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Product Liability Litigation Report

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EIGHTH CIRCUIT FINDS NO POST-SALE DUTY TO WARN IN DEFECTIVE PRINTING PRESS SUIT

The Eighth Circuit Court of Appeals has dismissed a negligent post-sale failure to warn claim in a products liability case involving a 60-year-old printing press. ***Robinson v. Brandtjen & Kluge, Inc.*, No. 06-3668 (8th Cir., decided September 11, 2007)**. The plaintiff, an employee of a printing company in South Dakota, severely injured her hand in 2001 when she was manually feeding a printing press that the defendant manufactured in 1939. The press had been sold to a newspaper in 1940 and was acquired by the plaintiff's employer in 1991 or 1992. It was designed for automatic feeding, but plaintiff's employer converted it into a foil stamping press that was fed exclusively by hand. Plaintiff's strict liability claim was denied because of the unforeseeable equipment modification which was also held to be a superseding, intervening cause that shifted liability for her negligence claim from the defendant to the employer.

As to her negligent post-sale duty to warn claim, the Eighth Circuit agreed with the district court that "[g]iven the passage of time, it would be unreasonable to require [defendant] to identify all owners of its platen presses…. By the time the current owner acquired the press, [it] was a 'member of a universe too diffuse and too large for manufacturers or sellers of original equipment to identify.'" The court also found "there is undisputed evidence that [defendant] did undertake a post-sale warning campaign, and that the [current owner] received actual notice of the warning. Whatever the scope of the post-sale duty to warn, it does not extend to warning each individual employee of a company that owns a press some sixty-one years after the sale." (citations omitted).

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MDL JUDGE REFUSES TO CERTIFY MEDICAL MONITORING CLASS IN WELDING FUMES CASE

A federal court in Ohio has denied class certification in one of the active 1,775 welding fume cases transferred to it by the Judicial Panel on Multi-District Litigation. *In re Welding Fume Prods. Liab. Litig.,* MDL Docket No. 1535 (U.S. Dist. Ct., N.D. Ohio, Eastern Div., decided September 14, 2007). That case,

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transferred from California, involved 16 plaintiffs who did not allege existing injury caused by inhaling the manganese in welding fumes. Rather, these plaintiffs alleged exposure and a significantly increased risk of serious injury; they sought injunctive relief, primarily a medical monitoring program, and asked the court to certify eight separate statewide classes with two subclasses each. The subclasses would consist of current and former welders, and the statewide classes were confined to those states that have recognized medical monitoring as a cause of action or an item of damages.

First, the court found that there would be no choice-of-law conflicts because the plaintiffs had "devised a reasonable mechanism to deal with, at trial, the relatively few state-to-state differences" by seeking to certify single state subclasses. The court further found that the putative class satisfied the numerosity, commonality and adequacy requirements of the class action rule. Because the court found that the claims and defenses failed the typicality requirement, however, it declined to certify the class. Essentially, the court determined that differences in defendants' conduct and the variable working environments in which all of the welder plaintiffs performed were not universal across the class, thus defeating typicality. According to the court, "[t]o reach the necessary level of typicality, the court would have to try the claims only of plaintiffs who all: (a) used certain welding products, (b) welded in specific work environments, (c) worked at specific plants for specific employers, and/or (d) were provided certain warnings. Obviously, the class size and the class issues diminish with each restriction, to the point that trial of a class that meets the typicality requirement would not advance the overall litigation."

The court ordered the plaintiffs to advise the court what they planned to do as it had jurisdiction under the Class Action Fairness Act and they could continue to pursue their individual claims. The court noted, however, that they might want to dismiss their claims, "as one of the bases for their motion for class certification was that the value of prosecuting 'a medical monitoring claim is likely too small to merit an individual action.'"

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CAR RENTAL IMMUNITY UNDER FEDERAL LAW FOUND UNCONSTITUTIONAL

A federal court in Florida has determined that Congress exceeded its authority under the Commerce Clause of the U.S. Constitution in enacting a federal law that grants immunity to the car rental industry for liability under state law for physical or property damage resulting from the use of a rental vehicle. *Vanguard Car Rental USA, Inc. v. Huchon*, No. 06-10082 (U.S. Dist. Ct., S.D. Fla., decided September 14, 2007). The plaintiffs were car rental companies that expected to be sued by a person injured in a wreck with a leased vehicle driven by their lessee. They sought a declaration under federal law that they were not liable for damages from the accident. Thereafter, the injured party, Jean Huchon, sued plaintiffs under Florida's dangerous instrumentality doctrine. The cases were consolidated, and Huchon sought to dismiss the petition for declaratory judgment on several grounds, while plaintiffs moved for summary judgment, claiming they could not be held vicariously liable to Huchon under 49 U.S.C. § 30106.

