Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

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CALIFORNIA COURT ALLOWS CLAIMS AGAINST DRUG MAKER TO PROCEED FOR HARM FROM GENERIC EQUIVALENT

A California Court of Appeal has determined that negligent misrepresentation claims may proceed against the manufacturer of a name-brand prescription drug even though the plaintiff was allegedly injured by long-term ingestion of its generic equivalent. *Conte v. Wyeth, Inc.*, No. 4437382 (Cal. Ct. App., 1st App. Dist., Div. 3, decided November 7, 2008). So ruling, the court recognized "that a defendant who authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product."

The case involved a woman who developed "a debilitating and incurable neurological disorder" allegedly as a result of taking a generic version of Wyeth's Reglan® for nearly four years to treat her gastroesophageal reflux disease. The plaintiff claimed that "the defendants knew or should have known of a widespread tendency among physicians to misprescribe Reglan and generic metoclopramide for periods of 12 months or longer, even though the medication is only approved for 12 weeks of use, because the drug[']s labeling substantially understates the risks of serious side[]effects from extended use." She sued Wyeth for negligent misrepresentation and the generic manufacturers for strict products liability.

Wyeth moved for summary judgment on the grounds that plaintiff could not show that her physician relied on its product information and that a name-brand pharmaceutical manufacturer owes no duty to those who take only generic versions of the product. The generic manufacturers moved for summary judgment on grounds of federal preemption and plaintiff's lack of reliance on their warnings or product labeling. The trial court granted summary judgment in favor of all defendants.

According to the appeals court, a material factual dispute existed about whether the plaintiff's physician read or relied on the *Physician's Desk Reference* information about Reglan, which Wyeth had prepared. There was

CONTENTS

no dispute, however, that her physician had not read any information supplied by the generic manufacturers, so the appeals court reversed the judgment in favor of Wyeth and affirmed the summary judgment in favor of the three generic manufacturers.

Most of the court's discussion focuses on whether California law allows a name-brand manufacturer to be held liable for injuries caused by a generic equivalent, a question of first impression in the state. While the court recognizes that it is departing "from the majority of courts to have wrestled with this particular issue," it contends that recognizing such liability comports with traditional tort law theory and shows how it would be "highly likely" and, thus, foreseeable, that "a prescription for Reglan written in reliance on Wyeth's product information will be filled with generic metoclopramide. And, because by law the generic and name-brand versions of drugs are biologically equivalent, it is also eminently foreseeable that a physician might prescribe generic metoclopramide in reliance on Wyeth's representations about Reglan. In this context, we have no difficulty concluding that Wyeth should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic metoclopramide."

COURT FINDS NO COMMON UNDERSTANDING OF CLOTHES DRYER ADVERTISEMENT

The Seventh Circuit Court of Appeals has determined that consumers would have too many ways of interpreting advertisements for clothes dryers to allow deceptive advertising claims relating to the stainless steel composition of the machines' drum to proceed as a class action. ***Thorogood v. Sears, Roebuck & Co.*, No. 08-1590 (7th Cir., decided October 28, 2008)**. The named plaintiff contended that he believed the entire drum was made of stainless steel when that was not the case, and thus, the drum could rust and cause rust stains on the clothes in the dryer. He sought to certify a class of purchasers from 28 states and the District of Columbia.

The court discusses the many downsides to class actions, including (i) the potential for collusion between class counsel and lawyers for the defendants, (ii) the "enhanced risk of costly error" when disputes are resolved in a single forum "rather than letting a consensus emerge from several trials," and (iii) the potential for undermining federalism where claims based on the laws of many states are combined before a single federal district court.

According to the court, "this case turns out to be a notably weak candidate for class treatment" because "there are *no* common issues of law or fact, so there would be no economies from class action treatment." The court questions whether any of the 500,000 members of the class believe "that when a dryer is labeled or advertised as having a stainless steel drum, this implies, without more, that the drum is 100 percent stainless steel because otherwise it might rust and cause rust stains in the clothes dried in the dryer."

Judge Richard Posner, writing for the three-judge panel, notes, "It is not as if rust stains were a common concern of owners of clothes dryers. There is no suggestion of that either, and it certainly is not common knowledge. (At argument the plaintiff's lawyer, skeptical that men ever operate clothes

SHB offers expert, efficient and innovative representation to clients targeted by class action and complex litigation. We know that the successful resolution of products liability claims requires a comprehensive strategy developed in partnership with our clients.

