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Product Liability Litigation Report

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U.S. SUPREME COURT TO REVIEW PUNITIVE DAMAGES IN SMOKER LITIGATION FOR THIRD TIME

The U.S. Supreme Court has granted the petition for *certiorari* filed by Philip Morris USA Inc. from the Oregon Supreme Court's refusal to disturb a punitive damages award nearly 100 times the compensatory damages in a smoking and health lawsuit. *Philip Morris USA Inc. v. Williams*, No. 07-1216 (U.S., *cert*. granted June 9, 2008). According to a "liveblog" feed posted on *SCOTUS Blog*, the Court has limited its grant to the first question presented which relates to a procedural issue. Thus, it would appear that the U.S. Supreme Court will not address whether the award was "grossly excessive" under the U.S. Constitution's Due Process Clause.

In January 2008, the Oregon Supreme Court upheld a $79.5 million punitive damages award against the cigarette manufacturer, justifying it on grounds other than those that caused the U.S. Supreme Court to twice overturn it (the Court's second reversal and remand established the principle that juries may not use a punitive damages verdict to punish a defendant for harm allegedly caused to parties not before the court). The state high court ruled that the trial court did not err in refusing to give the multi-page punitive damages instruction that Philip Morris proffered because it contained both correct and incorrect statements of the law. Further details about the state court's decision appear in the February 7, 2008, issue of this Report. *See SCOTUSblog*, June 9, 2008.

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SOLICITOR GENERAL SUPPORTS WYETH'S FDA PREEMPTION ARGUMENT BEFORE U.S. SUPREME COURT

The U.S. Solicitor General has filed the government's *amicus* brief in a case appealed to the U.S. Supreme Court from Vermont, seeking the reversal of a $7 million judgment for a woman allegedly injured by a prescription drug manufactured by Wyeth Pharmaceuticals, Inc. and a state court order that the company modify the drug's label to address the risk of gangrene from an intravenous injection of its anti-nausea medication. *Wyeth v. Levine*, No. 06-1249 (U.S., *amicus* brief filed June 5, 2008). Supporting Wyeth's position, the federal government argues that the Food and Drug Administration's approval of a

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prescription drug preempts state-law product liability claims. The brief relies in large part on the U.S. Supreme Court's recent ruling on medical device preemption and notes that the FDA weighs the health risks and benefits of drugs as labeled and has been made aware of any relevant risks. According to the brief, "Because FDA's approval strikes a balance between competing considerations, state laws that strike a different balance conflict with FDA's determination and are impliedly preempted."

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DOCUMENTS LOSE PRIVILEGE FOR PARTY'S FAILURE TO TAKE REASONABLE PRECAUTIONS TO PREVENT DISCLOSURE

A federal court in Maryland has determined that 165 documents inadvertently given to an opponent during e-discovery in a patent dispute were not protected by the attorney-client privilege or work-product protection because the company claiming the privilege took insufficient precautions to prevent their production. *Victor Stanley, Inc. v. Creative Pipe, Inc.*, No. 06-2662 (U.S. Dist. Ct., D. Md., decided May 29, 2008). The parties had negotiated a protocol for the review and production of electronically stored information (ESI) and, because the court extended the discovery period, defendants decided not to obtain a clawback agreement as to the potential inadvertent disclosure of privileged material, instead committing to an individualized document review.

When plaintiff's counsel reviewed defendants' ESI production, they found potentially protected documents and immediately notified defendants' counsel who responded by asserting that the production of any privileged or protected information had been inadvertent. On the basis of the affidavits filed in a dispute over the documents' protected status, the court found that the defendants had produced to the plaintiff (i) all the text-searchable ESI files that were identified as non-privileged by the keyword search that a computer forensics expert performed, and (ii) all the non-text searchable files that, following defendant and counsel's limited title-page search, were determined not to be privileged.

