Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

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FEDERAL JUDGE DROPS PLAINTIFFS WITH BOILERPLATE COMPLAINTS IN DRUG CASE

A federal court in Arkansas has issued an order dropping the claims of a number of plaintiffs who allege that their ingestion of Prempro® for the relief of menopausal symptoms caused them personal injury. *In re: Prempro Prods. Liab. Litig.*, MDL Nos. 4:03CV1507 & 4:09CV00021 (U.S. Dist. Ct., E.D. Ark., W. Div., filed January 14, 2009). According to the court, which gave the claimants an opportunity to file new complaints, "[t]he current Complaint is an excellent example of the generic, omnidirectional complaints of which I have repeatedly expressed disfavor." The court was particularly concerned about the plaintiffs' failure to provide any specificity about their use of hormone therapy and to directly link their claims to particular defendants. "Simply claiming that you took hormone therapy and suing every hormone therapy manufacturer (here Plaintiffs name Wyeth and John Does 1-10) is not enough."

Product Liability Law 360 reports that the operating complaint in the case alleges that the defendants long marketed the estrogen hormone-replacement drugs, which purportedly led to breast cancer, by trying to convince doctors and the public that menopause is a chronic disease that must be treated. The complaint apparently alleges negligence, strict products liability, negligent misrepresentation, fraud, and intentional infliction of emotional distress. The defendants have reportedly mounted a vigorous defense and filed a motion to dismiss January 12, 2009. Among other matters, the defendants claim that their manufacturing, marketing and labeling practices are regulated by federal law, and their drugs were made and sold in compliance with federal law. They also raise assumption of the risk and lack of causation in their defense. *See Product Liability Law 360*, January 16, 2009.

CALIFORNIA SUPREME COURT ALLOWS CLAIMS IN GENERIC DRUG CASE TO PROCEED AGAINST NAME-BRAND MANUFACTURER

The California Supreme Court has reportedly decided not to review an appeals court ruling that allows negligent misrepresentation claims to proceed against the manufacturer of a name-brand prescription drug even though the

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plaintiff was allegedly injured by the long-term ingestion of its generic equivalent. *Conte v. Wyeth, Inc.*, No. 169116 (Cal., decided January 21, 2009). Further details about the lower court's ruling appear in the November 13, 2008, issue of this Report. The court also declined to revive similar claims that the plaintiff filed against the generic manufacturers; those claims were dismissed by the intermediate appeals court due to lack of evidence that the plaintiff's physician had relied on their warnings or product labeling.

The appeals court found that a material factual dispute existed about whether the plaintiff's physician read or relied on the *Physician's Desk Reference* information about the drug at issue, which information Wyeth had prepared. Most of its ruling focused on whether California law allows a name-brand manufacturer to be held liable for injuries caused by a generic equivalent and concluded that it did under traditional tort law theory. According to the appeals court, 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."

A Wyeth spokesperson was quoted as saying that the company was "disappointed" by the decision and that the California Supreme Court had "declined to review a decision of an intermediate appellate court that rejected a long line of cases in which courts have uniformly found that a drug manufacturer of a brand drug cannot be liable for injuries caused by a generic version of the brand drug sold by another manufacturer." The company is reportedly "confident" that it will prevail on the merits at trial. *See Product Liability Law 360* and *SFGate.com*, January 22, 2009.

INDIANA SUPREME COURT ALLOWS CITY TO PROCEED WITH NUISANCE CLAIMS AGAINST GUN MAKERS

The Indiana Supreme Court has turned aside a request to review an intermediate appellate court's decision allowing nuisance claims filed by the city of Gary against handgun manufacturers and distributors to proceed. *Smith & Wesson Corp. v. City of Gary*, No. N/A (Ind., decided January 13, 2009). The Brady Center to Prevent Gun Violence represents the city in this lawsuit which alleges that manufacturers and dealers know about sales to illegal buyers, that is, those who for reasons of criminal background or mental instability are barred by law from purchasing guns, and could change the gun distribution system but have intentionally failed to do so. According to the complaint, these practices contribute to a high rate of handgun murders in the city.

