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Product Liability Litigation Report

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MISSISSIPPI COURT RECOMMENDS HEARINGS ON THE ADMISSIBILITY OF EXPERT TESTIMONY

A deeply divided Mississippi Supreme Court has ruled that parties must be afforded an opportunity to be heard before a trial court decides whether to admit expert testimony. ***Smith v. Clement*, No. 2006-CA-00018 (Miss., decided October 4, 2007)**. The issue arose in a case involving severe burn injuries from a school bus fire. The school district sought indemnity from the gas company that converted its school buses from gasoline to propane use; the district retained a mechanical engineer to support its propane-system defect theory. The gas company filed a motion to strike the expert's affidavit as insufficient under the U.S. Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

After reviewing the affidavit and a rebuttal affidavit and conducting a summary judgment hearing, the trial court granted the motion to strike, finding that the expert's opinions "are nothing more than unsupported conclusions which are devoid of a factual basis and not the product of reliable principles and methods." The court also granted the gas company's summary-judgment motion. The school district had argued during the hearing that its expert was not given an opportunity to further expound on his scientific theory as to causation.

According to the Mississippi Supreme Court majority, basic fairness requires that the expert-evidence proponent be given the opportunity to develop a record before a trial court makes a determination as to its admissibility. Thus, said the court, "Prior to any *Daubert* determination or other decision regarding the proffer of expert evidence, the parties must be afforded the opportunity to be heard. We generally recommend that the trial court conduct an in limine hearing specifically on the subject, as this procedure will result in full briefing and argument by the parties regarding the proposed expert testimony. This will not only assist the trial court in its function as evidentiary gatekeeper; it will provide a fuller record for an appellate court should the parties contest the evidentiary ruling." The court further noted that "an in limine hearing may not be necessary in all cases," but suggested that it would "provide the most efficient manner of addressing the issue in many cases." The court reversed the order striking the expert's affidavit and the summary-judgment grant.

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In dissent, the chief justice, joined by three of his colleagues, opined that the trial court applied the correct *Daubert* standard in striking the expert's affidavit and also found it unnecessary that courts "hold an actual hearing" to comply with *Daubert*. The dissenters faulted the expert's proponents for failing to file a response to the motion to strike his affidavit in which they "could have offered argument as to how their expert's testimony was supported by reliable principles and methods." The dissenters were concerned with the affidavit because it lacked a foundation for the expert's conclusion that the copper tubing which was allegedly responsible for the 1995 fire was the same tubing installed by the gas company in 1981. They would have ruled that the trial court did not abuse its discretion in striking the affidavit.

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SIXTH CIRCUIT ISSUES RULING ON FEDERAL COURT JURISDICTION UNDER CAFA

The Sixth Circuit Court of Appeals has remanded putative class claims to state court, affirming a district court ruling that the defendant failed to demonstrate by a preponderance of the evidence that the amount in controversy met jurisdictional requirements. ***Smith v. Nationwide Prop. & Cas. Ins. Co., No. 07-5956 (6th Cir., decided October 1, 2007)***. The plaintiff had filed his initial complaint in state court in 2004, seeking relief for breach of an insurance contract only for himself. He filed an amended complaint in September 2006 on behalf of himself and a class of plaintiffs with similar claims. The amended complaint specifically alleged individual compensatory damages not in excess of $74,999 each and limited the total class claims to less than $4,999,999, while also disclaiming "any compensatory damages, punitive damages, declaratory, injunctive or equitable relief greater than $74,999 per individual Class member."

The district court found the provisions of the Class Action Fairness Act of 2005 (CAFA) applicable to the matter, but ruled nonetheless that it lacked jurisdiction because the defendant had failed to establish the minimum amount in controversy of $5 million. The appeals court first considered whether CAFA applied to the case, because the initial complaint was filed before CAFA became effective. Looking to state law, the court determined that its relation-back doctrine did not apply to the amended complaint, because the addition of class claims constituted the assertion of new claims by additional parties. According to the court, "To relate the class claims back to the time of the filing of Smith's original complaint would unfairly prejudice Defendant in this matter, and the district court did not err when it did not do so."