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<< back to top

dryers—oddly, since his client does—asked us to ask our wives whether they are concerned about rust stains in their dryers. None is.)" Finding the plaintiff's concerns "idiosyncratic" and, in the interest of exercising "caution in class certification generally," the court instructed the district court to decertify the class.

FIRST CIRCUIT REMANDS SANCTIONS RULING IN DEFECTIVE SCREW CLASS ACTION

The First Circuit Court of Appeals has overturned a sanctions order against a law firm that substituted named plaintiffs four times before terminating a putative class action against the manufacturer of allegedly defective screws designed for use with pressure-treated wood. ***Jensen v. Phillips Screw Co., No. 07-2766 (1st Cir., decided October 29, 2008)***. Nearly $9,000 in sanctions were awarded to the defendant under 28 U.S.C. § 1927, which allows them to be imposed against lawyers who "multipl[y] the proceedings … unreasonably and vexatiously." The successive class representatives, named over a period of some 10 months, involved a man who had settled his claims with the company, a man who did not want to sue the company, a man who did not use the screws at issue, and a man whose name was withdrawn without any explanation.

The appeals court examined the circumstances surrounding the substitution and withdrawal of each class representative, in light of the scant evidence that was before the district court when the sanctions order was issued, and found the evidence insufficient to sustain the award. Yet, the district court was ordered to revisit the issue on remand with the option of allowing the submission of additional evidence.

The appeals court suggested that the parties consider calling "it quits," speculating that "each side has spent more than the dollar amount of the sanctions in briefing and arguing this appeal." A concurring judge contended that the record permitted at least "a finding of recurring negligence" based on a cumulative course of conduct involving "the successive proffer and then abandonment of four successive lead plaintiffs" that "wasted court time and imposed litigation costs on the defense." But even this judge conceded that simple negligence alone would not justify sanctions.

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FORD MOTOR CO. TO APPEAL JURY AWARD TO WOMAN WITH SECONDHAND ASBESTOS EXPOSURE

According to a news source, Ford Motor Co. plans to appeal a $3.6 million verdict for injuries allegedly caused by secondhand exposure to the asbestos in brakes made by Ford and another company. *Daly v. Ford Motor Co.*, No. 07-19211 (17th Judicial Cir. Ct., Broward County, Fla., verdict reached November 3, 2008). Following a three-week trial, a jury made the award to a woman who was allegedly exposed to the asbestos while working for Ford dealerships in Wisconsin, helping her husband repair the brakes on their personal vehicles and handling the asbestos-laden clothes her husband wore home from work. The jury concluded that the woman developed terminal mesothelioma from the exposure, but was also 15 percent responsible for her disease, a finding that plaintiffs intend to challenge. A Ford spokesperson was quoted as saying, "While we are

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<< back to top

sorry that Mrs. Daly is ill, we are disappointed with the verdict in this case. We believe that Mrs. Daly is actually suffering from renal cell carcinoma due to her smoking, not mesothelioma." *See Product Liability Law 360*, November 7, 2008.

PRESIDENT-ELECT OBAMA COULD FACE DOZENS OF FEDERAL COURT VACANCIES

With numerous vacancies in the federal courts as the Bush administration comes to a close, President-Elect Barack Obama (D) will have an opportunity early in his administration to begin shaping the federal judiciary. According to a **chart** prepared by the Administrative Office of the U.S. Courts, 42 vacancies currently exist on the U.S. Circuit Courts of Appeals, with 26 nominations pending. Twenty additional **vacancies** are anticipated within the next few months. Because the U.S. Supreme Court grants review in so few cases, the federal appellate courts play a significant role in shaping the law. Currently, the United States is divided into 12 judicial circuits, and each court of appeals has from six to 28 permanent circuit judgeships, or 179 in all, depending on the amount of work in the circuit.

AMERICAN ASSOCIATION FOR JUSTICE SEEKS FOOTHOLD IN NEW POLITICAL CLIMATE

Plaintiffs' lawyers have reportedly sensed a political opportunity to "roll back limitations on personal-injury and class-action lawsuits," according to a November 3, 2008, *Wall Street Journal* article, which describes the renewed efforts of the American Association for Justice (AAJ) to challenge "'pre-emption,' or federal regulations that block product-safety lawsuits by consumers and states." With the Democrats now holding a firm majority in Congress, plaintiff and consumer groups "see an ally" in President-Elect Barack Obama despite his earlier vote "to force more class actions to be filed in federal court, where juries have shown to be less sympathetic to plaintiffs." Trial lawyers are also apparently seeking to bar mandatory-arbitration clauses in consumer contracts that require customers to waive rights to class action litigation and jury trials.