The court refused to dismiss the petition, but agreed with Huchon that the federal statute was beyond the power allocated Congress by the Commerce Clause, which gives Congress the power to regulate commerce among the states. According to the court, section 30106, which "regulates the assignment of benefits and burdens between parties to a commercial transaction" rather than the use of roads and highways, regulates tort liability. And because "[t]here is no evidence that vicarious tort liability for car rental or leasing companies would undercut some larger federal regulatory scheme for the car rental industry," the court found "no rational basis" to support a conclusion that such liability substantially affects interstate commerce.

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OHIO COURT ASKED TO DECIDE WHETHER TORT REFORM LAW IS CONSTITUTIONAL

According to a news source, a worker injured at an automobile plant has argued to Ohio's supreme court that a state tort reform law that took effect one month after he sustained his injury is unconstitutional. The injury case was filed in federal court in Ohio, which apparently certified the question to the state's supreme court. Douglas Groch injured his arm and wrist in March 2005 while using a trim press that had been delivered to the automobile plant in 1977. The tort reform law, which took effect in April 2005, prohibits suits related to a defective product 10 years after the product is delivered to the owner. Thus, the 10-year limitation for injuries caused by the trim press expired in 1987. Without the time limit, Groch would have had two years to sue over his injury, leading some on the court to question whether retroactive application of the new law interfered with constitutional rights. *See Toledo Blade*, September 20, 2007.

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PETITIONERS FILE U.S. SUPREME COURT BRIEF IN MEDICAL DEVICE PREEMPTION CASE

A man allegedly injured by a Medtronic catheter during coronary artery surgery has filed his opening brief in an appeal that asks whether federal law governing the approval of medical devices preempts state law claims seeking damages for injuries caused by devices given premarket approval by the Food and Drug Administration (FDA). ***Reigel v. Medtronic, Inc.*, No. 06-179 (U.S., cert. granted June 25, 2007)**. Attorneys for Public Citizen Litigation Group argue on behalf of the petitioner that the court should find no "clear and manifest" intent on the part of Congress to preempt state claims under the Medical Device Amendments to the Food, Drug, and Cosmetic Act. The district court and Second Circuit Court of Appeals found the petitioners' state law claims for manufacturing defects and inadequate warning preempted.

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Attorneys for Public Citizen Litigation Group argue on behalf of the petitioner that the court should find no "clear and manifest" intent on the part of Congress to preempt state claims under the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

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NEW YORK STATE SEEKS RESTITUTION FOR MERCK'S VIOXX®

New York State Attorney General Andrew Cuomo and New York City Mayor Michael Bloomberg have reportedly filed a lawsuit to recover public funds spent on Merck & Co., Inc.'s prescription-drug Vioxx®, which was recalled in 2004 after studies linked it to an increased risk of heart attack and stroke. The complaint, which apparently seeks tens of millions of dollars, alleges that "Merck tried to distort each negative disclosure about Vioxx. Merck cherry-picked outcomes from its own research, omitting material information that would have communicated Vioxx's real cardiovascular damages." A spokesperson for Merck's outside counsel has responded that the company "acted responsibly, from researching the drug prior to approval, to monitoring the drug when it was on the market and to voluntarily withdrawing the drug when we did."

New York State had listed Vioxx® on its preferred drug list and paid for its use from 1999 to 2004 through Medicaid and a prescription-assistance program for the elderly. Its lawsuit joins six other actions filed by states against the pharmaceutical company, although a recent New Jersey Supreme Court ruling denied certification of a nationwide class sought by third-party payers such as insurance and health care companies. "Ordinarily these types of lawsuits ride on the coattails of lawsuits filed by the plaintiff's bar and are designed to get a seat at the settlement table," one corporate defense attorney not involved with the Vioxx® litigation was quoted as saying. "But Merck hasn't issued any invitations to the dinner yet." *See The Wall Street Journal* and *The Financial Times,* September 18, 2007.