According to the court, "the Defendants are regrettably vague in their description of the seventy keywords used for the text-searchable ESI privilege review, how they were developed, how the search was conducted, and what quality controls were employed to assess their reliability and accuracy. While it is known that … a party and … [its] attorneys selected the keywords, nothing is known from the affidavits provided to the court regarding their qualifications for designing a search and information retrieval strategy that could be expected to produce an effective and reliable privilege review." The court further noted, "all keyword searches are not created equal; and there is a growing body of literature that highlights the risks associated with conducting an unreliable or inadequate keyword search or relying exclusively on such searches for privilege review." Nor, apparently, did defendants sample those text-searchable ESI files determined not to contain privileged information by the keyword search to see if the search results were reliable.

The court agreed with the plaintiff that the defendants waived any claim to attorney-client privilege or work-product protection for the documents at issue

"because they failed to take reasonable precautions by performing a faulty privilege review of the text-searchable files and by failing to detect the presence of the 165 documents, which were then given to the Plaintiff as part of Defendants' ESI production." The court discusses in a footnote an ongoing research project involving the National Institute of Standards and Technology and the Department of Defense to evaluate the effectiveness of an array of e-discovery search methodologies (http://trec-legal.umiacs.umd.edu). According to the court, "The goal of the project is to create industry best practices, … which, if adhered to, certainly would support an argument that the party employing them performed a reasonable ESI search, whether for privilege review or other purposes."

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MASSACHUSETTS COURT FINDS LACK OF JURISDICTION OVER PLAINTIFFS PRECLUDES CLASS CERTIFICATION

The Supreme Judicial Court of Massachusetts has upheld a lower court decision denying the certification of a nationwide class of plaintiffs who claimed deceptive trade practices in the purchase of insurance policies from a domiciliary carrier, finding that the court lacked personal jurisdiction over the nonresident plaintiffs. *Moelis v. Berkshire Life Ins. Co.*, No. SJC 10067 (Mass., decided May 22, 2008). The court acknowledged that state courts may bind absent plaintiffs in an action for money damages in the absence of minimum contacts with the forum state as long as due process protections are provided. "Those protections include notice, an opportunity to be heard and to participate in the litigation, and the opportunity for the plaintiff to remove himself or herself from the class." Massachusetts law does not allow "individual parties to remove themselves or 'opt out' of a class action." Thus, the court found that this alternative to minimum contacts could not be satisfied. As for the minimum contacts test, the court found that the purchase of insurance policies from a Massachusetts company, "through agents located in their home States, and their mailing of annual premium payments" to the company, were insufficient contacts with Massachusetts "to warrant the assertion of personal jurisdiction" over the nonresident plaintiffs.

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REVERSALS, SETTLEMENT AND MEDICAL MONITORING ADDRESSED IN PAINKILLER LITIGATION

Merck & Co. had reason to celebrate a number of developments in litigation involving the company's pain medication Vioxx® in recent weeks. On May 29, 2008, a Texas appeals court overturned a $26.1 million judgment against the company, rejecting plaintiff's experts' opinions on causation as "mere speculation" and thus finding the evidence "legally insufficient on the issue of causation," *Merck & Co., Inc. v. Ernst*, No. 14-06-00835 (Fourteenth Ct. App., Tex.); and a New Jersey appeals court nullified a $9 million punitive damages award, ruling that federal regulators approved the drug and a jury lacks the authority to decide whether the company defrauded the government. *McDarby v. Merck & Co., Inc.*, Nos. A-0076-07T1 and A-0077-07T1 (N.J. Super. Ct., App. Div.).

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According to a news source, attorneys general in 29 states and the District of Columbia settled deceptive marketing claims against Merck & Co. for $58 million. A company spokesperson was quoted as saying that the "agreement enables Merck to put this matter behind us and focus on what Merck does best, developing new medicines." The settlement will apparently require the company to submit consumer-targeted television commercials to the Food and Drug Administration for approval and prohibits the company from ghostwriting articles or studies, misusing scientific data when marketing to doctors and failing to disclose when its promotional speakers have conflicts of interest. The litigation alleged that the company aggressively marketed Vioxx® to consumers and health care professionals and misrepresented the cardiovascular safety of the drug. *See Seattle Post-Intelligencer*, May 20, 2008.

In a related development, the New Jersey Supreme Court has reinstated the dismissal of claims for medical monitoring filed by Vioxx® users who did not claim to be injured by the drug. ***Sinclair v. Merck & Co., Inc.*, No. A-117-06 (N.J., decided June 4, 2008)**. In a 5-1 decision, the court determined that the state's Products Liability Act does not include the remedy of medical monitoring for a defective product claim where no manifest injury is alleged.

