Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

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U.S. SUPREME COURT ISSUES 4-4 AFFIRMANCE IN DIABETES DRUG CASE

The U.S. Supreme Court has affirmed a Second Circuit Court of Appeals ruling allowing state-law claims to proceed against the manufacturer of a diabetes drug. ***Warner-Lambert Co. v. Kent*, No. 06-1498 (U.S., decided March 3, 2008)**. The plaintiffs, 27 Michigan residents who claimed that Rezulin® caused their liver damage, brought suit under a state statute that bars personal injury cases against drug makers unless plaintiffs can show the companies deliberately withheld information that would have led the Food and Drug Administration to deny approving the drug at issue. The Court's 4-4 ruling has no precedential value, and it was issued without opinion. The defendant argued that federal law preempts state-law claims against pharmaceutical companies.

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VIETNAM ERA CLAIMS AGAINST DEFOLIANT MANUFACTURERS DISMISSED

The Second Circuit Court of Appeals has affirmed the dismissal of personal injury claims filed by Vietnam War veterans and their families against the makers of Agent Orange, a defoliant used during that conflict. ***In re "Agent Orange" Prod. Liab. Litig.*, No. 05-1509 (2d Cir., decided February 22, 2008)**. The court also dismissed the putative class claims of Vietnamese nationals, finding that they had failed to state a cognizable claim under the Alien Tort Statute (ATS). ***Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, No. 05-1953 (2d Cir., decided February 22, 2008)**.

The war veterans were unable to recover under a settlement the manufacturers reached in 1984 with previous litigants because those who filed later did not discover their alleged injuries before the 1994 cut-off date. While the veterans' claims included allegations of manufacturing and design defects as well as failure to warn, the only issue before the appeals court was whether the government contractor defense applied to their design defect claim. Finding that it did, the appeals court affirmed the trial court's grant of defendants' motion for summary judgment.

As to the Vietnamese nationals' claims, the court rejected their argument that "the deployment of Agent Orange violated customary norms prohibiting the use of 'poisoned weapons' and the infliction of unnecessary suffering." According

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to the court, the various sources of international law on which plaintiffs relied do not constitute a universally accepted norm prohibiting the wartime use of the chemicals, because they were used as defoliants "and not as a poison designed for or targeting human populations." Because plaintiffs "do not allege, nor could they on this record prove, the required mens rea, they fail to make out a cognizable basis for their ATS claim."

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FEDERAL COURT ORDERS DISCLOSURE OF PAYMENTS TO SCIENTIFIC TREATISE AUTHORS

A federal court in Ohio has determined that information about the authors of scientific articles related to alleged links between exposure to welding fumes and certain neurological disorders is not protected by the work-product doctrine and must be produced to the plaintiffs. *In re: Welding Fume Prods. Liab. Litig.*, MDL NO. 1535 (U.S. Dist. Ct., N.D. Ohio, Eastern Div., decided February 19, 2008). During discovery, the parties disclosed payments to authors of articles and studies that would be relied on by their experts; the defendants reported 49 payees and payments in excess of $11 million, while plaintiffs reported 12 payees and payments of about $520,000. The defendants produced a chart to the special master for *in camera* review detailing 16 payees and more than $1.7 million in additional payments, but claimed the information in this chart was protected from disclosure to plaintiffs under the work-product doctrine.

The court noted the significance the parties had accorded to scientific literature in this litigation and discussed how such material can be quoted and cited in the courtroom under an exception to the hearsay rule that assumes the authors of learned treatises have "no bias in a particular case." Given the "magnitude of the financial incentives" for a number of the authors relied on in this litigation, the court also noted that it could have excluded any reference to them "altogether." The court decided not to do so, however, believing that "disclosure of possible financial bias coupled with cross-examination by the parties is a more appropriate and fine-tuned mechanism for arriving at the truth."

As to the work-product doctrine, the court discussed a split among the federal courts over whether Rule 26(b)(4)(B) of the Federal Rules of Civil Procedure excludes from disclosure identifying information about experts retained in anticipation of litigation but not expected to be called as witnesses at trial. The court found the line of cases allowing disclosure more persuasive, but concluded that exceptional circumstances existed in this case to allow disclosure regardless of the rule applied. "Having decided to allow the defendants to use these articles at trial," stated the court, "simple fairness calls for allowing the plaintiffs to discover possible sources of bias. Indeed, it would be an extraordinary circumstance to allow admission of these learned treatises based on the premise that the authors 'have no bias in any particular case,' and then *not* allow plaintiffs to discover known evidence that could be used to suggest the contrary."