After the nuisance claims made their first trip to the state supreme court where they were sustained, Congress adopted a law prohibiting civil liability actions in state or federal courts against gun makers or sellers. The defendants then filed a motion to dismiss, and the U.S. government intervened to argue that the law was constitutional. The trial court denied the motion because it found the law unconstitutional. The appeal from that decision raised the issue of whether

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the federal law barred the city's public nuisance claim. The intermediate appellate court did not consider whether the federal law was invalid, but found that the lawsuit fell under an exception to the law and thus was not barred.

According to a news source, gun control advocates hailed the state supreme court's decision denying review, while industry backers point to the dozens of decisions throughout the country that have dismissed similar claims mainly because of state laws that provide immunity for the gun industry. The defendants reportedly deny any improper conduct; they could petition the U.S. Supreme Court for review, but have apparently not yet decided whether to do so. *See Medill Reports*, January 13, 2009; *Indystar.com*, January 19, 2009.

RHODE ISLAND COURT REQUIRES STATE TO PAY COSTS OF LEAD PAINT MANUFACTURERS

The Rhode Island Superior Court has determined that the state must pay the costs incurred by the defendant paint companies relating to the appointment of examiners after the state prevailed before a jury on nuisance claims it brought against the companies for the abatement of lead paint in buildings throughout the state. *Rhode Island v. Lead Indus. Ass'n.*, No. PB/99-5226 (R.I. Super. Ct., filed January 22, 2009). After the jury verdict, the state insisted that examiners be appointed to immediately begin the abatement process and implement a complex remedial scheme. The companies sought a stay of the abatement proceedings, claiming that their appeal "presents complex liability issues of first impression and serious constitutional concerns that deserve appellate review before this Court moves forward with costly and potentially time-consuming remedial proceedings." The examiners were ultimately appointed, and the court ordered the defendants to initially pay their fees and costs with a final determination to be made at a later date. Thereafter, the state's supreme court reversed the jury's verdict, and the defendants sought reimbursement of all fees and costs associated with the examiners.

The court rejected the state's claim that sovereign immunity shielded it from liability for the costs, relying on "authority dating back over half a century that stands for the proposition that where a state voluntarily files an affirmative claim, as is the case here, the state waives sovereign immunity. Once it waives its sovereign immunity, it may be subjected to costs in the same manner as any private litigant." Finding the defendants to be the prevailing parties, due to the supreme court's reversal of the abatement judgment, the court determined that "[i]t would be unjust to require the Defendants to bear the cost of a remedy for which the Rhode Island Supreme Court has expressly stated they are not liable." Because the defendants consistently opposed the examiners' appointment and because the state suggested that the defendants could be reimbursed for the expenses if they prevailed on appeal, the court ordered the state to pay the defendants nearly $250,000 in fees and costs.

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OHIO TRIAL COURT REJECTS HISTORIAN'S TESTIMONY ON INDUSTRY MOTIVE AND INTENT IN VINYL CHLORIDE SUIT

An Ohio trial court has granted defendants' motion to exclude the testimony of plaintiff's expert, a historian, finding that his "opinions as to the conspiratorial actions and motives of 'the vinyl industry' are … within the ken of lay jurors, and impermissible attempts to introduce expert opinion as to the intent and motive of Defendants." *Quester v. B.F. Goodrich Co.*, No. 03-509539 (Cuyahoga County, Ohio, Ct. of Common Pleas, filed January 15, 2009). According to the court, the witness's area of expertise is history and the sole basis for his opinion was "the voluminous documentation produced through vinyl chloride injury litigation."

Because the witness had no scientific expertise, the court found him unqualified "to testify as to the state of the art, or to the technical/scientific details in the documentation." Because the witness was offered to tell jurors what the documents mean, the court found he was "no more qualified than lay jurors, and as such his 'conspiracy' opinions invade the province of the jury." The court also ruled that expert opinion about intent and motive, whether as to "the industry' or the documents' authors, "is not appropriate for expert testimony in a court of law." According to the court, such opinions are "more appropriately within the purview of counsel in argument rather than the expert witness on stand."

