

# Product Liability Litigation Report

#### A PUBLICATION OF SHOOK, HARDY & BACON L.L.P.



# SUPREME COURT SEEKS GOVERNMENT VIEWS ON MEDICAL DEVICE PREEMPTION

The U.S. Supreme Court has asked the U.S. solicitor general to submit its views on a case involving personal injury claims allegedly caused by a prescription medical device. *Riegel v. Medtronic, Inc.,* No. 06-179 (U.S. Supreme Court, *petition for cert. filed* Aug. 2006). At issue is whether the preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act preempts state-law claims seeking damages for injuries caused by medical devices that received pre-market approval from the Food and Drug Administration. The lower courts have apparently split on the issue. The federal government has, according to the appeal, switched a position taken in 1998 in support of state-law claims by recently arguing before the Third Circuit that federal law preempts such claims. *See Scotusblog.com,* November 6, 2006.

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# APPEALS COURT EXPLORES RELATIONSHIP BETWEEN FEDERAL AND STATE RULES OF EVIDENCE

The Tenth Circuit Court of Appeals has determined that the *Erie* doctrine, which requires that federal courts apply the substantive laws of the states in which they are sitting when exercising diversity jurisdiction, does not govern the admissibility of evidence under the Federal Rules. *Sims v. Great Am. Life Ins. Co.,* No. 04-5135 (10th Cir., decided November 7, 2006). According to the court, "The Federal Rules of Evidence are an act of Congress and, thus, subject neither to the dictates of the *Erie* doctrine nor to the Rules Enabling Act or Rules of Decision Act." Nevertheless, the court recognized that federal diversity courts cannot undercut the Constitution's allocation of law-making functions by making "substantive law affecting state affairs beyond the bounds of congressional legislative powers." Thus, the court cautioned trial courts to "analyze substantive state policy in considering the admissibility of evidence."

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# FEDERAL APPEALS COURT BREATHES LIFE INTO CLASS CLAIMS AGAINST ASBESTOS PLAINTIFFS' LAWYERS

The Third Circuit Court of Appeals has reversed summary judgment and a denial of class certification in a case involving claims by asbestos plaintiffs against their attorneys for breach of fiduciary duties. <u>Huber v. Taylor, No. 05-</u><u>1757 (1st Cir., decided October 31, 2006)</u>. The issues on appeal involved the district court's choice-of-law rulings, and the claims arose out of contracts that plaintiffs' lawyers entered to coordinate asbestos filings in Mississippi courts by plaintiffs from a number of different states. According to the named plaintiffs from Ohio, Pennsylvania and Indiana, the lawyers had financial incentives to negotiate better deals for claimants from southern states. The appeals court remanded the claims, finding that the district court had erred in its choice-of-law ruling and that the court's class-action analysis would have to be reconsidered in light of the application of Texas law.

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### FLORIDA COURT ISSUES RULING ON EXPERT TESTIMONY

The Florida Supreme Court has ruled that an expert may not testify on direct examination that he or she has relied on consultation with colleagues or other experts in forming an opinion. *Linn v. Fossum*, No. SC05-134 (Florida Supreme Court, decided November 2, 2006). The issue arose in a medical malpractice case where an expert was permitted to testify that she had determined the defendant's approach complied with the prevailing professional standard of care after she spoke about the case with several other specialists whom she regarded as representative of the relevant medical community. Reversing the judgment and remanding for a new trial, the court found that such testimony is inadmissible "because it results in improper bolstering and any probative value is outweighed by the danger of unfair prejudice and of misleading the jury that the expert's testimony has the approval of other experts in the field." The error was further ruled not harmless "because the competing expert opinions on the proper standard of care were the focal point of this medical malpractice trial."

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# ALI RELEASES PRELIMINARY DRAFT OF THE PRINCIPLES OF THE LAW OF AGGREGATE LITIGATION

The American Law Institute has apparently issued Preliminary Draft No. 4 (September 21, 2006) of the *Principles of the Law of Aggregate Litigation*. According to *Mass Tort Litigation Blog*, the draft's three chapters cover "General Principles of Aggregation," "Aggregate Treatment of Common Issues" and "Aggregate Settlements." *Mass Tort* also claims that the third chapter "advances two ideas that, if adopted as law, would dramatically enhance the power of aggregate counsel to negotiate binding settlements for classes or non-class client groups in mass torts."



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With regard to settlement classes, Section 3.07 reportedly challenges *Amchem Products v. Windsor* (U.S. 1997) in advocating "approval of a settlement class action even if it does not satisfy the requirements for certification of a litigation class." In addition, Section 3.17 would "allow clients to waive, in advance, the informed consent requirement of the aggregate settlement rule." This move would negate parts of state ethics rules, which currently require each individual client to consent to an aggregate settlement. Because the two proposals facilitate large group settlements, *Mass Tort* says both would be welcomed by plaintiffs' and defendants' counsel. *See Mass Tort Litigation Blog*, October 16, 2006.