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MATTEL APOLOGIZES TO CHINA FOR DESIGN FLAWS IN RECALLED TOYS

Mattel Inc. has reportedly apologized to Li Changjiang, the head of China's General Administration for Quality Supervision, Inspection and Quarantine, for a recall involving 21 million toys made in China. Li had criticized Mattel for its allegedly weak safety controls and reminded the toy maker that "a large part of your annual profit … comes from your factories in China," which manufactures approximately 65 percent of Mattel's inventory. The Chinese government has since shut down Lee Der Industrial Co. Ltd., the factory responsible for the lead paint in Mattel toys, but has denied accusations discrediting its reputation as an exporter. "Mattel takes full responsibility for these recalls and apologizes personally to you, the Chinese people, and all of our customers who received the toys," said Mattel Executive Vice President Thomas Debrowski, also acknowledging that the "vast majority of those products that were recalled were the result of a design flaw in Mattel's design, not through a manufacturing flaw in China's manufacturers."

The apology followed a report published in September 2007 by business professors Paul Beamish of the University of Western Ontario and Hari Bapuji of the University of Manitoba, who concluded that 76 percent of recalls since 1988 were caused by the U.S. makers' design and that recalls based on design flaws and manufacturing defects have both risen in the past two years. Meanwhile,

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several American retailers, including Target Brands, Inc., Tween Brands, Inc. and Dollar General Corp., recently told the House Energy and Commerce Committee that their stores had pulled additional Chinese-manufactured products due to high lead levels. The Toy Industry Association has also called for a federal mandate to require that all toys undergo lead testing before sale. "You can't trust the Chinese to do what they say they are doing," said David Greene, vice president of sourcing at Shalom International, which recalled 280,000 children's rings after an American laboratory identified lead in the jewelry. "They all say, 'We are using lead-free paint and lead-free components.' Experience shows they are not." *See The New York Times,* September 19, 2007; *Associated Press,* September 21, 2007.

The Toy Industry Association has also called for a federal mandate to require that all toys undergo lead testing before sale.

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RHODE ISLAND PROPOSES $2.4 BILLION LEAD-PAINT CLEANUP PLAN

Rhode Island Attorney General Patrick Lynch has proposed that three paint companies spend $2.4 billion to remove lead paint from 240,000 houses and apartments, 12,969 seasonal housing units, 419 child-care centers, and 339 elementary schools over a four-year period. The abatement plan, which would require 10,000 specialized workers and 8 million days of labor, follows the decision of a six-person jury that in February 2006 found Sherwin-Williams Co., NL Industries, Inc. and Millennium Holdings liable for creating a public nuisance when they sold leaded paint in the state decades ago. In 2007, Superior Court Judge Michael Silverstein denied the defendants' request for a retrial and rejected their petition to postpone planning the abatement pending an appeal in the Rhode Island Supreme Court. The companies now have until November 15 to respond to the plan created by Lynch's office, outside counsel and consultants, and several state agencies. An attorney representing Millennium Holdings has criticized the proposal as "completely unprecedented, unworkable and, indeed, harmful to the state." *See The Providence Journal,* September 15, 2007.

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ALL THINGS LEGISLATIVE AND REGULATORY

Congress Turns Attention to Federal Regulatory Preemption of State Law Claims

The Senate Judiciary Committee recently conducted two days of **hearings** to address whether federal agencies are "usurping" congressional and state authority. Among those testifying was the president of the National Conference of State Legislatures who also serves as a state representative in Delaware. She discussed the estimated costs to state governments of product safety regulations that would preempt state tort litigation and made reference to a Food and Drug Administration (FDA) rule that purports to preempt state product liability laws pertaining to prescription drug labeling. Regarding the latter, Representative Donna Stone (R-32) stated, "Once again, unelected federal bureaucrats … succeeded in forming state tort law policy over the objections of the states."

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A Chamber of Commerce spokesperson testified that "[t]he preemption doctrine is critically important to the business community and to the health of our national economy." Other witnesses, including a law professor from the Georgetown University Law Center, contended that recent assertions of state law preemption by federal agencies amounted to an unconstitutional arrogation of congressional power by the executive. Senator Patrick Leahy (D – Vt.), who chairs the judiciary committee, expressed his concern about "implied preemption" being used to "shield corporations from culpability and prevent injured Americans from obtaining redress for their injuries."

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Meanwhile, commentary in *The Wall Street Journal* indicated that an FDA funding bill containing funds critical for the agency's continuing operations also includes a provision saying that the bill should not be "construed to affect" drug company responsibility to add additional risk information to drug labeling, whether or not required by the FDA. According to the commentator, a practicing physician and former FDA deputy commissioner, this is nothing more than a "furtive give-away" that will "help trial lawyers more easily cash in" on state drug labeling lawsuits. *See The Wall Street Journal*, September 20, 2007.