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FLORIDA APPEALS COURT RULES STATE CANNOT RETROACTIVELY BAR ASBESTOS LAWSUITS

According to a press report, Florida's Fourth District Court of Appeal has determined that a 2005 law, which requires asbestos plaintiffs to show physical injury from asbestos exposure as a predicate to bringing a lawsuit, cannot be applied retroactively to cases already filed in the state. The decision apparently reaches a conclusion that differs with a sister court's ruling, a circumstance that could spur the Florida Supreme Court to hear the matter should an appeal be filed. The court reportedly indicated that allowing the law to bar plaintiffs from bringing asbestos claims would take away legal rights they already had. The ruling will affect 13 consolidated appeals before the court and could ultimately allow some 3,000 to 4,000 individual asbestos lawsuits to proceed in the state's Fourth Appellate District. Counsel for an asbestos defendant expressed disappointment in the decision, claiming that it would hurt "victims" of asbestos exposure because the law was intended "to conserve the limited and scarce judicial resources, and the limited and scarce resources of the defendants." *See Product Liability Law 360*, May 29, 2008.

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CALIFORNIA JURY AWARDS $6.2 MILLION DAMAGES IN STUN GUN DEATH

A California jury, finding that Taser International, Inc. failed to warn police that prolonged exposure to the electric shock from a stun gun could cause a risk of cardiac arrest, reportedly awarded $6.2 million to the estate and parents of a 40-year-old man who died after police shot him multiple times with the device. *Heston v. City of Salinas*, No. 05-03658 (N.D. Cal., jury verdict returned

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June 6, 2008). While the $1 million in compensatory damages will apparently be reduced by the jury's finding that the decedent was 85 percent responsible for his death, the punitive damages will not be affected. Taser has reportedly settled some 10 cases involving injuries sustained by police officers during training, but a spokesperson indicated it would appeal this award, stating "Certainly, this was a tragedy for the Heston family as well as for the officers involved. We, however, do not feel that the verdict is supported by the facts." *See Bloomberg.com*, June 7, 2008.

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ALL THINGS LEGISLATIVE AND REGULATORY

Congressional Democrats Prepare Legislation to Reverse Supreme Court's Medical Device Preemption Ruling

Representatives Frank Pallone (D-N.J.) and Henry Waxman (D-Calif.) reportedly plan to introduce legislation before the July 4 recess to overturn the U.S. Supreme Court's *Riegel v. Medtronic, Inc.* ruling by explicitly stating that federal regulation of medical devices does not preempt an injured patient's ability to seek damages under state law. With little time left on the legislative calendar for the 110th Congress, however, the bill may not reach the floor. It is apparently expected to reemerge before the 111th Congress, particularly if Democrats add to their majorities in the House and Senate and if a Democrat wins the presidential election. Opponents contend that preemption is needed to protect medical and pharmaceutical sectors as well as prevent the undermining of "the long-established FDA regulatory system." Trial lawyers reportedly counter that federal agencies under the Bush administration have made a concerted effort to preempt state law by adopting some 51 rules with express preemption provisions. The National Highway Traffic Safety Administration, for example, is reportedly finalizing a rule that will establish new requirements for car roofs to reduce fatalities and injuries from rollover crashes; a preliminary draft would allow the preemption of state product liability lawsuits if auto manufacturers meet the standard. *See CongressDaily AM*, June 4, 2008.

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FDA Issues Fewer Warning Letters to Regulated Companies

The Wall Street Journal reports that the Food and Drug Administration (FDA) has issued far fewer warning letters since the agency changed its policies in 2002 and required all such correspondence to be vetted by its chief counsel's office. Before the change took effect, the FDA apparently issued more than 1,000 warning letters annually, involving claims ranging from the mislabeling of food products to the improper manufacturing of medical equipment. In 2007, only 471 letters were issued.