The court further ruled that while a "disclaimer in a complaint regarding the amount of recoverable damages does not preclude a defendant from removing the matter to federal court upon a demonstration that damages are 'more likely than not' to 'meet the amount in controversy requirement,'" it was clear that the compensatory damages sought in the case did not meet the statutory minimum. The court also found that punitive damages were not likely to be awarded because state law "teaches that punitive damages are generally not available in breach of contract cases." "To decide otherwise on these facts would require a strained reading of the complaint and completely discount Plaintiff's express disclaimer," concluded the court.

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NINTH CIRCUIT JURIST ISSUES MAJORITY AND CONCURRING OPINIONS IN REMOVAL JURISDICTION CASE

The Ninth Circuit Court of Appeals has determined that a party seeking to remove a case to federal court where the complaint alleges damages less than the jurisdictional threshold for diversity cases but does not specify a total amount in controversy must show by a preponderance of the evidence that the amount reaches the requisite $75,000 threshold. ***Guglielmino v. McKee Foods Corp.*, No. 05-16144 (9th Cir., decided October 9, 2007)**. The judge who wrote the majority opinion in the case also penned a concurrence to express his dissatisfaction with the different burdens of proof placed on a removing defendant under varying circumstances. For example, when a complaint filed in state court alleges an amount sufficient to meet the threshold, the requirement is "presumptively satisfied unless it appears to a 'legal certainty' that the plaintiff cannot actually recover that amount." But where the state-court complaint is unclear or ambiguous, the removing defendant must provide evidence establishing that it is 'more likely than not,' a preponderance standard, that the amount in controversy exceeds the jurisdictional amount.

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The Ninth Circuit recently applied the "legal certainty" standard under the Class Action Fairness Act in *Lowdermilk v. U.S. Bank National Association,* 479 F.3d 994 (9th Cir. 2007). The concurring opinion in *Guglielmino* takes issue with the holding in *Lowdermilk*, contending that "the preponderance of the evidence standard should apply in any case where there is a challenge to the jurisdictional facts of the party seeking to assert federal jurisdiction." The concurrence further opines that this approach would be faithful to U.S. Supreme Court precedent and would strike "the proper balance between a plaintiff's desire to remain in state court and a defendant's statutory right to remove." Further details about *Lowdermilk* appear in the March 15, 2007, issue of this Report.

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U.S. SUPREME COURT DECLINES TOBACCO APPEAL, ALLOWS PLAINTIFF SUBSTITUTION IN MEDICAL DEVICE CASE, GRANTS CERT. TO CONSIDER FRAUD-ON-THE-FDA PREEMPTION EXCEPTION

The U.S. Supreme Court returned to Washington, D.C. to begin its new term at the beginning of October and promptly took a number of actions in closely watched products cases. The Court denied a petition for certiorari filed by cigarette manufacturers seeking to overturn a state court ruling that will allow up to 700,000 smokers to use findings from a class action tried before a jury to bring individual cases against the companies. While the Florida Supreme Court overturned a $145 billion verdict in the case when it de-certified the class, it ruled that individual smokers would not have to relitigate some of the general causation findings made by the class jury. *R.J. Reynolds Co. v. Engle*. *See The Wall Street Journal*, October 1, 2007.

In a case which asks the Court to decide whether compliance with federal regulations governing medical devices preempts state law claims for manufacturing defects and inadequate warnings, the Court granted a motion to substitute the estate of the deceased plaintiff for the decedent. The motion was

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filed more than six months after the plaintiff died, and this failure to comply with a Supreme Court rule prompted Chief Justice John Roberts and Justice Antonin Scalia to dissent from the grant. *Riegel v. Medtronic, Inc. See Product Liability Law 360*, October 1, 2007.

Meanwhile, the Court decided to hear the appeal of a case arising under a Michigan law that preempts state product liability claims for drugs approved by the Food and Drug Administration (FDA), but allows those claims where the approval was obtained through fraud. The drug at issue is Rezulin®, a diabetes drug that was approved by the FDA but later withdrawn from the market. On appeal from the MDL court to which the case had been transferred, the Second Circuit limited the application of a previous medical-device preemption ruling by the U.S. Supreme Court and found that Michigan's product liability preemption exception was not itself preempted. *Warner-Lambert Co. v. Kent. See ScotusBlog.com*, September 27, 2007.