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THINKING GLOBALLY

Department of Justice Settles False Claims Act Allegations Against Canadian Maker of Bullet-Proof Vests

The Department of Justice (DOJ) announced on January 23, 2009, that it had obtained a settlement with a Canadian textile manufacturer under the False Claims Act in an ongoing investigation into defective bullet-proof vests purchased by the United States and state and local governments. The Zylon® woven fabric made by Barrday Inc. allegedly "lost its ballistic capability quickly, especially when exposed to heat and humidity." According to the DOJ, Barrday was aware of the product defect by December 2001, but continued to sell the fabric for use in ballistic armor until 2003, when two police officers were shot through their vests and the company subsequently withdrew from the Zylon® market . A DOJ spokesperson was quoted as saying, "When a supplier of a component part distributes its product with knowledge of latent defects, that company violates the False Claims Act. This settlement will help ensure that component suppliers are held responsible for materials that put our first-responders at risk." While the Canadian manufacturer denies any culpability, it will cooperate in the investigation, which has already netted the U.S. government more than $46 million in settlements with other body armor companies, and it will pay more than $1 million to settle the claims. *See DOJ Press Release*, January 23, 2009.

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ALL THINGS LEGISLATIVE AND REGULATORY

PEN Report Questions Regulations for Nanotechnology-Based Dietary Supplements

The Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (PEN) has issued a report titled ***A Hard Pill to Swallow: Barriers to Effective FDA Regulation of Nanotechnology-Based Dietary Supplements***, which claims that the Food and Drug Administration has not adapted to the regulatory challenges presented by engineered nanomaterials. The report states that FDA cannot adequately regulate nanotechnology-based dietary supplements due to "lack of information, lack of resources and the agency's lack of statutory authority in certain critical areas." In particular, the report argues that FDA "does not have the capacity to identify nano-based dietary supplements that are being developed and marketed, unless manufacturers submit to the pre-market notification process for new dietary ingredients." Moreover, according to the authors, FDA has little regulatory authority over such manufacturers and lacks the scientific authority to enforce existing regulations.

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PEN urges Congress to grant FDA the regulatory authority to (i) carry out product registration, (ii) establish safety standards, (iii) conduct market reviews and pre-market testing, and (iv) improve adverse event reporting. "Until Congress acts, consumers who take dietary supplements containing engineered nanoparticles will be at additional, unknowable and potentially serious risk," concludes the report, which also contains a list of dietary supplements known to contain engineered nanomaterials as of March 2008.

LEGAL LITERATURE REVIEW

Christopher Robinette, "The Prosser Notebook: Classroom as Biography and Intellectual History," *Widener Law School Legal Studies Research Paper Series* (January 20, 2009)

Associate Law Professor Christopher Robinette was given access to the lecture notes taken by a student of William Prosser when he taught torts law 70 years ago at the University of Minnesota Law School. Prosser has been lauded as a great master of torts; his treatise *Prosser on Torts* has been called an authoritative and influential secondary legal source, and his textbook is still leading the market in the nation's law schools. Prosser also served as Reporter for the *Restatement (Second) of Torts*, which, as recently as 1996, was called "the most influential of the American Law Institute's volumes restating and reshaping American law."

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According to Robinette, Prosser's papers do not appear for the most part to have been preserved, so a law student's notes from lectures presented shortly after Prosser began teaching tort law serve to show how he began organizing his thoughts and positions on issues ranging from the intentional infliction of emotional distress to strict products liability. Robinette observes, "[o]ne of Prosser's major contributions to tort law was his role in altering the standard of

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liability in products liability from negligence to strict liability." He is also known for having stripped "strict liability from its 'illusory contract mask' and declaring its status as a tort doctrine." The article concludes by characterizing the law student's notebook from Prosser's lectures as a "treasure trove" because it "allows us a glimpse of Prosser at a particularly significant time in his career."

LAW BLOG ROUNDUP

Controversy over Law Banning Lead in Children's Products Continues

"Business groups have always hated this law. But now, they are in full hyperbolic rage because of the difficulty some small businesses are having complying right away." Lawyer Andy Hoffman, discussing industry concerns with the Consumer Product Safety Improvement Act and its phase-out of children's products with lead and phthalates. Consumer interests believe that the law, approved by overwhelming majorities in the House and Senate, effectively repairs "the damage caused by a weak and underfunded Consumer Product Safety Commission."

ThePopTort, January 23, 2009.