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OHIO HIGH COURT UPHOLDS LAW PLACING TIME LIMITS ON SUITS AGAINST PRODUCT MANUFACTURERS

Answering questions certified to it by a federal court, the Ohio Supreme Court has upheld the validity of a "tort-reform" law adopted in 2005 that bars

product users from filing suit against the manufacturer for any product-related injury that occurs more than 10 years after the product is delivered by the manufacturer to the end user. ***Groch v. General Motors Corp.*, No. 2008 Ohio 546 (Ohio, decided February 21, 2008)**. The case involved a factory worker who was injured in March 2005, about a month before the tort-reform law became effective, when his right arm and wrist were injured in a trim press. He filed suit after the law's effective date in state court against his employer and the manufacturers of the trim press, and the case was removed to federal court. The manufacturers argued that they were immune from liability under the new law because the press had been delivered to the workplace more than 10 years before the injury occurred, and the federal court sought rulings from the Ohio Supreme Court as to its constitutionality.

In a 6-1 decision, the court ruled that the law withstood challenges based on claimed infringements of the right to open courts, due process, equal protection, a remedy for injuries, and to protection from an unlawful taking. Nevertheless, the court ruled that the tort-reform law could not apply retroactively to this plaintiff because he had a vested right before the law went into effect, and "because it provided [him] with only 34 days to commence [his] suit, with the consequence that [he] lost [his] cause of action if [he] did not file suit within 34 days." According to the court, plaintiffs have two years from the time of injury to file their products claims, and because this plaintiff filed within two years, his lawsuit was timely.

SHB Public Policy Partners **Victor Schwartz** and **Mark Behrens** filed an *amicus* brief supporting the constitutionality of the law on behalf of a number of interests, including the National Federation of Independent Business Legal Foundation, Chamber of Commerce of the United States of America, National Association of Manufacturers, and American Tort Reform Association.

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MIXED RESULTS REACHED IN SUITS CLAIMING AUTISM LINK TO THIMEROSAL IN KIDS' VACCINES

A trial court in Baltimore, Maryland, has reportedly granted the summary judgment motion filed by pharmaceutical company Wyeth in a case alleging that the thimerosal in childhood vaccines caused a youngster to become autistic. *Blackwell v. Sigma Aldrich, Inc.*, No. 24-C-04-004829 (Baltimore City Circuit Court, Maryland, decided February 19, 2008). Additional details about the court's December 2007 ruling excluding the testimony of plaintiffs' expert witnesses can be found in the January 10, 2008, issue of this Report. Lead counsel for Wyeth was quoted as saying that the decision represented "a significant victory for good science generally." Counsel for the plaintiffs has apparently indicated that they plan to file an appeal. *See Product Liability Law 360*, February 20, 2008.

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Meanwhile, in a decision hailed by autism advocates, the U.S. Court of Federal Claims reportedly issued a sealed decision in November 2007, concluding that another child's autism was linked to exposure to the mercury-based preservative. According to a **document** filed in the litigation by the Department of Justice and posted on the *Huffington Post Blog*, federal medical personnel reviewed the case and determined that compensation from the vaccine injury fund was appropriate after finding, "the facts of this case meet the statutory criteria for demonstrating that the vaccinations CHILD received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed

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her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder." *See Product Liability Law 360*, February 29, 2008.

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MDL PANEL CENTRALIZES SUITS AGAINST MANUFACTURERS OF DRUG INJECTED FOR MRI TESTING

The Judicial Panel on Multidistrict Litigation has transferred dozens of cases filed against the manufacturers of a dye used in patients undergoing magnetic resonance imaging (MRI) to a federal district court in Ohio for coordinated pretrial proceedings. ***In re: Gadolinium Contrast Dyes Prods. Liab. Litig.*, MDL No. 1909 (J.P.M.L., transfer order entered February 27, 2008)**. The Food and Drug Administration issued a public health advisory in 2006, warning that the dye could cause an incurable disease that thickens the skin and connective tissue, especially in patients with kidney problems. The 24 lawsuits filed in 13 federal districts that were consolidated will be joined by an additional 44 related, or "potential tag-along," actions. According to the court, the cases "share questions of fact arising out of the allegation that gadolinium based contrast dyes may cause nephrogenic systemic fibrosis in patients with impaired renal function." The panel rejected a defendant's assertions that the contrast agents at issue are not the same, a global MDL will impinge on the defendants' due process rights, there are too few actions to warrant MDL treatment as to some of the defendants, and alternatives to centralization are available. *See Product Liability Law 360*, February 29, 2008.