Agency critics, who characterized the policy change as favorable to industry, have reportedly increased their condemnation of what they perceive as the Bush administration's toleration of lax regulatory enforcement. Former FDA Commissioner David Kessler was quoted as saying, "The number of warning

letters has always been one of the surrogate measures of FDA's enforcement performance. It's not the only measure, but any significant drop raises significant questions of what's going on." Compliance with such letters is voluntary, but the FDA can seize violators' products or take them to court. Current FDA Commissioner Andrew von Eschenbach reportedly acknowledged the decline in warning letters, but said the agency is focusing on more important transgressions. He added that the agency is using press releases and other forms of communication to advise the industry of problems it has noticed. The agency is also apparently ordering more product recalls now than it did in the 1990s. *See The Wall Street Journal*, June 7, 2008.

Information About Mercury in Silver Dental Fillings Released to Settle Lawsuit

To settle a lawsuit filed by consumer advocacy organizations, the Food and Drug Administration (FDA) has posted new information about potential health effects of mercury in silver dental fillings and agreed to move forward with a rulemaking that will classify dental amalgam and adopt special controls for its use. On its Web site, the FDA states that dental amalgams contain about 50 percent mercury by weight and that mercury "may have neurotoxic effects on the nervous systems of developing children and fetuses." While the agency does not recommend that those with such fillings have them removed and does not advise pregnant women and young children to avoid amalgam fillings, the FDA does provide links to the advice of regulatory authorities in other countries that follow the "precautionary principle," particularly with respect to the use of dental amalgam by pregnant women.

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The FDA has reopened the comment period for a proposed rule on mercury in dental amalgams and will accept public comments until July 28, 2008. The lawsuit that prompted the FDA's latest action was filed after the agency dismissed a petition calling for it to scrutinize dental amalgams. The plaintiffs reportedly claimed, "Whether by intention or lethargy, FDA's Center for Devices has protected the marketing of mercury fillings by doing none of its regulatory duties – neither classifying nor requiring proof of safety nor doing an environmental assessment nor seeking a valid recommendation from the scientific panel." *See Product Liability Law 360*, June 5, 2008.

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LEGAL LITERATURE REVIEW

Mark Behrens & Christopher Appel, "Medical Monitoring in Missouri After *Meyer ex rel. Coplin v. Fluor Corp.:* Sound Policy Should be Restored to a Vague and Unsound Directive," *St. Louis University Public Law Review*, 2007

Shook, Hardy & Bacon Public Policy lawyers **Mark Behrens** and **Christopher Appel** discuss a Missouri Supreme Court decision allowing plaintiffs without a present physical injury to recover medical monitoring as an item of compensable damages when they have established liability under a traditional

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tort law theory of recovery. They analyze the decision, compare it to contrary rulings from other jurisdictions and criticize it for failing to "establish any parameters for medical monitoring, leaving litigants and lower courts unguided to find their way in the tangle of medical, scientific, and policy issues involved in implementing the court's vague directive." The article suggests that courts consider not allowing lump-sum awards, eliminating double recoveries and establishing more specific criteria for when medical monitoring is "necessary in order to diagnose properly the warning signs of disease." Calling the court's opinion "weak" and "an anomaly," the article concludes by suggesting that other courts reject its approach and that the legislature "consider a statutory fix."

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David Kessler & David Vladeck, "A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims," *The Georgetown Law Journal*, 2008

Former FDA Commissioner David Kessler and Georgetown Law Professor David Vladeck, who recently testified during congressional hearings about the federal preemption of state-law product liability claims involving prescription drugs, have written an article that traces the evolution of the Food and Drug Administration's position on preemption and supports a regulatory system that allows injured plaintiffs to seek damages under failure-to-warn theories in state courts. The authors contend that "the FDA cannot safeguard our nation's drug supply on its own … For that reason, we believe it would be a mistake to preempt state-law failure-to-warn cases, which impose a complementary discipline on the marketplace, prompt disclosure of safety information that is not otherwise available to the FDA, physicians, health care providers, and patients, and provide redress to consumers injured through no fault of their own."

