, leaving lower courts with little guidance." She discusses several U.S. Supreme Court decisions to illustrate her thesis, including *Cent. Va. Cmty. Coll. v. Katz,* 126 S. Ct. 990 (2006); and *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.,* 545 U.S. 308 (2005). "Diminishing trial court discretion," she claims, "affects docket management, reduces courts' ability to police the behavior of lawyers and litigants, and harms the relationship between state and federal judicial systems."

**H. Hunter Twiford, et al., "CAFA's New Minimal Diverstiy Standard for Interstate Class Actions Creates a Presumption that Jurisdiction Exists, with the Burden of Proof Assigned to the party Opposing Jurisdiction," 25 *Mississippi College L. Rev.* (2006)**

Written by practitioners who edit a law blog on the Class Action Fairness Act of 2005 (CAFA), this article concludes that, "correctly interpreted," CAFA, which is silent as to who bears the burden of establishing the existence or non-existence of minimal diversity jurisdiction, places that burden on the party opposing jurisdiction. The authors contend that some courts are getting this wrong by overlooking section 2 of the Act, which addresses Congress's findings and purposes. And in the class action context, according to the authors, "where the stakes are very high, the outcome of motion practice to determine whether the case proceeds in federal or sate court can have enormous implications for both parties."

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**Christopher Drahozal and Laura Hines, "Secret Settlement Restrictions and Unintended Consequences." *Kansas L. Rev.* (forthcoming)**

University of Kansas Law Professors Christopher Drahozal and Laura Hines suggest that restrictions on secret settlements, which can be circumvented by forum shopping, pre-litigation settlement or resort to arbitration, "may have the unintended consequence of doing exactly the opposite," i.e., decreasing public access to information about alleged health and safety hazards. While they do not take a position on whether such access confers a benefit on society, they offer empirical data and analysis to allow "policymakers [to] make a reasoned choice among the different policy options."

< Back to Top

## LAW BLOG ROUNDUP

### They're Mad as … and Aren't Going to Take it Anymore

"The large company isn't just sitting around providing target practice for Motley Rice & Co. and the local-government entities it enlists as plaintiffs in its suits; it's filing preemptive litigation…" Walter Olson, writer and senior fellow at the Manhattan Institute, reporting on lawsuits that Sherwin-Williams Co. is filing to enjoin state courts on constitutional grounds from considering suits seeking damages for the use of lead-based paints in houses in Ohio cities in past decades.

pointoflaw.com, October 9, 2006

A Michigan lawyer who blogs under the name Camera Lucida commented in this regard, "I find it refreshing that a company has considered that the 14th Amendment might actually be available to provide some relief to the tyrannical use of litigation in state courts to challenge the sale of products which were legal, beneficial and sold in conformance with all state and Federal regulations at the time they were sold and applied."

cameralucida.wordpress.com, October 8, 2006

### Scholars Call for Access to Science Sequestered in Litigation

"'Sequestered science' is scientific knowledge concealed from the public. Since science is built on the sharing of information, decisions to sequester data can hinder advancement in research and place public health in jeopardy. Legitimate claims to secrecy – to preserve national security, investment value or individual confidentiality – must be weighed against their costs." A scientific blog, discussing *Duke Law Review* articles on the tradeoffs involved in decisions to sequester science in litigation. Among the recommended tools to provide access to such information are (i) establishing a "register of studies, made suitably anonymous, conducted pursuant to products liability or environmental damage lawsuits," (ii) using clinical trial registries as part of FDA's drug approval process to provide public access to study data, and (iii) barring judges from enforcing confidentiality agreements between plaintiffs and defendants.

defendingscience.org, October 10, 2006

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**How to: Finance the Costs of Litigation**

"Esquire Bank opened its doors last week in Brooklyn, N.Y., claiming to be the first bank in the country to specialize in serving trial lawyers. [Bank investor and plaintiffs' litigator Richard Bieder reportedly said,] "We need loans to keep moving a case forward, to hire experts, to help us through the ups and downs of law firms. That's what titillates me about this idea." *Wall Street Journal* reporter Peter Lattman, discussing a new development in personal injury litigation.

wsj.com, October 10, 2006

< Back to Top

## THE FINAL WORD

Israel's Supreme Court has reportedly struck down a damages award that included the cost of future weekly visits with a prostitute. The plaintiff, who had been injured in a traffic accident, apparently claimed that his sexual function had been impaired and that prostitutes provided his only successful outlet. A Tel Aviv district court, following local practice, allowed the cost as part of his continuing "medical care." According to a blogging member of Israeli and U.S. law faculties, "The practice, however, has ended. Henceforth, per Justice Rivlin, Israeli courts should limit their rulings to compensating for services that can be legally obtained.…The Court left open the question of whether sexual surrogate services can be compensated." *See prawfsblog.com*, October 16, 2006.

< 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, and food 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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### 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, United Kingdom**
+1-44-207-332-4500

**Miami, Florida**
+1-305-358-5171

**Overland Park, Kansas**
+1-913-451-6060

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

**Tampa, Florida**
+1-813-202-7100

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