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HOME GADGETRY RETAILER BLAMES BANKRUPTCY ON LAW SUITS OVER AIR PURIFIERS

According to a news source, the Sharper Image, an upscale consumer gadget store, has filed for bankruptcy protection, citing class action litigation alleging that its Ionic Breeze® air purifier does more harm than good. The company has apparently been facing significant sales declines since 2004 and plans to sell its inventory and close nearly half of its retail stores. A San Francisco court has reportedly certified an air-purifier class-action suit against the company; similar litigation is pending in both state and federal courts in Florida. A federal judge rejected a proposed settlement agreement with class-action plaintiffs in October 2007, and the company's stock plummeted. *See Product Liability Law 360*, February 20, 2008.

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ALL THINGS LEGISLATIVE AND REGULATORY

Safety Commission Issues Proposed Flammability Standard for Residential Upholstered Furniture

The Consumer Product Safety Commission (CPSC) has issued a **notice of proposed rulemaking** that would establish flammability standards for residential upholstered furniture under the Flammable Fabrics Act. The agency will accept

public comments on the draft until May 19, 2008, and commenters are invited to present their views orally, but no public hearing has yet been scheduled. CPSC began looking at the issue in 1993 at the request of the National Association of State Fire Marshals and issued an advance notice of proposed rulemaking (ANPR) the following year. A second ANPR was issued in 2003 to expand the proceeding to address "ignition of upholstered furniture by both small open flames and by smoldering cigarettes." According to the notice, the proposed standard establishes two approaches for manufacturers: they can either have (i) upholstery cover material that complies with a prescribed smoldering ignition resistance test; or (ii) an interior fire barrier that complies with specified smoldering and small open flame ignition resistance. *See Federal Register*, March 4, 2008.

Public Citizen Explores CPSC Rulemaking Delays

The non-profit public-interest organization Public Citizen has published a **report**, titled "Held Back: Unfinished Consumer Product Safety Commission Rules, Class of 2007," that examines the history of a number of product safety rules that have yet to be finalized. According to the report, "the seven unfinished rules that the agency has worked on at least since 2004 – some dating to the 1990s – cover hazards that cause more than 900 deaths and more than $460 million in property losses annually." Public Citizen apparently believes that some of the delays can be attributed to limited resources and laws that encourage the Consumer Product Safety Commission (CPSC) to defer to voluntary industry standards. But, says the report, "the CPSC also appears simply to lack a sense of urgency." Public Citizen analyzes initiatives relating to upholstered furniture, bedclothes flammability, cigarette lighters, clothing textile standard amendments, bed rail strangulation, crib slat entrapment, and baby bath seats.

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Public Citizen criticizes the agency for relying on voluntary standards, noting that the law requires CPSC "to issue a formal pronouncement when it decides to 'rely on' a voluntary standard. But the agency has taken that legal step only twice in its history. In the hundreds of other cases in which the CPSC has deferred to voluntary standards, it has done so informally, leaving itself with no enforcement power whatsoever."

Gardiner Harris, "Justices Add Legal Complications to Debate on F.D.A.'s Competence," *The New York Times*, **February 21, 2008**

This article places the U.S. Supreme Court's ruling on medical device preemption in the context of recent reports which have concluded "that poor management and scientific inadequacies have made the [Food and Drug Administration] incapable of protecting the country against unsafe drugs, medical devices and food." The Court ruled in *Riegel v. Medtronic, Inc.,* No. 06-179 (U.S., decided Feb. 20, 2008), that common-law claims involving the safety and effectiveness of medical devices given pre-market approval by the Food and Drug Administration (FDA) are preempted under federal law.