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NEW ENGLAND JOURNAL OF MEDICINE ARTICLE ADDRESSES AUTISM CLAIMS PENDING IN VACCINE COURT

"To win a [Vaccine Injury Compensation Program] award, the claimant does not need to prove everything that is required to hold a vaccine maker liable in a product liability lawsuit. But a causal connection must be shown," writes Stephen Sugarman, a professor of law at the University of California-Berkeley, in a recent *New England Journal of Medicine* article describing the federal Vaccine Injury Compensation Program (VICP). Sugarman addresses the thousands of autism claims currently pending before the U.S. Court of Federal Claims that administers the VICP, which "provides compensation to children who have serious adverse effects from any childhood vaccine." VICP generally presumes that a vaccine caused an injury "if medical records show that a child had one of several listed adverse effects within a short period after vaccination." If families claim a vaccine caused an adverse event that is not on the list, which an advisory committee periodically amends "as the consensus view changes," then the "burden of proof rests with them." Sugarman notes that autism is not on VICP's current list of vaccine-related adverse events.

VICP, however, announced in 2002 that it would consider some test cases to address the causation question raised by autism claims, "putting aside the question of harm to any particular child," according to Sugarman. Although not expected to reach a decision until 2008, the vaccine-court judges have already heard the first of nine cases alleging that vaccines triggered autism in children. In addition, Sugarman writes, families "dissatisfied" with any VICP conclusion have recourse to the regular legal system in the form of product-liability lawsuits. "Other claimants are having better luck with different end-run approaches – suing companies that make thimerosal, for instance, arguing the preservative suppliers are not vaccine makers; filing class-action suits on behalf of parents; or demanding medical-monitoring for vaccinated children who do not yet show signs of autism," Sugarman concludes, in acknowledging that the government has been generally successfully in requiring claimants to first seek VICP compensation. *See The New England Journal of Medicine,* September 27, 2007.

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STAND N' SEAL® RECALL DEMONSTRATES CPSC LIMITATIONS

A recent *New York Times* article has cited the nationwide recall of Stand n' Seal®, an aerosol sealant manufactured by BRTT Inc., as evidence that the Consumer Product Safety Commission (CPSC) lacks the resources to meet the challenges of the modern marketplace. CPSC had recalled the product in 2005, nearly three months after BRTT, then known as the Roanoke Cos., received initial reports of severe respiratory illness in its consumers. The illnesses reportedly followed a decision to switch the active ingredient in Stand n' Seal® to Flexipel S-22WS, despite an explicit warning from the chemical's manufacturer that it should not be used in aerosol form. Roanoke, however, allegedly failed to remove the suspect ingredient after the recall and restocked retailers with 50,000 cans of Stand n' Seal® containing Flexipel S-22WS. Although consumers continued to report illnesses, the company apparently told CPSC that it had addressed the problem by reformulating Stand n' Seal® with a strong-smelling additive to remind users to secure proper ventilation. Home Depot, the exclusive retailer of Stand n' Seal®, eventually took the product off the market, conceding in 2007 that the replacement cans "have been identified as containing the same potentially harmful formulation as the recalled batches."

"Critics say the Stand n' Seal® case demonstrates how [CPSC] is too overwhelmed with reports of injuries and with new hazards to comprehensively investigate or follow up on many complaints," the article contends, in arguing that the agency did not properly oversee the recall and lacked the laboratory equipment to test Roanoke's solution. Though acknowledging its role in the botched recall, CPSC has also blamed its inaction on misinformation allegedly provided by the manufacturer. "The point is to get the recall out there, to get the consumer informed of what's happening and then try to get the product out of consumer hands," CPSC Acting Chair Nancy Nord was quoted as saying. "I think a recall process works very well." *See The New York Times,* October 8, 2007.