Stephen Choi, G. Mitu Gulati & Eric Posner, "Which States Have the Best (and Worst) High Courts?," *University of Chicago, Public Law Working Paper*, May 2008

A trio of law professors has undertaken the task of ranking the states' supreme courts by examining "opinion quality (or influence as measured by out-of-state citations), independence (or non-partisanship), and productivity (opinions written)." The authors discuss different ways of aggregating the results and compare their approach with the work of other scholars and the U.S. Chamber of Commerce which ranks states' litigation climate on the basis of corporate lawyer surveys. According to this survey, which analyzed published opinions from 1998 to 2000, California and Delaware had the most influential courts, Georgia and Mississippi had the most productive courts, and Rhode Island and New York had the most independent courts. The article concludes by calling for scholars to develop new measurement instruments to address difficult-to-measure aspects of performance, and for the "reform of states high courts that repeatedly appear at the bottom" when multiple rankings converge.

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LAW BLOG ROUNDUP

Legal Rulings to Celebrate

"Hear that cheering sound from the other side of the Hudson River?" *The Wall Street Journal's* Ashby Jones, discussing the New Jersey and Texas appellate court decisions that reversed multimillion-dollar awards made to plaintiffs who claimed that New Jersey-based Merck & Co.'s Vioxx® caused serious illness and death.

WSJ Law Blog, May 29, 2008.

When the Law and the Arts Collide – Make Dinnerware!

"Given reader interest in Supreme Court bobble-head dolls, and other artistic representations of pressing legal problems, it might be worth checking out the whole collection." Temple University Beasley School of Law Associate Professor David Hoffman, blogging about a Harvard Law School graduate who makes melamine dinner plates depicting legal decisions. His *BMW v. Gore* plate shows a strangely deformed and painted car--in that case, which involved an undisclosed paint job on a high-end automobile and a multimillion-dollar punitive damages award, the U.S. Supreme Court laid down a few constitutional parameters regarding "grossly excessive" punitive damages awards.

Concurring Opinions Blog, June 9, 2008.

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THE FINAL WORD

FDA Regulation of Nanotechnology and Nano-Sunscreens Sought

A coalition of environmental and consumer advocacy organizations has filed a **petition** with the Food and Drug Administration (FDA) "calling on the agency to address the human health and environmental risks of untested and unlabeled nanomaterials in consumer products." Spearheaded by the International Center for Technology Assessment (ICTA), the initiative seeks (i) the amendment of FDA regulations "to include nanotechnology definitions necessary for proper regulation," (ii) "comprehensive nano-product regulation, including nanomaterial-specific toxicity testing and mandatory nano-product labeling," as well as (iii) "regulations classifying nano-sunscreens as new drug products which require premarket review of health and safety evidence." According to ICTA, the FDA has not tested or reviewed sunscreens containing zinc oxide and titanium dioxide nanoparticles; as such, "the petition requests [that the] FDA declare those products an imminent hazard to public health and order manufacturers [to] cease production until FDA nanotechnology regulations are developed and implemented."

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UPCOMING CONFERENCES AND SEMINARS

Lorman Education Services, Kansas City, Missouri – June 18, 2008 – "Electronic Discovery and Document Storage," Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Madeleine McDonough** will discuss issues related to corporate e-discovery. Her sessions are titled "Practical Considerations in Defending Corporate E-Discovery Programs" and "Practical Considerations to Reduce the Risk That E-Discovery May Improperly Be Used as Leverage."

American Conference Institute, Boston, Massachusetts – September 23-24, 2008 – "Managing Legal Risks in Structuring & Conducting Clinical Trials," Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Madeleine McDonough** will join a former FDA enforcement lawyer to discuss issues arising from compliance with state and federal laws requiring the registration of clinical trials and disclosure of results.

American Conference Institute, Chicago, Illinois – October 29-30, 2008 – "Defending and Managing Automotive Product Liability Litigation," Shook, Hardy & Bacon Tort Partner **H. Grant Law** will serve on a panel discussing "Preemption: Examining the Current Viability of the Defense in Auto Product Liability Cases."

Brooklyn Law School, Brooklyn, New York – November 13-14, 2008 – "The Products Liability *Restatement*: Was It a Success?," Shook, Hardy & Bacon Public Policy Partner **Victor Schwartz** will present along with a number of other distinguished speakers including *Restatement* reporters James Henderson and Aaron Twerski. Seminar brochure not yet available.

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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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