According to at least one academic, citizens are now at the mercy of a government health agency incapable of protecting them and rules that prohibit them from seeking compensation in court when they are injured. Agency supporters contend that deference to the agency is better than allowing "unlearned, unscientific

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state juries second-guessing F.D.A.'s science-based decisions." An industry trade group representative was quoted as saying, FDA's "expert staff is most qualified to make such highly scientific and technical judgments." Plaintiffs' lawyers argue that companies will be less careful and patients will suffer without the threat of litigation.

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LEGAL LITERATURE REVIEW

Brian Galle & Mark Seidenfeld, "Admin Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power," *Duke Law Journal* (forthcoming 2008)

Authored by Florida State University College of Law professors, this article examines the roles of Congress, the courts and federal agencies in making determinations about when federal law should preempt state regulation. Arguing that agencies can be more democratic and deliberative than Congress and "are usually a better forum for resolving questions of the state-federal balance," the authors contend that they should be permitted to "preempt or regulate without the need for express congressional approval." They conclude that if they are correct about which entities can best make preemption decisions, "then the critical – and so-far neglected – question the Court ought to face is how it can best promote some kind of executive role in reviewing state burdens on national and international trade."

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LAW BLOG ROUNDUP

Stock Ownership and U.S. Supreme Court Justice

"The tie brought one fat tear to our eye. A tie? Ah, the wasted time! Attorney fees! This sad little per curiam order! And we wonder. Did it have to be like this?" *Wall Street Journal* reporter Ashby Jones, blogging about the U.S. Supreme Court's 4-4 affirmance in a drug preemption case that was deadlocked because Chief Justice John Roberts held stock in the defendant's parent company and recused himself from considering it. Law bloggers are calling for the jurists to just sell their stock if certiorari is granted in a given case.

WSJ Law Blog, March 3, 2008.

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An Accurate Portrayal of Big-Firm Lawyers? We Hope Not.

"[T]he picture of the typical New York firm in *Michael Clayton* is so much more accurate than in common tv fare that lay audiences might think the film is inaccurate for its failure to conform to their Perry Mason/LA Law/Law & Order/Boston Legal-inspired mental image." Columbia Law Professor Michael Dorf, musing about the award-winning film starring George Clooney. He notes that hit men are called in to kill the class-action opponents of the corporate defendant and that a top litigator at defendant's law firm breaks down because he finds documents damaging to the client's position.

Dorf on Law, March 2, 2008.

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THE FINAL WORD

"Lawsuit Inc.," *The Wall Street Journal,* **February 25, 2008**

Questioning whether state attorneys general (AGs) should be allowed to hire "for-profit tort lawyers" to file their lawsuits, this article suggests that the profits gained from such outsourcing are being funneled back to the AGs to help finance their election campaigns. The article focuses on Mississippi's attorney general who has contracted, on a contingency fee basis, with 27 firms to serve as outside counsel in 20 state lawsuits filed over a period of five years against major corporations. Apparently, all 27 firms or their partners "made $543,000 in itemized campaign contributions to [the AG] over the past two election cycles." The article concludes "if this kind of sweetheart arrangement existed between a public official and business interests, you can bet [Mississippi's AG] would be screaming about corruption…. A decision to prosecute is an awesome power, and it ought to be motivated by evidence and the law, not by the profit motives of private tort lawyers and the campaign needs of an ambitious Attorney General."

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UPCOMING CONFERENCES AND SEMINARS

Food & Drug Law Institute (FDLI) & FDA, Washington, D.C. – March 26-27, 2008 – "FDLI's 51st Annual Conference," Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Madeleine McDonough** will serve on a panel discussing "Clinical Trials: Developments in Human Subject Protection." Other confirmed speakers include U.S. Supreme Court Justice Antonin Scalia, and Food & Drug Administration Commissioner Andrew von Eschenbach.

American Bar Association, Phoenix, Arizona – April 9-11, 2008 – "2008 Emerging Issues in Motor Vehicle Product Liability Litigation," Shook, Hardy & Bacon Tort Partner **H. Grant Law** will make opening remarks and moderate a panel discussion about issues that manufacturers must address when they evaluate the claims filed against them. Shook, Hardy & Bacon Class Actions and Complex Litigation Partner **Tammy Webb** will discuss "Recent Trends in Automotive Class Actions."

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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).

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