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# PRODUCT LIABILITY ISSUES CONSIDERED AT U.S. CHAMBER OF COMMERCE LEGAL REFORM SUMMIT

"No one knows the future, but if the [Democrats] control, I will assure you that they [the trial lawyer lobby] won't simply stop with tort reform," said Shook, Hardy & Bacon Public Policy Partner <u>Victor Schwartz</u>, who addressed the U.S. Chamber of Commerce on legislation that would criminalize product liability cases. Backed by Democrats and the Association of Trial Lawyers, the proposed law would allow "criminal penalties in cases for knowingly producing and distributing defective products."

Schwartz expressed concern that criminal prosecution would help trial lawyers attain large punitive damages in civil suits. Moreover, because courts still do not agree on the definition of "defect," Schwartz also worried that the law would have "unintended consequences." "What is it?," he asked about alleged defects. "Is it a reasonably dangerous product? Is it a product in which you have to show an alternative product? Does it meet consumers' expectations?" *See National Journal's "Congress Daily PM,"* October 26, 2006.

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# ICON ISSUES REPORT ON NANOTECHNOLOGY IN THE WORKPLACE

The International Council on Nanotechnology (ICON) recently published a phase-one report, *Current Knowledge and Practices Regarding Environmental Health and Safety in the Nanotechnology Workplace*. Part of a biphasic plan to evaluate "health, environmental and stewardship practices in nanotechnology manufacturing," the report analyzes efforts to gather data on the industry's "best practices." Surveying industry, government and academic initiatives, the report categorizes its results according to four research approaches: (i) "Cataloging of current practices"; (ii) "Voluntary Reporting Programs"; (iii) "Recommended 'Best Practices' and Frameworks"; and (iv) "Databases and Other Activities." The report concludes that, of the methods reviewed, few "have produced significant information documenting current environmental health and safety (EH&S) practices in nanotechnology sectors." The phase-two report will apparently focus on existing workplace practices in nanotechnology firms across the globe.

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# LEGAL LITERATURE REVIEW

James Muehlberger and Cary Silverman, "Lawsuits Without Injury: The Rise of Consumer Protection Claims," *HarrisMartin's Litigation Watch: Arthritis Drugs,* October 2006

Shook, Hardy & Bacon's James Muehlberger and Cary Silverman have published an article about how personal injury lawyers are turning to consumer protection laws "to bring massive lawsuits where no one was actually injured in the hopes of receiving 'statutory damages,' minimum awards set by statute in the absence of proof of injury, treble (triple) damages and awards of attorneys' fees." According to the article, the consumer protection claims that are being filed are, in many instances, standard products liability or contract claims. Pharmaceutical companies have been particularly susceptible to consumer protection lawsuits that generally allege "the company promoted the drug as safe and effective, when the product was either not as effective as consumers might have been led to believe or the company's advertising failed to disclose to the public a known risk associated with the drug." The article concludes by calling for courts and legislatures to "restore the 'consumer' to consumer protection laws ... by ensuring that those who lose money because they were deceived are made whole, while eliminating the lawyer and interest-group generated lawsuits that are brought for profit and politics."

#### <u>A. Mitchell Polinsky and Steven Shavell, "Mandatory versus</u> <u>Voluntary Disclosure of Product Risks," *Stanford Law and Economics Olin* <u>Working Paper, October 2006</u></u>

Law Professors A. Mitchell Polinsky and Steven Shavell, who also serve with the National Bureau of Economic Policy, explore the options companies face when they have information about their products that may not be favorable. They have constructed mathematical models companies can use to compute the social value of information and whether disclosure of the information is in a company's best interest. While the authors recognize that some "bad" information must be disclosed to federal agencies and to ward off liability for nondisclosure, they also observe that "disclosure requirements and liability for nondisclosure also have an undesirable effect – they reduce the incentive of firms to acquire information about product risks in the first place (through research, product testing, and the like)."

#### Elizabeth Weeks, "Beyond Compensation: Using Torts to Promote Public Health," Journal of Health Care & Law Policy, 2007

University of Kansas Law Professor Elizabeth Weeks makes the case in this forthcoming article for using the tort system to bolster public health efforts. She acknowledges the drawbacks to this approach, i.e., it allows individuals and their attorneys "to set the health policy agenda"; it can result in the loss of a useful product to the marketplace "because the manufacturer faces staggering liability from a few injured consumers"; and "the benefits may not be dispersed through society" but are concentrated, rather, on a few plaintiffs who garner a windfall. Nevertheless, Weeks contends that "the public at large may enjoy a public health windfall by means of an efficient and highly responsive tort law system" because private litigation can effect change quickly, the science can be advanced by highly motivated plaintiffs and "high profile litigation may capture the public's attention." "restore the 'consumer' to consumer protection laws..."