Consumer Product Safety Legislation Circulates on the Hill

A number of bills (e.g., S. 2037, S. 2045) recently introduced in the 110th Congress would give the Consumer Product Safety Commission (CPSC) greater powers over defective product recalls, increase staffing at the agency, allow state attorneys general to implement the law, provide whistleblower protection for the employees of consumer product manufacturers, ban the sale of recalled products, and increase penalties for violations of the law. A bill (H.R. 3588) that would increase the agency's budget and require mandatory routine product testing has also been introduced on the heels of hearing testimony involving lead-tainted toys and acknowledgements by CPSC leaders that agency personnel levels have fallen since it was created in 1973, leaving fewer than 90 individuals to visit U.S. ports to inspect the 15,000 plus product types for which the CPSC is responsible. *See Associated Press*, September 20, 2007.

Meanwhile, the CPSC has issued a joint statement on enhancing consumer product safety with a Chinese product oversight agency, which agreed to "immediately undertake the creation and implementation of a comprehensive plan to eliminate the use of lead paint on Chinese manufactured toys exported to the United States." The U.S. and Chinese governments entered a memorandum of understanding regarding consumer product safety in 2004, and this new statement refers to implementing work plans regarding the safety of fireworks, toys, lighters, and electrical products. The CPSC further agrees to "undertake outreach efforts to U.S. importers, stressing their role in quality and safety assurance through thoroughly evaluated product designs and specifications, testing, training, and the communication of U.S. regulations and standards to their Chinese suppliers."

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White House OMB Issues Memorandum on Federal Risk Assessment Principles

The While House Office of Management and Budget (OMB) has issued its updated **principles** for risk analysis that are intended to apply primarily to risk analyses related to environmental, health and safety risks. Because they have been issued in a less-formal, less-prescriptive memorandum format, they may not be as controversial as a draft risk assessment bulletin that was roundly criticized by the National Academy of Sciences (NAS) in January 2007. NAS was particularly concerned about dividing oversight between OMB and other federal agencies depending on whether the risk analysis is influential or non-influential. According to NAS, "the effort to separate risk assessments arbitrarily into two broad categories does not appropriately recognize the continuum of risk assessment efforts in terms of potential impact on economic, environmental, cultural, and social values. Any attempt to divide that continuum into two categories is unlikely to succeed and will not substantially improve the quality of risk assessments." NAS also objected to some of the draft bulletin's definitions.

The memorandum continues to indicate that oversight of "influential" risk analyses should fall to OMB, calling on federal agencies to refer to OMB's 2007 *Final Bulletin for Agency Good Guidance Practices* when addressing best practices for influential scientific information. This bulletin cites an executive order that gives OMB authority to review agency action, whether regulatory or in the form of guidance, with an expected impact of $100 million or more. According to a news source, OMB's new memo is similar to a document prepared by the industry-funded Center for Regulatory Effectiveness (CRE), particularly in the way it highlights the role of the CRE-supported Information Quality Act in future risk assessment procedures. A government watchdog organization contends that while the new memo reiterates risk assessment policies in place since 1995, "taken in the context of other regulatory changes made by the Bush administration," the memo "continues a policy of less regulation even as the public demands more protections of our food, consumer products, environment and workplace." *See ombwatch.org*, September 19, 2007; *Inside EPA*, September 21, 2007.

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LEGAL LITERATURE REVIEW

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

This article explains why the Food and Drug Administration's (FDA) recent efforts to preempt the litigation of failure-to-warn claims in state courts are legally unsupportable and do little to protect public health. David Kessler, who is the dean of a medical school and formerly chaired the FDA under two presidents, and David Vladeck, who teaches at the Georgetown University Law Center, show that holding drug manufacturers liable for injuries in failure-to-warn cases does not undermine or otherwise interfere with the FDA's authority to approve the content of prescription drug labels. They view litigation as a way to enhance that authority, because litigation generally (i) addresses post-approval

experience with a drug and (ii) gives the public access to information the agency does not see. They contend that pro-preemption arguments "undermine the incentives drug manufacturers have to change labeling unilaterally to respond to newly discovered risks, or to seek labeling changes from the FDA." And while the authors give the agency high marks for the job it does protecting consumers, they argue that its "pro-preemption arguments are based on what we see as an unrealistic assessment of the agency's practical ability, once it has approved the marketing of a drug, to detect unforeseen adverse effects of the drug and to take prompt and effective remedial action."