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TOPPS FOLDS AFTER SECOND-LARGEST BEEF RECALL IN U.S. HISTORY

Topps Meat Co. LLC has reportedly closed its doors after recalling more than 21.7 million pounds of ground beef products due to possible *E. coli* contamination. The company has stated that it discovered the contamination through routine sampling conducted by the New York State Department of Health and first issued a voluntary recall on September 25 that involved 350,000 pounds of ground breed. Media reports, however, have also implicated the U.S. Department of Agriculture (USDA), which allegedly identified a problem in early September but waited 18 days to instruct Topps to recall millions of frozen hamburger patties. USDA apparently confirmed on September 7 the presence of *E. coli* strain O157: H7 in beef bought by the family of a Florida teen suffering from kidney failure. The teen has since filed a lawsuit against Topps in a New York state court. Thirty people in eight states have reported *E. coli* infections matching the strain found in the beef patties, according to the U.S. Centers for Disease Control and Prevention. "This is tragic for all concerned," said Topps' Chief Operation Officer Anthony D'Urso. "In one week we have gone from the largest U.S. manufacturer of frozen hamburgers to a company that cannot overcome the economic reality of a recall this large." *See Portfolio Media,* October 5, 2007.

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ALL THINGS LEGISLATIVE AND REGULATORY

Congressional Research Service Issues Report on the Government's Authority to Recall Products

The Congressional Research Service (CRS), which provides Congress with objective, non-partisan policy research and analysis, has released a **report**, "The FDA's Authority to Recall Products," that analyzes current legislative and regulatory mechanisms for product recalls and reviews recall provisions in legislative proposals introduced in the 110th Congress. The report discusses recent recalls involving tainted pet foods, peanut butter and toothpaste and notes the limitations on the Food and Drug Administration's (FDA) recall authority. According to CRS, the agency "only has the authority to order recalls of infant formula, medical devices, and human tissue products." As to other consumer products, the FDA may only request voluntary recalls. "Companies typically recall tainted products voluntarily but this may not always be the case." The report identifies potential weaknesses in current law and recognizes that this Congress "has shown significant interest in the issue of food safety" with some 10 reform bills under active consideration.

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LEGAL LITERATURE REVIEW

Andrew Morriss, et al., "Bootleggers, Baptists & Televangelists: Regulating Tobacco by Litigation," *U. Illinois Law & Economics Research Paper*, August 2007

This article, authored by legal scholars and law professors, describes how a coalition of "bootleggers" (cigarette manufacturers) and "televangelists" (state attorneys general and private plaintiff's lawyers) succeeded in bringing about an unprecedented settlement agreement that provided benefits to all the major players, but left the "Baptists" (public health interests) with little to show for their efforts. One of the co-authors created the bootlegger/Baptist theory in the 1980s to describe how bans on Sunday sales of alcohol were achieved through an unlikely collaboration of alcohol interests, that would profit by illegally selling higher priced alcohol on Sundays, and public health advocates who were interested in restrictions on the sale and consumption of alcohol. The collaboration achieved results for many reasons, including that politicians could appear to be taking the moral high ground on the issue by voting in favor of such laws in the face of significant constituent opposition. The authors criticize the more recent bootlegger/televangelist regulation-by-litigation paradigm because it lacks transparency and results in a massive transfer of wealth with little or no oversight. They propose a number of ways to destabilize bootlegger/televangelist alliances which have shifted in recent years to the food industry and gun sale arena.

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Richard Cupp & Christopher Frost, "Successor Liability for Defective Products: A Redesign Ongoing," *Brooklyn Law Review*, 2007

Exploring how the courts have handled product liability cases filed against successor corporations since the *Restatement (Third) of Torts: Products Liability* was completed in 1997, this article contends that the "the judicial landscape on this issue remains varied." The *Restatement* predicted that the courts would reject less restrictive approaches to successor liability and, by embracing a traditional approach that requires an injured consumer to prove any of a number of exceptions before imposing liability, would agree to shift risk from the corporation to the consumer. On the contrary, according to the authors, the less restrictive approaches, which impose liability where "the successor is sufficiently similar to the predecessor that it is in essence continuing the predecessor's enterprise," or "the successor continues to market a product line previously sold by the precedessor," are continuing to find judicial acceptance. They argue that these approaches are better because, as between the innocent consumer and the innocent successor corporation, "the successor corporation has a means by which to protect itself and channel responsibility back to the responsible predecessor corporation through a discounted purchase price."