#### Jenny Miao Jiang, "Whimsical Punishment: The Vice of Federal Intervention, Constitutionalism, and Substantive Due Process in Punitive Damages Law," 94 California Law Review 793 (2006)

With thanks to plaintiff's attorney Elizabeth Cabraser for support and guidance, this student author argues that the U.S. Supreme Court's punitive damages jurisprudence has raised more questions than it has answered and has not promoted uniformity. She recommends two approaches to the issue: (i) abandon the current amorphous measures of reasonability, i.e., "reprehensibility," "comparability" or "potential harm," in favor of detailed guidelines bearing a resemblance to the Federal Sentencing Guidelines, setting forth the circumstances under which punitive damages may be imposed and the aggravating and mitigating factors that will dictate the award calculation; or (ii) limit a court's review to procedural due process compliance and no longer permit courts "to assess the *substance* of punitive damages awards." According to Jiang, civil defendants do not have a federal constitutional right not to have "excessive" or "unreasonable" punitive damages leveled against them, because substantive punitive damages assessments are within the province of the states.

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### LAW BLOG ROUNDUP

#### Judge Wants to Question Settling Class Plaintiffs

"[Cook County Circuit Judge Nancy Arnold] was reportedly ready to approve the settlement of the shareholders derivative action, but stumbled over the nearly \$12 million in attorney's fees, which she called a 'substantial sum.'" *The Wall Street Journal's* online law blogger Peter Lattman, reporting that plaintiffs represented by embattled Milberg Weiss were to be questioned by a court-appointed independent monitor as to when they became Boeing shareholders, how many shares they owned and how they got involved as litigants. Judge Arnold was evidently concerned about criminal charges brought against the law firm in May 2006 for allegedly paying kickbacks to people to serve as plaintiffs in class-action lawsuits.

wsj.com, November 13, 2006.

#### Tell Us What You Really Think

"Positively insane cuckoo bonkers." Blogger Ted Frank, characterizing the defeated South Dakota ballot measure that would have ended civil immunity for judges and jurors and established a "special grand jury" to oversee such matters.

Overlawyered.com, October 27, 2006.

#### Legal Reality

"Another example of the ways in which litigants, forcing the past through the gauntlet that any set of facts must traverse in order to state a successful legal claim, create a narrative that bears about the same resemblance to lived reality that a dressmaker's dummy does to a human being." Southwestern Law School Professor Paul Horowitz, commenting on the story family members tell With thanks to plaintiff's attorney Elizabeth Cabraser for support and guidance, this student author argues that the U.S. Supreme Court's punitive damages jurisprudence has raised more questions than it has answered and has not promoted uniformity.

"Positively insane cuckoo bonkers."



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about their decedent, on his death bed, blaming "those darn cigarette people" for lying about the purported risks of smoking in a punitive damages case argued before the U.S. Supreme Court October 31, 2006.

Prawfsblawg.blogs.com, October 31, 2006.

#### Nanotechnology, Risk Assessment and Labeling

"It's a concept that's raising a lot of excitement – and a lot of safety concerns." Consumers Union spokesperson Carolyn Cairns, referring to her testimony before the Food and Drug Administration about nanotechnology and reiterating the organization's call for the FDA to develop risk-assessment and labeling procedures for foods, drugs and cosmetics that directly expose consumers to nanomaterials.

Consumerreports.org/safetyblog, November 13, 2006.

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# THE FINAL WORD

Darshak M. Sanghavi, "Preschool Puberty, and a Search for the Causes," *The New York Times,* October 17, 2006

"It turns out that there have been clusters of cases in which children have prematurely developed signs of puberty, outbreaks similar to epidemics of influenza or environmental poisonings," writes *Times* reporter Darshak Sanghavi in this article on the alleged effect of "drugs, cosmetics and environmental contaminants" on children's development. Beginning with past reports of hormones in the food supply, Shanghavi explores several theories regarding the premature onset of puberty, from testosterone creams to shampoos containing lavender and tea tree oil, which hypothetically act like estrogen. He also quotes endocrinologists who believe that manufacturing chemicals may be responsible for some cases of early-onset puberty. According to Sanghavi, EPA is reportedly planning to introduce a program, slated for December 2007, to study these "endocrine disruptors," although many endocrinologists have apparently criticized the government's lack of oversight thus far.

#### **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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