Kevin Clermont & Theodore Eisenberg, "CAFA Judicata: A Tale of Waste and Politics," *Cornell Legal Studies Research Paper*, September 2007

Cornell University Law Professors Kevin Clermont and Theodore Eisenberg analyzed published federal court decisions addressing various issues involving the Class Action Fairness Act of 2005 (CAFA) and conclude that (i) most of the early litigation was wasted on interpreting "sloppily drafted provisions on effective date and on federal jurisdiction"; and (ii) most federal judges, with the exception of Republican males, interpreted the statute narrowly, "in a way to dampen the early hopes of overly enthusiastic removers." This article explains the study's methodology and findings in some detail, noting potential weaknesses in the data and efforts to control for confounders. The authors suggest that state-court plaintiffs who file their class-action suits in federal court to reduce litigation costs and time delays, assuming that the defendant will remove them to federal court anyway, may be engaging in "foolish economy" where plaintiffs are "actually winning a good share of the CAFA battles and getting remanded."

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LAW BLOG ROUNDUP

Hot Off the Presses

"It's worth reading. I had the pleasure of reading an earlier draft, and now that I've gotten my hands on the finished product, I can't wait to read the final version." Seton Hall Law School Professor Howard Erichson, giving a thumbs up to Richard Nagareda's book *Mass Torts in a World of Settlement.* Nagareda, who teaches administrative law at Vanderbilt, opines that mass torts are primarily a problem of governance where rival teams of lawyers govern rather than litigate. He suggests replacing the current system with a private administrative framework to address mass personal-injury claims.

Mass Tort Litigation Blog, September 17, 2007.

Texas High Court Makes 180-Degree Turn

"In a wrongful death action in the Texas Supreme Court, plaintiffs recently moved for recusal of four justices for *anti-plaintiff bias*." Georgetown University Law Center fellow David Arkush, blogging about changes to the state's high court that have purportedly resulted, in 2004 and 2005, in defendants winning their appeals in 87 percent of tort cases and prevailing on 18 of 22 petitions alleging "no evidence" to support the jury's verdict, despite findings by trial judges and the court of appeals of sufficient evidence to support liability.

CL&P Blog, September 23, 2007.

"In a wrongful death action in the Texas Supreme Court, plaintiffs recently moved for recusal of four justices for anti-plaintiff bias."

Toy Import Safety High on U.S. Government's Agenda

"A lot needs to change to protect children and others from hazardous products, but the recall rules are high on every reformer's list." U.S. PIRG Consumer Program Director Ed Mierzwinski, discussing recent hearings before Congress about lead-contaminated children's products. U.S. PIRG, the federation of state Public Interest Research Groups that lobby on behalf of consumer interests, is critical of U.S. recall laws that allow retailers and distributors to control the recall process and negotiate its terms.

U.S. PIRG Consumer Blog, September 17, 2007.

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THE FINAL WORD

ATRA Proposes "Transparency Code" for State Attorneys General

The American Tort Reform Association (ATRA) this month published a "Transparency Code" for state attorneys general in the commentary section of the *National Law Journal.* Based on legislation recently enacted in some states, the voluntary standards were "designed to improve government transparency and accountability when state attorneys general hire outside counsel to litigate on behalf of state residents," according to an ATRA press release. The code specifically recommends that attorneys general (i) disclose all contracts with state vendors, including outside counsel; (ii) seek "the highest quality services at the best value"; (iii) subject contracts to legislative oversight when necessary; (iv) require outside counsel working on a contingency fee basis to provide detailed information on "hours worked, services performed and fees received from the state"; and (v) deposit all monies recovered in excess of $250,000 in the state treasury "for appropriation by the legislature" unless a settlement allocates funds to a specific entity. "As ATRA issues its Transparency Code today, we urge all attorneys general to adopt it so their respective states' citizens, taxpayers and legislators can more readily understand the value of outsourced legal work," ATRA President Sherman Joyce was quoted as saying. *See ATRA Press Release,* September 17, 2007.

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Meanwhile, Jim Copland, the director of the Manhattan Institute's Center for Legal Policy, recently published commentary in *The Examiner* criticizing the states' use of outside counsel in "public nuisance" trials against paint companies that sold leaded paint before 1978. Copland in particular notes the potential for corruption and highlights the desire of litigators to see lead paint as analogous to the "multibillion-dollar tobacco and asbestos business lines." "While nominally filed on behalf of states and municipalities, the lead paint suits are the fruits of deals trial lawyers cut with government officials, who gave the private lawyers control of state litigation for a share of the proceeds," Copland writes. "The lawyers' strategy has mirrored what they used in extracting billions from the tobacco suits to recoup states' health care expenses – unsurprisingly, since the lead paint litigation involved the same lawyers." *See The Examiner,* September 19, 2007.

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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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GLOBAL PRODUCT LIABILITY LAW FIRM OF THE YEAR 2005|2006|2007 WHO'S WHO LEGAL

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