Another View of the Controversy

"It is clear that there is not enough time for the CPSC to clarify the issue by the implementation date of February 10. Therefore, the only feasible alternative is for Congress to delay implementation." Former William Mitchell College of Law Adjunct Professor Kenneth Ross, blogging about Republican congressional demands that hearings be held to sort out confusion over the Consumer Product Safety Commission's (CPSC) implementation of the ban on lead in children's products under the Consumer Product Safety Improvement Act. Ross also contends that "[v]irtually no one will be in full compliance by February 10 and there is a question about enforcement of these rules, many of which are unclear and incomplete."

Products Liability Prof Blog, January 25, 2009.

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THE FINAL WORD

U.S. Judicial Conference Releases Proposed Changes to Expert Witness Rules for Comment

The U.S. Judicial Conference is seeking comments on proposed changes to Federal Rule of Civil Procedure 26, which governs disclosure and discovery with respect to expert trial witnesses. "The core changes to the rule would extend work-product protection to drafts of Rule 26(a)(2)(B) expert reports and Rule 26(a)(2)(C) party disclosures, and also to attorney-expert communications," according to a January 20, 2009, article in *U.S. Law Week,* which noted that the

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Standing Committee on Rules of Practice and Procedure offered the amendments as a "balance between protection and discovery." Comments must be submitted by February 17, 2009.

The proposal would amend Rule 26(a)(2) to create a new obligation on parties to disclose the subject matter of their expected experts' testimony as well as a summary of the expected facts and opinions. The amendments would also extend work-product protection to drafts of expert reports, drafts of party disclosures, and communications—oral, written, electronic, or otherwise—between expert witnesses and counsel.

The changes reportedly provide three exceptions to allow discovery for parts of attorney-expert communications relating to (i) "compensation"; (ii) "identifying facts or data the attorney provided to the expert and that the expert considered in forming the opinions to be expressed"; and (iii) "identifying assumptions that the attorney provided to the expert and that the expert relied upon in forming the opinions to be expressed." If accepted by the U.S. Supreme Court and Congress, the proposed rules would take effect on December 1, 2010.

The American Bar Association apparently requested the revisions due to the rule's uneven application in the courts. Last visited in 1993, Rule 26(a)(2)(B) contains a note that says litigants should not "be able to argue that materials furnished to their experts are privileged or otherwise protected from disclosure when such persons are testifying or being deposed," prompting counsel to invest in costly legal maneuvers to retain privilege for the purpose of exploratory consulting.

Some legal scholars have, however, initiated a letter-writing campaign opposing the changes. "Dilution of inquiry into the expert's partisan relationship with retaining counsel is directly contrary to the changes many scholars have long advocated in our system of expert testimony," said Law Professors John Leubsdorf of Rutgers University and William Simon of Columbia University in their November 30, 2008, statement to the standing committee. The advisory committee's **report**, along with the proposed changes to the text of the rule and detailed discussion and questions, are posted on the federal judiciary Web site.

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UPCOMING CONFERENCES AND SEMINARS

Grocery Manufacturers Association, Rancho Mirage, California – February 24-26, 2009 – "2009 Food Claims & Litigation Conference." The conference will address emerging issues in food-related litigation, including (i) recent developments in product liability cases; (ii) pre-litigation risk management for consumer products; and (iii) non-traditional discovery methods. Shook, Hardy & Bacon Pharmaceutical and Medical Device Litigation Partners **Frank Rothrock** and **Paul La Scala** will address "Country-of-Origin-Labeling: A Legal Mandate for Some, a Marketing Opportunity for Others, and a Litigation Risk for All"; Shook, Hardy & Bacon Pharmaceutical and Medical Device Litigation Partner **Madeleine McDonough** will present on "Pre-Litigation Risk Management for Consumer Products Companies."

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American Bar Association, Phoenix, Arizona – April 2-3, 2009 – "2009 Emerging Issues in Motor Vehicle Product Liability Litigation." Shook, Hardy & Bacon Tort Partner **Frank Kelly** joins a distinguished faculty to serve on a panel discussing "The Science Behind the Sentiment: Understanding Punitive Damages in an Era of Anti-Corporate Bias." CLE credit is available for this program, which is presented by the ABA's Tort Trial & Insurance Practice Section; Products, General Liability and Consumer Law Committee and Automobile Law Committee.

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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