Shook, Hardy & Bacon Public Policy Partner **Victor Schwartz** told the *Journal* that trial lawyers "used the last Congress to learn where the soft spots were." As the largest single contributor in the current election cycle, the AAJ has apparently donated $2.5 million primarily to Democratic candidates. If the new Congress adopts the AAJ agenda, some experts like Lester Brickman, a law professor at the Benjamin N. Cardozo School of Law at Yeshiva University in New York, anticipate "a perfect storm that will engulf business interests." "With all the other issues – taxes, financial crises, the war – this has been a B-minus issue. But in terms of real money, this isn't a B-minus," concurs Schwartz.

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<< back to top

ALL THINGS LEGISLATIVE AND REGULATORY

Commerce Department Report Urges Legal Reform to Boost Foreign Investment

The U.S. Department of Commerce recently published a report, titled "**The U.S. Litigation Environment and Foreign Direct Investment: Supporting U.S. Competitiveness by Reducing Legal Costs and Uncertainty**," that links a decades-long decline in foreign direct investment (FDI) to an "increasingly cumbersome and expensive U.S. legal system." "The United States is increasingly seen from abroad as a nation where lawsuits are too commonplace," states the report, which notes that tort costs "as a percentage of the GPD [gross domestic product] are triple that of France and the United Kingdom and at least double that of Germany, Japan, and Switzerland."

The report points to several factors felt to discourage international investors who fear the high costs and uncertain results of U.S. litigation. These factors include punitive damages "designed to punish the defendant and deter future bad conduct," class action lawsuits, plaintiff forum shopping, and a litigation culture that emphasizes the possibility of an extreme verdict. As a result, the Commerce Department recommends that (i) states continue to enact tort reform to address issues within their own jurisdictions; (ii) state and federal judges make it a priority "to enforce existing legal standards"; and (iii) the United States sets "a goal to reduce the costs associated with tort litigation from the current level of 2 percent GDP to a level half this size."

Although the report praises some recent tort reform efforts, such as the Class Action Fairness Act and the U.S. Supreme's decision to limit punitive damages in *State Farm v. Campbell,* it also cites U.S. Treasury Secretary Henry Paulson, who called the current legal system "an Achilles heel for our economy." *See Law360,* October 31, 2008.

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EPA Provides Notice About TSCA Inventory Status of Carbon Nanotubes

The Environmental Protection Agency (EPA) has issued a **notice** indicating that the manufacturers and importers of carbon nanotubes may be required to submit a pre-manufacture notice under the Toxic Substances Control Act (TSCA) because the agency considers these substances to be "new chemicals."

Under TSCA, manufacturers of new substances must file a pre-manufacture notice at least 90 days before manufacture unless the substance is excluded from this requirement. Substances excluded are those, such as pesticides, foods, drugs, and cosmetics, that are regulated by other agencies. According to EPA, chemical manufacturers are likely to be affected by its notice. *See Federal Register*, October 31, 2008.

Shook, Hardy & Bacon L.L.P.

<< back to top

U.S. Customs and Border Protection Expands Importer Self-Assessment Program to Include Product Safety

In partnership with the Consumer Product Safety Commission (CPSC), U.S. Customs and Border Protection (CBP) has **instituted** a voluntary pilot project that adds a product-safety component to its border-protection/trade-compliance self-assessment program. Those importers choosing to participate must participate in the self-assessment program and agree to comply with all laws administered by the two agencies, including the Consumer Product Safety Improvement Act of 2008, Federal Hazardous Substances Act, Flammable Fabrics Act, Prevention Packaging Act, and a Pool and Spa Safety Act. They must also agree to "[m]aintain an internal control system that ensures the integrity of product safety." The incentive for participation is less oversight "during entry and post entry."

According to the notice, CBP and CPSC "have developed a list of best practices to ensure compliance with CPSC's current regulations and will be working through this program to adapt those best practices to meet CPSC's new statutory scheme. Within the realm of their respective authorities, CBP and CPSC will verify that companies have adequate controls and processes in place to ensure product safety at all points in the product life-cycle of imported products and to comply with these mandatory standards." The CPSC will reduce product safety tests on goods imported by program participants. The pilot program will be assessed after two years to determine if it should be made permanent. *See Federal Register*, October 29, 2008.