Gregory Mandel, "Nanotechnology Governance," *Alabama Law Review*, (forthcoming in 2008)

Law professor Gregory Mandel argues that the time for development of a flexible and transparent governance system to oversee nanotechnology is now. He provides an introduction to this emerging technology, examines its risks and benefits, reviews current regulatory mechanisms, and recommends ways to improve them. Noting that public concerns about the lack of adequate regulation of biotechnology scuttled some projects, Mandel believes that "[f]or the first time in history, there is the opportunity to develop a governance system simultaneously with an emerging technology." He argues that the limitless opportunities presented by nanotechnology "cannot be achieved if nanotechnology is not developed in a secure manner that maintains public confidence." Mandel proposes regulatory mechanisms that would ensure data collection and submission, industry self-auditing and reporting, flexible rulemaking procedures, and wide and diverse stakeholder involvement. He concludes, "The opportunity to reap the potentially spectacular health, environmental, industrial, and economic benefits of nanotechnology will be severely hampered if it is not managed properly. The opportunity will be hampered because society will face inefficient costs and delays and unnecessary risks, and also because distrust of the governance system or future high-profile problems caused by inadequate regulation could result in a public backlash against nanotechnology."

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Law professor Gregory Mandel argues that the time for development of a flexible and transparent governance system to oversee nanotechnology is now.

LAW BLOG ROUNDUP

A Worthy Investment?

"Merck has spent more than $1 billion over the past three years fighting lawsuits over its Vioxx painkiller. And with each passing day, the investment appears to be worth every penny." *Wall Street Journal* writer Peter Lattman, discussing Merck's litigation successes since it withdrew Vioxx® from the market in 2004. The company is currently facing some 27,000 lawsuits.

WSJ Law Blog, October 5, 2007.

Texas and Tort Reform

"So Texas is clearly getting more doctors. They just might not be the ones you want." Plaintiff's lawyer Eric Turkewitz, blogging about a recent *New York Times* article regarding the effects of tort reform on the medical profession in Texas. Apparently, caps on malpractice awards have resulted in an influx of doctors to the state, but, according to Turkewitz, disciplinary actions against doctors have also increased 79 percent since 2002, "the last full year before the caps were imposed."

"So Texas is clearly getting more doctors. They just might not be the ones you want."

TortDeform, October 5, 2007.

Food Safety, Front and Center

"Spinach. Peanut butter. Hamburgers. Pet food. No, I'm not preparing for a trip to the grocery store (but if I were, I might unknowingly be adding salmonella, E. coli, and aflatoxin to my grocery list). I'm talking about food safety." Public health student Kristen Perosino, discussing recent food contamination outbreaks and proposed legislation that would attempt to address the U.S. government's fragmented and complicated food-safety system.

The Pump Handle, October 5, 2007.

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THE FINAL WORD

CAFA and Multidistrict Litigation to Be Addressed During Law School Symposiums

The *University of Pennsylvania Law Review* will be hosting a **symposium** November 30-December 1, 2007, to address "Fairness to Whom? Perspectives on the Class Action Fairness Act of 2005." Legal scholars, judges and lawyers "will consider CAFA from six different perspectives: history, jurisdictional policy, federalism, regulatory policy, impact on the federal courts, and impact on the legal profession." Among those taking part will be individuals with the Federal

Judicial Center who have been tracking CAFA developments in the federal courts. The only practicing lawyer on the program agenda is plaintiff's attorney Elizabeth Cabraser, with Lieff Cabraser Heimann & Bernstein, LLP, in San Francisco. Papers and commentary from the symposium will be published in Volume 156 of the law review.

The *Tulane Law Review* will be hosting a **symposium** on multidistrict litigation (MDL) February 15-16, 2008. Participants include a number of MDL judges, academics and lawyers representing both plaintiffs and defendants. According to the law review, "[t]he symposium will cover a wide range of issues across the national landscape of multidistrict litigation, from the actual workings of the United States Judicial Panel and the selection of the transferee court, to the questions of coordination between simultaneous MDLs in both state and federal courts, the formation of ad hoc districtwide MDLs. the use of bellwether trials and other settlement devices, attorney strategies in multidistrict litigation, and the role of MDL in the solution to the problems of complex litigation."

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UPCOMING CONFERENCES AND SEMINARS

American Conference Institute, New York City, New York – December 12-14, 2007 – "12th Annual Drug and Medical Device Litigation" conference. Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Harvey Kaplan** will serve on a panel that will discuss "Jury Communication: Changing Perceptions of the Industry/FDA and Putting Adverse Events and the Approval Process in Context."

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 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.

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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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