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THINKING GLOBALLY

Federal Court Permits Domestic Manufacturer to Shift Blame to Chinese Manufacturer in Defective Heater Lawsuit

A federal court in Texas has ordered that a Chinese company be designated as a "responsible third party" in litigation over a defective portable electric heater that allegedly caused $2.4 million in damages to a business that provides jewelry and services for corporate employee recognition programs. *Diamond H. Recognition LP v. King of Fans, Inc.*, No. 4:08-CV-384-Y (U.S. Dist. Ct., N.D. Tex, Fort Worth Div., order filed October 29, 2008). King of Fans, which sold the heater to the plaintiff, filed a motion seeking the designation, contending that "it merely sold the heater in question and that SingFun is the party responsible for any defect that caused the fire at Diamond's facility." Diamond countered that while a seller is not generally liable for harm in a Texas product liability lawsuit, "an otherwise immune seller may be held liable when the manufacturer is beyond the court's jurisdiction."

Calling Diamond's argument "novel" and of "some appeal," the court ruled that it mischaracterizes the section of law on which the company relied to assert its exception to immunity theory. According to the court, "[t]hat section is a defensive device that provides a general rule of no liability unless the plaintiff can prove facts invoking an exception to the rule. The exceptions listed in section 82.003(a)(7) are theories of imposing liability, not causes of action."

Shook, Hardy & Bacon L.L.P.

<< back to top

The court also noted that the parties did not "address the question of whether SingFun would be subject to this Court's jurisdiction in any detail. Thus, the question of whether Singfun is indeed beyond the Court's jurisdiction and the effect jurisdiction over SingFun might have on the chapter 33 and 82.003(a)(7) analysis remains open."

While the court designated the Chinese company a responsible third party, this does not automatically add SingFun as a party to the litigation. So the court gave the parties additional time to implead third parties or join additional parties. Plaintiff's counsel has reportedly indicated that it intends to sue the Chinese manufacturer, although U.S. courts many not be able to exercise jurisdiction over SingFun unless it does business in the country. Legal commentators have also pointed out that manufacturers are difficult to sue for products liability under the Chinese court system. *See Product Liability Law 360,* October 30, 2008.

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LEGAL LITERATURE REVIEW

Mark Behrens & Frank Cruz-Alvarez, "Rhode Island Supreme Court Joins Other State Courts in Rejecting Product-Based Public Nuisance Claims," *Class Action Watch*, October 2008

Shook, Hardy & Bacon Public Policy Partner **Mark Behrens** and Product Liability Litigation Associate **Frank Cruz-Alvarez** have co-authored an article that analyzes the July 2008 "landmark decision that rejected the highest profile effort to date to turn public nuisance theory into a 'super tort' that would circumvent the well-settled requirements of products liability law." Behrens and Cruz-Alvarez discuss why the Rhode Island Supreme Court terminated the nine-year lead-based paint litigation by refusing to recognize public nuisance liability and note how the court placed important limitations on contingency fee agreements between the attorney general's office and its outside counsel.

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Victor Schwartz, Cary Silverman & Christopher Appel, "Consumer Product Safety Reform Could Mean a Boon for Safety or a Boondoggle for Plaintiffs' Lawyers: It's Up to the CPSC, State AGs, the Courts, and You," BNA *Product Safety & Liability Reporter*, November 3, 2008

Shook, Hardy & Bacon Public Policy Partner **Victor Schwartz**, Of Counsel **Cary Silverman** and Staff Attorney **Christopher Appel** have co-authored an article focusing on those provisions of the new consumer product safety law that create an online product hazard database, give state attorneys general enforcement authority, prohibit the Consumer Product Safety Commission from expressing an opinion about the preemptive effect of its exercise of regulatory authority, and establish whistleblower protections. The authors conclude that the law "should prove a boon for product safety," but caution the agency to exercise its responsibilities carefully and state attorneys general to "resist the temptation to overstep their limited authority." The article also suggests that the courts "respect the need for preemption in appropriate circumstances and remain vigilant in preventing abuse of the Act's whistleblower provisions."

<< back to top

LAW BLOG ROUNDUP

Election Results Give Hope to Plaintiffs' Bar

"High on the list for the plaintiffs' bar is legislatively reducing the scope of preemption." Western New England School of Law Professor William Childs, discussing a November 3, 2008, *Wall Street Journal* article about the anticipated fallout for the U.S. civil justice system following the election of Barack Obama as the next president.

TortsProf Blog, November 6, 2008.

"High on the list for the plaintiffs' bar is legislatively reducing the scope of preemption."

Closing Days of Bush Administration Likely to Usher in Rush of Regulations

"First, as evidenced most recently by the Clinton Administration's midnight rules, court challenges alleging that corners were cut, comment periods were clipped, or costs and benefits were inadequately weighed, almost certainly get to the court house steps with better-than-average prospects." Pennsylvania State University – Dickinson School of Law Professor Jamison Colburn, blogging about the trend among presidents to push through regulations that will advance their agendas as their terms in office come to a close. Colburn also discusses other ways that such rules can be undone to assuage the concerns of "[m]any administrative and environmental lawyers I know [who] have been agonizing over so-called 'midnight regulations': the rules every outgoing Administration ramrods through the pipeline before it's too late."

Dorf on Law, November 7, 2008.

Closely Watched Argument in *Wyeth v. Levine* Leaves Commentators Speculating

"It's unclear how this [C]ourt, seen as one of the most business-friendly in 50 years, will rule." Journalist Ed Silverman, repeating a familiar law bloggers' refrain in the days following the U.S. Supreme Court's oral argument in a case raising the question whether Food and Drug Administration approval of drug labeling prevents consumers from filing state product-liability lawsuits challenging the adequacy of the warnings. Silverman notes that Justice Anthony Kennedy got a concession from the plaintiff's lawyer that "if the FDA adequately weighed the risks versus the benefits of the IV-push method, and included those findings on the label, then he wouldn't have a case."

Pharmalot.com, November 3, 3008.

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<< back to top

THE FINAL WORD

National Study Examines Awards in Civil Bench and Jury Trials; Product Liability Damages Show Increase

The latest installment of the U.S. Department of Justice's **Civil Justice Survey of State Courts** has found that "Over 14,000 plaintiff winners received monetary damages in civil trials nationwide in 2005, with less than 5 percent receiving damages exceeding $1 million." Compiled by the department's Bureau of Justice Statistics (BJS), the data represents the first national survey and expands on earlier efforts to document civil trial awards in the most populous U.S. counties for 1992, 1996 and 2001. This new study concluded that with the exception of products liability and medical malpractice cases, median damage awards have declined in the nation's most populous counties. "The median final damage award (the amount at which half the awards are higher and half are lower) was $28,000," according to the survey. "The median final award for plaintiff winners in motor vehicle accident cases was $15,000."

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The statistics also revealed that plaintiffs fared better in bench trials in contrast to cases tried before juries. They were "most likely to win in cases involving an animal attack (75 percent), followed by motor vehicle accident (64 percent), asbestos (55 percent), and intentional tort (52 percent) cases. Plaintiffs had the lowest percentage of wins in medical malpractice trials (23 percent), product liability trials that did not involve asbestos (20 percent), and false arrest or imprisonment trials (16 percent), compared to plaintiffs in other tort cases." BJS also noted that plaintiffs "won in more than half (56 percent) of all general civil trials concluded in state courts," while in 2005, "a higher percentage of plaintiffs won in contract (66 percent) than in tort (52 percent) cases."

The report ultimately showed that "When adjusted for inflation, median damages awarded in general civil jury trials declined from $72,000 in 1992 to $43,000 in 2005, a decrease of 40 percent. For tort jury trials, the median damages declined by about 50 percent from $71,000 to $33,000 during the 1992 to 2005 period." BJS attributed this trend to a reduction in automobile accident trial awards, but also highlighted a "marked increase" in median jury awards in other tort categories.

In product liability jury trials, "the median award amounts were about 5 times higher in 2005 ($749,000) than they were in 1992 ($154,000)," concluded the survey. "For medical malpractice trials, the median damage awards were nearly 2.5 times higher in 2005 ($682,000) than they were in 1992 ($280,000)." *See Department of Justice Press Release* and *ABA Law Journal,* October 28, 2008; *The National Law Journal,* October 29, 2008.

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UPCOMING CONFERENCES AND SEMINARS

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.

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<< back to top

Insight Conferences, Calgary, Alberta – November 26-28, 2008 – "Electronic Records and Information Management." SHB Tort Partner **Amor Esteban** will present "Lessons Learned from e-Discovery in the U.S.," focusing on issues that include amendments to the Federal Rules and instances in which data sources are "not reasonably accessible" under Rule 26(b)(2)(B).

American Conference Institute, New York, New York – December 9-11, 2008 – "13th Annual Drug and Medical Device Litigation." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Marie Woodbury** will discuss "Successfully Asserting the Preemption Defense Post-*Riegel* and in Anticipation of *Levine*," and International Litigation and Dispute Resolution Partner **Simon Castley**, who is managing partner of SHB's London office, will serve on a panel to consider "Coordinating the Proliferation of Mass Tort Litigation Outside the U.S.: International Class Action and Product Liability Litigation Trends."

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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<< back to top